As filed with the Securities and Exchange Commission on February 11, 2019.

Registration No. 333–

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S–1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Xeris Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	2834	20-3352427
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1810
Chicago, IL 60601
1-844-445-5704
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Paul Edick
Chairman, President, and Chief Executive Officer
Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1810
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED (1)	PROPOSED MAXIMUM OFFERING PRICE PER SHARE (2)	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE (2)	AMOUNT OF REGISTRATION FEE
Common Stock, $0.0001 par value per share	5,750,000	$14.70	$84,525,000	$10,245

(1) Includes shares that the underwriters have the option to purchase.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low prices of the registrant's common stock as reported on the Nasdaq Global Select Market on February 7, 2019.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant files a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

[Table of Contents](#)

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated February 11, 2019

Preliminary Prospectus

5,000,000 Shares

Common Stock

We are offering 5,000,000 shares of common stock. Our common stock is listed on the Nasdaq Global Select Market under the symbol “XERS”. On February 7, 2019, the last sale price of our common stock as reported on the Nasdaq Global Select Market was $14.76 per share. The final public offering price will be determined through negotiation between us and the lead underwriters in the offering and the recent market price used throughout this prospectus may not be indicative of the final offering price.

We are an “emerging growth company” under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and for filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should read carefully the discussion of the material risks of investing in our common stock under the heading “Risk Factors” starting on page 10 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public offering price	$	$
Underwriting discount (1)	$	$
Proceeds, before expenses, to Xeris Pharmaceuticals, Inc.	$	$

(1) We refer you to “Underwriting” beginning on page 169 of this prospectus for additional information regarding underwriting compensation.

Delivery of the shares of common stock is expected to be made on or about , 2019. We have granted the underwriters an option for a period of 30 days to purchase an additional 750,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Joint Book-Running Managers

Jefferies **SVB Leerink** **RBC Capital Markets**

Mizuho Securities

The date of this prospectus is , 2019.

TABLE OF CONTENTS

	PAGE
PROSPECTUS SUMMARY	1
RISK FACTORS	10
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	57
USE OF PROCEEDS	59
DIVIDEND POLICY	60
CAPITALIZATION	61
DILUTION	63
SELECTED FINANCIAL INFORMATION	64
MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	66
BUSINESS	79
MANAGEMENT	133
EXECUTIVE COMPENSATION	141
DIRECTOR COMPENSATION	152
CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS	154
PRINCIPAL STOCKHOLDERS	156
DESCRIPTION OF CAPITAL STOCK	159
SHARES ELIGIBLE FOR FUTURE SALE	163
MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS	165
UNDERWRITING	169
LEGAL MATTERS	177
EXPERTS	178
WHERE YOU CAN FIND MORE INFORMATION	179
INDEX TO FINANCIAL STATEMENTS	F-1

Neither we nor the underwriters have authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus, any amendment or supplement to this prospectus and any related free writing prospectus. We and the underwriters take no responsibility for, and can provide no assurances as to the reliability of, any information that others may give you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus or in any free writing prospectus is only accurate as of its date, regardless of its time or delivery or the time of any sale of our common stock. Our business, financial condition, results of operations and future growth prospects may have changed since that date.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context otherwise requires, we use the terms "Xeris," the "Company," "we," "us," "our" and similar designations in this prospectus to refer to Xeris Pharmaceuticals, Inc.

Our Company

We are a specialty pharmaceutical company leveraging our novel non-aqueous formulation technology platforms, XeriSol and XeriJect, to develop and commercialize ready-to-use injectable and infusible drug formulations. We have developed a ready-to-use, room-temperature stable liquid glucagon formulation that, unlike any currently available products, can be administered without any preparation or reconstitution. Our lead product candidate, Gvoke HypoPen, delivers ready-to-use glucagon via a commercially-available auto-injector for the treatment of severe hypoglycemia, a potentially life-threatening condition, in people with diabetes. We have completed three Phase 3 clinical trials for our Gvoke HypoPen and submitted a New Drug Application, or NDA, to the U.S. Food & Drug Administration, or the FDA, in August 2018. The FDA has set June 10, 2019 as the Prescription Drug User Fee Act, or PDUFA, action goal date for our NDA. If our NDA is approved at that time, we believe we will have the first ready-to-use, room-temperature stable liquid glucagon formulation that can be administered without any preparation or reconstitution. Additionally, through our interactions with the European Medicines Agency, or EMA, regarding our development path in Europe, we have finalized our regulatory plan and initiated a requisite Phase 3 pivotal trial to support our European Marketing Authority Application, or MAA. We also are applying our novel ready-to-use, room-temperature stable liquid glucagon formulation for the management of hypoglycemia associated with additional intermittent and chronic conditions with significant unmet medical need. In addition, we are applying our technology platforms to convert other commercially-available drugs into ready-to-use, room-temperature stable liquid formulations to address the needs in multiple therapeutic areas and conditions, including epilepsy and diabetes.

Our Technology Platforms and Our Pipeline

Our proprietary non-aqueous formulation technology platforms are designed to address solubility and stability challenges presented by current aqueous formulations of certain drugs. Our proprietary XeriSol and XeriJect platforms offer the opportunity to eliminate the need for reconstitution and refrigeration, enable long-term room-temperature stability, significantly reduce injection volume and allow for a more convenient subcutaneous or intramuscular administration as opposed to intravenous infusion, all of which we believe are distinct advantages over existing aqueous formulations of marketed and development-stage products and product candidates. We believe that our technology platforms can lead to products that will improve outcomes and enable easier administration while reducing costs for payors and the healthcare system. XeriSol is best suited for peptides and small molecules that currently encounter formulation challenges. XeriJect is best suited for drugs and biologics consisting of large molecules, such as proteins, monoclonal antibodies and vaccines.

Table of Contents

We are the sponsor of five active Investigational New Drug, or IND, applications for our Gvoke HypoPen and ready-to-use glucagon for the treatment of severe hypoglycemia and the intermittent and chronic conditions listed below, respectively, and one IND for ready-to-use diazepam for the treatment of epileptic seizures. The following table summarizes key information about our internal product candidates.

	Product Candidate	Indication	Development Stage (Preclinical / Phase 1 / Phase 2 / Phase 3 / Under Review)	Next Milestone: Event	Next Milestone: Expected Date
Ready-to-Use Glucagon for Hypoglycemia	Gvoke HypoPen	Severe Hypoglycemia	Under Review	FDA decision	6.10.19
	Glucagon Pen - EU	Severe Hypoglycemia	Phase 3	Ph 3 Results	1H '19
	Self-Administered Glucagon	Post-Bariatric Hypoglycemia*	Phase 2	Ph 2 Results (Vial/Syringe)	1H '19
	Continuous Glucagon	Congenital Hyperinsulinism*	Phase 2	Initiate Ph 3	1H '19
	Continuous Glucagon	Hypoglycemia-Associated Autonomic Failure	Phase 2	Ph 2 Results	2H '19
	Self-Administered Glucagon	Exercise-Induced Hypoglycemia	Phase 2	Ph 2 Results	2H'19
Ready-to-Use Products for Epilepsy and Diabetes	Diazepam	Acute Repetitive Seizures* Dravet Syndrome*	Phase 1	Ph 1 Results	1H '19
	Pramlintide-Insulin	T1D / T2D Blood Sugar Control	Preclinical	Initiate Ph 2	2H '19

* Orphan Drug Designation

Additionally, we are providing our ready-to-use glucagon in a vial to Oregon Health & Science University, or OHSU, for its ongoing Phase 1 closed-loop dual-hormone artificial pancreas study and expect OHSU to report top-line results in the second half of 2019. Based on the results, we plan to support advancement of this OHSU program and other artificial pancreas programs with ready-to-use glucagon in a vial.

Severe Hypoglycemia and Limitations of Existing Products

Hypoglycemia, a key concern of people with both Type 1 Diabetes, or T1D, and Type 2 Diabetes, or T2D, occurs when a person has a deficiency of glucose in their bloodstream, often as a result of insulin treatment. Symptoms of hypoglycemia include fatigue, shakiness, anxiety, headache, nausea and vomiting, and in severe cases hypoglycemia can result in cardiovascular disease, seizure, coma and, if left untreated, death. Treatment-associated hypoglycemia in people with diabetes remains the major limiting factor in the glycemic management of T1D and T2D. In the United States, all of the approximately 1.3 million people with T1D and approximately 4.3 million people with T2D who require insulin therapy to lower their blood glucose levels are at risk for hypoglycemia. Hypoglycemic events of any severity are a daily concern for people with diabetes and represent the greatest barrier to optimal glycemic control. Severe hypoglycemic events are extremely frightening for patients and caregivers and can result in seizure, coma and, if left untreated, death. The American Diabetes Association, or ADA, recommends that glucagon be prescribed for all individuals at increased risk of clinically significant hypoglycemia for use in the event of an emergency.

Because of the urgent nature of severe hypoglycemia, the majority of severe hypoglycemic events are treated on an emergency basis, outside of a healthcare facility. Two emergency glucagon products are currently available to treat severe hypoglycemia. Each product is sold as a vial of lyophilized, glucagon powder with an exposed needle/syringe that contains a liquid diluent. The glucagon powder must be combined with the liquid diluent at the time of use and drawn into a syringe in accordance with a complex multi-step reconstitution and dose calibration procedure. Additionally, once reconstituted, the glucagon must be used immediately because once the lyophilized glucagon is combined with water, the solution becomes unstable and can fibrillate, rendering it inactive and potentially toxic.

In published comparative human factors studies with currently marketed emergency glucagon kits, only 6% to 31% of users were able to successfully administer the full dose of glucagon. In other words, in these studies, test subjects failed to deliver the full dose of glucagon 69% to 94% of the time. The complex, unreliable administration of currently marketed products inhibits patient interest in carrying a kit and physician focus on ensuring each clinically appropriate patient at increased risk has a filled prescription. In 2018, U.S. sales for emergency glucagon kits totaled approximately $246 million, based on approximately 662,000 total prescriptions written for approximately 978,000 single-dose kits.

Our Gvoke HypoPen

Our key priority is developing and commercializing our lead product candidate, Gvoke HypoPen, for the treatment of severe hypoglycemia in people with diabetes. Our Gvoke HypoPen delivers our ready-to-use glucagon formulation via a commercially-available auto-injector. We believe our Gvoke HypoPen addresses the administration challenges of currently marketed emergency glucagon kits, and, if approved, has the potential to be the preferred emergency glucagon product. The key features of our Gvoke HypoPen are:

- *Ready-to-use:* With its easy two-step administration process, the user simply pulls off the red cap and pushes the Gvoke HypoPen down on the skin for five seconds, until the window turns red. There is no reconstitution required at the time of emergency.
- *Easy-to-use:* In our human factors study, 99% of users were able to successfully administer the full dose with our Gvoke HypoPen.
- *No dose calibration required:* The Gvoke HypoPen will be offered in two pre-measured doses, 0.5 mg for pediatric administration and 1 mg for adolescents and adults.
- *No visible needle:* The needle in the Gvoke HypoPen is not visible to the user.
- *Auto-retraction:* The needle auto-retracts after administration for safety.
- *Auto-locks:* The device auto-locks after use for safety.
- *Two-year, room-temperature stability:* No refrigeration is required at any time.

We submitted a NDA to the FDA in August 2018 utilizing the 505(b)(2) regulatory pathway. To generate additional information regarding the entire treatment episode, including preparation and administration time of our Gvoke HypoPen compared to Eli Lilly's Glucagon Emergency Kit, we completed an additional Phase 3b clinical trial of our Gvoke HypoPen in the second quarter of 2018. We also intend to offer our ready-to-use glucagon in a pre-filled syringe presentation, Gvoke PFS, which may be preferred by some healthcare professionals.

Gvoke HypoPen Market Potential

Based on current market data, as well as our caregiver and patient and healthcare professional perceptions studies, we believe that our Gvoke HypoPen, if approved, has the potential to increase demand for emergency glucagon treatments among people with diabetes. Despite the risk of experiencing a severe hypoglycemic event, we believe that emergency glucagon therapy is under-appreciated, under-evaluated and under-taught, resulting in a market that is under-penetrated. According to a 2015 study published in the journal *Endocrine Practice*, approximately 50% of people with T1D and approximately 3% of people with T2D with a new insulin prescription had a filled glucagon prescription. We intend to market our Gvoke HypoPen to all 3.5 million people that we believe are clinically appropriate for glucagon. We believe by increasing penetration into the market for emergency glucagon kits and based on the current price per unit for currently marketed kits, the U.S. potential annual sales opportunity may total up to $2.0 billion.

We expect to initially target approximately 8,000 healthcare professionals that are high prescribers of current glucagon kits and/or mealtime insulin products, using an expected initial sales force of 60-70 individuals. As part of our marketing strategy, we plan to activate patient demand efficiently and effectively through targeted direct-to-patient promotion, as the majority of people with diabetes are concentrated in 15 states.

Ready-to-Use Glucagon for Hypoglycemia Associated with Intermittent and Chronic Conditions

We are applying our ready-to-use, liquid-stable glucagon formulation to treat five intermittent and chronic conditions with significant unmet medical need: Post-Bariatric Hypoglycemia, or PBH; Congenital Hyperinsulinism, or CHI; Hypoglycemia-Associated Autonomic Failure, or HAAF; Exercise-Induced Hypoglycemia, or EIH; and management of diabetes via glucagon in a fully-integrated, bi-hormonal artificial pancreas closed-loop system. By applying our ready-to-use glucagon to these conditions, we expect to leverage operating efficiencies across our supply chain, research and development, and commercial and medical organizations.

We also are applying our technology platforms to develop additional product candidates, such as ready-to-use, liquid-stable diazepam delivered via a commercially-available auto-injector for the emergency treatment of epileptic seizures, and a fixed-dose co-formulation of pramlintide and insulin, or Pram-Insulin, for the management of diabetes. Additionally, based on the promising data seen in some of our early clinical trials as well as formulations in our laboratory, we believe we have the potential to advance a number of programs in other indications and that our strong product candidate portfolio will support our vision to effectively and efficiently meet the needs of our target markets.

Intellectual Property and Barriers to Entry

We own the worldwide rights to our proprietary formulation technology platforms and our product candidates, with 75 patents issued globally as of February 7, 2019, including a composition of matter patent covering our ready-to-use glucagon formulation that expires in 2036. The FDA has granted orphan drug status to four indications for our product candidates, which are our ready-to-use glucagon for PBH and CHI and our ready-to-use, liquid-stable formulation of diazepam for the treatment of Dravet Syndrome, a rare form of epilepsy that presents in the first year of life, and acute repetitive seizures in patients with epilepsy. Additionally, we have received orphan drug designation from the EMA for CH and Noninsulinoma Pancreatogenous Hypoglycaemia Syndrome, or NIPHS, which includes patients with PBH.

Management

Our management team includes veterans in drug development, discovery and commercialization, with executive experience in leading global pharmaceutical and healthcare companies, including Durata Therapeutics, Baxter Healthcare, Merck, Searle, Takeda, Warner Chilcott, MedPointe Healthcare, Amylin Pharmaceuticals, PowderJect Technologies and Alpharma.

Our Strategy

Our strategy is to utilize our proprietary non-aqueous formulation technology platforms to convert marketed and development-stage products that have poor solubility and stability into ready-to-use, user-friendly injectable and infusible drugs for multiple therapeutic areas and conditions, including hypoglycemia, epilepsy and diabetes. We also seek to apply our formulation technology platforms to enhance the formulations of proprietary marketed and development-stage products and product candidates of other pharmaceutical and biotechnology companies. The key elements of our strategy include the following objectives:

- Rapidly secure regulatory approval for our lead product candidate, Gvoke HypoPen, for severe hypoglycemia.
- Maximize the commercial potential for our Gvoke HypoPen.
- Continue to advance our ready-to-use glucagon portfolio to address hypoglycemia associated with other intermittent chronic conditions.
- Continue to leverage our technology and expertise to develop a portfolio of additional product candidates.
- Collaborate with pharmaceutical and biotechnology companies to apply our technology platforms to enhance the formulations of their proprietary products and candidates.

The nature of our product candidates and target conditions provides us with a potentially faster and capital-efficient development and regulatory pathway to approval.

Risks Affecting Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary and include the following:

- As a company, we have a limited operating history and no history of commercializing pharmaceutical products and have incurred significant losses since inception. We expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We are dependent on the success of our glucagon product candidates, particularly our Gvoke HypoPen. We cannot be certain that our Gvoke HypoPen or any of our other product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our product candidates or generate product revenues.
- Our business depends entirely on the success of our product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed.
- The market opportunity for our product candidates may be smaller than we estimate.
- Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties. If we fail to comply with continuing U.S. and non-U.S. regulations or new safety data arise, we could lose our marketing approvals and our business would be seriously harmed.
- We operate in a competitive business environment and, if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected, and we may not successfully commercialize our product candidates, even if approved.
- Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates. If our clinical trials fail to demonstrate efficacy and safety to the satisfaction of the FDA or other regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidates.
- Our reliance on third-party suppliers, including single-source suppliers and a limited number of options for alternate sources for our product candidates, including our Gvoke HypoPen, could harm our ability to develop our product candidates or to commercialize any product candidates that are approved.
- Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.
- We have drawn down $35.0 million from our loan and security agreement with Oxford Finance LLC and Silicon Valley Bank. The final tranche of an additional $10.0 million is only available if we receive approval of our Gvoke HypoPen NDA by the FDA before September 30, 2019.
- Our independent registered public accounting firm has identified a material weakness in our internal control over financial reporting which will require remediation.

Corporate Information

We were incorporated in 2005 under the laws of the state of Delaware. Our principal executive offices are located at 180 N. LaSalle St., Suite 1810, Chicago, Illinois 60601, and our phone number is 1-844-445-5704. Our website address is *http://www.xerispharma.com*. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus.

The "Xeris" name, and the XeriJect, XeriSol, GVOKE, GVOKE HYPOPEN, HYPOPEN, and CSI Glucagon names and related images, logos and symbols appearing in this prospectus are our properties, trademarks and service marks. Other marks appearing in this prospectus are the property of their respective owners.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- Only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- Reduced disclosure about our executive compensation arrangements;
- No advisory votes on executive compensation or golden parachute arrangements; and
- Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

THE OFFERING

Shares of common stock offered by us	5,000,000 shares.
Shares of our common stock outstanding after this offering	25,893,205 shares (or 26,643,205 shares assuming full exercise of the underwriters' option to purchase additional shares).
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to 750,000 additional shares of our common stock.
Use of proceeds	We currently intend to use the net proceeds of this offering, together with our existing cash and cash equivalents and short-term investments, to support the commercial launch of Gvoke HypoPen, including investments in sales and marketing, direct-to-consumer marketing, inventory and our commercial and medical affairs infrastructure; to advance our other pipeline product candidates; and the remainder for working capital and other general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see "Use of Proceeds."
Nasdaq Global Select Market symbol	"XERS".
Risk factors	Investment in our common stock involves substantial risks. You should read this prospectus carefully, including the section entitled "Risk Factors" and the financial statements and the related notes to those statements included in this prospectus, before investing in our common stock.

The number of shares of common stock outstanding after this offering is based on 20,893,205 shares of our common stock outstanding as of December 31, 2018, which includes 84,839 shares of unvested restricted stock, and excludes:

- 2,315,677 shares of common stock issuable upon exercise of options issued under our 2011 Stock Option/Stock Issuance Plan at a weighted-average exercise price of $4.46 per share;
- 723,137 shares of common stock issuable upon exercise of options issued under our 2018 Stock Option and Incentive Plan at a weighted-average exercise price of $20.05 per share;
- 8,635 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $5.912 per share and 94,012 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $11.169 per share;
- 1,934,591 shares of common stock reserved for issuance under our 2018 Stock Option and Incentive Plan;
- 401,932 shares of common stock reserved for future issuance under our 2018 Employee Stock Purchase Plan; and
- 750,000 shares of common stock reserved for future issuance under our Inducement Equity Plan adopted by our board of directors in February 2019.

Except as otherwise noted, all information in this prospectus assumes:

- no exercise of outstanding options after December 31, 2018; and
- no exercise of the underwriters' option to purchase additional shares.

SUMMARY FINANCIAL INFORMATION

The following tables summarize our financial and operating data for the periods indicated. The summary statements of operations data for the years ended December 31, 2016 and 2017 have been derived from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the nine months ended September 30, 2017 and 2018 and the summary balance sheet data as of September 30, 2018 have been derived from our unaudited interim financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future, and the results for the nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the full year ending December 31, 2018 or any other period.

The summary financial information below should be read in conjunction with the information contained in “Selected Financial Information,” “Management's Discussion and Analysis of Financial Condition and Results of Operations,” our financial statements and notes thereto, and other financial information included elsewhere in this prospectus.

(in thousands, except share and per share data)	YEARS ENDED DECEMBER 31, 2016	YEARS ENDED DECEMBER 31, 2017	NINE MONTHS ENDED SEPTEMBER 30, 2017 (unaudited)	NINE MONTHS ENDED SEPTEMBER 30, 2018 (unaudited)
Statements of Operations Data:				
Grant income	$ 1,022	$ 1,540	$ 1,073	$ 1,611
Service revenue	53	16	16	53
Cost of revenue	8	4	4	42
Gross profit	1,067	1,552	1,085	1,622
Operating expenses:				
Research and development	10,238	20,166	13,588	28,264
General and administrative	4,060	8,015	4,917	12,388
Expense from operations	14,298	28,181	18,505	40,652
Loss from operations	(13,231)	(26,629)	(17,420)	(39,030)
Other income (expense):				
Interest income	5	124	45	796
Interest expense	(2)	(2)	(1)	(1,490)
Change in fair value of warrants	24	(46)	(32)	63
Other expense	(5)	(1)	—	—
Total other income (expense)	22	75	12	(631)
Net loss	$ (13,209)	$ (26,554)	$ (17,408)	$ (39,661)
Net loss per share-basic and diluted (1)	$ (7.17)	$ (13.09)	$ (8.63)	$ (4.36)
Weighted average number of common shares outstanding, basic and diluted (1)	1,842,416	2,028,224	2,016,112	9,104,491

(in thousands)	AS OF SEPTEMBER 30, 2018 ACTUAL	AS OF SEPTEMBER 30, 2018 AS ADJUSTED (2)
Balance Sheet Data:		
Cash and cash equivalents	$ 75,745	$ 144,345
Short-term investments	55,296	55,296
Working capital (3)	127,462	196,062
Total assets	137,591	206,191
Long-term debt, net of unamortized deferred costs	31,642	31,642
Other long-term liabilities	2,621	2,621
Total liabilities	42,471	42,471
Additional paid in capital	195,422	264,021
Total stockholders' equity	95,120	163,720

(1) See Note 2 to our audited financial statements and Note 2 to our unaudited interim financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, unaudited basic and diluted net loss per share and the shares used in computing basic and diluted net loss per share.

(2) The table above presents our balance sheet data as of September 30, 2018 on an actual basis and on an as adjusted basis to give effect to the sale of 5,000,000 shares of common stock offered by us in this offering at an assumed public offering price of $14.76 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on February 7, 2019, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase (decrease) in the assumed public offering price of $14.76 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on February 7, 2019, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $4.7 million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $13.9 million, assuming the assumed public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and other information contained in this prospectus, including our financial statements and the related notes and the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before you make an investment decision. If any of the events contemplated by the following discussion of risks were to occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

Risks Related to our Financial Position and Need for Financing

As a company, we have a limited operating history and no history of commercializing pharmaceutical products and have incurred significant losses since inception. We expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

We are a clinical-stage pharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not generated any product revenues and have financed our operations primarily through private placements of our preferred stock, borrowings under the Loan and Security Agreement that we entered into with Oxford Finance LLC and Silicon Valley Bank, and our initial public offering in June 2018, or our IPO. We do not expect to generate any product revenues unless one or more of our product candidates receives regulatory approval and is commercialized. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies prior to regulatory approval of any product candidates, especially pharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have incurred significant losses in every fiscal year since inception. We incurred net losses of $13.2 million and $26.6 million in the years ended December 31, 2016 and 2017, respectively. For the nine months ended September 30, 2018 and 2017, we reported a net loss of $39.7 million and $17.4 million, respectively. In addition, our accumulated deficit as of September 30, 2018 was $100.2 million. Substantially all our operating losses have resulted from costs incurred in connection with research and development of our product candidates and clinical and regulatory initiatives to obtain approvals for our product candidates.

We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance and commercialize new products and incur additional operational and reporting costs associated with being a public company. In particular, we anticipate that our expenses will increase substantially as we:

- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements;
- build commercial infrastructure to support sales and marketing for our product candidates;
- hire and retain additional personnel and add operational, financial and management information systems; and
- continue to operate as a public company.

All of our product candidates are still in development and none have been approved for sale. We submitted a New Drug Application, or NDA, for our Gvoke HypoPen to the U.S. Food and Drug Administration, or FDA, in

August 2018. The FDA has set June 10, 2019 as the Prescription Drug User Fee Act, or PDUFA, action goal date for our NDA. However, the FDA may not approve our Gvoke HypoPen. Our ability to generate revenue from our product candidates and to transition to profitability and generate positive cash flows is uncertain and depends on the successful development and commercialization of our product candidates. Successful development and commercialization will require achievement of key milestones, including completing clinical trials of our product candidates that are under clinical development, obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We have not generated any revenue from our product candidates, including our Gvoke HypoPen, and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any of our product candidates. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and begin to sell, our product candidates. We do not expect to commercialize any of our product candidates before the second quarter of 2019, if ever. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain marketing approval for our product candidates, including our Gvoke HypoPen;
- obtain commercial quantities of our product candidates, if approved, at acceptable cost levels;
- commercialize our product candidates, if approved, by developing our own sales force for commercialization in the United States or in other key territories by entering into partnership or co-promotion arrangements with third parties;
- set an acceptable price for our product candidates, if approved;
- obtain and maintain third-party coverage and adequate reimbursement for our product candidates, if approved; and
- achieve an adequate level of market acceptance of our product candidates, if approved, in the medical community and with third-party payors, including placement in accepted clinical guidelines for the conditions for which our product candidates are intended to target.

If any of our product candidates are approved for commercial sale, we expect to incur significant sales and marketing costs as we prepare for its commercialization. Even if we receive marketing approval and expend these costs, our product candidates may not be commercially successful. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We may require additional capital to sustain our business, and this capital may cause dilution to our stockholders and might not be available on terms favorable to us, or at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Pharmaceutical development is a time-consuming, expensive and uncertain process that takes years to complete. In addition, if any of our product candidates are approved, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs. We plan to use the net proceeds of this offering, together with our existing cash and cash equivalents, short-term investments

and expected revenue from sales of Gvoke HypoPen to support the expected commercial launch of our Gvoke HypoPen, including investments in sales and marketing, inventory and our commercial and medical affairs infrastructure, to advance our other pipeline product candidates and for working capital and other general corporate purposes. We will be required to expend significant funds in order to commercialize our Gvoke HypoPen, as well as any of our other product candidates that receive marketing approval. The net proceeds of this offering together with our existing cash and cash equivalents, short-term investments and expected revenue from sales of Gvoke HypoPen may not be sufficient to fund all of the efforts that we plan to undertake.

We may be required to obtain further funding through public equity offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing obtained by us would be senior to our common stock, would likely cause us to incur interest expenses, and could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may increase our expenses and make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions and in-licensing opportunities. We may also be required to secure any such debt obligations with some or all of our assets. For example, our Loan and Security Agreement is secured by substantially all of our existing property and assets other than our intellectual property assets, subject to certain exceptions. Our Loan and Security Agreement also contains a negative pledge on intellectual property owned by us, pursuant to which we have agreed not to encumber any of our intellectual property.

If we raise additional funds through collaborations or marketing, distribution or licensing, or royalty-based financing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. Securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development and commercialization, if approved, of our product candidates. It is also possible that we may allocate significant amounts of capital toward solutions or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Any of these negative developments could have a material adverse effect on our business, operating results, financial condition and common stock price.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Our Loan and Security Agreement provides for term loans of up to an aggregate of $45.0 million, of which $20.0 million was borrowed upon signing. Following submission of an NDA for our Gvoke HypoPen, we drew down an additional $15.0 million in September 2018. We become eligible to draw the remaining $10.0 million if we receive approval of our Gvoke HypoPen NDA by the FDA before September 30, 2019, and then only available to be drawn until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

All obligations under our Loan and Security Agreement are secured by substantially all of our existing property and assets other than our intellectual property assets, subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity.

Failure to satisfy our current and future debt obligations under our Loan and Security Agreement could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. Events of default include our failure to comply with customary affirmative covenants as well as our breach of customary negative covenants in the Loan and Security Agreement. Affirmative covenants include the maintenance of a $5.0 million minimum cash balance in the event that we maintain one or more permitted accounts at other institutions. Negative covenants include prohibition on the payment of dividends and distributions, certain mergers and change of control events, and the occurrence of material adverse changes in the company's business or its prospect of repayment of its obligations.

In the event of an acceleration of amounts due under our Loan and Security Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

Risks Related to the Product Development and Regulatory Approval of Our Product Candidates

We are dependent on the success of our glucagon product candidates, particularly our Gvoke HypoPen. We cannot be certain that our Gvoke HypoPen or any of our other product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our product candidates or generate product revenues.

We have devoted a significant portion of our financial resources and business efforts to the development of the Gvoke HypoPen. We submitted an NDA for the Gvoke HypoPen in the third quarter of 2018, however, we have not received approval from regulatory authorities to market the Gvoke HypoPen or any other product candidate in any jurisdiction, and it is possible that neither our Gvoke HypoPen nor any other product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. The FDA's decision to accept the NDA for filing and set a PDUFA date does not indicate that it has made any decision regarding approval nor does it guarantee approval by June 10, 2019, if at all. We cannot be certain that our Gvoke HypoPen or any of our other product candidates will receive marketing approval.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and by comparable regulatory authorities in other countries. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. Our Gvoke HypoPen is considered to be a drug-device combination product by the FDA, and its NDA will require review and coordination by the FDA's drug and device centers prior to approval. We cannot predict whether we will obtain regulatory approval to commercialize our Gvoke HypoPen or any of our other product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any delay or setback in the regulatory approval or commercialization of any of these product candidates will adversely affect our business.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway for our product candidates;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our Gvoke HypoPen or any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that there are unacceptable risks associated with the device component of our glucagon HypoPen or that there are deficiencies with the information submitted to demonstrate the safety, effectiveness and reliability of the device component;

- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our Gvoke HypoPen or any of our other product candidates is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously-approved drugs with the same conditions of approval as those of our Gvoke HypoPen or any of our other product candidates (as applicable);
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may audit some or all of our clinical research and human factors study sites to determine the integrity of our data and may reject any or all of such data;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

At our pre-NDA meeting with the FDA in December 2017, we presented the results from our two Phase 3 Gvoke HypoPen clinical trials that had been completed as of that meeting. Our first Phase 3 clinical trial was a non-inferiority comparison of the Gvoke HypoPen against Eli Lilly's glucagon determined by an increase in plasma glucose concentration from below 50.0 mg/dL to greater than 70.0 mg/dL within 30 minutes after receiving glucagon. In this trial, our Gvoke HypoPen did not meet a primary endpoint for noninferiority in the intent-to-treat, or ITT, population due to one response failure in excess of the pre-specified threshold of three response failures. In the same trial, two subjects were censored from the modified ITT, or mITT, population because of a clinically significant protocol violation, and the remaining subjects were used for the per-protocol analysis. In accordance with FDA and International Council for Harmonisation guidance for evaluation of non-inferiority studies, we presented a series of analyses implementing ITT, mITT, and per-protocol cohorts for all the endpoints for this clinical trial to the FDA at this pre-NDA meeting. In that meeting, the FDA agreed overall that the totality of data for our Gvoke HypoPen is sufficient to support NDA review. However, certain of our analyses may be viewed as post-hoc analyses, and although we believe that post-hoc analyses can provide additional information regarding results from this trial, retrospective analyses can result in the introduction of bias and may be given less weight by the FDA, including for purposes of determining whether to approve our NDA.

The FDA provided additional comments to address prior to NDA submission related to the pre-filled syringe presentation of our ready-to-use glucagon, or Gvoke PFS. Based on these comments, we conducted additional studies, the results from which were included in our Gvoke HypoPen submission to the FDA.

In order to generate additional information regarding the entire treatment episode, we completed an additional non-inferiority Phase 3b clinical trial in the second quarter of 2018 comparing our Gvoke HypoPen to Eli Lilly's glucagon, the results of which were included in our NDA submission. Even though we completed this Phase 3b clinical trial, the FDA or other regulatory authorities may require us to conduct additional clinical trials prior to approval.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We intend to utilize the 505(b)(2) pathway for the regulatory approval of certain of our product candidates, including our Gvoke HypoPen. If the FDA does not conclude that the Gvoke HypoPen or such other product candidates meet the requirements of Section 505(b)(2), final marketing approval of our product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

We are pursuing a regulatory pathway pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, for the approval of certain of our product candidates, including our Gvoke HypoPen, which allows us to rely on submissions of existing clinical data for the drug. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval.

If the FDA determines that our Gvoke HypoPen or our other product candidates do not meet the requirements of Section 505(b)(2), we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. In March 2010, President Obama signed into law legislation creating an abbreviated pathway for approval under the Public Health Service Act, or PHS Act, of biological products that are similar to other biological products that are approved under the PHS Act. The legislation also expanded the definition of biological product to include proteins such as insulin. The new law contains transitional provisions governing protein products such as insulin, that under certain circumstances, might permit companies to seek approval for their insulin products as biologics under the PHS Act and might require that our XeriSol pramlintide-insulin co-formulation be approved under the PHS Act rather than in a 505(b)(2) NDA. In addition, if any of our product candidates are approved under Section 505 of the FDCA as of the March 23, 2020 transition date and are then “deemed to be a license” for the biological product under section 351 of the PHS Act, we could lose certain unexpired exclusivities and this could materially harm our business. If our product candidates do not meet the requirements of Section 505(b)(2) or are otherwise ineligible for approval via the Section 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Some pharmaceutical companies and other actors have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA recently adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if it does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's new interpretation, the approval of one or more of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product candidates, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates. If our clinical trials fail to demonstrate efficacy and safety to the satisfaction of the FDA or other regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

We cannot be certain that existing clinical trial results will be sufficient to support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Moreover, success in clinical trials in a particular indication does not ensure that a product candidate will be successful in other indications. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials or successful later-stage trials in other related indications. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of the applicable NDA to the FDA, the Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate revenue.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

Certain of our product candidates, including our Gvoke HypoPen, are drug and device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as “combination products” in the United States and Europe. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process and the lack of a well-established review process and criteria. The EMA has a parallel review process in place for combination products, the potential effects of which in terms of approval and timing could independently affect our ability to market our combination products in Europe.

Delays in conducting clinical trials could result in increased costs to us and delay our ability to obtain regulatory approval for our product candidates.

Any delays in conducting clinical trials and related drug development programs could materially affect our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned, or will be completed on schedule, if at all. A clinical trial can be delayed for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates, competitive or comparator products or supportive care products or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in a trial;
- delays or failures in reaching agreement on acceptable terms with prospective study sites or other contract research organizations, or CROs;

- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- receipt by a competitor of marketing approval for a product targeting an indication that our product candidate targets, such that we are not "first to market" with our product candidate;
- delays in recruiting or enrolling subjects to participate in a clinical trial, particularly with respect to our product candidates for certain rare indications, including those for which we have obtained, or plan to seek, orphan drug designation;
- failure of a clinical trial or clinical investigators to be in compliance with current Good Clinical Practices, or cGCPs;
- unforeseen safety issues;
- inability to monitor subjects adequately during or after treatment;
- difficulty monitoring multiple study sites;
- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;
- failure of our third-party clinical trial managers to satisfy their contractual duties, comply with regulations, or meet expected deadlines; and
- determination by regulators that the clinical design of a trial is not adequate.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the Internal Review Boards, or IRBs, at the sites where the IRBs are overseeing a trial, a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we have done and plan to do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to include safety warnings, require them to be taken off the market or otherwise limit their sales.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The range and potential severity of possible side effects from systemic therapies are significant. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings. Recent developments in the pharmaceutical industry have prompted heightened government focus on safety reporting during both pre- and post-approval time periods and pharmacovigilance. Global health authorities may impose regulatory requirements to monitor safety that may burden our ability to commercialize our drug products.

To date, patients treated with our ready-to-use glucagon have experienced drug-related side effects typically observed with glucagon products, including nausea, vomiting and headaches. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. It is possible that there may be side effects associated with our other product candidates' use. In such an event, our trials could be suspended or

terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects.

Even if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, including “black box” warnings, contraindications or dissemination of field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could also prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

We have received orphan drug designation for our product candidates with respect to certain indications and intend to pursue such designation for others, but we may be unable to obtain such designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted.

We have received orphan drug designation from the FDA for four indications for our product candidates, which are our ready-to-use glucagon for Post-Bariatric Hypoglycemia, or PBH, and congenital hyperinsulinism, and our ready-to-use diazepam for acute repetitive seizures and Dravet Syndrome. We have also received orphan drug designation from the EMA for Noninsulinoma Pancreatogenous Hypoglycaemia Syndrome, or NIPHS, which includes patients with PBH. We intend to pursue such designation for others in specific orphan indications in which there is a medically plausible basis for its use. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Although we intend to seek orphan drug designation for certain additional indications, we may never receive such designation. Moreover, obtaining orphan drug designation for one indication does not mean we will be able to obtain such designation for another indication.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. For a product that obtains orphan drug designation on the basis of a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, such as our diazepam for acute repetitive seizures and our ready-to-use glucagon for PBH product candidates, in order to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. Orphan drug exclusivity means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is

safer, more effective or makes a major contribution to patient care. Even with respect to the indications for which we have received orphan designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of our product candidates could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity for the same drug and same condition. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off-label in our approved indication, and different drugs for the same condition may already be approved and commercially available.

In Europe, the period of orphan drug exclusivity is ten years, although it may be reduced to six years if, at the end of the fifth year, it is established that the criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. We have received orphan drug designation from the EMA for our ready-to-use glucagon for the treatment of congenital hyperinsulinism and Noninsulinoma Pancreatogenous Hypoglycaemia Syndrome, or NIPHS, which includes patients with post-bariatric hypoglycemia, or PBH.

Our failure to successfully identify, develop and market additional product candidates could impair our ability to grow.

As part of our growth strategy, we intend to identify, develop and market additional product candidates leveraging our formulation technology platforms. We are exploring various therapeutic opportunities for our pipeline programs. We may spend several years completing our development of any particular current or future internal product candidates, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. While we identified several potential applications of our ready-to-use glucagon, including our Gvoke HypoPen and several intermittent and chronic conditions, there is no guarantee that we will be able to utilize our formulation technology platforms to advance additional product candidates.

In the future, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license product candidates, approved products or the underlying technology to us. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we identify internally or acquire would require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and other regulatory authorities.

Risks Related to the Commercialization and Marketing of our Product Candidates

Our business depends entirely on the success of our product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed.

To date, we have expended significant time, resources and effort on the development of our product candidates, and a substantial portion of our resources going forward will be focused on seeking marketing approval for and planning for potential commercialization of our lead product candidate, our Gvoke HypoPen, in the United States. Our business and future success are substantially dependent on our ability to successfully and timely obtain regulatory approval for and commercialize our Gvoke HypoPen. Our other product candidates are in earlier stages of development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate product revenues in the immediate term will depend on our ability to successfully obtain marketing approval for and commercialize our Gvoke HypoPen. Any delay or setback in the regulatory approval or commercialization of any of our product candidates will adversely affect our business.

Even if all regulatory approvals are obtained, the commercial success of our product candidates depends on gaining market acceptance among physicians, patients, patient advocacy groups, healthcare payors and the medical community. The degree of market acceptance of our product candidates will depend on many factors, including:

- the scope of regulatory approvals, including limitations or warnings contained in a product candidate's regulatory-approved labeling;
- our ability to produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;
- our ability to establish and maintain commercial manufacturing arrangements with third-party manufacturers;
- our ability to build and maintain sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;
- the acceptance in the medical community of the potential advantages of the product candidate, including with respect to our efforts to increase adoption of our product candidates such as our Gvoke HypoPen by patients and healthcare providers;
- the incidence, prevalence and severity of adverse side effects of our product candidates;
- the willingness of physicians to prescribe our product candidates and of the target patient population to try these therapies;
- the price and cost-effectiveness of our product candidates;
- the extent to which each product is approved for use at, or included on formularies of, hospitals and managed care organizations;
- any negative publicity related to our or our competitors' products or other formulations of products that we administer, including as a result of any related adverse side effects;
- alternative treatment methods and potentially competitive products;
- the potential advantages of the product candidate over existing and future treatment methods;
- the strength of our sales, marketing and distribution support; and
- the availability of sufficient third-party coverage and reimbursement.

Additionally, if the Gvoke HypoPen or any of our other product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products, require us to take our approved product off the market or ask us to voluntarily remove the product from the market;

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy, or REMS, including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, patients and third-party payors, we may never generate significant revenue from these products, and our business, financial condition and results of operations may be materially harmed. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new therapeutics are introduced that are more favorably received than our products or that render our products obsolete, or if significant adverse events occur. If our products do not achieve and maintain market acceptance, we will not be able to generate sufficient revenue from product sales to attain profitability.

The market opportunity for our product candidates may be smaller than we estimate.

The potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions of the current market size and current pricing for commercially available products and are based on industry and market data obtained from industry publications, studies conducted by us, our industry knowledge, third-party research reports and other surveys. Industry publications and third-party research generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. For example, our projections for the potential size of the market for our Gvoke HypoPen are based on our belief that we would be able to increase the adoption of emergency glucagon products by patients and care providers. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, then the actual market for our product candidates, including our Gvoke HypoPen, could be smaller than our estimates of our potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

Our company has limited experience marketing and selling drug products and is currently developing an internal sales organization. If we are unable to establish marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our product candidates, we may not be able to generate product revenues.

We currently do not have sufficient infrastructure for the sales, marketing or distribution of our product candidates, and the cost of establishing and maintaining such an organization may exceed the benefits of doing so. In order to commercialize our product candidates, we must expand our marketing, sales, distribution, managerial and other non-technical capabilities and/or make arrangements with third parties to perform these services. We intend to establish a sales force to market our Gvoke HypoPen in the United States, if we obtain FDA approval. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates, including our Gvoke HypoPen. We are building out our commercial organization in anticipation of receiving marketing approval of our Gvoke HypoPen. If the expected commercial launch of our Gvoke HypoPen is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We cannot be sure that we will be able to hire a sufficient number of sales representatives or that they will be effective at promoting our products that receive regulatory approval, if any. In addition, we will need to commit significant additional management and other resources to establish and grow our sales organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other companies to recruit, hire, train and retain sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products include:

- our inability to recruit and train adequate numbers of sales and marketing personnel;
- the inability of sales personnel to obtain access to or to persuade adequate numbers of physicians to prescribe any of our product candidates that receive regulatory approval; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

In the event that we are unable to effectively implement our sales organization or distribution strategy on a timely and effective basis, if at all, the commercialization of our product candidates could be delayed which would negatively impact our ability to generate product revenues.

We intend to leverage the sales and marketing capabilities that we establish for our Gvoke HypoPen to commercialize additional product candidates for the management of other hypoglycemic conditions, if approved by the FDA, in the United States. If we are unable to do so for any reason, we would need to expend additional resources to establish commercialization capabilities for those product candidates, if approved.

In addition, we intend to establish collaborations to commercialize our product candidates outside the United States, if approved by the relevant regulatory authorities. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such efforts, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, such collaborators may not have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and such efforts may not be successful.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.

Our future revenues and profitability will be adversely affected if U.S. and foreign governmental, private third-party insurers and payors and other third-party payors, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities fail to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for some patients to afford them and physicians may not prescribe them. In addition, limitations on the amount of reimbursement for our products may also reduce our profitability. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. There have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our product candidates for which we obtain marketing approval. Government and other third-party payors are also challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. On December 27, 2018, the District Court for the District of Columbia invalidated a recent reimbursement formula change under the 340B program. The 340B program imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. It is unclear how this decision could affect covered hospitals who might purchase our products in the future, and affect the rates we may charge such facilities for our approved products.

Market acceptance and sales of our products and product candidates that we develop, if approved, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. In the United States, no uniform policy of coverage and reimbursement for

drugs exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. We cannot be certain that reimbursement will be available for any of our product candidates, or that reimbursement rates will not change for our current products. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could negatively affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Furthermore, third-party payors are increasingly requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We expect to experience pricing pressures in connection with the sale of our products that we develop due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA, became law in the United States, and is significantly impacting the provision of, and payment for, health care. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our products and our product candidates.

Some patients may require health insurance coverage to afford our products, if approved, and if we are unable to obtain adequate coverage and reimbursement by third-party payors for our products, our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

Pricing pressure from healthcare industry consolidation and our competitors may impact our ability to sell our products at prices necessary to support our current business strategies.

Our market is subject to competitive pricing pressure as a result of product competition and a trend of consolidation in the healthcare industry to aggregate purchasing power as healthcare costs increase and reforms initiated by legislators, regulators and third-party payors to curb these costs are implemented.

For example, Eli Lilly's Glucagon Emergency Kit, or GEK, is covered at or above 94% with unrestricted access across commercial, Medicare, Managed Medicaid and State Medicaid plans. Of our target patient population, approximately 50% are commercially-insured, one-third are covered by Medicare and approximately 15% are covered by Medicaid. However, as the healthcare industry consolidates, competition to provide products and services to industry participants has become more intense and may intensify as the potential purchasers of our products or third-party

payors use their purchasing power to exert competitive pricing pressure. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our potential purchasers. If competitive forces drive down the prices we are able to charge for our products, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business.

Even if we successfully obtain approval for, produce and distribute our Gvoke HypoPen, its success will be dependent on its proper use by patients, healthcare practitioners and caregivers.

While we have designed our Gvoke HypoPen to be operable by patients, caregivers and healthcare practitioners, we cannot control the successful use of the product by patients, caregivers and healthcare practitioners. Even though our Gvoke HypoPen was used correctly by individuals in our human factors study, there is no guarantee that these results will be replicated by users in the future. If we are not successful in promoting the proper use of our Gvoke HypoPen, if approved, by patients, healthcare practitioners and caregivers, we may not be able to achieve market acceptance or effectively commercialize our Gvoke HypoPen. In addition, even in the event of proper use of our Gvoke HypoPen, individual devices may fail. Increasing the scale of production inherently creates increased risk of manufacturing errors, and we may not be able to adequately inspect every device that is produced, and it is possible that individual devices may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of any of our product candidates that receive approval, result in negative press coverage, or increase the risk that we may be sued.

Guidelines and recommendations can reduce the use of our product candidates.

Government agencies and industry associations such as the American Diabetes Association promulgate guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations from these organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines affecting our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

Risks Related to our Industry and the Ongoing Legal and Regulatory Requirements to which our Product Candidates are Subject

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties. If we fail to comply with continuing U.S. and non-U.S. regulations or new safety data arise, we could lose our marketing approvals and our business would be seriously harmed.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for manufacturing, distribution, sale, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, third-party suppliers and their facilities are required to comply with extensive FDA requirements and requirements of other similar agencies even after approval, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMPs, and applicable Quality System Regulations, or QSRs. As such, we and our third-party suppliers are subject to continual review and periodic inspections, both announced and unannounced, to assess compliance with cGMPs and QSRs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. These unknown problems could be discovered as a result of any post-marketing follow-up studies, routine safety surveillance or other reporting required as a condition to approval.

Regulatory agencies may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, or DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our products for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

If our product candidates fail to comply with applicable regulatory requirements, or if a problem with one of our products or third-party suppliers is discovered, a regulatory agency may:

- restrict the marketing or manufacturing of such products;
- restrict the labeling of a product;
- issue warning letters or untitled letters which may require corrective action;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties including fines, imprisonment and disgorgement of profits;
- suspend or withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us;
- close the facilities of our third-party suppliers;
- suspend ongoing clinical trials;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or recommend or require a product recall.

The FDA's and foreign regulatory agencies' policies are subject to change, and additional federal, state, local or non-U.S. governmental regulations may be enacted that could affect our ability to maintain compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that may arise from future legislation or administrative action, either in the United States or abroad.

We operate in a competitive business environment and, if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our product candidates, even if approved.

The pharmaceutical and biotechnology industries are characterized by intense competition and significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Any product candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future. While we believe that our product and product candidate platform, development expertise and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Many of our current and potential competitors are major pharmaceutical companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. Our ability to compete successfully will depend on our ability to develop future products that reach the market in a timely manner, are well adopted by patients and healthcare providers and receive adequate coverage and reimbursement from third-party payors. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing products competitive to our product candidates.

For example, we have numerous competitors in the severe hypoglycemia market, which currently include Eli Lilly's Glucagon Emergency Kit and Novo Nordisk's GlucaGen, and in the future may include a subcutaneous dasiglucagon auto-injector, being developed by Zealand Pharma, and an intranasal glucagon dry powder, being developed by Eli Lilly. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of severe hypoglycemia that compete directly or indirectly with our glucagon HypoPen, if approved. For example, based on its public disclosure of its submission of an NDA to the FDA for its intranasal glucagon in 2018, we believe Eli Lilly's product candidate could receive marketing approval prior to our PDUFA target action date. Competitors may also develop and patent processes or products earlier than we can or obtain regulatory clearance or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products, if approved, could be negatively affected and our results of operations could suffer.

The widespread acceptance of currently available therapies with which our product candidates will compete may limit market acceptance of our product candidates even if commercialized. For example, emergency glucagon products are currently available for hypoglycemia and are widely accepted in the medical community and have a long history of use. These treatments will compete with our Gvoke HypoPen, if approved, and may limit the potential for our Gvoke HypoPen to receive widespread acceptance if commercialized.

If the FDA approves a competitor's application for a product candidate or drug-device combination product before our application for a similar product candidate or drug-device combination product, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505(b)(2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505(b)(2) application for our Gvoke HypoPen is approved first and we receive three-year marketing exclusivity, we may still be subject to competition from other companies with approved products or approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate. In some cases, even this limited bioequivalence testing can be waived by the FDA. Competition from generic equivalents to our product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

Even if we obtain FDA approval of our lead product candidate, Gvoke HypoPen, or our other product candidates in the United States, we may never obtain or maintain foreign regulatory approvals to market our products in other countries.

We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. In order to market products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain clearance or approval in the United States. In addition, with respect to our Gvoke HypoPen, we are engaged in ongoing interactions with European regulatory authorities regarding our development path in Europe. For our Gvoke HypoPen, because Eli Lilly's Glucagon Emergency Kit is not approved in Europe, we are conducting an additional

clinical trial comparing our Gvoke HypoPen to Novo Nordisk's GlucaGen, in addition to our existing clinical trials involving Eli Lilly's Glucagon Emergency Kit. Such requirements may increase our development expenses and delay our regulatory development plans for potential European approval of our Gvoke HypoPen. There can be no assurance that the results that we observed from our prior clinical trials for our Gvoke HypoPen will be replicated in our ongoing and any future clinical trials that we undertake, or that any such results will be sufficient to secure approval in Europe.

In addition, some countries only approve or certify a product for a certain period of time, and we are required to re-approve or re-certify our products in a timely manner prior to the expiration of our prior approval or certification. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, or if we fail to have our products re-approved or re-certified, our business, results of operations and financial condition could be adversely affected. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. In addition, the clinical standards of care may differ significantly such that clinical trials conducted in one country may not be accepted by healthcare providers, third-party payors or regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any drug we develop will be unrealized.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, including our Gvoke HypoPen, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, or AKS, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the requirements under the federal open payments program and its implementing regulations;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly known as the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate." However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, the Centers for Medicare & Medicaid Services, or CMS, has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization, or PA, and step therapy, or ST, for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" while a definition of "price concession" in the regulations. It is unclear whether these proposed changes we be accepted, and if so, what effect such changes will have on our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2027. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government

to recover overpayments to providers from three to five years. Since 2016, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing or delaying penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable debate, and members of Congress and the Trump Administration have indicated that each will address such costs through new legislative and administrative measures. To date, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, improve transparency in drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products.

At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these other countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for approved products. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform

government program reimbursement methodologies for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent labeling and post-marketing testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the Trump administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement or modification. It is difficult to predict how these requirements will be implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with investigators, healthcare practitioners, consultants, third-party payors and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. These include the following:

- Anti-Kickback Statute. The federal AKS makes it illegal for any person or entity (including a prescription drug manufacturer or a party acting on its behalf) to knowingly and willfully solicit, offer, receive or pay remuneration, directly or indirectly, in cash or in kind, in exchange for or intended to induce or reward either the referral of an individual for, or the purchase, order, prescription or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity can be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Violations of the AKS carry potentially

significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs.

- *False Claims Laws.* The federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or knowingly avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties.
- *Anti-Inducement Law*. The anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.
- *HIPAA*. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (including private payors) or making false or fraudulent statements relating to healthcare matters. Similar to the federal AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Additionally, HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations on covered entities and their business associates, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information.
- *Transparency Requirements.* The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members.
- *Analogous State and Foreign Laws*. Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, and are generally broad and are enforced by many different federal and state agencies as well as through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, and some state laws require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom may receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as

Medicare and Medicaid, disgorgement, contractual damages, reputational harm and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials in the European Union, or EU, we may be subject to additional privacy restrictions. The collection and use of personal health data in the EU is governed by the provisions of the General Data Protection Regulation, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We currently have operations in the United States and we maintain relationships with CMOs in certain parts of Europe, Asia and the United States for the manufacture of our product candidates. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with laws and regulations in each new jurisdiction in which we plan to operate, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The creation and implementation of international business practices compliance programs, particularly FCPA compliance, is costly and such programs are difficult to enforce, especially in countries in which corruption is a recognized problem and where reliance on third parties is required. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Indictment alone under the FCPA can lead to suspension of the right to

do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor.

Accordingly, our failure to comply with the FCPA or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations and other similar laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under such laws would have a negative impact on our operations and harm our reputation and ability to procure government contracts. We cannot assure you that our compliance policies and procedures are or will be sufficient or that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, such as the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries can further reduce prices. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies, which is time-consuming and costly. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage

against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks Related to our Dependence on Third Parties

We depend on third parties to conduct the clinical trials for our product candidates, and any failure of those parties to fulfill their obligations could harm our development and commercialization plans.

We depend on independent clinical investigators, CROs, academic institutions and other third-party service providers to conduct clinical trials with and for our product candidates. Although we rely heavily on these parties for successful execution of our clinical trials, we are ultimately responsible for the results of their activities and many aspects of their activities are beyond our control. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, but the independent clinical investigators may prioritize other projects over ours or may fail to timely communicate issues regarding our products to us. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The delay or early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials, or our reliance on results of trials that we have not directly conducted or monitored could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition.

We maintain compliance programs related to our clinical trials through our clinical operations and development personnel working with our finance and legal groups' support. Our clinical trial vendors are required to monitor and report to us the possible remedial action required for the conduct of clinical studies, and we are obliged to take the appropriate action. We also monitor clinical trial vendors through our regulatory and quality assurance staff and service providers. However, we cannot assure you that our programs and personnel will timely and fully discover any fraud or abuse that may occur in connection with our clinical trials. Such fraud or abuse, if it occurs, could have a material adverse effect on our research, development, and commercialization activities and results.

Our reliance on third-party suppliers, including single-source suppliers and a limited number of options for alternate sources for our product candidates, including our Gvoke HypoPen, could harm our ability to develop our product candidates or to commercialize any product candidates that are approved.

We do not currently own or operate manufacturing facilities for the production of any of our product candidates, including our Gvoke HypoPen. We rely on third-party suppliers to manufacture and supply our products. We currently rely on a number of single-source suppliers, such as Bachem Americas, Inc., or Bachem, for active pharmaceutical ingredient, or API, Pyramid Laboratories Inc., or Pyramid, for drug product and SHL Pharma, LLC, or SHL Pharma, for auto-injector and final product assembly, and we have entered into supply agreements with Bachem, Pyramid and SHL Pharma. Our third-party suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our products. As a result, there can be no assurances that we will be able to obtain sufficient quantities of key materials or products in the future, which could have a material adverse effect on our business.

For us to be successful, our third-party suppliers must be able to provide us with raw materials, components and products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Reliance on third-party suppliers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that products will not be delivered on a timely basis, the possibility of increases in pricing for our products, and the possibility of breach or termination of a manufacturing agreement or purchase order by the third party.

Our product candidates, including Gvoke HypoPen, are drug-device combination products that will be regulated under the drug regulations of the FDCA based on its primary mode of action as a drug. Third-party manufacturers

may not be able to comply with the cGMP regulatory requirements applicable to drug-device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSRs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with applicable cGMPs and QSRs. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP or QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

There are a limited number of third-party suppliers that are compliant with cGMP and/or QSRs, as required by the FDA, the European Union, and other regulatory authorities, and that also have the necessary expertise and capacity to manufacture our materials and products. As a result, it may be difficult for us to locate third-party suppliers for our anticipated future needs, and our anticipated growth could strain the ability of our current third-party suppliers to deliver products, raw materials and components to us. If we are unable to arrange for third-party suppliers for our materials and products, or to do so on commercially reasonable terms, we may not be able to complete development of or market our products.

The introduction of new cGMP or QSR regulations or product specific requirements by a regulatory body may require that we source alternative materials, modify existing manufacturing processes or implement design changes to our products that are subject to prior approval by the FDA or other regulatory authorities. We may also be required to reassess a third-party supplier's compliance with all applicable new regulations and guidelines, which could further impede our ability to manufacture and supply products in a timely manner. As a result, we could incur increased production costs, experience supply interruptions, suffer damage to our reputation and experience an adverse effect on our business and financial results.

In addition, our reliance on third-party suppliers involves a number of additional risks, including, among other things:

- our suppliers may fail to comply with regulatory requirements or make errors in manufacturing raw materials, components or products that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;
- we may be subject to price fluctuations by suppliers due to terms within long-term supply arrangements or lack of long-term supply arrangements for key materials and products;

- our suppliers may lose access to critical services or sustain damage to a facility, including losses due to natural disasters or geo-political events, that may result in a sustained interruption in the manufacture and supply of our products;
- fluctuations in demand for our products or a supplier's demand from other customers may affect their ability or willingness to deliver materials or products in a timely manner or may lead to long-term capacity constraints at the supplier;
- we may not be able to find new or alternative sources or reconfigure our products and manufacturing processes in a timely manner if a necessary raw material or components becomes unavailable; and
- our suppliers may encounter financial or other hardships unrelated to our demand for materials, products and services, which could inhibit their ability to fulfill our orders and meet our requirements.

If any of the above risks materialize and we are unable to satisfy commercial demand for our products in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products. In addition, we could be forced to secure new materials or develop alternative third-party suppliers, which can be difficult given our product complexity, long development lead-times and global regulatory review processes.

We may in the future elect to manufacture certain new or existing products ourselves, without the assistance of third-party suppliers. However, in order to make that election, we will need to invest substantial additional funds and recruit qualified personnel in order to operate our own manufacturing facility on a commercial basis. There can be no assurance that we will be able to successfully manufacture our own products, and if we are not able to make or obtain adequate supplies of our raw materials, components or products, it will be more difficult for us to launch new products, supply our current markets and compete effectively.

If our third-party manufacturers of our product candidates are unable to increase the scale of their production of our product candidates, or increase the product yield of manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and subsequent commercialization of our Gvoke HypoPen or any of our other product candidates in our pipeline or that we may develop, our third-party manufacturers will be required to increase their production and automate and otherwise optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to automate and otherwise optimize their manufacturing process to increase the product yield for our Gvoke HypoPen and other components of our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining quality, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate revenues and have a material adverse impact on our business and results of operations.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically have entered, and in the future may enter, into academic, commercial, service, collaboration, licensing, feasibility, consulting and other agreements that contain indemnification provisions. We have in the past and may in the future agree to indemnify the counterparties from losses arising from claims relating to the products, processes or services made, used, sold or performed. We may also agree to indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We expect to seek one or more collaborators for the development and commercialization of one or more of our product candidates, particularly with respect to our pipeline product candidates or foreign geographies. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Risks Related to our Intellectual Property

Our success depends on our ability to protect our intellectual property and proprietary technology, as well as the ability of our collaborators to protect their intellectual property and proprietary technology.

Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we may in the future also license or purchase patent applications filed by others. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Although we currently own all of our patents and our patent applications, similar risks would apply to any patents or patent applications that we may in-license in the future.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party preissuance submission of prior art to the USPTO and/or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivations proceedings, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Pending and future patent applications may not result in patents being issued which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in

various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates in such countries.

Issued patents that we have or may in the future obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our or our future licensors' patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or in the future licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

In the future, we may enter into license agreements with third parties pursuant to which they have the right, but not the obligation, in certain circumstances to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of those licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that those licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. We have not conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, so we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in any future licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will not: (a) be sufficient to protect our technology, (b) provide us with a basis for commercially viable products or (c) provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Where available, we will seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

A third party or former employee or collaborator may claim an ownership interest in one or more of our patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. New patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the America Invents Act, signed into law in September 2011, could increase those uncertainties and costs. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefining prior art and providing more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the America Invents Act has reformed the United States patent law in part by changing the U.S. patent system from a “first to invent” system to a “first inventor to file” system. The first inventor to file provision, however, only became effective on March 16, 2013, so it is still not yet clear what, if any, impact the America Invents Act will have on the operations of our business. The America Invents Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window

from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and uses a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our product candidates.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Agreements through which we may license patent rights may not give us sufficient rights to permit us to pursue enforcement of those licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Others may claim an ownership interest in our intellectual property which could expose us to litigation and have a significant adverse effect on our prospects.

A third party may claim an ownership interest in one or more of our patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical

testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

The pharmaceutical industry is characterized by frequent patent litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. Generally, we do not conduct independent reviews of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. In the future, we may receive communications from various industry participants alleging our infringement of their patents, trade secrets, or other intellectual property rights and/or offering licenses to such intellectual property. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling products or using technology that contains the allegedly infringing intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In connection with such litigation or claims, we may be required to obtain licenses or make changes to our products or technologies, and if we fail to do so, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers

or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Our unpatented trade secrets, know-how, confidential and proprietary information, and technology may be inadequately protected.

We rely in part on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants, and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

There is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secret protections against them, which could have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

We submitted our NDA for our Gvoke HypoPen in August 2018 under Section 505(b)(2) of the FDCA, and we expect to submit NDAs for our other product candidates, to the FDA for approval under this section. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies and/or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. An NDA under Section 505(b)(2) would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for a previously approved drug.

For NDAs submitted under Section 505(b)(2), the patent certification and related provisions of the Hatch-Waxman Act apply. Accordingly, if we rely for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, we will be required to include patent certifications in our 505(b)(2) application regarding any patents covering the listed drug. If there are patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and we seek to obtain approval prior to the expiration of one or more of those patents, we will be required to submit a Paragraph IV certification indicating our belief that the relevant patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of our 505(b)(2) application. Otherwise, our 505(b)(2) application cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. While we did not submit any Paragraph IV certifications in connection with our 505(b)(2) NDA for our Gvoke HypoPen, and do not expect to submit any Paragraph IV certifications for our other current product candidates, there can be no assurance that we will not be required to submit a Paragraph IV certification in respect of any future product candidates for which we seek approval under Section 505(b)(2).

If we submit any Paragraph IV certification that may be required, we will be required to provide notice of that certification to the NDA holder and patent owner shortly after our 505(b)(2) application is accepted for filing. Under the Hatch-Waxman Act, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner's or NDA holder's receipt of notice (whichever is later), a one-time, automatic stay of the FDA's ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or

more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) submissions and require us to submit traditional NDAs under Section 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. In addition, the FDA could reject any future 505(b)(2) application and require us to submit an ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours. These factors, among others, may limit our ability to commercialize our product candidates successfully.

Risks Related to Employee Matters, Managing Growth and Ongoing Operations

If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.

We may face liability claims related to the use or misuse of our product candidates and, if approved, our products. These claims may be expensive to defend and may result in large judgments against us. During the course of treatment, patients using our product candidates could suffer adverse medical effects for reasons that may or may not be related to our product candidates. We will face even greater risks upon any commercialization by us of our product candidates. Any of these events could result in a claim of liability. Any such claims against us, regardless of their merit, could result in significant costs to defend or awards against us that could materially harm our business, financial condition or results of operations. In addition, any such claims against us could result in a distraction to management, decreased demand for our products, an adverse effect on our public reputation, and/or difficulties in commercializing our products. To date, we have not received notice of any product liability claims against us. We maintain total product liability insurance coverage of $5.0 million.

Although we maintain product liability insurance for claims arising from the use of our product candidates in clinical trials prior to FDA approval and for claims arising from the use of our products after FDA approval at levels that we believe are appropriate, we may not be able to maintain our existing insurance coverage or obtain additional coverage on commercially reasonable terms for the use of our other product candidates and products in the future. Also, our insurance coverage and resources may not be sufficient to satisfy any liability resulting from product liability claims, which could materially harm our business, financial condition or results of operations.

Product liability claims could result in an FDA or other regulatory authority investigation of the safety or efficacy of our products, our manufacturing processes and facilities, our marketing programs, our internal safety reporting systems or our staff conduct. A regulatory authority investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval. Product liability claims could also result in investigation, prosecution or enforcement action by the DOJ or other federal or state government agencies.

Our business could suffer if we lose the services of key members of our senior management, or if we are not able to attract and retain other key employees and consultants.

We are dependent upon the continued services of key members of our executive management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our executive management team, including Paul Edick, our Chief Executive Officer, Barry Deutsch, our Chief Financial Officer, Steven Prestrelski, our Chief Scientific Officer and Co-Founder, John Shannon, our Chief Operating Officer, Ken Johnson, our Senior Vice President, Clinical Development, Regulatory, Quality Assurance and Medical Affairs, and Beth Hecht, our Senior Vice President, General Counsel and Corporate Secretary. The loss of any one of these individuals could disrupt our operations or our strategic plans. Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be

difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified scientific, technical and managerial personnel, for whom we compete with numerous other companies, academic institutions and organizations. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We will need to increase the size of our organization, and we may encounter difficulties managing our growth.

As of January 31, 2019, we had 100 employees. As our product candidates continue to progress toward potential approval and commercialization, we anticipate the need to hire additional employees as required to add depth and specialized expertise to our team. This growth could place a strain on our administrative and operational infrastructure. If the product candidates that we are developing continue to advance in clinical trials, we will need to expand our development, regulatory, manufacturing, quality, compliance, recordkeeping, information technology, training, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to develop additional relationships with various collaborators, CROs, suppliers, manufacturers and other organizations. We may not be able to establish such relationships or may incur significant costs to do so. Our ability to manage our growth will also require us to continue to improve our operational, financial and management controls, reporting systems and procedures, and other compliance programs and processes, which will further increase our operating costs. Failure to manage our growth effectively could cause us to over-invest or under-invest in infrastructure, and result in losses or weaknesses in our infrastructure, which could adversely affect us. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to monitor our suppliers carefully for quality assurance, and our business could suffer.

We may be required to maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

As a result of the need to maintain substantial levels of inventory due to single third-party sourcing and long lead-time to develop alternate third-party sources, we intend to carry a high level of inventory for strategic materials and products and are subject to the risk of inventory obsolescence. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

As a result of being a public company, we will continue to incur significant additional costs which may adversely affect our operating results and financial condition.

We expect to continue to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, the SEC and The Nasdaq Global Select Market. These rules and regulations have increased our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, we will continue to incur additional costs associated with our public company reporting requirements and we expect those costs to continue to increase in the future. For example, we will be required to devote significant resources to complete the assessment and documentation of our internal control system and financial process under Section 404 of the Sarbanes-Oxley Act, including an assessment of the design of our information systems associated with our internal controls.

We have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them

before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, or the Exchange Act, as amended. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences. We will incur significant costs to remediate any material weaknesses we identify through these efforts. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

New laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act and rules adopted by the SEC and The Nasdaq Global Select Market, would likely result in increased costs to us as we respond to their requirements, which may adversely affect our operating results and financial condition.

We identified a material weakness in our internal control over financial reporting in our audit for the fiscal year ended December 31, 2017. If we fail to remediate this weakness or experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We are required under Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2019. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

We may further enhance the computer systems processes and related documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

For example, for the year ended December 31, 2017, we identified a material weakness in our internal control over financial reporting due to a lack of proper segregation of duties within our finance and accounting function. This weakness was due to our inability to implement the appropriate segregation of duties within our historical enterprise resource planning, or ERP, system. Since August 2017, we have made efforts to design manual controls to mitigate the risk. In addition, in December 2017, we implemented a new ERP system. If we are unable to conclude that our internal control over financial reporting is effective or take effective remedial measures to improve our internal control, we could lose investor confidence in the accuracy and completeness of our financial reports, which would likely cause the price of our common stock to decline.

When we cease to be an “emerging growth company” under the federal securities laws, our auditors will be required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our auditors are unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, compliance, purchasing and inventory management. Our current systems are not fully redundant. While we will attempt to mitigate interruptions, we may experience difficulties in implementing some upgrades which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may not be able to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Despite our implementation of security measures, our information systems, like those of other companies, are vulnerable to damages from computer viruses, natural disasters, unauthorized access, cyber attack and other similar disruptions. Any system failure, accident or security breach could result in disruptions to our operations. For example, third parties may attempt to hack into systems and may obtain our proprietary information, which could cause significant damage to our reputation, lead to claims against the Company and ultimately harm our business.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors’ and officers’ liability insurance, general liability insurance, property insurance and workers’ compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage any acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

From time to time we expect to consider opportunities to acquire or make investments in other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential acquisitions and strategic investments involve numerous risks, including:

- problems assimilating the purchased technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management’s attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We have no current commitments with respect to any acquisition or investment and we have never entered into or completed an acquisition. We do not know if we will be able to identify suitable acquisitions, complete any such

acquisitions on favorable terms or at all, successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to grow through acquisitions successfully depends upon our ability to identify, negotiate, complete and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time consuming and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to integrate any acquired businesses, products or technologies effectively, our business, results of operations and financial condition will be materially adversely affected.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon

completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm to our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, to provide accurate information to the FDA or comparable non-U.S. regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”). We continue to examine the impact this tax reform legislation may have on our business. The overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Risks Related to Our Common Stock and this Offering

Our stock price has been and will likely continue to be volatile, and you may not be able to sell shares of our common stock at or above the offering price, if at all.

The trading price of our common stock may be highly volatile and could be subject to large fluctuations in response to the risk factors discussed in this section, and others beyond our control, including:

- the timing and results of applications for FDA review and approval of our Gvoke HypoPen and other regulatory actions with respect to our product candidates;
- regulatory actions with respect to our competitors’ products and product candidates;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of our competitors;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of our pipeline product candidates;
- commencement or termination of collaborations for our development programs;
- the results of our efforts to develop additional product candidates or products;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure or discontinuation of any of our development programs;
- the pricing and reimbursement of our Gvoke HypoPen, if approved, and of other product candidates that may be approved;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In recent years, the stock markets, and particularly the stock of smaller pharmaceutical and biotechnology companies, at times have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. Broad market and industry factors may significantly affect the market price of our common stock unrelated to our actual operating performance. Since shares of our common stock were sold in our IPO in June 2018 at a price of $15.00 per share, our stock price has fluctuated significantly, ranging from an intraday low of $13.31 to an intraday high of $27.98 through February 7, 2019. If the market price of our common stock after this offering does not exceed the public offering price, you may lose some or all of your investment. If the market price of shares of our common stock after this offering does not exceed the offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

If you purchase shares of common stock in this offering, you will suffer immediate dilution in the net tangible book value of your investment.

The offering price of our common stock is substantially higher than the net tangible book value per share of our common stock before giving effect to this offering. Therefore, if you purchase shares of our common stock in this offering, you will incur immediate substantial dilution of $8.43 per share, based on an assumed public offering price of $14.76 per share, the last reported sale price of our common stock on the Nasdaq Global Select Market on February 7, 2019 and our net tangible book value as of September 30, 2018. Furthermore, if the underwriters exercise their option to purchase additional shares, you will experience further dilution. For additional information on the dilution that you will experience immediately after this offering, see the section titled "Dilution."

Securities analysts may publish inaccurate or unfavorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline.

The trading market for our common stock is influenced by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. As a newly public company, the analysts who

publish information about our common stock will have had relatively little experience with our company, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. If any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and the reduced disclosure requirements applicable to "emerging growth companies" may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we have elected to take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

As a result, our public filings may not be comparable to companies that are not "emerging growth companies". We may remain an "emerging growth company" until the fiscal year-end following the fifth anniversary of the completion of our IPO, though we may cease to be an "emerging growth company" earlier under certain circumstances, including (i) if the market value of our common stock that is held by nonaffiliates exceeds $700 million as of any June 30, in which case we would cease to be an "emerging growth company" as of the following January 1, or (ii) if our gross revenue exceeds $1.07 billion in any fiscal year.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. In addition, we qualify as a "smaller reporting company," which allows us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Investors may find our common stock less attractive if we rely on these exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline and/or become more volatile.

Our management might apply the proceeds of this offering in ways that do not increase the value of your investment.

Although we currently intend to use the net proceeds from this offering in the manner described in the section titled "Use of Proceeds" in this prospectus, our management will have broad discretion as to the use of the net proceeds of this offering and you will be relying on the judgment of our management regarding the application of these proceeds. We might apply the net proceeds of this offering in ways with which you do not agree, or in ways that do not yield a favorable return. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering or to assess whether proceeds are being used appropriately. If our management applies these proceeds in a manner that does not improve our operating results and yield a significant return, if any, on our investment of these net proceeds, the market price of our common stock could decline. For more information on our management's planned use of proceeds, please read "Use of Proceeds" elsewhere in this prospectus. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Sales of a substantial number of shares of common stock could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell

shares, could reduce the market price of our common stock. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. Upon completion of this offering, based on the number of shares outstanding as of December 31, 2018, we will have outstanding 25,893,205 shares of common stock (which includes 84,839 shares of unvested restricted stock), of which 542,933 are subject to lock-up agreements entered into in connection with this offering and will be available for sale in the public market beginning 90 days after the date of this prospectus. Any of our remaining shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates of ours.

In addition, holders of an aggregate of approximately 537,274 shares of our common stock are entitled, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have registered the shares of common stock issuable upon exercise or settlement of all equity awards issued or reserved for issuance under our 2018 Stock Option and Incentive Plan, 2018 Employee Stock Purchase Plan and our Inducement Equity Plan under a Registration Statement on Form S-8. These shares can be freely sold in the public market upon issuance and once vested, subject to the lock-up agreements described above and Rule 144 in the case of our affiliates.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2017, we had federal net operating loss carryforwards of $55.8 million and federal research and orphan drug credit carryforwards of $2.0 million. If not utilized, these carryforwards will expire at various dates between 2025 and 2036. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Our existing net operating losses or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize our net operating losses or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which may be outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits.

We do not anticipate paying any cash dividends in the foreseeable future, and accordingly, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, under our Loan and Security Agreement, we are restricted from paying any dividends or making any distributions on account of our capital stock. Our ability to pay cash dividends also may be prohibited by future loan agreements. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Investors seeking cash dividends should not invest in our common stock.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management

team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws;
- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty by one or more of our directors, officers or employees, any action asserting a claim against us pursuant to the Delaware General Corporation Law, or any action asserting a claim against us that is governed by the internal affairs doctrine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our bylaws designate certain courts as the sole and exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of or based on a fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Our amended and restated bylaws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provision.

This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in this court could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Delaware Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders.

In addition, our amended and restated bylaws further provide that the United States District Court for the Northern District of Illinois will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, and that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provision. We have chosen the United States District Court for the Northern District of Illinois as the exclusive forum for Securities Act causes of action because our principal executive offices are located in Chicago, Illinois. However, on December 19, 2018, the Delaware Court of Chancery issued a decision declaring that such federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are ineffective and invalid under Delaware law. On January 17, 2019, that decision was appealed to the Delaware Supreme Court. Unless and until the Court of Chancery's decision is reversed by the Delaware Supreme Court or otherwise abrogated, we will not seek to enforce our federal forum selection provision designating the Northern District of Illinois as the exclusive forum for Securities Act claims. In the event that the Delaware Supreme Court affirms the Court of Chancery's decision or otherwise determines that federal forum selection provisions are invalid, our Board intends to amend promptly our amended and restated bylaws to remove our federal forum selection bylaw provision. As a result of the Court of Chancery's decision or a decision by the Supreme Court of Delaware affirming the Court of Chancery's decision, we may incur additional costs associated with our federal forum selection bylaw provision, which could have an adverse effect on our business, financial condition or results of operations.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the timing or likelihood of approval by the FDA of our NDA for our Gvoke HypoPen;
- our estimates regarding the market opportunities for our product candidates;
- the commercialization, marketing and manufacturing of our product candidates, if approved;
- the pricing and reimbursement of our Gvoke HypoPen or any other of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of our Gvoke HypoPen or any other of our product candidates for which we receive marketing approval;
- the initiation, timing, progress and results of our research and development programs and future preclinical and clinical studies;
- our ability to advance any other product candidates into, and successfully complete, clinical studies and obtain regulatory approval for them;
- our ability to identify additional product candidates;
- the implementation of our strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to use the proceeds of this offering in ways that increase the value of your investment;
- our expectations related to the use of proceeds from this offering, and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of components and drug product for commercialization of our Gvoke HypoPen or any other of our product candidates;
- our ability to maintain and establish collaborations;
- our financial performance;
- our ability to effectively manage our anticipated growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to remediate the material weakness identified by our independent registered public accounting firm and avoid any findings of material weakness or significant deficiencies in the future; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of 5,000,000 shares of our common stock in this offering will be approximately $68.6 million, or approximately $79.0 million if the underwriters exercise in full their option to purchase additional shares, based on the assumed public offering price of $14.76 per share, the last reported sale price of our common stock on the Nasdaq Global Select Market on February 7, 2019, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed public offering price of $14.76 per share would increase (decrease) the net proceeds to us from this offering by $4.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by $13.9 million, assuming no change in the assumed public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

As of September 30, 2018, we had cash and cash equivalents and short-term investments of $131.0 million. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, as follows:

- approximately $40.0 million to support the commercial launch of Gvoke HypoPen, including investments in sales and marketing, direct-to-consumer marketing, inventory and our commercial and medical affairs infrastructure;
- approximately $30.0 million to advance our other pipeline product candidates, including conducting Phase 3 clinical trials (i) for the glucagon HypoPen for Europe, (ii) for PBH, and (iii) for CHI; Phase 2 clinical trials for HAAF and EIH; and preclinical and clinical trials for ready-to-use diazepam and Pram-Insulin; and
- the remainder for working capital and other general corporate purposes.

Based on our current plans, we believe our existing cash and cash equivalents and short-term investments, together with the net proceeds from this offering, expected revenue from sales of our Gvoke HypoPen, and available borrowing under our loan facility of $10.0 million upon approval of our Gvoke HypoPen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA, will be sufficient to fund our operations and capital expenditure requirements through at least the first quarter of 2022.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. For example, we may use a portion of the net proceeds for the acquisition of businesses or technologies to continue to build our pipeline, our research and development capabilities and our intellectual property position, although we currently have no agreements, commitments or understandings with respect to any such transaction. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the status of and results from nonclinical studies or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our results of operations, financial condition, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors. Under our Loan Agreement with Oxford Finance LLC and Silicon Valley Bank, we are restricted from paying any dividends or making any distributions on account of our capital stock. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Loan Agreement” for a description of the restrictions on our ability to pay dividends.

Table of Contents

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2018:

- on an actual basis; and
- on an as adjusted basis to give further effect to the sale and issuance by us of 5,000,000 shares of our common stock in this offering at the assumed public offering price of $14.76 per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on February 7, 2019, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information below in conjunction with the financial statements and the related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	AS OF SEPTEMBER 30, 2018	
(In thousands, except share and per share data)	**ACTUAL**	**AS ADJUSTED**
	(Unaudited)	
Cash and cash equivalents	$ 75,745	$ 144,345
Short-term investments	$ 55,296	$ 55,296
Long-term debt, net	$ 31,642	$ 31,642
Other long-term liabilities	2,621	2,621
Stockholders' equity:		
Common stock, $0.0001 par value; 150,000,000 shares authorized, 20,860,339 shares issued and outstanding, actual; 150,000,000 shares authorized, 25,860,339 shares issued and outstanding, as adjusted	2	3
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding, actual and as adjusted	—	—
Additional paid in capital	195,422	264,021
Accumulated deficit	(100,246)	(100,246)
Accumulated other comprehensive loss	(58)	(58)
Total stockholders' equity	95,120	163,720
Total capitalization	$ 129,383	$ 197,983

A $1.00 increase (decrease) in the assumed public offering price of $14.76 per share, the last reported sale price of our common stock on The Nasdaq Global Select Market on February 7, 2019, would increase (decrease) the as adjusted amount of cash and cash equivalents, additional paid in capital, total stockholders' equity and total capitalization by approximately $4.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us in this offering would increase (decrease) the as adjusted amount of cash and cash equivalents, short-term investments, additional paid in capital, total stockholders' equity and total capitalization by approximately $13.9 million, assuming the assumed public offering price of $14.76 per share, the last reported sale price of our common stock on The Nasdaq Global Select Market on February 7, 2019, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above excludes each of the following:

- 2,350,125 shares of common stock issuable upon exercise of options issued under our 2011 Stock Option/Stock Issuance Plan at a weighted-average exercise price of $4.42 per share;

- 298,410 shares of common stock issuable upon exercise of options issued under our 2018 Stock Option and Incentive Plan at a weighted-average exercise price of $20.73 per share;
- 19,931 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $5.912 per share and 94,012 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $11.169 per share;
- 2,374,918 shares of common stock reserved for future issuance under our 2018 Stock Option and Incentive Plan;
- 401,932 shares of common stock reserved for future issuance under our 2018 Employee Stock Purchase Plan; and
- 750,000 shares of common stock reserved for future issuance under our Inducement Equity Plan adopted by our board of directors in February 2019.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock after this offering. As of September 30, 2018 our net tangible book value was $95.1 million, or $4.58 per share. Our historical net tangible book value represents total tangible assets less total liabilities, all divided by the number of shares of common stock outstanding on September 30, 2018.

After giving effect to the sale of 5,000,000 shares of common stock offered in this offering at an assumed public offering price of $14.76 per share, which was the last reported sale price of our common stock on The Nasdaq Global Select Market on February 7, 2019, and after deducting underwriting discounts and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2018 would have been $163.7 million, or $6.33 per share. This represents an immediate increase in net tangible book value of $1.77 per share to existing stockholders and an immediate dilution of $8.43 per share to investors participating in this offering. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$14.76
Net tangible book value per share as of September 30, 2018	$4.56	
Increase in net tangible book value per share attributable to new investors	1.77	
As adjusted net tangible book value per share after giving effect to this offering		6.33
Dilution per share to new investors in this offering		$ 8.43

The above discussion and tables are based on 20,860,339 shares of our common stock issued and outstanding as of September 30, 2018, which includes 104,673 shares of unvested restricted stock, and exclude:

- 2,350,125 shares of common stock issuable upon exercise of options issued under our 2011 Stock Option/Stock Issuance Plan at a weighted-average exercise price of $4.42 per share;
- 298,410 shares of common stock issuable upon exercise of options issued under our 2018 Stock Option and Incentive Plan at a weighted-average exercise price of $20.73 per share;
- 19,931 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $5.912 per share and 94,012 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of $11.169 per share;
- 1,934,591 shares of common stock to be reserved for future issuance under our 2018 Stock Option and Incentive Plan;
- 401,932 shares of common stock to be reserved for future issuance under our 2018 Employee Stock Purchase Plan; and
- 750,000 shares of common stock reserved for future issuance under our Inducement Equity Plan adopted by our board of directors in February 2019.

To the extent that outstanding options are exercised or shares are issued under our equity incentive plans, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

SELECTED FINANCIAL INFORMATION

The selected statements of operations data for the years ended December 31, 2016 and 2017 and the selected balance sheet data as of December 31, 2016 and 2017 are derived from our audited financial statements included elsewhere in this prospectus. The selected statements of operations data for the nine months ended September 30, 2017 and 2018 and the selected balance sheet data as of September 30, 2018 have been derived from our unaudited interim financial statements appearing elsewhere in this prospectus. The selected financial data in this section are not intended to replace the financial statements and the related notes. The unaudited interim financial data, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and the related notes included elsewhere in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the information for the periods presented. Our historical results are not necessarily indicative of the results that may be expected in the future, and the results for the nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the full year ending December 31, 2018 or any other period.

You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	YEARS ENDED DECEMBER 31		NINE MONTHS ENDED SEPTEMBER 30,	
	2016	2017	2017	2018
(in thousands, except share and per share data)			(unaudited)	
Statements of Operations Data:				
Grant income	$ 1,022	$ 1,540	$ 1,073	$ 1,611
Service revenue	53	16	16	53
Cost of revenue	8	4	4	42
Gross profit	1,067	1,552	1,085	1,622
Operating expenses:				
Research and development	10,238	20,166	13,588	28,264
General and administrative	4,060	8,015	4,917	12,388
Expense from operations	14,298	28,181	18,505	40,652
Loss from operations	(13,231)	(26,629)	(17,420)	(39,030)
Other income (expense):				
Interest income	5	124	45	796
Interest expense	(2)	(2)	(1)	(1,490)
Change in fair value of warrants	24	(46)	(32)	63
Other expense	(5)	(1)	—	—
Total other income (expense)	22	75	12	(631)
Net loss	$ (13,209)	$ (26,554)	$ (17,408)	$ (39,661)
Net loss per share - basic and diluted (1)	$ (7.17)	$ (13.09)	$ (8.63)	$ (4.36)
Weighted average number of common shares outstanding, basic and diluted (1)	1,842,416	2,028,224	2,016,112	9,104,491

(in thousands)	AS OF DECEMBER 31, 2016	AS OF DECEMBER 31, 2017	AS OF SEPTEMBER 30, 2018 (unaudited)
Balance Sheet Data:			
Cash and cash equivalents	$ 32,269	$ 42,045	$ 75,745
Short-term investments	—	—	55,296
Working capital (2)	30,647	39,193	127,462
Total assets	33,533	44,998	137,591
Long-term debt, net of unamortized deferred costs	—	—	31,642
Other long-term liabilities	42	90	2,621
Total liabilities	2,569	4,950	42,471
Total convertible preferred stock	62,898	97,878	—
Total stockholders' equity (deficit)	(31,934)	(57,830)	95,120

(1) See Note 2 to our audited financial statements and Note 2 to our interim unaudited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share and the shares used in computing basic and diluted net loss per share.

(2) We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. In addition to financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in "Risk Factors."

Overview

We are a specialty pharmaceutical company leveraging our novel technology platforms, XeriSol and XeriJect, to develop and commercialize ready-to-use, non-aqueous formulation injectable and infusible drug formulations. We have developed a ready-to-use, room-temperature stable liquid glucagon formulation that, unlike any currently available products, can be administered without any preparation or reconstitution. Our lead product candidate, Gvoke HypoPen, delivers ready-to-use glucagon via a commercially-available auto-injector for the treatment of severe hypoglycemia, a potentially life-threatening condition, in people with diabetes. We have completed three Phase 3 clinical trials for our Gvoke HypoPen and submitted a New Drug Application, or NDA, to the U.S. Food & Drug Administration, or the FDA, in August 2018. The FDA has set June 10, 2019 as the Prescription Drug User Fee Act, or PDUFA, action goal date for our NDA. If our NDA is approved at that time, we believe we will have the first ready-to-use, room-temperature stable liquid glucagon formulation that can be administered without any preparation or reconstitution. Additionally, through our interactions with the European Medicines Agency, or EMA, regarding our development path in Europe, we have finalized our regulatory plan and initiated a requisite Phase 3 pivotal trial to support our European Marketing Authority Application, or MAA. We also are applying our novel ready-to-use, room-temperature stable liquid glucagon formulation for the management of hypoglycemia associated with additional intermittent and chronic conditions with significant unmet medical need. In addition, we are applying our technology platforms to convert other commercially-available drugs into ready-to-use, room-temperature stable liquid formulations to address the needs in multiple therapeutic areas and conditions, including epilepsy and diabetes.

We have begun building out our commercial organization, including individuals in operations and marketing as well as medical affairs, in preparation for a commercial launch of the Gvoke HypoPen in the United States in the second half of 2019. Outside the United States, we plan to pursue development and commercialization partnerships. We currently contract with third parties for the manufacture, assembly, testing, packaging, storage and distribution of our products.

Since our inception in 2005, we have devoted substantially all of our resources to research and development initiatives, undertaking preclinical studies of our product candidates, conducting clinical trials of our most advanced product candidates, organizing and staffing our company and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales.

We have funded our operations to date primarily with proceeds from the sale of preferred and common stock, bank financings and grant awards received from the National Institutes of Health, or NIH, and other philanthropic organizations. In particular, we have received cash proceeds of $104.9 million from sales of our preferred stock, $35.0 million from drawdowns of the Loan and Security Agreement, $10.6 million from grant awards from the NIH and other philanthropic organizations, and $98.4 million from our June 2018 initial public offering, or IPO, of our common stock pursuant to a registration statement on Form S-1, as amended. In the IPO, we sold an aggregate of 6,555,000 shares of our common stock under the registration statement at a public offering price of $15.00 per share, including 855,000 shares of our common stock pursuant to the exercise of the underwriters' option to purchase additional shares. Net proceeds were approximately $89.0 million, after deducting underwriting discounts and commissions as well as other offering expenses. The Loan and Security Agreement includes an additional $10.0 million that will be available beginning upon approval of our Gvoke HypoPen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

For the years ended December 31, 2016 and 2017, our net loss was $13.2 million and $26.6 million, respectively. For the nine months ended September 30, 2017 and 2018, our net loss was $17.4 million and $39.7 million, respectively. We have not been profitable since inception, and as of September 30, 2018, our accumulated deficit was $100.2 million. In the near term, we expect to continue to incur significant expenses, operating losses and net losses as we:

- prepare for a potential commercial launch of our Gvoke HypoPen, including hiring our sales force;
- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements;
- hire and retain additional personnel and add operational, financial and management information systems; and
- continue to operate as a public company.

We do not expect to generate significant product revenue unless or until we obtain marketing approval of, and begin to sell, our product candidates. We expect to continue to seek public equity and debt financing to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our product candidates. In addition, we may not be profitable even if we commercialize any of our product candidates.

Components of our Results of Operations

Revenue

Grant income is derived from grants that we received from the NIH and other philanthropic organizations to help bring necessary drugs to the market place where there are currently unmet needs. As of September 30, 2018, we are eligible to receive $2.1 million in grants from the NIH and other philanthropic organizations that will help fund our ongoing clinical development for intermittent and chronic glucagon programs as well as our auto-injectable diazepam program for the treatment of epileptic seizures. These awards will be recognized as grant income when we have performed the services as outlined in the grant agreements.

Service revenue is derived from the feasibility studies we perform for third parties to determine whether our XeriSol and XeriJect technologies may enhance the formulation of such parties' proprietary drugs.

Cost of revenue includes employees' time, materials and overhead applied to the feasibility studies.

Research and Development

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. Research and development costs that are paid in advance of performance are capitalized until services are provided or goods are delivered. Research and development expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for facility-related costs.

Research and development activities are central to our business model. We expect research and development expenses to increase in the near term as we (i) complete clinical development of our Gvoke HypoPen; (ii) progress our intermittent and chronic glucagon programs for Post-Bariatric Hypoglycemia, Congenital Hyperinsulinism, Hypoglycemia-Associated Autonomic Failure and Exercise-Induced Hypoglycemia; (iii) initiate clinical development

for our ready-to-use diazepam rescue pen; and (iv) conduct additional preclinical work for our Pramlintide-Insulin program. Our research and development expenses may vary significantly over time due to uncertainties relating to the terms and timing of regulatory approvals and unexpected results of our clinical trials.

General and Administrative

General and administrative expenses consist principally of salaries, stock-based compensation and related costs for personnel in executive, marketing and administrative positions, facility costs not otherwise included in research and development, marketing expenses, professional fees for legal, audit and accounting services, fees paid for market research and trade shows, and travel costs for marketing and administrative employees.

As a public reporting company, we have incurred greater expenses, including increased payroll, legal and compliance, accounting, insurance and investor relations costs. We expect some of these costs to continue to increase in conjunction with our anticipated growth as a public reporting company. We also expect selling and marketing costs to increase significantly as we prepare for the expected commercial launch of our Gvoke HypoPen in the United States, if approved, including the build out of a sales force in 2019.

Interest Expense and Other Income

Other income consists primarily of interest expense related to our Loan and Security Agreement, interest income earned on short-term deposits and investments, and the change in the fair market value of our warrants.

Income Tax

We have incurred operating losses since inception and therefore do not have any taxable income. As of December 31, 2017, we have $55.8 million in net operating loss carryforwards and $2.0 million in federal research credits that begin to expire in 2025. Additionally, we have a California Competes Tax Credit Allocation agreement and Illinois EDGE agreement that will reduce future taxable income in those respective states by up to $1.5 million and $1.4 million, respectively.

Results of Operations

Comparison of Nine Months Ended September 30, 2017 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2017 and 2018:

(in thousands)	NINE MONTHS ENDED SEPTEMBER 30, 2017	NINE MONTHS ENDED SEPTEMBER 30, 2018	INCREASE (DECREASE)
	(unaudited)	(unaudited)	
Grant income	$ 1,073	$ 1,611	$ 538
Service revenue	16	53	37
Cost of revenue	4	42	38
Gross profit	1,085	1,622	537
Operating expenses:			
Research and development	13,588	28,264	14,676
General and administrative	4,917	12,388	7,471
Expense from operations	18,505	40,652	22,147
Loss from operations	(17,420)	(39,030)	(21,610)
Other income (expense):			
Interest income	45	796	751
Interest expense	(1)	(1,490)	(1,489)
Change in fair value of warrants	(32)	63	95
Total other income (expense)	12	(631)	(643)
Net loss	$(17,408)	$(39,661)	$ (22,253)

Gross Profit

Gross profit increased for the nine month period ended September 30, 2018 in comparison with the nine month period ended September 30, 2017 due to increased grant-funded activities performed during the current period.

Research and Development

The following table summarizes our research and development expenses by functional area for the nine months ended September 30, 2017 and 2018:

(in thousands)	NINE MONTHS ENDED SEPTEMBER 30, 2017	NINE MONTHS ENDED SEPTEMBER 30, 2018
Clinical and preclinical	$ 5,417	$ 8,795
Product development	5,667	13,210
Compensation and related personnel costs	2,458	5,861
Stock-based compensation	46	398
Total research and development expenses	$ 13,588	$ 28,264

The following table summarizes our research and development expenses by program for the nine months ended September 30, 2017 and 2018:

(in thousands)	NINE MONTHS ENDED SEPTEMBER 30, 2017	NINE MONTHS ENDED SEPTEMBER 30, 2018
Gvoke HypoPen	$ 7,268	$ 14,898
Intermittent and chronic glucagon programs	2,740	2,894
Additional pipeline programs	—	1,335
Overhead (personnel, facilities and other expenses)	3,580	9,137
Total research and development expenses	$ 13,588	$ 28,264

Research and development expenses increased $14.7 million for the nine months ended September 30, 2018 in comparison to the nine months ended September 30, 2017. These increases were primarily driven by increased product development expenses of $7.5 million in support of our Gvoke HypoPen NDA filing and additional pipeline programs, increased personnel expenses of $3.8 million due to additional headcount and other employee-related costs and increased expenses of $3.4 million associated with our clinical trials and preclinical studies.

General and Administrative

General and administrative costs increased $7.5 million for the nine months ended September 30, 2018 in comparison to the nine months ended September 30, 2017. These increases were primarily driven by increases in personnel expenses due to additional headcount and other employee related costs of $4.9 million, marketing and market research expenses of $1.9 million, and professional consulting fees of $0.7 million.

Other Income (expense)

For the nine months ended September 30, 2018, interest expense related to our debt issuances in 2018 was $1.5 million. Interest income earned on short-term investments and interest bearing accounts for the nine months ended September 30, 2018 was $0.8 million. In addition, the fair market value of our warrants decreased for the nine months ended September 30, 2018 in comparison to the nine months ended September 30, 2017 by $95,000. The change in fair value of warrants decreased as the fair value of the stock that it converts into decreased over the respective periods.

Table of Contents

Comparison of the Years Ended December 31, 2016 and 2017

The following table summarizes our results of operations for the years ended December 31, 2016 and 2017:

(in thousands)	YEARS ENDED DECEMBER 31, 2016	2017	INCREASE (DECREASE)
Grant income	$ 1,022	$ 1,540	$ 518
Service revenue	53	16	(37)
Cost of revenue	8	4	(4)
Gross profit	1,067	1,552	485
Operating expenses:			
Research and development	10,238	20,166	9,928
General and administrative	4,060	8,015	3,955
Expense from operations	14,298	28,181	13,883
Loss from operations	(13,231)	(26,629)	(13,398)
Other income (expense):			
Interest income	5	124	119
Interest expense	(2)	(2)	—
Change in fair value of warrants	24	(46)	(70)
Other income (expense)	(5)	(1)	4
Total other income	22	75	53
Net loss	$(13,209)	$(26,554)	$ (13,345)

Gross Profit

Gross profit increased by $485,000 for the year ended December 31, 2017 when compared to the year ended December 31, 2016, primarily driven by an increase in grant income of $518,000. This increase was primarily driven by several clinical trials and preclinical studies for our CHI, PBH and auto-injector for auto-injectable diazepam formulation for treatment of epileptic seizures that were covered by grants awarded to us.

Research and Development

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2016 and 2017:

(in thousands)	FOR THE YEARS ENDED DECEMBER 31, 2016	2017
Clinical and preclinical	$ 2,128	$ 9,233
Product development	5,406	6,654
Compensation and related personnel costs	2,626	4,217
Stock-based compensation	78	62
Total research and development expenses	$ 10,238	$ 20,166

The following table summarizes our research and development expenses by program for the years ended December 31, 2016 and 2017:

	FOR THE YEARS ENDED DECEMBER 31,	
	2016	2017
(in thousands)	(in thousands)	
Gvoke HypoPen	$ 4,687	$ 10,339
Other ready-to-use glucagon products	2,088	4,013
Pipeline product candidates	257	60
Overhead (personnel, facilities and other expenses)	3,206	5,754
Total research and development expenses	$ 10,238	$ 20,166

Research and development expense increased $9.9 million for the year ended December 31, 2017 when compared to the year ended December 31, 2016. This increase was primarily driven by expenses associated with clinical trials, product development and an increase in headcount. In 2017, we started and completed two Phase 3 clinical trials for our Gvoke HypoPen and started Phase 2 clinical trials for PBH and CHI. We produced two registration batches and one engineering batch for the Gvoke HypoPen in 2017 that will be used to support our planned NDA submission in the third quarter of 2018. We also produced clinical supplies for the PBH and CHI programs as well as preclinical material for our intermittent and chronic glucagon programs and diazepam program. We increased headcount in 2017 from 10 to 24 employees to support our current research and development activities.

General and Administrative

General and administrative costs increased $4.0 million for the year ended December 31, 2017 when compared to the year ended December 31, 2016. This increase was primarily driven by increased expenses associated with an increase in headcount and marketing and market research expenses. In 2017, we increased our headcount from three to 17, including the addition of marketing, market research and medical affairs departments, and as a result compensation and related benefit expenses increased $3.4 million. Marketing and market research expenses increased $0.5 million in 2017 as we performed extensive market research for our existing product candidates as well as evaluated several new potential product candidates.

Other Income

Other income increased $53,000 to $75,000 for the year ended December 31, 2017 as a result of the interest income earned on our cash and cash equivalents. This increase was partially offset by the change in the fair market value of our warrants. The change in fair value of warrant liability represents non-cash (expense) income and is driven by the increase in the fair value of the preferred stock that it converts into.

Liquidity and Capital Resources

Our primary uses of cash are to fund product development costs, operating expenses and working capital requirements. In connection with our IPO, we received aggregate net proceeds of $89.0 million. Prior to our IPO, we funded our operations primarily through private placements of convertible preferred stock, issuance of debt, and grants awarded from the NIH and other philanthropic organizations. As of September 30, 2018, we have $2.1 million in awarded unused grants that can be utilized to offset program costs for several of our intermittent and chronic glucagon programs as well as our diazepam program, in accordance with the grant agreements.

Capital Resources and Funding Requirements

We have incurred operating losses since inception, and we have an accumulated deficit of $100.2 million at September 30, 2018. Based on our current plans, we believe our existing cash and cash equivalents and short-term investments together with the estimated net proceeds from this offering of approximately $69.6 million, expected revenue from sales of our Gvoke HypoPen, and available borrowing under our loan facility of $10.0 million upon approval of our Gvoke HypoPen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA, will be sufficient to fund our operations and capital expenditure requirements through at least the first quarter of 2022. We expect to incur substantial additional expenditures in the near term to support our ongoing activities and the expected commercial launch of our Gvoke HypoPen. Additionally, we expect to incur

additional costs as a result of operating as a public company. We expect to continue to incur net losses for the next several years. Our ability to fund our product development and clinical operations, including completion of our planned Phase 2 and Phase 3 clinical trials, as well as commercialization of our product candidates, will depend on the amount and timing of cash received from planned financings. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of our Gvoke HypoPen;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse marketing developments;
- the effect on our product development activities of actions taken by the FDA or other regulatory authorities;
- our degree of success in commercializing our Gvoke HypoPen, if approved; and
- the number and types of future products we develop and commercialize.

Until we obtain regulatory approval to market our product candidates, if ever, we cannot generate revenues from sales of our products. Even if we are able to sell our products, we may not generate a sufficient amount of product revenues to finance our cash requirements. Accordingly, we may need to obtain additional financing in the future which may include public or private debt and equity financings. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to successfully commercialize our product candidates. The issuance of equity securities may result in dilution to stockholders. If we raise additional funds through the issuance of debt securities, these securities may have rights, preferences and privileges senior to those of our common stock and the terms of the debt securities could impose significant restrictions on our operations. The failure to raise funds as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. If additional funding is not secured when required, we may need to delay or curtail our operations until such funding is received, which would have a material adverse impact on our business prospects and results of operations.

Loan Agreement

In February 2018, we entered into the Loan and Security Agreement that provides a senior secured loan facility of up to an aggregate principal amount of $45.0 million. The first tranche was $20.0 million and was drawn down in February 2018. The second tranche was $15.0 million and was drawn down in September 2018. The third tranche is $10.0 million and is available beginning upon approval of our Gvoke HypoPen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

The interest rate under the Loan and Security Agreement is the thirty-day U.S. LIBOR rate plus 6.75%, which was approximately 8.86% as of September 30, 2018. Payments on the Loan and Security Agreement are interest only for the first 24 months, which can be extended by an additional twelve months if the third tranche is drawn. The total term of the loan is 59 months, and the principal payments will begin in either 36 months or 24 months, contingent on the third tranche being drawn.

Pursuant to the Loan and Security Agreement, we provided a first priority security interest in all existing and future-acquired assets, excluding intellectual property and certain other assets, owned by us. The Loan and Security Agreement contains a negative pledge on intellectual property owned by us. We also issued warrants to the Lenders to purchase common stock, which is further discussed in Note 7, “Warrants,” of the notes to our unaudited condensed financial statements included elsewhere in this prospectus.

The Loan and Security Agreement allows us to voluntarily prepay the outstanding amounts thereunder, but not less than $2.0 million of the outstanding principal at any time. Prior to April 1, 2020, we are subject to a prepayment penalty equal to 1.50% of the principal amount being prepaid. In the event we draw on the third tranche, the period subject to 1.50% prepayment is extended to April 1, 2021. No prepayment fee exists for prepayments made after April 1, 2020, or April 1, 2021 in the event the third tranche is issued. A final payment fee of 6.5% multiplied by the original principal amount of each tranche drawn is due upon the earlier to occur of the maturity date of the Loan

and Security Agreement, the acceleration of the Loan and Security Agreement or prepayment of such borrowings. The Loan and Security Agreement includes a non-utilization fee of 2.0% multiplied by the principal amount of tranche three payable to Lenders in October 2019, if we elect not to draw the third tranche.

The Loan and Security Agreement also contains customary indemnification obligations and customary events of default, including, among other things, failure to fulfill certain obligations under the Loan and Security Agreement and the occurrence of a material adverse change in our business, operations or condition, a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of the Lenders' lien in the collateral or in the value of such collateral. In the event of default under the Loan and Security Agreement, we would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 5%. All such interest would be payable on demand and in cash. Further, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan and Security Agreement.

The Loan and Security Agreement includes certain restrictions on, among other things, our ability to incur additional indebtedness, change the name or location of the business, merge with or acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with affiliates, create liens, open new deposit accounts, sell assets or pay subordinated debt.

Cash Flows

	NINE MONTHS ENDED SEPTEMBER 30,	
(in thousands)	**2017**	**2018**
Net cash used in operating activities	$ (15,563)	$ (37,944)
Net cash used in investing activities	(464)	(56,538)
Net cash provided by financing activities	29,672	128,182
Increase in cash and cash equivalents	$ 13,645	$ 33,700

The increase in cash used in operating activities for the nine month period ended September 30, 2018 was primarily due to our net loss adjusted for non-cash charges primarily driven by increased spending in research and development and general and administrative operating expenses. For a discussion regarding the increase in spending, refer to "Results of Operations" above.

The increase in cash used by investing activities for the nine month period ended September 30, 2018 was primarily due to purchases of short-term investments with a portion of the net proceeds from the IPO.

The increase in cash provided by financing activities for the nine month period ended September 30, 2018 was primarily due to the net proceeds from the IPO of approximately $89.0 million after deducting payments for IPO costs, net proceeds from the Loan and Security Agreement of $34.7 million and net proceeds from the sale of Series C Preferred Stock of $4.4 million, partially offset by net proceeds from the sale of Series C Preferred Stock of $29.6 million in the prior year.

	FOR THE YEARS ENDED DECEMBER 31,	
(in thousands)	**2016**	**2017**
Net cash used in operating activities	$ (16,087)	$ (24,663)
Net cash used in investing activities	(35)	(700)
Net cash provided by financing activities	3,904	35,139
Increase (decrease) in cash and cash equivalents	$ (12,218)	$ 9,776

Net cash used in operating activities for the year ended December 31, 2017 was $24.7 million, consisting primarily of a net loss of $26.6 million offset by non-cash charges of $0.8 million and an increase in net operating assets and

liabilities of $1.1 million. Non-cash charges were primarily for stock compensation expense and depreciation of fixed assets. The increase in net operating assets and liabilities was primarily related to an increase in accrued expenses and accounts payable related to employee costs and clinical and research and development expenses partially offset by an increase in accounts receivable. Net cash used in operating activities for the year ended December 31, 2016 was $16.1 million, consisting primarily of a net loss of $13.2 million offset by non-cash charges of $0.7 million and a decrease in net operating assets and liabilities of $3.6 million. Non-cash charges were primarily for stock compensation expense and depreciation of fixed assets. The decrease in net operating assets and liabilities was primarily related to the payment of accrued expenses and accounts payable related to employee costs and clinical and research and development expenses.

Net cash used in investing activities for the year ended December 31, 2017 was $0.7 million, consisting of purchases of additional research laboratory equipment to facilitate our increased research and development activities. In 2016 we purchased $35,000 of computer and related hardware equipment used in our research and development activities and furniture for the Austin office. We will continue to incur capital expenditures in 2018.

Net cash provided by financing activities for the year ended December 31, 2017 was $35.1 million due primarily to the sale of $35.0 million of our Series C Preferred Stock. Net cash provided in financing activities for the year ended December 31, 2016 was $3.9 million due primarily to the sale of $4.0 million of our Series C Preferred Stock.

Contractual Obligations and Commitments

As of December 31, 2017, we were obligated to pay the following amounts for our operating leases:

(in thousands)	TOTAL	LESS THAN 1 YEAR	1-2 YEARS	3-5 YEARS	MORE THAN 5 YEARS
Operating leases	$5,395	$ 730	$ 1,693	$ 2,271	$ 701

In the nine months ended September 30, 2018 we entered into a second lease for office space in Chicago as well as executed the Loan and Security Agreement. We are obligated to pay the following amounts under those agreements as of September 30, 2018.

(in thousands)	TOTAL	LESS THAN 1 YEAR	1-2 YEARS	3-5 YEARS	MORE THAN 5 YEARS
Operating leases	$ 6,225	$ 294	$ 1,987	$ 3,556	$ 388
Future principal payments under Loan and Security Agreement	35,000	—	9,000	26,000	—

In November 2018, we signed an amendment to our existing office lease in Chicago, Illinois, to occupy an additional 40,850 square feet of space and expect to move into this additional space in March 2019. The lease term expires on June 30, 2031.

We enter into contracts in the normal course of business with clinical trial sites, manufacturing organizations and vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancellable contracts and not included in the table above.

As of September 30, 2018, we have received $0.8 million out of an expected $0.9 million in grant proceeds for the development of a stable liquid glucagon for use in an artificial pancreas. Under the terms of the agreement, we will be required to pay up to four times the award received upon commercialization of glucagon for use in the artificial pancreas. If we undergo a change in control, then we will be required to pay a mid-single digit percentage of the gross proceeds, capped at four times the award amount less any amounts already paid. Additionally, if sales of glucagon for use in the artificial pancreas exceed $750 million in the first five years after the first commercial sale, then we would be required to make an additional payment equal to the original award amount.

As of September 30, 2018, we received $0.9 million in grant proceeds to help fund our EIH program. Under terms of this agreement, we will be required to pay up to two times the award amount upon the commercialization of an EIH product. These amounts are a low double-digit percentage of annual gross sales of an EIH product, capped at $0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, if sales exceed $1 billion, we will be required to pay an additional amount equal to two times the award amount.

As of September 30, 2018, we received $1.0 million in grant proceeds to help fund our chronic glucagon programs. Under terms of this agreement we will be required to pay up to two times the award amount upon the commercialization of any chronic glucagon program. These amounts are a low double-digit percentage of annual gross sales of all chronic glucagon programs, capped at $0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, for each chronic glucagon program where sales exceed $500 million, we will be required to pay an additional amount equal to two times the award amount.

The amounts we may have to repay under the grant agreements are contingent upon future events and therefore not included in the table above. We have also received awards from the NIH National Institute of Diabetes and Kidney Diseases, which awards are not subject to any repayment obligations.

Off-Balance Sheet Arrangements

As of September 30, 2018, we had unused letters of credit for $143,000 that are used to secure leases.

Internal Controls

Our internal policies and procedures relating to control over financial reporting are designed to provide reasonable assurance as to the reliability of our financial reporting. During 2017, we identified a material weakness in our internal control over financial reporting due to a lack of proper segregation of duties within our finance and accounting function, as one individual had control over two or more phases of a transaction or operation. This weakness was due to our inability to implement the appropriate segregation of duties within our historical enterprise resource planning system. Since August 2017, we have made efforts to design manual controls to mitigate the risk. In addition, in December 2017, we implemented a new enterprise resource planning system that allowed for greater segregation of duties.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks related to changes in interest rates.

Interest Rate Risk

Cash and Cash Equivalents and Short-Term Investments—We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash and cash equivalents and short-term investments. A hypothetical one-percentage point increase or decrease in interest rates applicable to our cash and cash equivalents and short-term investments outstanding at September 30, 2018 would increase or decrease interest income by approximately $1.3 million on an annual basis. Any changes to interest income on short-term investments would only be realized if sold prior to maturity.

Loan and Security Agreement—Our interest rate risk relates primarily to U.S. dollar LIBOR-indexed borrowings. Based on our outstanding borrowings at September 30, 2018, a one-percentage point increase or decrease in interest rates would affect interest expense on the debt by $0.3 million on an annualized basis.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

We have based our management’s discussion and analysis of our financial condition and results of operations on our financial statements that have been prepared in accordance with generally accepted accounting principles, or GAAP,

in the United States. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses and stock-based compensation. We base our estimates on historical experience and on various other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully discussed in Note 2 to our audited financial statements included in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, laboratory equipment and facilities costs, and other external costs.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are used or the services are performed.

When preparing our financial statements, we are required to estimate our accrued clinical expenses. This process involves reviewing open contracts and communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with parties depend on factors, such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred.

Stock-based compensation

The following table summarizes the reporting of total stock-based compensation expense resulting from employee stock options and restricted stock awards:

(in thousands)	YEARS ENDED DECEMBER 31, 2016	YEARS ENDED DECEMBER 31, 2017	NINE MONTHS ENDED SEPTEMBER 30, 2017	NINE MONTHS ENDED SEPTEMBER 30, 2018
Research and development	$ 78	$ 62	$ 46	$ 398
General and administrative	462	437	305	751
Total stock-based compensation	$ 540	$ 499	$ 351	$ 1,149

We account for our stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. Prior to our IPO, we estimated the grant date fair value of each option award using the Black-Scholes option-pricing model. For option awards granted subsequent to our IPO, our board of directors determined the grant date fair value based on the

closing price on our common stock as reported on The Nasdaq Global Select Market on the date of grant. We recognize stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of our common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are estimated as follows:

- *Expected Term.* We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based measurement of our options. Therefore, we have opted to use the "simplified method" for estimating the expected term of options, which is the average of the weighted-average vesting period and contractual term of the option.
- *Expected Volatility*. As we have limited trading history for our common stock, the expected stock price volatility assumption is determined based on the historical volatilities of a peer group of publicly traded companies as well as the historical volatility of our own common stock since we began trading subsequent to our IPO in June 2018. In evaluating similarity, we consider factors such as stage of development, risk profile, enterprise value and position within the industry. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.
- *Expected Dividends.* The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our common stock.

Prior to our IPO in June 2018, our valuations were performed by a third-party valuation company using a discounted cash flow, or DCF, analysis. This method was chosen based on our sources of historical capital and potential future capital needs. For the December 31, 2017 valuation, we went from the DCF valuation technique to a hybrid method, which uses market approaches to estimate our enterprise value. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the scenarios is calculated using an option-pricing method, or OPM. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

For stock awards since our IPO in June 2018, our board of directors determines the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

The intrinsic value of all outstanding options as of the date of this prospectus was $24.5 million based on the estimated fair value of our common stock of $14.76 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on February 7, 2019.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Accounting for Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. We determine our deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2017, we did not have any significant uncertain tax positions.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in 2017. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Recent accounting pronouncements

See Note 2 to our audited financial statements and Note 2 to our interim unaudited financial statements beginning on page F-1 of this prospectus for a description of recent accounting pronouncements applicable to our financial statements.

JOBS ACT ACCOUNTING ELECTION

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period.

BUSINESS

Overview

We are a specialty pharmaceutical company leveraging our novel non-aqueous formulation technology platforms, XeriSol and XeriJect, to develop and commercialize ready-to-use injectable and infusible drug formulations. We have developed a ready-to-use, room-temperature stable liquid glucagon formulation that, unlike any currently available products, can be administered without any preparation or reconstitution. Our lead product candidate, Gvoke HypoPen, delivers ready-to-use glucagon via a commercially-available auto-injector for the treatment of severe hypoglycemia, a potentially life-threatening condition, in people with diabetes. We have completed three Phase 3 clinical trials for our Gvoke HypoPen and submitted a New Drug Application, or NDA, to the U.S. Food & Drug Administration, or the FDA, in August 2018. The FDA set June 10, 2019 as the Prescription Drug User Fee Act, or PDUFA, action goal date for our NDA. If our NDA is approved at that time, we believe we will have the first ready-to-use, room-temperature stable liquid glucagon formulation that can be administered without any preparation or reconstitution. Additionally, through our interactions with the European Medicines Agency, or EMA, regarding our development path in Europe, we have finalized our regulatory plan and initiated a requisite Phase 3 pivotal trial to support our European Marketing Authority Application, or MAA. We also are applying our novel ready-to-use, room-temperature stable liquid glucagon formulation for the management of hypoglycemia associated with additional intermittent and chronic conditions with significant unmet medical need. In addition, we are applying our technology platforms to convert other commercially-available drugs into ready-to-use, room-temperature stable liquid formulations to address the needs in multiple therapeutic areas and conditions, including epilepsy and diabetes. We own the worldwide rights to our proprietary formulation technology platforms and our product candidates, with 74 patents issued globally, including a composition of matter patent covering our ready-to-use glucagon formulation that expires in 2036.

Our proprietary XeriSol and XeriJect non-aqueous formulation technologies allow for the subcutaneous, or SC, and intramuscular, or IM, delivery of highly-concentrated, ready-to-use formulations of peptides, proteins, antibodies and small molecules using commercially-available syringes, auto-injectors, multi-dose pens and infusion pumps. Current aqueous formulations of certain drugs present numerous challenges for patients and care providers, including multi-step reconstitution, refrigeration requirements, large injection volumes and intravenous, or IV, administration over several hours. Our broadly-applicable platforms offer the opportunity to eliminate reconstitution and refrigeration, enable long-term room-temperature stability, significantly reduce injection volume and allow for a more convenient SC or IM administration as opposed to IV infusion, all of which we believe are distinct advantages over these existing aqueous formulations. We believe that our technology platforms can lead to products that will improve outcomes and enable easier administration while reducing costs for payors and the healthcare system.

Our key priority is developing and commercializing our lead product candidate, Gvoke HypoPen, for the treatment of severe hypoglycemia in people with diabetes to address limitations of currently marketed emergency glucagon kits. Hypoglycemia, a key concern of people with both Type 1 Diabetes, or T1D, and Type 2 Diabetes, or T2D, occurs when a person has a deficiency of glucose in their bloodstream, often as a result of insulin treatment. Symptoms of hypoglycemia include fatigue, shakiness, anxiety, headache, nausea and vomiting, and in severe cases, hypoglycemia can result in cardiovascular disease, seizure, coma, and, if left untreated, death. The current standard of care for severe hypoglycemia in the ambulatory setting is the emergency administration of glucagon, a hormone that raises the concentration of glucose in the bloodstream. Currently marketed emergency glucagon kits consist of a glucagon powder that must be reconstituted with a liquid diluent and drawn into a syringe using a multi-step procedure that can be difficult to successfully administer, particularly in an emergency. In published comparative human factors studies with currently marketed kits, only 6% to 31% of users were able to successfully administer the full dose of glucagon. In other words, in these studies, test subjects failed to deliver the full dose of glucagon 69% to 94% of the time. The underuse or unsuccessful use of currently marketed kits leaves people at risk of experiencing prolonged severe hypoglycemic events, which if left untreated, can lead to serious health consequences and death.

We believe our Gvoke HypoPen addresses the administration challenges of currently marketed products, and, if approved, has the potential to be the preferred emergency glucagon product. Our ready-to-use Gvoke HypoPen does not require reconstitution or refrigeration and features two-year, room-temperature stable liquid glucagon

delivered in an auto-injecting device with no visible needle. In our human factors study, 99% of users were able to successfully administer the full dose with our ready-to-use Gvoke HypoPen.

Our goal is to establish our Gvoke HypoPen, if approved, as the preferred emergency glucagon product and drive greater adoption and penetration of emergency glucagon therapy by offering a glucagon product that better meets the needs of patients and caregivers. The ADA recommends that glucagon be prescribed for all individuals at increased risk of clinically significant hypoglycemia for use in the event of an emergency. People with diabetes who are treated with insulin or substances that promote production of insulin are increased risk of clinically significant hypoglycemia. There are an estimated 1.3 million people with T1D who are treated with insulin because their bodies do not naturally produce insulin, all of whom are clinically appropriate for glucagon. Approximately 4.3 million additional people with T2D are treated with insulin because their bodies do not use insulin properly, of which we estimate that approximately 50% are clinically appropriate for glucagon. Therefore, we estimate the potential target population for emergency glucagon therapy totals approximately 3.5 million people in the United States. Our commercial strategy is to penetrate this market efficiently with a concentrated sales force by targeting high prescribers of glucagon and mealtime insulin and activate demand through targeted direct-to-patient promotion. We also plan to use our medical affairs team to actively drive market access and obtain payor coverage for our Gvoke HypoPen.

Due to the limitations of currently marketed products, only approximately 662,000 total prescriptions for emergency glucagon kits were written in 2018 in the United States, resulting in the purchase of approximately 978,000 single-dose kits. Based on our market research, we intend to market two Gvoke HypoPens per package and to target all 3.5 million people that we believe are clinically appropriate for glucagon. In 2018, U.S. sales for emergency glucagon kits were approximately $246 million, but we believe that increasing penetration, including by new entrants that address unmet patient and caregiver needs such as our Gvoke HypoPen, may result in a potential sales opportunity totaling up to $2.0 billion. Outside of the United States, we estimate there are an additional 3.5 million people with diabetes in Europe and an additional 12.5 million people with diabetes in Japan and China that are clinically appropriate for emergency glucagon treatment. Following the receipt of EMA scientific advice, we initiated a requisite Phase 3 pivotal trial of our glucagon pen to support our European MAA. We expect top-line results from this trial in the first half of 2019 and plan to seek MAA approval in the second half of 2020. We plan to pursue development and commercialization collaborations for all non-U.S. markets.

We are also applying our glucagon formulation to five intermittent and chronic use conditions with significant unmet medical need. In 2018, all five development programs have either produced positive clinical trial results or advanced into clinical trials. We plan to continue to advance all five of these programs going forward. These additional applications are:

- Post-Bariatric Hypoglycemia, or PBH, a serious complication of bariatric surgery that can arise from excessive insulin, or hyperinsulinism, due to the change in gastric anatomy resulting from bariatric surgery.
- Congenital Hyperinsulinism, or CHI, a condition caused by several genetic defects that result in severe, persistent hypoglycemia in infants and children, which can lead to brain damage and death.
- Hypoglycemia-Associated Autonomic Failure, or HAAF, in which chronic hypoglycemia impairs the body’s natural response to restore blood sugar levels and can lead to an individual becoming unaware of the onset of a severe hypoglycemic event and result in cardiovascular disease, seizure, coma, and, if left untreated, death.
- Exercise-Induced Hypoglycemia, or EIH, in people with diabetes. Exercise, particularly aerobic exercise, often results in a significant drop in blood glucose levels for people on insulin.
- Management of diabetes via glucagon in a fully-integrated, bi-hormonal artificial pancreas closed-loop system.

By applying our ready-to-use glucagon to treat multiple conditions, we expect to leverage operating efficiencies across our supply chain, research and development, and commercial and medical organizations.

We also are applying our technology platforms to develop additional product candidates, such as ready-to-use, liquid-stable diazepam delivered via a commercially-available auto-injector for the emergency treatment of epileptic

seizures and a fixed-dose co-formulation of pramlintide and insulin, or Pram-Insulin, for the management of diabetes. Additionally, based on the promising data seen in some of our early clinical trials as well as formulations in our laboratory, we believe we have the potential to advance a number of additional programs in additional indications and that our strong product candidate portfolio, complemented by external expansion opportunities, will support our vision to effectively and efficiently meet the needs of our target markets.

The nature of our product candidates and target conditions provides us with a potentially faster and capital-efficient development and regulatory pathway to approval. The FDA has granted orphan drug status to four indications for our product candidates, which are our ready-to-use glucagon for PBH and CHI and our ready-to-use, liquid-stable formulation of diazepam for the treatment of Dravet Syndrome and acute repetitive seizures, or ARS, in patients with epilepsy. Additionally, we have received orphan drug designation for the EMA for CH and Noninsulinoma Pancreatogenous Hypoglycaemia Syndrome , or NIPHS, which includes patients with PBH.

In the United States, this designation provides us with research and development tax credits and exemption from FDA user fees, as well as seven years of orphan drug exclusivity upon product approval. In the EU, this designation provides us with ten years of market exclusivity upon product approval and a single MAA application to the EMA through centralized review and the potential for reduced regulatory review fees. In addition, because certain conditions that we intend to target are rare conditions, we believe our clinical trials may be of smaller size than studies for conditions that are not rare conditions. Furthermore, because the product candidates developed using our technology platforms are designed to be reformulations of currently approved products, in the United States, we expect to utilize the FDA's pathway under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA, which permits submissions to rely, in part, on the safety and effectiveness of a previously approved product, which may potentially result in a more expeditious pathway to FDA approval. Similarly, in the EU, we intend to submit an MAA through the Centralised Procedure via Article 8(3) – Full Mixed Dossier, which offers data protection and market exclusivity for up to 11 years.

Our management team includes veterans in drug development, discovery and commercialization, with executive experience in leading global pharmaceutical and healthcare companies, including Durata Therapeutics, Baxter Healthcare, Merck, Searle, Takeda, Warner Chilcott, MedPointe Healthcare, Amylin Pharmaceuticals, PowderJect Technologies and Alpharma.

Our Pipeline

The following table summarizes key information about our internal product candidates.

	Product Candidate	Indication	Development Stage (Preclinical / Phase 1 / Phase 2 / Phase 3 / Under Review)	Next Milestone: Event	Next Milestone: Expected Date
Ready-to-Use Glucagon for Hypoglycemia	Gvoke HypoPen	Severe Hypoglycemia	Under Review	FDA decision	6.10.19
Ready-to-Use Glucagon for Hypoglycemia	Glucagon Pen - EU	Severe Hypoglycemia	Phase 3	Ph 3 Results	1H '19
Ready-to-Use Glucagon for Hypoglycemia	Self-Administered Glucagon	Post-Bariatric Hypoglycemia*	Phase 2	Ph 2 Results (Vial/Syringe)	1H '19
Ready-to-Use Glucagon for Hypoglycemia	Continuous Glucagon	Congenital Hyperinsulinism*	Phase 2	Initiate Ph 3	1H '19
Ready-to-Use Glucagon for Hypoglycemia	Continuous Glucagon	Hypoglycemia-Associated Autonomic Failure	Phase 2	Ph 2 Results	2H '19
Ready-to-Use Glucagon for Hypoglycemia	Self-Administered Glucagon	Exercise-Induced Hypoglycemia	Phase 2	Ph 2 Results	2H'19
Ready-to-Use Products for Epilepsy and Diabetes	Diazepam	Acute Repetitive Seizures* Dravet Syndrome*	Phase 1	Ph 1 Results	1H '19
Ready-to-Use Products for Epilepsy and Diabetes	Pramlintide-Insulin	T1D / T2D Blood Sugar Control	Preclinical	Initiate Ph 2	2H '19

* Orphan Drug Designation

Additionally, we are providing ready-to-use glucagon to Oregon Health & Science University, or OHSU, in their ongoing Phase 1 closed-loop dual-hormone artificial pancreas study and expect OHSU to report top-line results in the second half of 2019. Based on the results, we plan to support advancement of OHSU and other artificial pancreas programs with ready-to-use glucagon.

Our Strategy

Our strategy is to utilize our proprietary non-aqueous formulation technology platforms to convert marketed and development-stage products that have poor solubility and stability into ready-to-use, user-friendly injectable and infusible drugs for multiple therapeutic areas and conditions, including hypoglycemia, epilepsy and diabetes. We also seek to apply our formulation technology platforms to enhance the formulations of proprietary products and candidates of other pharmaceutical and biotechnology companies. The key elements of our strategy include:

- ***Rapidly secure regulatory approval for our lead product candidate, Gvoke HypoPen, for severe hypoglycemia***. We have completed three Phase 3 clinical trials for our Gvoke HypoPen and submitted a NDA to the FDA early in August 2018 utilizing the 505(b)(2) regulatory pathway, which has been accepted for review by the FDA with a PDUFA action goal date of June 10, 2019. Additionally, through our interactions with the European Medicines Agency, or EMA, regarding our development path in Europe, we have finalized our clinical study plan and initiated a Phase 3 pivotal trial to support EMA registration of an MAA.
- ***Maximize the commercial potential for Gvoke HypoPen***. If approved, we plan to commercially launch our Gvoke HypoPen in the United States in the second half of 2019. We expect to initially target approximately 8,000 healthcare professionals who are high prescribers of current glucagon kits and/or mealtime insulin products, using an expected initial sales force of 60-70 individuals, and activate demand through targeted direct-to-patient promotion. We have accelerated our build of our commercial organization and critical infrastructure, including individuals in operations, supply chain, medical affairs, pharmacovigilance, compliance, regulatory, marketing, sales leadership, market access and sales operations, as well as our medical affairs organization. Outside of the United States, we plan to pursue development and commercialization partnerships.
- ***Continue to advance our ready-to-use glucagon portfolio to address other conditions associated with hypoglycemia***. We plan to apply our ready-to-use, room-temperature stable liquid glucagon to address multiple conditions that could benefit from intermittent or chronic administration, such as PBH, CHI, HAAF and EIH in diabetes. We are also evaluating our liquid-stable glucagon as the glucagon component of a fully-integrated, bi-hormonal artificial pancreas. During 2018, all five of these programs have either produced positive clinical trial results or advanced into clinical trials. Through these programs, our primary goal is to secure FDA approval of a vial of our liquid glucagon for self-administration via a syringe or for use in filling a pump reservoir. We plan to leverage efficiencies across our portfolio, such as our supply chain, research and development, and our commercial and medical organizations. We plan to use commercially available drug delivery devices for our liquid-stable glucagon formulation and associated intermittent and chronic glucagon programs.
- ***Continue to leverage our technology and expertise to develop a portfolio of additional product candidates***. We are exploring the application of our formulation technology platforms to other commercially available drugs for multiple conditions. We are developing an improved formulation of diazepam for the treatment of ARS in patients with epilepsy as well as patients with Dravet syndrome, to be administered through a ready-to-use auto-injector. We have completed formulation development and preclinical pharmacokinetic studies. An IND application for our ready-to-use diazepam rescue pen for ARS went into effect on November 28, 2018. This IND authorized us to initiate a study evaluating the pharmacokinetics and pharmacodynamics of our ready-to-use, room-temperature stable liquid diazepam formulation in normal volunteers. We initiated this trial in December 2018 and expect top-line results in the first half of 2019. If results are positive, we plan to initiate a Phase 2 clinical trial in the second half of 2019. We formulated and completed several preclinical studies of a fixed-ratio pramlintide-insulin coformulation combination product for the treatment of diabetes and plan to begin a Phase 2 clinical trial in the second half of 2019. Finally, we have advanced several additional formulation programs in the past year, and plan to continue to advance these programs to clinical trials.

- ***Collaborate with pharmaceutical and biotechnology companies to apply our technology platforms to enhance the formulations of their proprietary products and candidates***. We are pursuing formulation and development partnerships to apply our XeriSol and XeriJect technology platforms to enhance the formulation, delivery and clinical profile of other companies' proprietary drugs and biologics. We currently are working with several companies on feasibility programs to evaluate the formulation of their proprietary therapeutics with, depending on the type of molecule, XeriSol or XeriJect. Active programs include feasibility evaluations with Regeneron Pharmaceuticals, Inc., Asahi Kasei Pharma Corporation, Hawaii Biotech, Inc. and Islet Sciences, Inc. on XeriJect monoclonal antibody formulations, a XeriJect biologic product formulation, a XeriJect vaccine formulation, and a XeriSol co-formulation of a peptide and small molecule for insulin-dependent diabetes, respectively. We plan to continue to explore the application of our formulation technology platforms to proprietary drugs and biologics from additional pharmaceutical and biotechnology companies.

Our Technology Platforms

Overview

Our proprietary non-aqueous formulation technology platforms are designed to address the challenges presented by current aqueous formulations of certain drugs. Injectable pharmaceuticals have conventionally used aqueous delivery systems to administer drugs and biologics, but, in the presence of water, many drugs have poor solubility and low stability. To optimize their stability and enable longer-term storage, many of these products are freeze dried into a powder and, when needed, must be reconstituted with a liquid diluent, which is often a challenging multi-step procedure with the potential for error. Furthermore, the drug product begins to break down once combined with water, which requires the drug to be used immediately or otherwise refrigerated. In addition, these products can require complicated formulations and large injection volumes to make them soluble. For many products, these volumes are too large for SC or IM delivery and instead necessitate IV infusion over several hours. These drugs can be difficult or painful to administer and have limited portability, resulting in an overall poor experience for patients and caregivers.

Our proprietary XeriSol and XeriJect platforms offer the opportunity to eliminate the need for reconstitution and refrigeration, enable long-term room-temperature stability, significantly reduce injection volume and allow for a more convenient SC or IM administration as opposed to IV infusion, all of which we believe are distinct advantages over existing aqueous formulations of marketed and development-stage products and product candidates. We believe that our technology platforms can lead to products that will improve outcomes and enable easier administration while reducing costs for payors and the healthcare system.

Our XeriJect formulation platform is best suited for drugs and biologics consisting of large molecules, such as proteins, monoclonal antibodies and vaccines. XeriSol is best suited for peptides and small molecules that currently encounter formulation challenges. With XeriJect, we have formulated suspensions with a protein concentration in excess of 400 mg/mL, far exceeding current aqueous formulation systems with maximum achievable protein concentrations of 50-250 mg/mL. These biocompatible non-aqueous, injectable solutions or suspensions formulated with our platforms can then be packaged for administration in a commercially-available auto-injector, pre-filled syringe, vial, multi-dose pen or infusion pump

Ready-to-Use Glucagon

Our novel, room-temperature stable liquid glucagon formulation represents a significant advancement over the current freeze-dried, or lyophilized, glucagon, enabling a ready-to-use solution that can be quickly and easily injected or infused subcutaneously. This formulation is designed to provide the flexibility to dose different volumes of liquid glucagon using a range of delivery devices to suit the needs of people with hypoglycemic conditions. We believe our ready-to-use glucagon has the potential to change the paradigm for treatment or prevention of hypoglycemic conditions and improve the lives of people who experience hypoglycemia.

Our Product Candidates

Gvoke HypoPen

Our Gvoke HypoPen offers a ready-to-use, room-temperature stable glucagon that is designed to be administered subcutaneously in a simple two-step process. In our human factors study, 99% of users were able to successfully

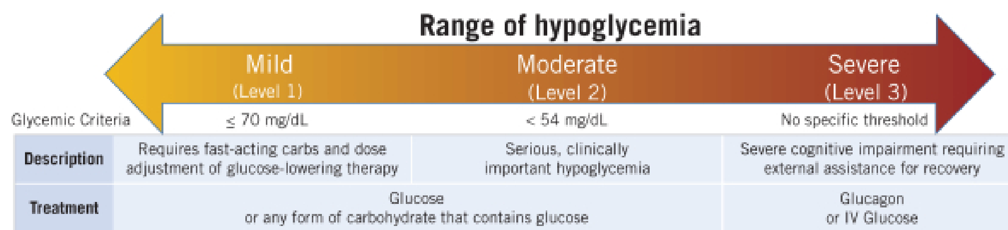
administer the full dose with our Gvoke HypoPen. Conversely, in published human factors studies of currently marketed emergency glucagon kits, only 6% to 31% of users were able to successfully administer the full dose. If approved, we believe we can establish our Gvoke HypoPen as the preferred emergency glucagon product and drive greater adoption and penetration of emergency glucagon therapy for patients and caregivers. We have completed three Phase 3 clinical trials for our Gvoke HypoPen and submitted a NDA to the FDA in August 2018, which the FDA has accepted for review and issued a PDUFA action goal date of June 10, 2019. If our NDA is approved at that time, we believe we will have the first ready-to-use, room-temperature stable liquid glucagon formulation that can be administered without any preparation or reconstitution.

Additionally, through our interactions with the EMA regarding our development path in Europe, we have finalized our regulatory plan and initiated a requisite Phase 3 pivotal trial to support our European MAA. We have no current plans to submit our Gvoke HypoPen for regulatory approval in Canada, but we have submitted a clinical trial application to Health Canada to support the inclusion of Canadian clinical research sites in XSGP-301, XSGP-303, XSGP-304, and XSMP-204 clinical trials.

Hypoglycemia Background

Diabetes is a widespread condition that affects an estimated 425 million people worldwide. There are an estimated 20.2 million drug-treated people in the United States. Among people with diabetes in the United States, all of the approximately 1.3 million people with T1D and 4.3 million people with T2D require insulin therapy to lower their blood glucose levels to achieve normal blood sugar levels and avoid hyperglycemia. Conversely, insulin treatment in people with diabetes can also lead to hypoglycemia, a deficiency of glucose in the bloodstream, which is more common in people with diabetes who are treated with insulin or substances that promote production of insulin. In 2014, the U.S. Department of Health and Human Services National Action Plan for Adverse Drug Event Prevention highlighted diabetes agent-associated hypoglycemia as one of its three primary concerns because of the severity and increasing prevalence of the problem. In 2017, the American Diabetes Association, or ADA, stated that hypoglycemia remains the major limiting factor in the glycemic management of T1D and T2D.

Hypoglycemia is categorized by level of severity, expressed as mild, moderate or severe hypoglycemic events. Definitions, symptoms and treatment recommendations for hypoglycemia per the ADA and the American Association of Clinical Endocrinologists, or AACE, are summarized in the figure below:



Hypoglycemic events of any severity are a daily concern for people with diabetes. Severe hypoglycemic events are extremely frightening for patients and caregivers and can result in cardiovascular disease seizure, coma, and, if left untreated, death. Fear of hypoglycemia and the morbidity and mortality risks associated with it is a constant reality for people with diabetes. According to scientific literature, fear of hypoglycemia is a critical impediment to psychological well-being and quality of life and represents the greatest barrier to optimal glycemic control. Studies have shown that only 14% of those aged 18–25 years and 29% of those aged 26–50 years achieved optimal glycemic control by taking insulin.

The ADA recommends that glucagon be prescribed for all individuals at increased risk of clinically significant hypoglycemia, defined as blood glucose <54 mg/dL, for use in the event of an emergency. Glucagon works to raise the glucose levels in a person's blood by inducing the liver to convert glycogen, a type of stored sugar in the body, into glucose.

While patients can take preventive measures, hypoglycemic events still occur. On average, people with T1D experience an episode of mild or moderate hypoglycemia twice per week and 30% to 40% of people with T1D

experience one to two episodes of severe hypoglycemia per year. On average, half of people with T2D treated with insulin experience an episode of mild or moderate hypoglycemia twice per month. People with T2D treated with insulin are also at risk of severe hypoglycemia, and approximately 21% of these individuals experience an episode of severe hypoglycemia at least once annually.

Limitations of Existing Products

Because of the urgent nature of severe hypoglycemia, the majority of severe hypoglycemic events are treated on an emergency basis, outside of a healthcare facility. Two emergency glucagon products are currently available to treat severe hypoglycemia: Eli Lilly's Glucagon Emergency Kit, or GEK, which represents approximately 78% of U.S. sales, and Novo Nordisk's GlucaGen, which represents approximately 22% of U.S. sales. Each product is sold as a vial of lyophilized, glucagon powder with an exposed needle/syringe that contains a liquid diluent. The glucagon powder must be combined with the liquid diluent at the time of use and drawn into a syringe in accordance with a complex multi-step reconstitution and dose calibration procedure. Long-term storage of the combined solution is impractical because once the lyophilized glucagon is combined with water, the solution becomes unstable and can fibrillate, rendering it inactive and potentially toxic.

The multi-step reconstitution and dose calibration procedure required for current glucagon kits outlined below can be intimidating, particularly in an emergency situation, for likely glucagon kit users, a group that includes caregivers, co-workers, friends, teachers or other bystanders.

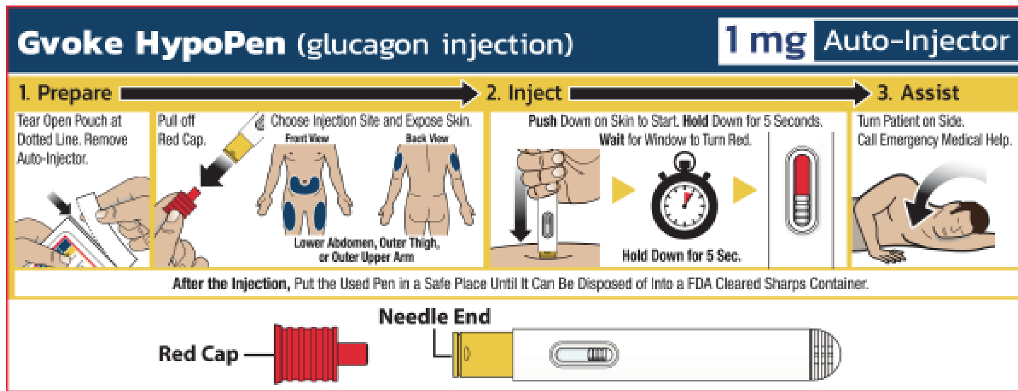
Step-by-Step Instructions for GEK

1. Flip off the seal from the vial of Glucagon powder.
2. Remove the needle cover from the syringe. DO NOT REMOVE THE PLASTIC CLIP FROM THE SYRINGE, as this may allow the push rod to come out of the syringe.
3. Insert the needle into the rubber stopper on the vial, then inject the entire contents of the syringe into the vial of Glucagon powder.
4. Remove the syringe from the vial, then swirl the vial until the liquid becomes clear. Glucagon should not be used unless the solution is clear and of a water-like consistency.
5. Insert the same syringe into the vial and slowly withdraw all the liquid. To use on children weighing less than 44 pounds, withdraw half of the liquid (0.5 mark on the syringe).
6. Cleanse site on buttock, arm or thigh and inject Glucagon immediately after mixing, and then withdraw the needle. Apply light pressure against the injection site.
7. Turn the person on his/her side. When an unconscious person awakens, he/she may vomit. **Call 911 immediately after administering Glucagon. If the person does not awaken within 15 minutes, you may administer a second dose of Glucagon, if previously instructed to do so by a healthcare professional.**
8. As soon as the person is awake and able to swallow, give him/her a fast-acting source of sugar (such as fruit juice), followed by a snack or meal containing both protein and carbohydrates (such as cheese and crackers, or a peanut butter sandwich).
9. Discard any unused reconstituted Glucagon. Remember to notify your healthcare professional that an episode of severe hypoglycemia has occurred. These are not the complete instructions. Go to "Information for the User" for complete instructions on how to administer Glucagon.

In 2018, we conducted a quantitative study with 700 caregivers and people with diabetes evaluating the market perceptions of current glucagon kits, which we refer to as our Caregiver and Patient Perceptions Study. In that study, only one third of respondents had a highly favorable opinion of the current kits and only half were confident that a glucagon kit user would be able to correctly administer the current emergency glucagon products. Furthermore, in three published comparative human factors studies with currently marketed kits, only 6% to 31% of users were able to successfully administer the full dose of glucagon. In other words, in these studies, test subjects failed to deliver the full dose of glucagon 69% to 94% of the time. Accordingly, a diabetes patient experiencing a severe hypoglycemic episode who relies on a bystander to administer glucagon may not receive the full dose of glucagon needed to restore their blood glucose levels. Failure to promptly treat severe hypoglycemia leaves the person at critical risk of irreversible brain damage and heart problems, especially in people who already have coronary artery disease. If emergency medical treatment is not successful, the severe hypoglycemic event can be fatal.

Xeris Gvoke HypoPen Key Features and Benefits

Leveraging our patented XeriSol technology, we believe our Gvoke HypoPen offers an important advancement in the treatment of severe hypoglycemia. We are developing the Gvoke HypoPen as a ready-to-use, room-temperature stable liquid glucagon delivered via auto-injector available in 1 mg and 0.5 mg pre-measured doses for adult and pediatric use, respectively. We have designed the Gvoke HypoPen to be easy to administer, as depicted in the figure below.



The key features of our Gvoke HypoPen are:

- *Ready-to-use:* With its easy two-step administration process, the user simply pulls off the red cap and pushes the Gvoke HypoPen down on the skin for five seconds, until the window turns red. There is no reconstitution required at the time of emergency.
- *Easy-to-use:* In our human factors study, 99% of users were able to successfully administer the full dose with our Gvoke HypoPen.
- *No dose calibration required:* The Gvoke HypoPen will be offered in two pre-measured doses, 0.5 mg for pediatric administration and 1 mg for adolescents and adults.
- *No visible needle:* The needle in the Gvoke HypoPen is not visible to the user.
- *Auto-retraction:* The needle auto-retracts after administration for safety.
- *Auto-locks:* The device auto-locks after use for safety.
- *Two-year, room-temperature stability:* No refrigeration is required at any time.

We also intend to offer our ready-to-use glucagon in a pre-filled syringe presentation, Gvoke PFS, which may be preferred by some healthcare professionals.

In contrast to currently marketed emergency glucagon kits, our Gvoke HypoPen features the following benefits:

	GEK	Xeris Gvoke HypoPen
No Reconstitution in Emergency	X	✓
Auto-Injection	X	✓
Needle Auto-Retraction and Needle Guard	X	✓
Dose Volume Pre-measured for Pediatrics	X	✓
Room-Temperature Stable as a Liquid	X	✓
Rate of Successful Full Dose Delivery in Human Factors Studies	6 - 31%	99%
Route of Administration	SC or IM	SC

In our Caregiver and Patient Perceptions Study, more than 75% responded that they would prefer our Gvoke HypoPen over currently available glucagon kits. In 2018, we conducted a quantitative study of over 400 healthcare professionals, which we refer to as our Healthcare Professional Perceptions Study. In that study, results indicated that glucagon would be prescribed to more people across all clinically appropriate patient segments if our Gvoke HypoPen were available. Based on this market research, we believe that the glucagon market will become more penetrated and that our Gvoke HypoPen will become the preferred emergency glucagon delivery solution.

Xeris Gvoke HypoPen Market Potential

Based on current market data as well as our Caregiver and Patient and Healthcare Professional Perceptions Studies, we believe that our Gvoke HypoPen, if approved, has the opportunity to increase penetration of the glucagon market in severe hypoglycemia by increasing the number of diabetes patients who have a filled glucagon prescription and by increasing the number of glucagon products they have on hand.

There are approximately 20.2 million drug-treated people with diabetes in the United States, and the compound annual growth rate in incidence of diagnosed and treated people with diabetes is approximately 4% per year. An additional 84 million people in the United States are pre-diabetic and may progress to T2D. The ADA recommends that glucagon be prescribed for all individuals at increased risk of clinically significant hypoglycemia for use in the event of an emergency. Based on our Healthcare Professional Perceptions Study, we believe almost all people with T1D and approximately 50% of people with T2D on insulin are considered clinically appropriate for glucagon. In the United States, there is an estimated 1.3 million people with T1D who are treated with insulin because their bodies do not naturally produce insulin and approximately 4.3 million additional people with T2D who are treated with insulin because their bodies do not use insulin properly. In the aggregate, we estimate that the potential target population for emergency glucagon therapy totals approximately 3.5 million people in the United States. We intend to sell our Gvoke HypoPen in a package of two, based on responses from our market research indicating that potential buyers would purchase, on average, two pens per person. We believe by increasing penetration into the market for emergency glucagon kits and based on the current price of approximately $280 per unit for currently marketed kits, the annual U.S. potential sales opportunity may total up to $2.0 billion.

Despite the risk of experiencing a severe hypoglycemic event, we believe that emergency glucagon therapy is underappreciated, under-evaluated and under-taught, resulting in a market that is under-penetrated. According to a 2015 study published in the journal *Endocrine Practice*, approximately 50% of people with T1D and approximately 3% of people with T2D with a new insulin prescription had a filled glucagon prescription. We believe that the drawbacks of currently marketed products and the lack of conversations regarding glucagon limit their adoption. Two of the top reasons given by people with diabetes for nonrenewal of glucagon prescriptions were that they were not confident that a caregiver or other person would be able to correctly administer the currently available kit, and their healthcare professional did not discuss the need for a new one with them. In the United States, approximately 662,000 total prescriptions for emergency glucagon kits were written in 2018 in the United States, resulting in the

purchase of approximately 978,000 single-dose kits. In 2018, U.S. sales for emergency glucagon kit totaled approximately $246 million.

In our Healthcare Professional Perceptions Study, results indicated that glucagon would be prescribed to more people across all clinically appropriate patient segments if our Gvoke HypoPen was available. Similarly, in our Caregiver and Patient Perceptions Study, almost two-thirds of people with T1D and T2D who use insulin said they would proactively ask for a prescription for our Gvoke HypoPen if available. Importantly, over half of those same people do not currently have a filled glucagon prescription. During an emergency hypoglycemic event, these individuals would often be required to seek treatment through ambulance calls, hospital admissions or office visits. We believe that these studies show that more people would want to have emergency glucagon on-hand if there was a product that better met their needs. We believe this represents an opportunity for our Gvoke HypoPen, if approved, to shift the site of care from the emergency room or hospital to less costly settings such as the home.

We believe that a relevant market analogue for our Gvoke HypoPen is the epinephrine auto-injector, including EpiPen, for life-threatening allergic reactions. The table below provides a comparison of the severe allergy and hypoglycemia markets.

	SEVERE ALLERGIC REACTION (EPINEPHRINE)	SEVERE HYPOGLYCEMIA (GLUCAGON)
Clinically Appropriate Patient Population in the United States	5.2 million patients	3.5 million patients
No. of Units Sold in the United States (2018)	~8.2 million auto-injectors	~978,000 kits*

* Single-dose units of Eli Lilly's Glucagon Emergency Kits and Novo Nordisk's GlucaGen

We believe this comparison of the allergy and hypoglycemia markets supports the potential of our Gvoke HypoPen, if approved, to increase both the number of clinically appropriate people who have glucagon, as well as the number of glucagon products they have on hand.

Outside the United States, we estimate that an additional 3.5 million people with diabetes in Europe and an additional 12.5 million people with diabetes in Japan and China are clinically appropriate for glucagon treatment. However, only approximately 733,000 emergency glucagon products were sold in the United Kingdom, Germany, France, Italy and Spain combined, and only approximately 414,000 were sold in Japan and China combined, which we believe indicates that the market for emergency glucagon products is significantly under-penetrated in those regions.

Commercial Strategy

If approved, we will seek to replace currently marketed emergency glucagon kits with our Gvoke HypoPen, increase the number of at-risk people who carry emergency glucagon and promote access to emergency glucagon products. While our sales force and medical teams expect to focus on driving awareness and adoption of our Gvoke HypoPen by healthcare professionals, we believe accelerated growth and expanded uptake will come from targeted direct-to-patient messaging that, because the majority of people with diabetes are concentrated in 15 states, will allow us to efficiently and effectively reach our target audience.

We are preparing to launch our Gvoke HypoPen product as soon as practicable following approval, with our PDUFA action goal date of June 10, 2019. In July 2018, Eli Lilly announced its NDA submission for its intranasal glucagon product candidate. We believe this competing product candidate could receive FDA approval and launch at least two months ahead of our Gvoke HypoPen. Therefore, we plan to accelerate our commercial launch activities. Our plan to execute on our go-to-market strategy for our Gvoke HypoPen includes the following:

- **Create awareness and anticipation prior to launch**. We plan to use the FDA's NDA review period to both better understand the market and create excitement and anticipation for our company and our technology. We expect to hire ten regional medical affairs directors prior to commercial launch to establish additional

relationships with key opinion leaders and gain insight into current practice patterns and burdens. We also plan to begin to raise awareness in the market on the incidence, prevalence and impact of severe hypoglycemic events.

- **Drive awareness and adoption of our Gvoke HypoPen**. If approved by the FDA, we plan to drive awareness and adoption of our Gvoke HypoPen to replace current emergency glucagon kits in the market.
  - **Healthcare Professionals:** At launch, our targets will consist of high glucagon prescribing healthcare professionals. Approximately 3,000 healthcare professionals issue 50% of current glucagon prescriptions. We plan to hire 60-70 sales representatives initially to reach these professionals.
  - **Patients and Caregivers:** We intend to activate patient advocacy organizations and leverage channels such as direct-to-consumer tactics, social media, digital presence, traditional offline channels and press coverage to drive awareness and communicate our value proposition to patients and caregivers. Because we do not anticipate having the first product to market in a competitive landscape, we plan to increase our spend on direct-to-consumer tactics. Because of our earlier than expected action date, we plan to accelerate these activities into late 2019. Epidemiology and census data indicate that 15 states account for almost 60% of people with diabetes, allowing us to be efficient and effective with our promotional activities.
- **Penetrate the market**. We believe that the Gvoke HypoPen market is currently significantly underpenetrated due to the lack of, and limitations in, current treatment options. We are designing our Gvoke HypoPen to offer healthcare professionals, patients and caregivers a ready-to-use alternative that facilitates administration of the full dose of glucagon every time it is used. We believe this offering, paired with our commercial focus, has the potential to grow the market in two ways:
  - **Healthcare Professionals:** In addition to the 3,000 healthcare professionals who issue about half of the current glucagon prescriptions, we will target approximately 5,000 healthcare professionals who are high meal time insulin prescribers, but who are under-indexed in prescribing glucagon. We intend to reach these professionals using our initial sales representatives.
  - **Patients and Caregivers:** We believe there is an opportunity to activate patient and caregiver demand for our Gvoke HypoPen. Our Gvoke HypoPen is designed as an easy-to-use solution for a segment of patients and caregivers who currently lack the confidence in administering current emergency glucagon kits and would rather rely on emergency responders for treatment.
- **Promote access:** Current emergency glucagon kits have favorable market access, and current trends indicate a relatively low level of management of these products by payors. For example, Eli Lilly's GEK is covered at or above 94% with unrestricted access across commercial, Medicare, Managed Medicaid and State Medicaid plans. A Diabetes Health Coverage: State Laws and Programs report reviewing state insurance mandated coverage, Medicaid coverage and state-sponsored diabetes programs showed that 46 states and the District of Columbia have a diabetes statutory mandate for coverage, whether as medication or supply. Of our target patient population, approximately 50% are commercially-insured, one-third are covered by Medicare and approximately 15% are covered by Medicaid. However, gaining market access and formulary coverage for new products takes substantial time and resources. As a result, we plan to increase our focus on promoting access to our Gvoke HypoPen. We plan to engage with payors to more fully understand their drivers and barriers and convey the health and pharmacoeconomic value of our Gvoke HypoPen prior to launch.

We plan to establish a distribution channel in the United States for the commercialization of our Gvoke HypoPen. We expect to sell our Gvoke HypoPen to wholesale pharmaceutical distributors, who, in turn, will sell our Gvoke HypoPen to pharmacies and other customers. We expect to use a third-party logistics provider for key services related to logistics, warehousing and inventory management, distribution, contract administration, order management and chargeback processing and accounts receivable management. Outside of the United States, we plan to collaborate with local companies.

Clinical Experience

We have completed three Phase 3 clinical trials for our Gvoke HypoPen and submitted a NDA to the FDA in August 2018. The FDA set June 10, 2019 as the PDUFA action goal date for our NDA. In addition, we have evaluated our Gvoke HypoPen in six preclinical studies, one Phase 1 pharmacokinetic (PK) and pharmacodynamic (PD) study and

two Phase 2 clinical trials. Additionally, through our interactions with the EMA regarding our development path in Europe, we have finalized our regulatory plan and initiated a requisite Phase 3 pivotal trial to support our European MAA for severe hypoglycemia. We expect top-line results from this trial in the first half of 2019. The following table summarizes the completed clinical trials for our Gvoke HypoPen.

PROTOCOL NO./TITLE	PHASE OF DEVELOPMENT	DESIGN/OBJECTIVES	STUDY POPULATION AND DEMOGRAPHICS	DOSE (NO. EXPOSED EACH TREATMENT) AND DOSAGE FORM/ PRODUCT CONFIGURATION
Completed				
XSGP-302 A Phase 3 Study to Evaluate the Glucose Response of Glucagon Rescue Pen (Glucagon Injection) In Pediatric Patients With Type 1 Diabetes	Phase 3a	Non-randomized, open-label, single dose/efficacy, PD, PK, safety and tolerability	Children (2<6, 6<12 and 12<18 years) with T1D n=31	Ages 2<6 years (n=7), single dose of 0.5mg Glucagon Rescue Pen; ages 6<12 years (n=13), single dose of 0.5mg Glucagon Rescue Pen; ages 12<18 years (n=11), single dose of 1mg Glucagon Rescue Pen followed by single dose of 0.5mg Glucagon Rescue Pen 7 to 28 days later/ Rescue Pen
XSGP-301 Glucagon Rescue Pen (Glucagon Injection) Compared To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 3, Randomized, Blinded, 2-Way Crossover Study To Evaluate Efficacy and Safety	Phase 3a	Double-blind, randomized, two-way crossover/efficacy (return to plasma glucose >70.0 mg/dL) of Glucagon Rescue Pen 1 mg to be non-inferior to Eli Lilly's glucagon; compare the PD characteristics of Glucagon Rescue Pen versus Eli Lilly's glucagon; safety and tolerability; PK.	Adult patients with T1D n=80	Glucagon Rescue Pen 1mg (n=78), Eli Lilly's glucagon 1mg (n=79)/Rescue Pen

PROTOCOL NO./TITLE	PHASE OF DEVELOPMENT	DESIGN/OBJECTIVES	STUDY POPULATION AND DEMOGRAPHICS	DOSE (NO. EXPOSED EACH TREATMENT) AND DOSAGE FORM/ PRODUCT CONFIGURATION
XSGP-303 Glucagon Rescue Pen (Glucagon Injection) Compared To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) For Induced Hypoglycemia Rescue In Adults With T1D: A Phase 3B Multi-Centered, Randomized, Controlled, Single-Blind, 2-Way Crossover Study To Evaluate Efficacy And Safety	Phase 3b	Non-inferiority, multi-centered, randomized controlled, single-blind, two-period, two-way crossover efficacy and safety	T1D adult male/female patients 18-75 years of age n=81	Glucagon Rescue Pen 1 mg, Eli Lilly's glucagon 1 mg/ Rescue Pen
XSGP-202 Glucagon Rescue Pen (Glucagon Injection) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 2A Pilot Study To Evaluate Protocol Design Issues For An Upcoming Phase 3 Clinical Study	Phase 2	Open-label 2-way crossover Explore safety efficacy in treatment of insulin-induced hypoglycemia	T1D adult male/female patients 18–65 years of age n=7	Glucagon Rescue Pen 0.5 mg (n=6) and 1 mg (n=7), subcutaneous injections given one week apart/Pre-Filled Syringe
XSGP-201 A Randomized, Phase 2, Double-Blind, 3-Way Crossover Study With Glucagon Rescue Pen (Glucagon For Injection) To Evaluate Safety, Tolerability and Comparative Pharmacokinetics and Pharmacodynamics To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) In Healthy Volunteers	Phase 2	Double-blind, Randomized, 3-way crossover/Safety, tolerability, PK and efficacy vs. marketed comparator	Healthy male/female volunteers 18–60 years of age n=28	Subcutaneous injection of: Glucagon Rescue Pen 0.5 mg (n=29) and 1 mg (n=28); and Eli Lilly's glucagon (rDNA origin) 1 mg/ Pre-Filled Syringe

PROTOCOL NO./TITLE	PHASE OF DEVELOPMENT	DESIGN/OBJECTIVES	STUDY POPULATION AND DEMOGRAPHICS	DOSE (NO. EXPOSED EACH TREATMENT) AND DOSAGE FORM/ PRODUCT CONFIGURATION
XSGP-101 A Two-Way Crossover Comparative PD/PK Study Of Glucagon Rescue Pen (Glucagon Injection) Administered By Auto-Injector And Pre-Filled Syringe	Phase 1	Two-way crossover comparative bioequivalence, safety, tolerability and PD/PK of Glucagon Rescue Pen administered via auto-injector vs. pre-filled syringe	Healthy male/female volunteers 18-64 years of age n=32	Glucagon Rescue Pen 1 mg/Pre-Filled Syringe 1 mg

Completed Phase 3 Clinical Trials

XSGP-302: A Phase 3 Study to Evaluate the Glucose Response of Glucagon Rescue Pen (Glucagon Injection) In Pediatric Patients With Type 1 Diabetes

In 2017, we conducted a sequential non-randomized, open-label, single dose efficacy and safety Phase 3 clinical trial in pediatric subjects with T1D. This clinical trial included a total of 31 subjects (seven subjects 2 to <6 years, 13 subjects 6 to <12 years and eleven subjects 12 to <18 years). In this clinical trial, we induced hypoglycemia, defined as plasma glucose <80 mg/dL, with administration of insulin and then treated subjects with our Gvoke HypoPen. The primary endpoint of this clinical trial was to assess the increase in plasma glucose of subjects from baseline to 30 minutes after injection of an age-appropriate dose of our Gvoke HypoPen, defined as 0.5 mg dose for subjects 2 to <12 years and in separate visits both a 0.5 mg and 1.0 mg dose for subjects 12 to <18 years.

All three age groups met the primary endpoint of non-zero glucose response at 30 minutes post-administration of our Gvoke HypoPen. All evaluable subjects achieved a target glucose increase of at least 25 mg/dL. Following administration, plasma glucose levels over time showed similar glucose responses for subjects in each age group and in each dose in the 12 to <18 years age group. Further, in each age group the observed effect was statistically significant with increases from baseline in mean plasma glucose at 30 minutes following administration of an age-appropriate dose of our Gvoke HypoPen. Administration of 0.5 mg of our Gvoke HypoPen in the 12 to <18 years age resulted in a glucose response that was similar to the age-appropriate dose of 1 mg of our Gvoke HypoPen.

Overall, our Gvoke HypoPen was observed to be well-tolerated. All auto-injectors, or AIs, delivered a full dose. There were no discontinuations due to adverse events, or AEs, no severe AEs, no device-related AEs and no serious adverse events, or SAEs. The majority of treatment-emergent AEs observed were gastrointestinal disorders.

The following table summarizes additional trial design parameters and clinical results that we observed from XSGP-302:

GLUCAGON DOSE	0.5 MG DOSE			1 MG DOSE
SUBJECT AGES	2 TO < 6 YEARS	6 TO < 12 YEARS	12 TO < 18 YEARS	12 TO < 18 YEARS
n	7	13	11	11
% with >25 mg/dL rise in glucose within 30 minutes	100	100	100	100
Glucose Cmax (mg/dL) Mean (SD)	207.8 (35.9)	206.9 (49.6)	212.1 (40.6)	198.9 (60.0)
Glucose Tmax (minutes) Mean (SD)	67.7 (11.1)	66.4 (15.7)	78.2 (11.5)	81.8 (15.6)
% with nausea	42.9	53.8	36.4	36.4
% with emesis	14.3	23.1	0	18.2

XSGP-301: Glucagon Rescue Pen (Glucagon Injection) Compared To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 3, Randomized, Blinded, 2-Way Crossover Study To Evaluate Efficacy and Safety

In 2017, we completed a non-inferiority, prospective, randomized, controlled, double-blinded, two-period, two-way crossover, comparative efficacy and safety Phase 3 pivotal clinical trial in male and female patients aged 18 to 75 years with T1D in an inpatient setting. The trial was conducted across seven locations in the United States and enrolled 80 subjects. The objectives of this clinical trial were to compare the safety, tolerability and efficacy of our Gvoke HypoPen and Eli Lilly's glucagon, as determined by an increase in plasma glucose concentration from below 50 mg/dL to greater than 70 mg/dL within 30 minutes after receiving glucagon. We also evaluated an additional primary endpoint of plasma glucose > 70 mg/dL or increase by >20 mg/dL within 30 minutes. This additional primary endpoint was defined and pre-specified for analysis prior to unblinding the study. Additional endpoints of interest included plasma glucose of >70 mg/dL or resolution of all induced neuroglycopenic symptoms within 30 minutes of glucagon, relief of hypoglycemia symptoms, global feeling of hypoglycemia and glucose elevation 0-90 minutes post-injection.

In this clinical trial, we induced severe hypoglycemia by an IV infusion of regular insulin followed by initial and subsequent bolus doses if plasma glucose after 30 minutes was > 60 mg/dL. Subjects were also administered an IV infusion of regular insulin based on a subject's historical use of basal insulin. The investigator adjusted the IV insulin infusion rate if the rate of glucose change after 30 minutes was < 1 mg/dL/minute. Investigators were instructed to avoid any bolus doses or basal infusion rate increases within 20 minutes of blinded study drug administration. Once the initial plasma glucose measurement < 50 mg/dL was achieved, the IV insulin infusion was stopped. Once the confirmatory plasma glucose reading < 50 mg/dL was achieved, subjects were administered blinded study drug via the subcutaneous route in the upper arm, leg or abdomen.

Subjects were randomized to receive glucagon in one of two sequence groups: our Gvoke HypoPen followed by Eli Lilly's glucagon, or Eli Lilly's glucagon followed by our Gvoke HypoPen. Following glucagon dosing, plasma glucose was monitored every five minutes until 90 minutes post-dosing. Additional blood samples were collected at regular intervals. Subjects also completed a questionnaire regarding hypoglycemia symptoms at the start of the hypoglycemia induction period and periodically until 45 minutes post-treatment with glucagon. Tolerability was assessed by comparing adverse event reports between the groups. In addition, subjects completed questionnaires concerning injection site discomfort. After a wash-out period of seven to 28 days, subjects returned to the clinic and the study procedures were repeated with each subject crossing over to the other treatment group.

Analyses of the primary endpoints were performed according to pre-specified intent-to-treat, or ITT, modified intent-to-treat, or mITT, and per-protocol methods. The ITT cohort was defined as all subjects randomized to one of the two sequence groups. The mITT cohort was defined as the ITT cohort minus one subject that mistakenly received two doses of Eli Lilly's glucagon. The per-protocol cohort was defined as the mITT cohort minus any subjects adjudicated for at least one major protocol violation. Criteria for major protocol violations were defined and pre- specified prior to unblinding of the trial. Following adjudication of major protocol violations, two subjects, one in each study arm, who received a clinically significant (20%) increase in basal IV insulin rate during the final 20 minutes of the induction procedure were censored to establish the per-protocol cohort.

For the ITT and mITT analysis, three or fewer response failures were defined as the pre-specified threshold demonstrating non-inferiority of our Gvoke HypoPen. For the primary endpoint of glucose increase >70 mg/dL within 30 minutes, the total difference in response failures was four, representing one more than the pre-specified threshold of three response failures. For the additional primary endpoint of plasma glucose >70 mg/dL or increase by >20 mg/dL within 30 minutes, the total difference in response failures was two and, therefore, ITT analysis of this additional primary endpoint demonstrated that our Gvoke HypoPen was non-inferior to Eli Lilly's glucagon. The per-protocol analysis of both primary endpoints met the pre-specified threshold. Certain of our analyses may be viewed as post-hoc analyses, and although post-hoc analyses can result in the introduction of bias and may be given less weight by the FDA, we believe that this retrospective analysis can provide additional information regarding results from this trial.

We believe the clinical trial results support the potential of our Gvoke HypoPen to reverse severe hypoglycemia in a reliable manner. In accordance with FDA and International Council for Harmonisation guidance for evaluation of non-inferiority studies, we presented a series of analyses implementing ITT, mITT and per-protocol cohorts for this clinical trial to the FDA at a pre-NDA meeting held in December 2017. In that meeting, the FDA agreed overall that the totality of data for our Gvoke HypoPen is sufficient to support NDA review.

Additionally, a single dose of our Gvoke HypoPen increased plasma glucose and improved clinical symptoms such as cognitive impairment and other neuroglycopenic/neurogenic symptoms that are associated with severe hypoglycemia in 100% of subjects. We also observed comparable increases in plasma glucose concentration from below 50 mg/dL to greater than 70 mg/dL within 30 minutes after receiving our Gvoke HypoPen and comparable resolution of clinical symptoms to Eli Lilly's glucagon, such as cognitive impairment and other neuroglycopenic/neurogenic symptoms that are associated with severe hypoglycemia, as well as comparable pharmacodynamics.

The following table summarizes the efficacy outcomes for XSGP-301.

	mITT RESPONSE RATE	
CLINICAL COMPARISON	**GVOKE HYPOPEN**	**ELI LILLY GLUCAGON**
Subjects successfully rescued from induced hypoglycemia without other rescue therapy (e.g., intravenous dextrose)	100% (78/78)	100% (79/79)
Plasma glucose >70 mg/dL within 30 minutes of glucagon (primary endpoint)	Intent-to-treat† 94.9% (74/78) Per-protocol 96.1% (74/77)	Intent-to-treat 100% (79/79) Per-protocol 100% (78/78)
Plasma glucose of >70 mg/dL or ³ 20 mg/dL increase within 30 minutes of glucagon (additional primary endpoint)	Intent-to-treat 97.4% (76/78) Per-protocol 97.4% (75/77)	Intent-to-treat 100% (79/79) Per-protocol 100% (78/78)
Plasma glucose of >70 mg/dL or resolution of all induced neuroglycopenic symptoms within 30 minutes of glucagon	100% (78/78)	100% (79/79)
Resolution of hypoglycemia symptoms	100% (78/78)	100% (79/79)
Global feeling of hypoglycemia improvement pre/post injection	100% (77/77)	100% (79/79)
Sustained glucose elevation from 0-90 minutes post-injection	100% (78/78)	100% (79/79)

† one (1) additional endpoint failure exceeded the non-inferiority threshold of N=3; all other comparisons demonstrate non-inferiority vs. Eli Lilly's glucagon.

Overall, all treatment regimens were well-tolerated. One SAE of hypoglycemia was reported for a participant treated with Eli Lilly's glucagon. The SAE was determined by the study investigator not to be related to the study drug and resolved during the trial. The incidence of AEs was low in both groups, and the most commonly reported AE was nausea: 20.5% for our Gvoke HypoPen and 12.7% for Eli Lilly's glucagon (p=not significant), followed by vomiting and headache. AEs were generally mild or moderate in severity, transient and resolved with no treatment.

XSGP-303: Glucagon Rescue Pen (Glucagon Injection) Compared to Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) For Induced Hypoglycemia Rescue in Adult Patients With T1D: A Phase 3b Multi-Centered, Randomized, Controlled, Single Blind, 2-Way Crossover Study To Evaluate Efficacy and Safety.

In the second quarter of 2018, we completed a non-inferiority, prospective, randomized, controlled, single-blinded, two-period, two-way crossover, comparative efficacy and safety Phase 3b clinical trial in male and female patients aged 18 to 75 years with T1D in an inpatient setting. The trial was conducted across six locations in the United States and Canada and enrolled 81 subjects. The objectives of this clinical trial were to compare the safety, tolerability and efficacy of our Gvoke HypoPen and Eli Lilly's glucagon, as determined by an increase in plasma glucose concentration from below 50 mg/dL to greater than 70 mg/dL within 30 minutes after receiving glucagon. We also evaluated an additional endpoint of plasma glucose > 70 mg/dL or increase by > 20 mg/dL within 30 minutes. Additional endpoints of interest also included plasma glucose of >70 mg/dL or resolution of all induced neuroglycopenic symptoms within 30 minutes of glucagon, relief of hypoglycemia symptoms, global feeling of

hypoglycemia and total elapsed time required from decision to dose and actual time of injection (e.g. preparation time).

Consistent with our XSGP-301 trial, in XSGP-303 we induced severe hypoglycemia by an IV infusion of regular insulin followed by initial and subsequent bolus doses if plasma glucose after 30 minutes was > 60 mg/dL. The subjects' IV infusion of regular insulin was based upon their historical use of basal insulin. The investigator adjusted the IV insulin infusion rate if the rate of glucose change after 30 minutes was < 1 mg/dL/minute. Investigators were instructed to avoid any bolus doses when a subject's plasma glucose was < 60 mg/dL. Once the initial plasma glucose measurement < 50 mg/dL was achieved, the IV insulin infusion was stopped. Once the confirmatory plasma glucose reading < 50 mg/dL was achieved, subjects were administered blinded study drug via the subcutaneous route in the abdomen.

Subjects were randomized to receive glucagon in one of two sequence groups: our Gvoke HypoPen followed by Eli Lilly's glucagon, or Eli Lilly's glucagon followed by our Gvoke HypoPen. Following glucagon dosing, plasma glucose was monitored every five minutes until 90 minutes post-dosing. Additional blood samples were collected at regular intervals. Subjects also completed a questionnaire regarding hypoglycemia symptoms at the start of the hypoglycemia induction period and periodically until 180 minutes post-treatment with glucagon. Tolerability was assessed by comparing adverse event reports between the groups. In addition, subjects completed questionnaires concerning injection site discomfort. After a wash-out period of seven to 28 days, subjects returned to the clinic and the study procedures were repeated with each subject crossing over to the other treatment group.

Analyses of the primary endpoints were performed according to pre-specified intent-to-treat, or ITT, and per-protocol methods. The ITT cohort was defined as all subjects randomized to one of the two sequence groups. The per-protocol cohort was defined as the ITT cohort minus any subjects adjudicated for at least one major protocol violation.

For the ITT analysis, three or fewer response failures were defined as the pre-specified threshold demonstrating non-inferiority of our Gvoke HypoPen. For the primary endpoint of glucose increase from below 50 mg/dL to >70 mg/dL within 30 minutes, all subjects who received a study drug experienced successful plasma glucose recovery. As there were no treatment failures observed, the ITT analysis of the primary endpoints demonstrated that our Gvoke HypoPen was non-inferior to Eli Lilly's glucagon.

Criteria for major protocol violations were defined and pre-specified prior to starting the trial. Following adjudication of major protocol violations, two subjects in the Gvoke HypoPen arm were identified who were administered study drug despite not being within a steady state of hypoglycemia. In addition, subjects who did not receive a study drug were considered major protocol violations. These subjects were censored to establish the per-protocol cohort. Despite the major protocol violation in the subjects who received Gvoke HypoPen, plasma glucose recovery was achieved within 30 minutes and the subjects successfully met the study primary endpoint.

We believe the results of XSGP-303 corroborate the outcomes observed in XSGP-301 and further support the potential of our Gvoke HypoPen to reverse severe hypoglycemia in a reliable manner. We incorporated the results of this study into the NDA submission.

The following table summarizes the efficacy outcomes for XSGP-303.

Clinical Comparison	RESPONSE RATE	
	GVOKE HYPOPEN	ELI LILLY GLUCAGON
Subjects successfully rescued from induced hypoglycemia without other rescue therapy (e.g., D50).	100% (76/76)	100% (78/78)
Plasma glucose >70 mg/dl in 30 minutes. (primary endpoint)	Intent-to-treat 100% (76/76) Per-protocol 100% (73/73)	Intent-to-treat 100% (78/78) Per-protocol 100% (73/73)

Clinical Comparison	RESPONSE RATE	
	GVOKE HYPOPEN	ELI LILLY GLUCAGON
Plasma glucose of >70 mg/dl or ³ 20 mg/dl increase within 30 minutes of glucagon.	Intent-to-treat 100% (76/76) Per-protocol 100% (73/73)	Intent-to-treat 100% (78/78) Per-protocol 100% (73/73)
Plasma glucose of >70 mg/dl or resolution of all induced neuroglycopenic symptoms within 30 minutes of glucagon.	100% (76/76)	100% (78/78)
Resolution of hypoglycemia symptoms	100% (76/76)	100% (78/78)
Global feeling of hypoglycemia improvement pre/post injection†	100% (73/73)	100% (76/76)
Sustained glucose elevation from 0-90 minutes post-injection	100% (76/76)	100% (78/78)

† Population of subjects only includes those reporting hypoglycemic symptoms at baseline.

Overall, all treatment regimens were well-tolerated. There were no reported SAEs. The incidence of AEs was low in both groups and the most commonly reported AE was nausea, followed by vomiting and headache. AEs were generally mild or moderate in severity, transient and resolved with no treatment.

XSGP-101: A Two-Way Crossover Comparative PD/PK Study Of Glucagon Rescue Pen (Glucagon Injection) Administered By Auto-Injector And Pre-Filled Syringe

At our pre-NDA meeting in December 2017, the FDA recommended to us that we address three areas of inquiry regarding our Gvoke PFS: the characterization of PD/PK data to compare changes in serum plasma glucose levels and serum hormone levels when glucagon is administered by an auto-injector versus hand injection, a human factors validation study for this presentation and device reliability testing for this presentation. As a result of this meeting, with respect to the Gvoke PFS, we initiated our XSGP-101 clinical trial in the first quarter of 2018. Based on the results of this trial which, combined with the human factors studies and device reliability testing, we included the Gvoke PFS in our Gvoke HypoPen NDA submission to the FDA.

In the second quarter of 2018, we completed a Phase 1 two-way crossover comparative PD/PK study of glucagon administered by auto-injector versus pre-filled syringe to demonstrate bioequivalence in fasted healthy subjects with low to normal plasma glucose levels. We enrolled 32 healthy male and female subjects, ranging from 19 to 63 years old, with a median age of 46.5 years. Subjects were randomly assigned to a treatment sequence and each received a 1 mg dose of glucagon via auto-injector and another 1 mg dose via pre-filled syringe. Both treatments were administered subcutaneously to the abdomen.

Analysis of the primary PK endpoints of plasma glucagon AUC(0-240min) and Cmax indicated bioequivalence of glucagon whether administered by auto-injector or pre-filled syringe. The PD endpoints of plasma glucose AUC(0-240min), Cmax, and Tmax also demonstrated bioequivalence and PD equivalence between the two devices.

Overall, auto-injector and pre-filled syringe treatments were generally well tolerated and similar AEs were observed between the two treatment groups. The most commonly experienced AEs were nausea, vomiting and headache. All of the AEs were mild or moderate in severity. There were no SAEs or discontinuations due to an AE.

Other Completed Supporting Trials

Phase 2 Clinical Trials

XSGP-201: A Randomized, Phase 2, Double-Blind, 3-Way Crossover Study with Glucagon Rescue Pen (Glucagon For Injection) To Evaluate Safety, Tolerability and Comparative Pharmacokinetics and Pharmacodynamics To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) In Healthy Volunteers

In 2014, we completed a double-blind, randomized, three-way crossover Phase 2 clinical trial of glucagon in 28 healthy male and female subjects 18 to 60 years of age to evaluate the safety, tolerability, PK and efficacy versus Eli Lilly's glucagon. Subjects were subcutaneously injected with glucagon via a pre-filled syringe in doses of 0.5 and 1 mg and with Eli Lilly's glucagon for injection in a dose of 1 mg.

Plasma glucose concentration-time curves showed little separation between treatment groups, and there were no substantial differences between our glucagon 1 mg and Eli Lilly's glucagon for injection 1 mg in terms of glucose area under the curve, maximum concentration, or Cmax, and time to reach maximum concentration, or Tmax.

Results showed that all treatments were well-tolerated and demonstrated a comparable safety profile. No SAEs were observed, and all AEs were transient and consistent with rescue injections of glucagon.

XSGP-202: Glucagon Rescue Pen (Glucagon Injection) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 2a Pilot Study To Evaluate Protocol Design Issues For An Upcoming Phase 3 Clinical Study

In 2015, we completed an open-label two-way crossover Phase 2 clinical trial to explore the safety and efficacy of glucagon for the treatment of insulin-induced hypoglycemia in seven adult males and females with T1D 18 to 65 years of age. Subjects were given our glucagon injection via the pre-filled syringe 0.5 mg (n=6) and 1 mg (n=7), as subcutaneous injections given one week apart.

All subjects in a state of insulin-induced hypoglycemia experienced objective and subjective response to rescue doses of glucagon with return of glucose to > 70 mg/dL and resolution of all hypoglycemia symptoms within 30 minutes of injection.

Results showed AEs were generally mild and corresponded to known effects of rescue doses of glucagon. Vasovagal syncope, or fainting, was observed in one patient, which met the definition of an SAE as an important medical event but was attributed by the investigator to study procedures.

Ongoing Clinical Trials

XSGP-304: G-Pen Compared to GlucaGen HypoKit for Induced Severe Hypoglycemia Rescue in Adults With Type 1 Diabetes: A Phase 3 Multi-Center Randomized, Controlled, Single Blind, 2-Way Crossover Study to Evaluate Efficacy and Safety

The objectives of this clinical trial were developed following scientific advice from the EMA in support of our planned European MAA. We are comparing the safety, tolerability and efficacy of our glucagon pen and Glucagen Hypokit (Novo Nordisk), as determined by an increase in plasma glucose concentration from below 54 mg/dL to greater than 70 mg/dL within 30 minutes after receiving glucagon or increase by 20 mg/dL within 30 minutes. Additional endpoints of interest include relief of hypoglycemia symptoms, global feeling of hypoglycemia and total elapsed time required from decision to dose and actual time of injection (e.g., preparation time). The trial involves two daytime clinical research center, or CRC, visits with random assignment to receive glucagon pen 1 mg during one period and Glucagen Hypokit 1 mg during the other. Each daytime visit is preceded by an overnight stay in the CRC. In the morning of the inpatient study visit, the subject is brought into a state of severe hypoglycemia through IV administration of regular insulin diluted in normal saline. After a hypoglycemic state with plasma glucose < 54 mg/dL (3 mmol/L) is verified, the subject is administered a dose of glucagon pen or Glucagen Hypokit via subcutaneous injection. Plasma glucose levels are monitored for up to 180 minutes post-dosing, with a value of >70.0 mg/dL (3.89 mmol/L) or an increase of > 20 mg/dL (>1.11 mmol/L) within 30 minutes of glucagon administration indicating a positive response. After 3 hours, the subject is given a meal and discharged when medically stable. After a wash-out period of 7 to 28 days, subjects return to the CRC, and the procedures are repeated with each subject crossed over to the other treatment. A follow-up visit as a safety check is conducted 2-7 days following administration of the final dose of study drug. We initiated this trial in the second half of 2018 to be conducted at six sites in North America and three in Europe. We have a target enrollment of 122 subjects and expect top-line results in the first half of 2019.

Preclinical Studies

Six preclinical studies, consisting of five studies in rats and one study in rabbits, demonstrated that our concentrated, non-aqueous solution of glucagon was safe in animal models. Studies included PK and PD studies, toxicity and potential impurities studies, toxicokinetic evaluations and local tolerance assessment. We conducted these studies during 2010 to 2018. These studies administered glucagon to a total of 206 rats and 8 rabbits.

Human Factors Summative Validation Study

In 2017, we conducted a human factors summative validation study in users, which confirmed that our Gvoke HypoPen can be correctly, safely and effectively used. Of the 75 injections, 74 (99%) were successful. There was a single failure that occurred when an untrained subject prematurely lifted the pen from the injection site within approximately 1.5 seconds of activation, resulting in a partial dose. The subject admitted to not reading the label guide. No mitigation response was needed as the failure was attributed to the participant's noncompliance with reading the label guide while performing the procedure. After reviewing the label guide, the subject successfully administered the injection during an unaided second attempt. The study concluded that the Gvoke HypoPen dose label, packaging, device and injection procedure, label guide and instructions for use had been successfully validated.

Ready-to-Use Glucagon for Hypoglycemia Associated with Intermittent and Chronic Conditions

We are applying our ready-to-use liquid-stable glucagon formulation to treat five intermittent and chronic conditions with significant unmet medical need. In particular, our formulation may be applied to conditions requiring continuous doses or smaller or mini-doses of glucagon over a longer administration period. We intend to leverage work across our programs to substantially reduce development costs for each indication and enable expanded uses for intermittent and chronic applications of ready-to-use glucagon to follow our Gvoke HypoPen. Aspects include:

- Chemistry, manufacturing and controls, or CMC
- Nonclinical toxicology program
- Clinical supplies manufacturing

For intermittent and chronic hypoglycemic conditions, we intend to leverage our completed preclinical studies across our glucagon portfolio, which consist of two toxicology studies in rats, one toxicology study in pigs, one tolerability study in rabbits, two PK studies in rats and one toxicology and PK study in rats (320 rats, 54 pigs and 8 rabbits). These preclinical studies demonstrated the safety of the ready-to-use glucagon and supported further clinical development. A number of additional toxicology studies are ongoing to support long-term chronic use of ready-to-use glucagon in additional hypoglycemic conditions.

For commercialization in our intermittent and chronic conditions, we expect to target endocrinologists, diabetologists and primary care providers that are currently prescribing glucagon and rapid acting insulin. Many of these physicians, particularly endocrinologists, are also currently treating PBH patients and we believe there is significant overlap between these physicians and those who would prescribe ready-to-use glucagon for HAAF and EIH. Furthermore, because there are few CHI patients and they are primarily treated at a handful of centers of excellence in the United States, we believe we can engage these clinicians with a small group of regional medical affairs directors.

In December 2013, we filed an IND application for the use of ready-to-use glucagon delivered via a wearable patch pump. This IND has supported our clinical development efforts in PBH and HAAF and an assessment in a bi-hormonal artificial pancreas closed-loop system. We are the sponsor of this IND, which is active as of the date of this prospectus.

Ready-to-Use Glucagon for Post-Bariatric Hypoglycemia

We are developing a ready-to-use glucagon formulation for chronic self-administration in PBH, a challenging complication of bariatric surgery that may significantly impair quality of life, but for which there are currently no approved treatments. In January 2018, we received orphan drug designation from the FDA for our ready-to-use glucagon for the treatment of patients with hyperinsulinemic hypoglycemia, of which PBH is a category. In November 2018, we received EU orphan product designation for the treatment of Noninsulinoma Pancreatogenous Hypoglycaemia Syndrome, or NIPHS, which includes patients with PBH.

Post-Bariatric Hypoglycemia Market

Obesity and related comorbidities such as T2D and cardiovascular disease are increasingly recognized as a major threat to individual and public health, with sustained weight loss difficult to achieve. Clinicians and patients alike have embraced the results of recent controlled clinical trials demonstrating the efficacy of surgical procedures performed on the stomach or intestines, known as bariatric surgery, to not only induce sustained weight loss but also to improve or normalize obesity-related comorbidities, including T2D. The number of bariatric surgeries performed in the United States has increased from an estimated 158,000 procedures per year in 2011 to 228,000 in 2017, growing nearly 45% in just six years. While benefits of bariatric surgery are now achieved with a lower risk of surgical complications, longer-term intestinal and nutritional complications can still occur.

One challenging and sometimes severe complication of bariatric surgery is hyperinsulinemic hypoglycemia. Hyperinsulinemic hypoglycemia, and more specifically PBH, is most commonly associated with Roux-en-Y gastric bypass, or RYGB, a procedure in which the small intestine is re-routed to a small resected stomach pouch. However, PBH has also been observed following sleeve gastrectomy, a procedure that reduces the size of the stomach. PBH is defined as documented plasma glucose levels below 70 mg/dL in conjunction with hypoglycemic symptoms and the relief of such symptoms with the normalization of glucose levels. Symptoms include palpitations, lightheadedness and sweating. A subset of post-bariatric patients develops very severe hypoglycemia involving a shortage of glucose in the brain, known as neuroglycopenic symptoms, typically occurring one to three years following bariatric surgery, associated with confusion, decreased attentiveness, seizure and loss of consciousness. For these patients, quality of life can be severely affected as many cannot care for themselves or even be left alone and may ultimately lose their employment due to this disability.

Hypoglycemia typically occurs after meals, particularly those rich in simple carbohydrates. Due to the change in gastric anatomy resulting from bariatric surgery, plasma insulin concentrations are inappropriately high at the time of hypoglycemia in these patients. Treatment of hypoglycemia requires rapid-acting carbohydrates such as glucose tablets, which in PBH patients can contribute to rebound hyperglycemia that triggers further insulin secretion and recurrent hypoglycemia.

There are currently no approved treatments for PBH. Current strategies to manage PBH include dietary modification aimed at reducing intake of high glycemic index carbohydrates. Both diet and off-label administration of pre-meal acarbose, an anti-diabetic drug used to treat T2D, aim to minimize rapid post-meal surges in glucose that trigger insulin secretion. Additional off-label therapies include those aimed at reducing insulin secretion. In severe cases, gastric restriction or banding has been required to slow gastric emptying and gastrostomy tubes have been used to provide the sole source of nutrition. Despite strict adherence to medical nutrition therapy and clinical use of multiple medical options, patients continue to have frequent hypoglycemia. While hypoglycemia most commonly occurs following meals, it can also occur in response to increased activity and emotional stress. Importantly, patient safety is additionally compromised when hypoglycemia unawareness develops with recurrent hypoglycemia. We believe there is an urgent need for therapeutic options to allow optimal nutrition, maintain health and quality of life and improve safety in patients with PBH.

Because episodes of hypoglycemia normally occur in the ambulatory setting, the reported prevalence of PBH varies, but we estimate that roughly 1% to 2% of bariatric surgery patients experience PBH. As bariatric procedures have been performed for over ten years, based on our analysis of market research, we estimate a standing population of approximately 85,000 patients who fail meal time nutritional therapy and experience PBH in the United States and require additional treatment options. A similar size patient population is estimated to exist in Europe. Depending on the severity of their condition, these patients may require chronic episodic administration of glucagon ranging from multiple times a month to multiple times a day.

Xeris Offering–Ready-to-Use Glucagon for PBH

We have developed a ready-to-use glucagon formulation that can be easily and quickly injected or infused subcutaneously from a syringe, pen or pump. Injection of small doses of our liquid-stable glucagon after meals may offer a novel mechanism for PBH patients to treat or prevent hypoglycemia. Importantly, these smaller and more physiologic doses are designed to prevent rebound hyperglycemia associated with glucose tablets, carbohydrate intake and rescue doses of glucagon. Further, small doses of glucagon may offer a direct treatment mechanism for

PBH, as opposed to indirect methods aimed at preventing hypoglycemia that are currently employed using various off-label therapeutic options.

Primary market research has shown endocrinologists are comfortable with glucagon's mechanism of action and current safety profile and view ready-to-use glucagon as a welcome treatment option for PBH patients. Physicians surveyed reported ready-to-use glucagon utilization of 68% to 97% if the product can prevent half of severe hypoglycemic events in PBH patients.

As there are currently no therapeutic options indicated for treatment of PBH and the condition has been designated a rare disease, we believe that payors will include our ready-to-use glucagon on their formularies, if approved. We intend to conduct additional payor research as product development progresses.

From 2015 to 2017, the NIH National Institute of Diabetes and Digestive and Kidney Diseases awarded us $1.78 million in Fast-Track Small Business Innovation Research, or SBIR, grants to demonstrate the potential benefits of ready-to-use glucagon in these patients. Collaborators on this grant include endocrinologists at the Joslin Diabetes Center and device engineers at the Harvard University John R. Paulson School of Engineering and Applied Science.

Clinical Experience

We have completed seven preclinical studies in multiple species, a proof-of-concept clinical trial and a randomized controlled Phase 2a clinical trial for our ready-to-use glucagon for PBH. A new IND application for self-administration of our ready-to-use glucagon with a vial/syringe went into effect on October 19, 2018. This IND authorized us to initiate a new Phase 2 trial evaluating our ready-to-use, room-temperature stable liquid glucagon formulation for patients who experience hyperinsulinemic hypoglycemia after bariatric surgery. We commenced this clinical trial in the second half of 2018 and expect top-line results in the first half of 2019. We expect the results from this trial will help enable the evaluation of ready-to-use glucagon in a future Phase 3 clinical trial using a vial/syringe in an outpatient setting.

Phase 2 Clinical Trials

XSGO-PB01: A Phase 2 Proof-Of-Concept Study of Sensor Guided, Clinician-Administered Delivery of Glucagon Infusion from a Patch Pump to Prevent Post-Prandial Hypoglycemia in Post-Bariatric Surgery Patients

In 2017, we conducted an iterative design-and-evaluation Phase 2 clinical trial to assess the performance of a novel event-based hypoglycemia prediction algorithm that triggered delivery of mini-doses of ready-to-use glucagon from a patch-pump. For the trial, which was conducted from the first quarter of 2016 through the second quarter of 2017, we recruited seven patients 18 to 65 years of age with a history of RYGB surgery and PBH with neuroglycopenia who were uncontrolled on medical nutrition therapy and medications. In the inpatient setting, subjects received a mixed-meal tolerance test, which is known to cause hypoglycemia in these patients. Upon receipt of an alarm based on continuous glucose monitor data, subjects were given small, subcutaneous infusions of ready-to-use glucagon from a pump, with the aim of preventing hypoglycemia. The primary endpoint of this study was to investigate the ability of the patch-pump to detect and direct timing of glucose administration. The secondary endpoint of this study was to investigate the safety profile of this product candidate.

Ready-to-use glucagon bolus through the infusion pump was observed to rapidly raise serum glucagon levels, and the doses employed were not associated with increased insulin or C-peptide concentrations. Nadir glucose and time spent under 75 mg/dL in the period after the glucagon bolus were reduced progressively with each new stage of protocol development, which involved either earlier hypoglycemia alarms or larger glucagon doses. All seven patients successfully completed nine treatment visits in this trial. Results showed the treatment to be well-tolerated, with discomfort at the infusion site and erythema the most frequent adverse events, and no SAEs.

Since this was the first implementation of the ready-to-use glucagon formulation in mini-doses in PBH, the dosage was chosen with caution to prevent rebound hyperglycemia that has been observed with use of rescue doses of glucagon. Using these results, we determined the dosage required to effectively prevent hypoglycemic events in the postprandial setting. The results of this trial were published in the peer-reviewed journal *Diabetes Technology & Therapeutics*.

XSGO-PB02: Closed-Loop Glucagon Pump for Treatment of Post-Bariatric Hypoglycemia

Following the positive proof-of-concept outcome of XSGO-PB01, in the fourth quarter of 2017, we initiated a randomized, placebo-controlled, double-blind Phase 2 clinical trial to assess the efficacy of ready-to-use glucagon to prevent and treat hypoglycemia occurring in patients with PBH in response to meals. The primary objective of this trial was to investigate the efficacy of our closed-loop glucagon pump for PBH measured by real-time continuous glucose monitoring, or CGM. Secondary objectives included safety and tolerability. Following a mixed-meal tolerance test, or MTT, subjects were randomized to either placebo or glucagon infusion on the first study visit and crossed-over to the other treatment during the second treatment visit. Investigators were masked to subject assignment. In study visits, a MMT was employed, and then subjects were treated based on CGM based measurements of subject blood glucose. The subject was treated with the study drug (Ready-to-use glucagon or placebo) at a dose of 300 mcg followed by 150 mcg if needed. Of 12 subjects that completed the trial, seven experienced severe hypoglycemia in response to MMT. Ready-to-use glucagon effectively treated hypoglycemia in comparison to placebo ($p = 0.0082$ glucagon vs. placebo). Rescue glucose was needed in 7 of 7 visits for subjects who received placebo and 0 of 7 visits for subjects who received ready-to-use glucagon. Both treatments were well tolerated with no reported SAEs. An abstract of these study results has been submitted to a clinical diabetes meeting for presentation in the first half of 2019.

This randomized controlled trial data supported the new IND and informed the design of our ongoing Phase 2 clinical trial using a vial/syringe to evaluate ready-to-use glucagon in PBH.

XSGR-PBH-201: A Phase 2, Interventional, Randomized, Double-Blind, Placebo-Controlled Pilot Study of Glucagon RTU in Subjects Who Experience Hyperinsulinemic Hypoglycemia After Bariatric Surgery

Following our IND authorization in October, we initiated a new Phase 2 clinical trial at six clinical research centers in North America. This study is a randomized, placebo-controlled, double-blind, two-treatment, two-period, crossover comparison in a CRC setting followed by a randomized, placebo-controlled, double-blind, two arm parallel comparison in the outpatient setting. The purpose of the trial is to evaluate the logistics of implementing an efficacy and safety study of ready-to-use glucagon, or Glucagon RTU, via vial/syringe to treat symptomatic postprandial hypoglycemia in subjects with PBH. It will also collect safety and efficacy information to help inform a future Phase 3 clinical trial.

During the CRC stage, subjects will undergo two high-carbohydrate, solid/liquid-meal tests. After each meal, subjects will self-administer blinded study drug (Glucagon RTU 300 mcg or placebo) when any postprandial autonomic symptom is experienced or hypoglycemia is confirmed with a blood glucose measurement < 70 mg/dL by blood glucose meter. After CRC study-related procedures are completed, subjects will enter the 12-week outpatient stage. The subjects will be discharged home with their assigned study drug: Glucagon RTU 300 mcg or placebo. Subjects also will be trained to self-administer their assigned study treatment, i.e., dose study drug with the presence of any postprandial autonomic symptoms or a blood glucose measurement < 70 mg/dL. During postprandial hyperinsulinemic hypoglycemia episodes, the trial will evaluate plasma glucose recovery (i.e., blood glucose (BG) ³ 70 mg/dL) at 15 minutes after dosing with Glucagon RTU and placebo. Safety, tolerability and quality-of-life will also be assessed. The trial will comprise 12 evaluable subjects. We expect top-line results from this trial in the first half of 2019.

Ready-to-Use Glucagon for Congenital Hyperinsulinism

We are evaluating our ready-to-use glucagon formulation for chronic management of congenital hyperinsulinism, for which there are currently no approved therapies. In the United States, 80 to 160 infants are born with CHI on an annual basis. We estimate that there are approximately 6,200 patients with CHI in the United States. In September 2014, we received orphan drug designation from the FDA for ready-to-use glucagon for the prevention of chronic, severe hypoglycemia in patients with CHI. In October 2014, we also received orphan drug designation from the EMA for ready-to-use glucagon for the treatment of CHI. We recently concluded a Phase 2 proof-of-concept trial and held an end of Phase 2 meeting with the FDA in December 2018. We plan to incorporate feedback from our meeting with the FDA into our Phase 3 clinical development program.

Congenital Hyperinsulinism Market

CHI is the result of several genetic defects that present as dysregulated increased insulin secretion, causing severe, persistent hypoglycemia in infants and children. CHI often responds poorly or not at all to current medical

approaches and can sometimes lead to surgical removal of the pancreas, or near-total pancreatectomy. In CHI, microscopic abnormalities in the pancreas can result in prolonged severe hypoglycemia which, if untreated, can cause death. Repeated episodes of severe and prolonged hypoglycemia, even if not fatal, can result in permanent neurologic damage, including developmental delay, mental retardation and focal central nervous system deficits.

Management of CHI is aimed at preventing morbidity associated with repeated hypoglycemic episodes, including permanent brain damage, as well as mortality. Currently, there are no approved drugs for CHI. While limited treatment options are available, they have marginal efficacy, are poorly tolerated by patients and negatively impact quality of life. Often, severe cases of CHI are resistant to diazoxide due to the type of genetic mutation. Other drugs, such as octreotide, have been used to reduce insulin secretion but may be ineffective in maintaining normal blood sugar and may cause substantial side effects.

Pancreatectomy is an option if a solitary focal lesion in the pancreas can be identified and surgically removed, typically resulting in a cure without the need for medication or continuous feedings. However, if the disease is not localized, near-total pancreatectomy would be required. Patients who undergo near-total pancreatectomy are at high risk for developing insulin-dependent diabetes later in life. This risk increases with the extent of pancreatic removal, but the risk is significant even with conservative surgical procedures. The use of pancreatectomy oftentimes addresses CHI but creates another chronic condition, insulin-dependent diabetes.

Xeris Offering—Continuous Subcutaneous Infusion of Ready-to-Use Glucagon

If approved, we believe our ready-to-use glucagon would enable safe, continuous administration of glucagon from a pump to manage CHI. IV glucagon is routinely used in the hospital and in conjunction with IV glucose to stabilize blood glucose levels in affected infants, but the IV must be changed every 24 hours or less due to the instability of glucagon in aqueous solution. The use of glucagon has historically been limited due to the lack of a stable formulation and convenient delivery system for long-term administration, especially in the home setting where a central catheter is impractical and a gastronomy-tube is cumbersome.

We believe that the continuous subcutaneous infusion of ready-to-use glucagon, if approved, is superior to the use of off-label drugs because ready-to-use glucagon:

- Offers a direct effect of increasing glucose levels compared to indirect mechanisms of glucose control.
- Enables release of patient’s excess glycogen stores.
- Avoids the side effects related to octreotide, nifedipine and diazoxide.

In addition, we believe that the continuous subcutaneous infusion of ready-to-use glucagon, if approved, is superior to the use of infused glucose because ready-to-use glucagon:

- Provides an approach to wean the patient off a central glucose line, such as an IV, to enable discharge from the hospital.
- Eliminates bloating observed with the high-volume glucose infusions often required to maintain normal blood glucose levels.

Finally, we believe that the continuous subcutaneous infusion of ready-to-use glucagon, if approved, is superior to pancreatectomy, because patients may be able to avoid the development of insulin-resistant diabetes as a lifetime condition. CHI patients who progress to adolescence typically normalize or at least no longer require intensive medical management. We believe that avoiding pancreatectomy is likely the most impactful result of management of CHI with ready-to-use glucagon.

In the short-term inpatient setting, we believe our ready-to-use formulation may enable administration of glucagon from a small, wearable, infusion pump. In the long term, we believe the glucagon pump system may enable outpatient administration of glucagon for prevention of hypoglycemia. We expect most patients that are candidates for ready-to-use glucagon would use the product until mid-adolescence and transition out of the standing patient pool.

There are currently no therapeutic options indicated for treatment of CHI, and current standard of care involves near-total pancreatectomy or use of multiple off-label therapeutics. We believe payors will include our ready-to-use

glucagon on their formularies because CHI is a rare pediatric disease and ready-to-use glucagon has the potential to reduce time spent in the NICU, avoid expensive pancreatectomies, as well as avoid the long-term costs associated with diabetes treatment resulting from pancreatectomy. We intend to conduct additional payor research as product development progresses.

From 2015 to 2017, we were awarded $2.1 million in SBIR grants from the NIH National Institute of Diabetes and Digestive and Kidney Diseases to initiate clinical studies in infant patients with CHI.

Clinical Experience

We recently concluded enrollment in a Phase 2 proof-of-concept randomized controlled clinical trial and previously completed a number of preclinical studies in multiple species that we are leveraging for all of our intermittent and chronic glucagon programs.

XSGO-CH01: A Phase 2 Proof-of-Concept Study of CSI Glucagon (Continuous Subcutaneous Glucagon Infusion) to Prevent Hypoglycemia with Lower Intravenous Glucose Infusion Rates in Children up to One Year of Age with Congenital Hyperinsulinism

XSGO-CH01 was a Phase 2, multi-center, randomized, placebo-controlled, double-blind trial with open-label follow up designed to assess the efficacy of CSI Glucagon delivered with a patch pump as a subcutaneous continuous infusion to prevent hypoglycemia with lower IV glucose infusion rates, or GIRs, in patients less than one year of age with congenital hyperinsulinism. The trial had a target enrollment of 24 subjects, with a built-in interim analysis after 12 subjects. However, only five subjects were enrolled over 23 months. In consultation with the lead study investigator at Cook Children's Medical Center, we concluded enrollment in September 2018 and analyzed available results. A total of five subjects were screened for inclusion and enrolled in the study (intent-to-treat). Subjects began in a baseline phase to stabilize GIR. Subjects were then randomized into a 2-day blinded treatment period, followed by an open label treatment period for up to 28 days. All subjects completed all three study periods with no adverse events observed. In this trial, CSI Glucagon within the tested dose range was observed to directly reduce GIR to a large and clinically meaningful extent (44%-66%) when used as a sole therapy. A summary of these results is provided in the following table:

Glucose Infusion Rate Response in Study XSGO-CH01

PER PROTOCOL (4 SUBJECTS)	BASELINE STABILIZATION	RANDOMIZED BLINDED TREATMENT (PLACEBO)	RANDOMIZED BLINDED TREATMENT (CSI GLUCAGON)	OPEN-LABEL CSI-GLUCAGON (CSI GLUCAGON)
Stable GIR	5/5[a]	0/2	2/2	4/4
GIR Response (reduction ≥ 20% at 24 hrs.)	N/A	1/2	2/2	N/A
GIR Response (reduction ≥ 33% at 48 hrs.)	N/A	0/2	2/2	4/4[b]
GIR change (range)	N/A	31% reduction, to 34% increase	53%-65% reduction	44%-66% reduction

a: The first enrolled subject, 01-01, was not deemed evaluable for responsive to glucagon based upon prior history of glucagon resistance, per investigator. Selection criteria were changed after this first patient enrollment to exclude glucagon resistance.

b: Treatment time varied from 4-52 hours.

CSI glucagon was well tolerated in this trial. There were no reported AEs, no skin reactions and no other negative treatment effects associated with study drug administration. CSI glucagon was well tolerated within the dose range of 5-20 µg/kg/hr. Furthermore, there were no reports of occlusions, leakage or other pump issues in the trial, or any instances of severe hypoglycemia during pump change-out.

Based on the results generated in this study, we believe CSI Glucagon has the potential to be used in an outpatient setting by caregivers following adequate training, if approved. In XSGO-CH01 CSI Glucagon within the tested dose range was observed to directly reduce GIR to a large and clinically meaningful extent (44%-66%) when used as a sole therapy. Given the distinct mechanism of action from other treatments for CHI, CSI Glucagon has the potential to serve as a complementary therapy with other available therapies. We believe the short-term positive treatment effects observed in the Phase 2 study support our efforts to evaluate CSI Glucagon in the context of a Phase 3 outpatient study, which we are designing in accordance with feedback we received from the FDA during our December 2018 end of Phase 2 meeting.

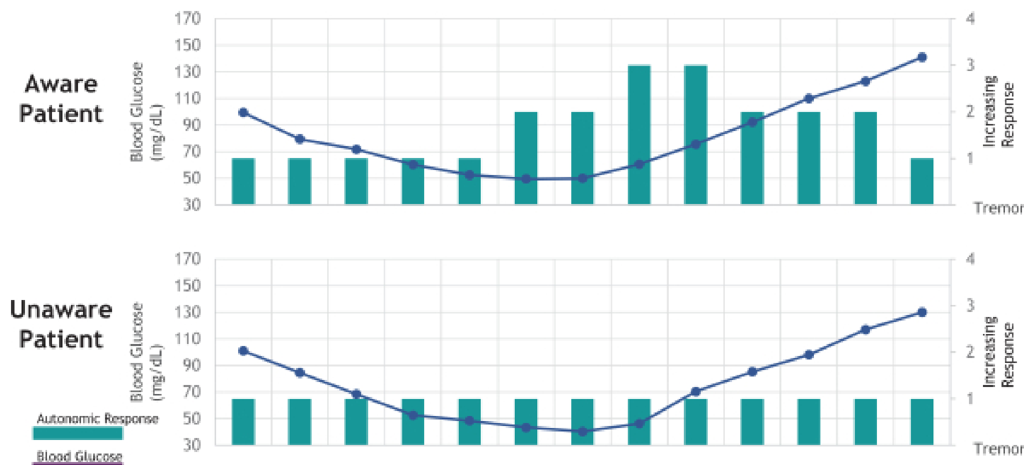
Ready-to-Use Glucagon for Hypoglycemia-Associated Autonomic Failure

We are evaluating our ready-to-use glucagon for HAAF, a condition for which there are currently no therapeutic options. We have initiated a Phase 2a clinical trial from which we expect to obtain top-line results in the second half of 2019. If clinical development is successful, we expect to submit a NDA under the 505(b)(2) pathway for FDA review.

Hypoglycemia-Associated Autonomic Failure Market

Typically, a decrease in plasma glucose below the normal range triggers defensive counter-regulatory responses that restore blood sugars. However, individuals with HAAF have defects in that counter-regulatory response. These individuals do not experience the physiological symptoms of worsening hypoglycemia and are at risk of being unaware of an impending severe hypoglycemic event. Chronic hypoglycemia is thought to lead to this defective glucose counter-regulation and hypoglycemia unawareness. The lack of awareness of an oncoming hypoglycemic event may result in the inability to treat or prevent it, creating a vicious cycle of recurrent hypoglycemia and possibly leading to the sudden onset of severe hypoglycemia, putting patients at risk for severe hypoglycemia, neuroglycopenia, seizure, coma and, if left untreated, death. As such, hypoglycemia unawareness is a major concern for this subset of people with T1D and T2D and their caregivers.

The figures below depict the effect of hypoglycemic unawareness where symptoms do not signal corresponding blood glucose.



It has been shown that the autonomic response and awareness of hypoglycemia can be restored with scrupulous avoidance of hypoglycemia for two to three weeks. However, this restoration can currently only be achieved with intensive diet and behavior modification, which we believe results in low participation and success rates.

Based on our research, we estimate that approximately 20% of people with T1D and 14% of people with T2D (primarily those on insulin) have HAAF. In primary market research, physicians indicated approximately half of patients with some form of HAAF are moderately to severely affected. However due to the need for better diagnosis procedures and guidelines for HAAF, the physicians surveyed also reported that they currently expect approximately 40% and 50% under-diagnosis rates of HAAF in people with T1D and T2D, respectively. We believe there is a critical unmet need for a therapeutic treatment for insulin deficient diabetes patients with HAAF.

Xeris Offering—Continuous Subcutaneous Infusion of Ready-to-Use Glucagon

We are developing a novel continuous subcutaneous glucagon infusion system incorporating our ready-to-use, liquid-stable glucagon formulation with an infusion pump. Continuous subcutaneous infusion of ready-to-use glucagon could be used to avoid hypoglycemia during a three- to four-week period to restore autonomic response and hypoglycemia awareness. Combined with patient training, the treatment may result in a significant long-term reduction in hypoglycemia rates post-intervention, particularly of severe hypoglycemia. If approved, we believe our ready-to-use glucagon has the potential to be the first product designed to prevent hypoglycemia for extended periods of time to enable re-establishment of hypoglycemia awareness and treat HAAF. We believe our ready-to-use glucagon, if approved, could provide substantial therapeutic benefit to patients who suffer from severe hypoglycemic events and are taken to the emergency room multiple times per year.

The use of glucagon to treat this condition has been hampered due to the lack of a room-temperature stable liquid glucagon formulation and a convenient delivery system for continuous administration. Attempts at off-label treatment with current emergency glucagon products require reconstitution of freeze-dried glucagon powder, and the drug chamber and infusion set would likely require replacement at least every 24 hours due to the instability of glucagon in aqueous solution.

There are currently no therapeutic treatment options for HAAF. However, since at least some payors currently cover diabetes coaching and training services conducted by certified diabetes educators, which are often used to help treat or manage HAAF, we believe payors will cover ready-to-use glucagon if we can demonstrate reversal of hypoglycemia unawareness. We intend to conduct additional payor research as product development progresses.

Clinical Experience

We have initiated a Phase 2a proof-of-concept randomized controlled clinical trial and have successfully completed a number of preclinical studies in multiple species that we are leveraging in our intermittent and chronic glucagon programs.

Ongoing Phase 2 Clinical Trial

XSGO-AF01: Fixed Rate Continuous Subcutaneous Glucagon Infusion (CSGI) vs Placebo in Type 1 Diabetes Mellitus Patients with Recurrent Severe Hypoglycemia: Effects On Counter Regulatory Responses to Insulin Induced Hypoglycemia

XSGO-AF01 is a prospective, randomized, controlled, double-blind, parallel four-group trial with the primary analysis after four weeks of treatment with continuous subcutaneous glucagon infusion, or CSGI, or placebo. After a one-week qualification on CGM, subjects will have their baseline hypoglycemia counter-regulatory response hormones quantified using a step-wise hypoglycemia induction procedure. Subjects meeting eligibility requirements will be randomized to one of four treatment groups, two glucagon, two placebo. Subjects will receive blinded study drug for four weeks, and they will be followed for an additional 26 weeks post-treatment. Subjects' counter-regulatory hormone response will be measured at baseline, the end of treatment (four weeks), and 13 and 26 weeks after treatment ends. We are conducting the trial at six sites in the United States and expect top-line results from 48 subjects in the second half of 2019. We expect data from this Phase 2a clinical trial to help outline pivotal study endpoints and inform a discussion with the FDA.

Ready-to-Use Glucagon for Exercise-Induced Hypoglycemia in Diabetes

We are evaluating our ready-to-use glucagon and plan to initiate an additional Phase 2 clinical study in the first half of 2019 for EIH, for which there are currently no approved therapies. Based on these results and previous data, we intend to discuss our registration pathway with FDA in the second half of 2019. In November 2013, we filed an IND application for the use of mini-dose ready-to-use glucagon for EIH. We are the sponsor of this IND, which is active as of the date of this prospectus.

Exercise-Induced Hypoglycemia in Diabetes Market

Exercise-induced hypoglycemia and the complexity of management aimed at its prevention represent major barriers to the adoption of regular physical activity for many individuals with diabetes treated with insulin. Although carbohydrate ingestion, including oral glucose tablets, can help ameliorate hypoglycemia, patients' carbohydrate requirements can be as high as 1 gram per minute of exercise, which can be counterproductive to weight management. Aerobic exercise, in particular, often results in a significant drop in blood glucose concentrations. Qualitative feedback has shown that the challenges in current exercise management strategies and the need to

consume carbohydrates is frustrating and may lead to minimized or complete omission of exercise for many patients. People with diabetes who use insulin are at risk of EIH. We believe there is a subset of these individuals that exercises at least three times per week per current guidelines, and who could potentially use a mini-dose of ready-to-use glucagon each time they exercised. If approved, our ready-to-use glucagon would represent a significant market opportunity in the treatment for EIH.

Xeris Offering—Mini-doses of Ready-to-Use Glucagon for Treatment of EIH

We are developing a mini-dose of our ready-to-use, liquid-stable glucagon and have observed appropriate dose-dependent PK and PD responses when administered subcutaneously at doses of 75, 150 and 300 µg in adults with T1D. Our previous proof-of-concept study demonstrated that 150 µg of this mini-dose glucagon corrected non-severe hypoglycemia to a substantially similar degree as oral glucose tablets that are commonly used during exercise in correcting non-severe hypoglycemia in adults with T1D, while enabling avoidance of unnecessary caloric intake.

Modestly increasing glucagon levels at the start of exercise has previously not been possible, since current commercially available glucagon preparations are unstable in aqueous solution. They exist as a lyophilized powder that must be reconstituted in diluent immediately prior to injection and are only indicated at an emergency dose of 1 mg for rescue from severe hypoglycemia. Despite the challenging reconstitution process, there has been significant documented off-label use of the current glucagon kits.

We have been awarded over $3.1 million in grants from organizations such as the Leona M. and Harry B. Helmsley Charitable Trust and the NIH National Institute of Diabetes and Digestive and Kidney Diseases, and we have worked with institutions including the Joslin Diabetes Center and the University of Pennsylvania for clinical development of our mini-dose glucagon product candidate.

Clinical Experience

We have successfully completed a number of preclinical studies in multiple species to support the safety of mini-dose glucagon, as well as three Phase 2 safety and efficacy clinical trials in subjects with T1D.

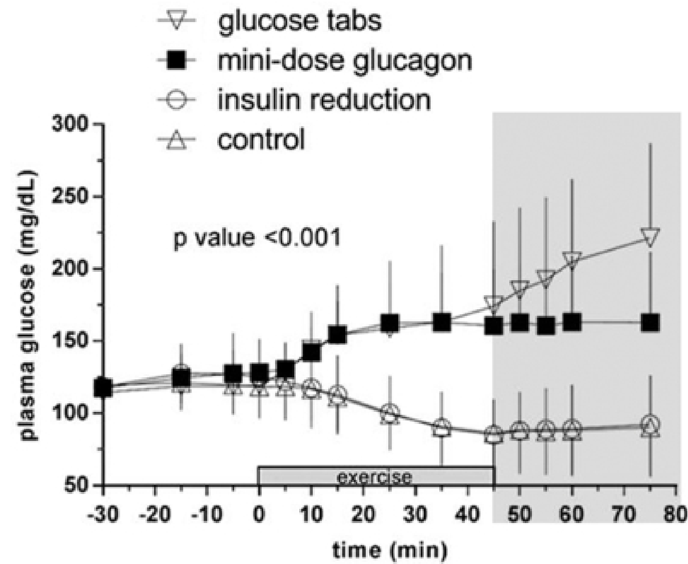
Phase 2 Clinical Trials

XSMP-203: The Use of Mini-Dose Glucagon to Prevent Exercise-Induced Hypoglycemia in Type 1 Diabetes

Based on our previous dose-finding trials (XSMP-201 and XSMP-202), we initiated a third Phase 2 clinical trial of mini-dose glucagon for EIH in the first quarter of 2016. The primary analysis of this trial was comparison of the glycemic response of 150 µg mini-dose glucagon against current standards of care, including basal insulin reduction and glucose tablet consumption, to mitigate exercise-induced hypoglycemia. In particular, this was a four-session, randomized crossover trial involving 15 adults with T1D who exercised at 50-55% VO2max for 45 minutes under conditions of no intervention (control), 50% basal insulin reduction, 40 g oral glucose tablets, or 150 µg subcutaneous mini-dose glucagon, all administered five minutes before exercise. Secondary endpoints were to investigate the safety profile of this product candidate.

During the exercise sessions conducted in this study, plasma glucose increased slightly with mini-dose glucagon compared to a decrease with control and insulin reduction, as depicted in the figure below. Plasma glucose increased more greatly with glucose tablets. Hypoglycemia (<70 mg/dL) was experienced by six subjects during control, five during insulin reduction and none with glucose tablets or mini-dose glucagon; however, five subjects experienced hyperglycemia (>250 mg/dL) with glucose tablets and one with mini-dose glucagon. The study was well-controlled, as insulin levels were not different among sessions, while glucagon levels increased only in the mini-dose glucagon arm, as expected.

In a Phase 2a randomized, controlled clinical study, T1D subjects (n=16) administered mini-dose glucagon completed a 45-minute exercise session without adjusting basal insulin or ingesting glucose tabs (calories).



The Phase 2a study concluded that mini-dose glucagon (150 µg) may have the potential to prevent EIH in adults with T1D. In addition, mini-dose glucagon may be more effective at preventing EIH than insulin reduction that was associated with a similar rate and magnitude of hypoglycemia as no intervention. Moreover, while mini-dose glucagon was as effective as glucose tablets for preventing exercise-induced hypoglycemia, mini-dose glucagon may result in less post-intervention hyperglycemia than ingestion of carbohydrates and avoids the consumption of unnecessary calories. The results of this study were published in the journal Diabetes Care.

Ongoing Trials

XSMP-204: A Phase 2 Randomized, Placebo-Controlled, Double-Blind, Parallel Study to Evaluate Glucagon RTU (Glucagon Injection) Compared to Standard of Care for the Prevention of Exercise-Induced Hypoglycemia During Regular Aerobic Exercise in Adults with Type 1 Diabetes

This trial is a single center randomized, placebo-controlled, double-blind, two-treatment, two-period, crossover comparison in a CRC setting followed by a randomized, placebo-controlled, double-blind, two arm parallel comparison with a third open-label arm in the outpatient setting. The purpose of the trial is to evaluate the preliminary efficacy of Glucagon RTU to prevent exercise-induced hypoglycemia in adults with T1D who perform regular, moderate-to-high intensity, aerobic exercise. T1D subjects, who receive daily insulin treatment via a subcutaneous infusion pump, will perform at least 45 minutes duration in an inpatient setting and at least 30 minutes duration in the outpatient setting and will be monitored for hypoglycemia in the exercise recovery period. The trial will examine if the subcutaneous administration of Glucagon RTU just before exercise, with or without a 50% reduction in basal rate insulin, compared to a 50% basal rate insulin reduction alone, prevents the occurrence of hypoglycemia (i.e., blood glucose £ 70 mg/dL; 3.89 mmol/L) measured by blood glucose meter during and after moderate-to-high intensity aerobic exercise by adult subjects with T1D in an outpatient setting. The trial has a target enrollment of 48 subjects and we expect top-line results in the second half of 2019.

Ready-to-Use Glucagon for Bi-Hormonal Artificial Pancreas Closed-Loop Systems

We are evaluating our ready-to-use glucagon for use in a bi-hormonal artificial pancreas closed-loop system. In mid-2018, OHSU initiated a Phase 1 proof-of-concept randomized three-way crossover clinical trial to evaluate the utility of such a system. We expect OHSU to report top-line results from this trial in the second half of 2019. Based on these results, we expect to move forward with a clinical program for a bi-hormonal artificial pancreas closed-loop system. In December 2013, we filed an IND application for the use of ready-to-use glucagon in a bi-hormonal

artificial pancreas closed-loop system. We are the sponsor of this IND, which is active as of the date of this prospectus.

Insulin-Dependent Diabetes Market

Continuous subcutaneous insulin infusion from a pump, or CSII, has been shown to improve glycemic control for people with diabetes. However, data from clinical trials indicate that even when used in closed-loop, insulin analogs, pumps and continuous glucose monitoring, or CGM, have generally modest effects in reducing hypoglycemic events because they are capable of only delivering or stopping delivery of insulin. As such, CSII users are still forced to ingest carbohydrate containing foods, over-the-counter glucose products, or utilize emergency glucagon products to counteract hypoglycemia.

We believe the quality of life for patients could be significantly improved by offering a bi-hormonal artificial pancreas that delivers both insulin and glucagon. While significant work has been done developing extensive algorithms and control systems needed for the bi-hormonal pump, a key limitation has been the lack of a glucagon formulation that does not require reconstitution and is stable for at least three days in a pump chamber. We believe the utilization of our ready-to-use glucagon in a bi-hormonal system has the potential to minimize the incidence of hypoglycemia, improve patient quality of life, and drive higher rates of adoption of CSII systems.

All patients utilizing an intensive insulin regimen are candidates for a bi-hormonal pump system. In the United States, this includes all 1.3 million people with T1D as well as approximately 500,000 people with T2D. Of this combined population, approximately one-third is currently utilizing CSII therapy.

Xeris Offering—Liquid-Stable Ready-To-Use Glucagon for a Bi-Hormonal Artificial Pancreas

A liquid-stable glucagon formulation is a critical component to facilitate a bi-hormonal artificial pancreas. Our ready-to-use glucagon has demonstrated stability at body temperature in a patch pump chamber. Collaborators in our bi-hormonal artificial pancreas program include endocrinologists at OHSU. In addition, numerous researchers have expressed interest in using our ready-to-use glucagon in research studies with novel bi-hormonal pump systems.

To support development of our ready-to-use glucagon for this application, we have been awarded approximately $1.9 million in funding from organizations such as the NIH National Institute of Diabetes and Digestive and Kidney Diseases and the JDRF.

Clinical Experience

We have successfully completed a number of preclinical studies in multiple species and a Phase 2a dose-ranging glucagon PK/PD study and a Phase 1a proof-of-concept randomized clinical trial is currently underway.

Ongoing Phase 1 Clinical Trial

NCT 03424044: A Randomized, Three-Way, Cross-Over Outpatient Study to Assess the Efficacy of a Dual-Hormone Closed-Loop System with XeriSol Glucagon vs Closed-Loop System with Insulin Only vs a Predictive Low Glucose Suspend System

This is a single center, randomized, three-way, crossover investigation-initiated trial conducted by OHSU using our ready-to-use glucagon in a vial. Subjects undergo the 76-hour study with 9 hours inpatient and 67 hours outpatient using the closed-loop artificial pancreas controller. The trial initiated in mid-2018 and is designed to compare the glucose control resulting from the use of a bi- and single-hormone closed-loop system as compared to a predictive low glucose suspend system, using the percent of time with sensed glucose below 70 mg/dl as the primary endpoint. The bi-hormonal closed-loop system is designed to reduce the time spent in the hypoglycemic range and increase the time spent in the target range, even after exercise, as compared to an insulin only closed-loop system and a predictive low glucose suspend system. This clinical trial has a planned enrollment of 19 subjects and we expect OHSU to report results in the second half of 2019.

Additional Programs

Ready-to-Use Diazepam

Leveraging our XeriSol formulation technology, we are developing a ready-to-use diazepam formulation for the treatment of ARS in patients with epilepsy. Approximately 160,000 people in the United States experience ARS.

Immediate treatment of epileptic seizures is critical to avoid increased risks of morbidity and mortality, including permanent neuronal damage, behavioral abnormalities and an increased probability in the need for life-long care.

Injectable and rectal gel formulations of diazepam are the current standard of care for the emergency treatment of epileptic seizures. In 2017, these diazepam formulations generated total U.S. sales of approximately $127 million, of which Diastat Rectal Gel and its generic formulations comprised $83 million. Diastat requires a multi-step procedure which makes it more difficult to administer while a patient is experiencing seizures. Additionally, the use of rectal gel in both middle school children and young adults with ARS is reduced because of social stigma. These characteristics are limitations that may diminish the specific demand for rectal diazepam products. Due to this limitation, we believe the market for diazepam in ARS is underpenetrated. We believe that a ready-to-use diazepam rescue pen would improve patient quality of life and drive adoption of diazepam to treat ARS.

Our ready-to-use diazepam rescue pen has demonstrated rapid onset and high bioavailability in preclinical models. We received orphan drug designation for our product candidate from the FDA and were awarded grants totaling $1.5 million from the Epilepsy Foundation and the NIH for this program. An IND application for our ready-to-use diazepam rescue pen for ARS went into effect on November 28, 2018. This IND authorized us to initiate a study evaluating the pharmacokinetics and pharmacodynamics of our ready-to-use, room-temperature stable liquid diazepam formulation in normal volunteers. We initiated this trial in December 2018 and expect top-line results in the first half of 2019. If results are positive, we plan to initiate a Phase 2 clinical trial in the second half of 2019.

XSDZ-101: A Randomized Crossover Study of the Comparative Bioavailability, Pharmacokinetics, and Tolerability of Diazepam After Subcutaneous, Intramuscular, and Rectal Administration in Healthy Subjects

This trial is a Phase 1, open-label, single-center, single-dose, three-way crossover study in 24 healthy adult subjects which will evaluate the bioavailability of ready-to-use diazepam (10 mg) administered subcutaneously to the abdomen and intramuscularly to the deltoid, as compared to the rectal administration of Diastat (10 mg) when each is administered under fasted conditions. The sequence of treatments will be randomly assigned and there will be a fixed 21-day washout period between treatments. This trial will also assess the safety and tolerability of ready-to-use diazepam administered subcutaneously and intramuscularly, as compared to rectal administration of the marketed gel formulation of diazepam (Diastat). A final safety visit will be completed 22 to 36 days after the last treatment.

XeriSol Pramlintide-Insulin Co-formulation

Leveraging our XeriSol platform, we are developing a ready-to-use fixed dose combination of insulin and pramlintide to be delivered via a vial and syringe. Pramlintide is an injectable amylin analog for both Type 1 and 2 diabetes. In normal physiology, amylin is a hormone that is co-secreted into the bloodstream at a fixed ratio with insulin by the b cells of the pancreas. The U.S. approval and launch of pramlintide (Symlin®) brought significant interest because of its ability, when used in combination with mealtime insulin, to flatten post-prandial blood glucose levels, reduce glucose excursions, and cause weight loss. Short-term and long-term clinical trials have found that adding pre-prandial pramlintide injections to insulin therapy reduced post-prandial glucose excursions and improved overall glycemic control (hemoglobin A1c levels) in patients with type 1 diabetes. Clinically, pramlintide accomplishes this by reducing food intake, delaying gastric emptying, and reducing endogenous glucose production in the liver by suppressing glucagon secretion. The use of pramlintide also allows for about 30% less insulin utilization due to differential efficacy.

Pramlintide is indicated in diabetics for use at all major meals for which patients are already administering four injections of a basal-bolus insulin per day. The addition of a pramlintide regimen would add three or more separate injections daily which could be a challenging proposition in this patient population. Thus, a daily pramlintide injection burden made it unattractive to pump users who often chose pumps to avoid repeated injections. We believe current use of pramlintide is quite limited because the injection burden issues outweigh the perceived benefits. To date, co-formulation/mixtures of pramlintide and insulin have experienced technical difficulties due to the physico-chemical incompatibility of a native mixture of each of these components. We believe our shelf stable XeriSol formulation of pramlintide and regular insulin as well as pramlintide and lispro Insulin can benefit patients by reducing the number of required injections. Our XeriSol formulation technology addresses the co-formulation problem with the generation stable pramlintide and regular insulin as well as pramlintide and lispro insulin. XeriSol forms a stable co-formulation of pramlintide and insulins (regular or lispro) without the need for novel excipients. XeriSol pramlintide-insulins can be presented as variable-fixed-ratio combination of either six or nine µg pramlintide at per unit of insulin. These ratios have been shown to have beneficial clinical efficacy profiles in previous studies. XeriSol pramlintide-insulin has several potentially valuable properties from a patient use perspective: potential

two-year shelf life stability when refrigerated and up to 90 days at temperatures up to room temperature. This stability profile is comparable to current vial-based insulin products and would not likely introduce a new regiment of storage and use for existing insulin patients.

In preclinical studies, we characterized the pharmacokinetics and pharmacodynamics (glycemic changes are presented for clarity) of pramlintide and various insulin formulations in normal and streptozotocin induced diabetic rats (mimicking T1DM) given as separate injections or as a XeriSol pramlintide-insulin combined dose. Consistent with pramlintide's known pharmacological action, there was no glucose lowering with pramlintide alone. Profiles for pramlintide were similar to either saline or XeriSol vehicle administered by SC injection in rats. XeriSol pramlintide-insulin demonstrated a longer duration of glucose lowering compared to separate injections of pramlintide (Symlin®) and insulin (Humulin®). Figures 1 and 2 below show a comparison of efficacy changes in glucose levels after injection of XeriSol pramlintide-insulin and pramlintide-lispro in comparison with separate injections of Symlin® and Humulin® or Symlin® and Humalog® in a rodent model. In a preclinical study, XeriSol pram-insulin maintained glucose control for approximately four hours as compared to separate injections of commercial product combinations (mimicking human SC administration) that begin to lose glucose control after approximately two hours.

We are preparing to study our novel XeriSol pramlintide-insulin co-formulation in a clinical trial in T1D in the third quarter of 2019. This study will compare XeriSol pramlintide-insulin versus separate injections of Symlin® and Humulin® in diabetic subjects. According to recent guidance from the FDA, the insulin component of our XeriSol pramlintide-insulin co-formulation is subject to the FDA's "deemed to be a license" provision of the Biologics Price Competition and Innovation Act of 2009, and may necessitate that we submit a biologics license application for any future marketing authorization by the FDA.

Figure 1 Glucose Levels after Injection of XeriSol™ Pramlintide-Insulin and Symlin®/Humulin® Co-Injection

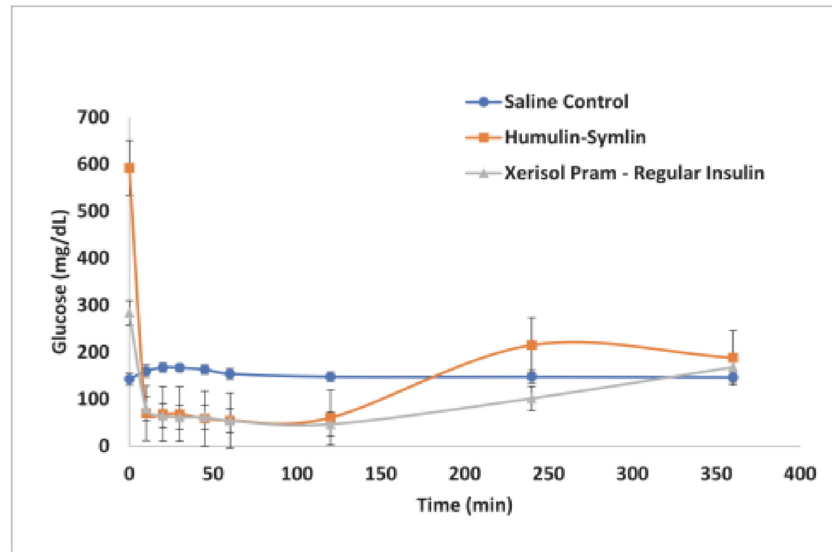
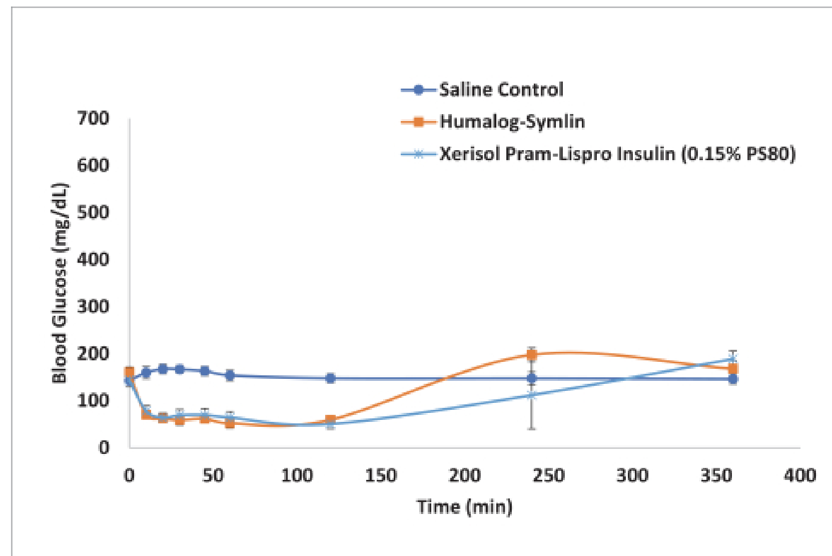


Figure 2 Glucose Levels after Injection of XeriSol™ Pramlintide-Lispro and Symlin®/Humalog® Co-Injection



Manufacturing and Supply

We currently contract with third parties for the manufacture, assembly, testing, packaging, storage and distribution of our products. In our experience, third party contract manufacturing organizations, or CMOs, are generally cost-efficient, high quality and reliable, and we currently have no plans to build our own manufacturing or distribution infrastructure. Our technical team has extensive pharmaceutical development, manufacturing, analytical, quality and distribution experience and is qualified and capable of managing supply chain operations across multiple CMOs. Our Quality System, Standard Operating Procedures and CMO interfaces are designed to promote cGMP compliance and effective regulatory communications. We selected our CMOs for specific competencies, and they have met our development, manufacturing, quality and regulatory requirements and were all involved in manufacturing our clinical supplies and commercial registration batches.

Glucagon is the active pharmaceutical ingredient, or API, used in our Gvoke HypoPen and our intermittent and chronic hypoglycemia products in development that utilize ready-to-use glucagon. We intend to use Bachem Americas, Inc., or Bachem, as our primary commercial source for API. Bachem holds a U.S. drug master file for glucagon produced at its facility in Switzerland, and its manufacturing process is fully validated. We have entered into a non-exclusive supply agreement with Bachem. While we believe that Bachem has sufficient capacity to satisfy our long-term requirements for our Gvoke HypoPen and other pipeline products utilizing ready-to-use glucagon, we are actively engaged in developing a second API source.

Manufacturing drug product for our Gvoke HypoPen requires an aseptic fill/finish facility capable of handling solvents and a cyclic olefinic polymer syringe. Pyramid Laboratories, Inc., or Pyramid, has been actively involved in the development of our product candidates, and we intend to use its facility in California to be our primary source for drug product. We have entered into a non-exclusive supply agreement with Pyramid. While we believe that Pyramid has sufficient capacity to satisfy our demand requirements for at least three to five years, we are evaluating alternate sourcing options.

The auto-injector used to deliver drug product in our Gvoke HypoPen is a proprietary multi-product device platform developed by SHL Medical AG, SHL Pharma, LLC, SHL Pharma, or SHL. We entered into a joint development agreement in January 2016 to develop an auto-injector suitable for our Gvoke HypoPen SHL produces device sub-assemblies in company-owned facilities in Taiwan and performs final drug product/device assembly operations at its facility in Florida. We have entered into a non-exclusive supply agreement with SHL. We intend to source the device from a single supplier over the life of the product.

We believe that a number of CMOs can provide suitable secondary packaging services for our Gvoke HypoPen, and we intend to enter into one or more commercial supply agreements. A number of third party logistic providers can provide commercial order processing and finished good distribution services to U.S. wholesale customers, and we expect to enter into one or more commercial distribution agreements in 2019.

Competition

Our industry is characterized by intense competition and a strong emphasis on proprietary products. We believe the key competitive factors that will affect the development and commercial success of our product candidates include likelihood of successful dose delivery, ease of administration, therapeutic efficacy, safety and tolerability profiles and cost. While we believe that our product and product candidate platform, development expertise and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products.

Two emergency glucagon products are currently available to treat severe hypoglycemia: Eli Lilly's GEK and Novo Nordisk's GlucaGen. Each kit is sold as a vial of lyophilized, glucagon powder with an exposed syringe/needle that contains a liquid diluent. The glucagon powder must be combined with the liquid diluent at the time of use and drawn into a syringe in accordance with a complex multi-step reconstitution and dose calibration procedure. Additionally, once reconstituted, the glucagon must be used immediately because once the lyophilized glucagon is combined with water, the solution becomes unstable and can fibrillate, rendering it inactive and potentially toxic. We believe that the drawbacks of currently marketed products and the lack of conversations regarding glucagon limit their adoption. In addition to the currently marketed GEK from Eli Lilly and Novo Nordisk's GlucaGen, we are currently aware of several product candidates that are expected to compete with our Gvoke HypoPen, if approved. Eli Lilly is developing an intranasal glucagon dry powder and submitted an NDA two months ahead of our NDA submission. While healthcare professionals as well as patients and caregivers believe both our Gvoke HypoPen and the intranasal dry powder are easy to use, they have expressed concern that the full dose of glucagon may not be delivered via intranasal absorption. Of note, in a Phase 1 clinical trial, a pediatric subject failed to achieve a $\geq$25 mg/dL rise in glucose because he blew his nose immediately after a 2 mg intranasal dose administration.

In our market research, respondents ranked the importance of successful full-dose delivery and ability to tell if the full dose was administered significantly higher than the needleless attribute. In our market research, caregivers and people with diabetes associated our Gvoke HypoPen with efficacious and successful dose delivery, as well as ease of ability to tell if the full dose was administered. Similarly, healthcare professionals indicated that one of the most appealing attributes of our Gvoke HypoPen is the greater likelihood of successful dose delivery.

In addition, Zealand Pharma is developing an SC dasiglucagon, a stable analog of human glucagon, in an auto-injector. Based on its public filings, Zealand has stated it intends to file an NDA in the second half of 2019. Zealand's dasiglucagon is currently in Phase 3 development and is being studied in adults and children. Data released to date indicate that Zealand's dasiglucagon will have a room-temperature stable shelf-life up to 12 months.

While there are currently no FDA approved products indicated for treatment of PBH, we are aware of a number of product candidates in development. For example, Eiger Biopharma is developing its product candidate exendin 9-39, a glucagon-like peptide-1 receptor antagonist, to be administered subcutaneously, which is currently in Phase 2 development.

Currently, there are no approved drugs for CHI and limited treatment options are available, but we are aware of several product candidates in development. For example, Rezolute is developing RZ358, an IV administered fully human antibody that inhibits the effects of elevated insulin via allosteric modulation of the insulin receptor, which is currently in Phase 2 development. In addition, Zealand Pharma is developing an SC infusion of dasiglucagon, which is currently in Phase 3 clinical development.

There are currently no approved products for the treatment of HAAF. Many other therapeutic compounds have been investigated in academic clinical research for the indirect prevention of hypoglycemia. While none of these

interventions have been successful to date, this research shows there is considerable interest in restoring hypoglycemia awareness and HAAF.

Currently, the first-line emergency treatment of epileptic seizures in the outpatient setting is the administration of diazepam in a non-sterile rectal gel marketed by Valeant Pharmaceuticals as Diastat. We are also aware of other product candidates for which a NDA has been recently submitted for the treatment of ARS in patients with epilepsy. For example, Neurelis announced that in August 2018, they submitted a NDA for VALTOCO, which is a NRL-1, an intranasal formulation of diazepam. In addition, Aquestive is developing AQST-203, a buccal soluble formulation of diazepam, which is currently in Phase 3 development.

Intellectual Property

Proprietary protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We have been building and continue to build our intellectual property portfolio relating to our product candidates and technology. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also intend to rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us or our partners in the future will be commercially useful in protecting our technology.

Patent Rights

As of February 7, 2019, we owned 75 issued patents globally, of which 13 are issued U.S. patents. As of February 7, 2019, we owned 77 patent applications pending globally, of which 11 are patent applications pending in the United States. As of May 31, 2018, three of our U.S. issued patents have pending continuations or divisionals in process which may provide additional intellectual property protection if issued as U.S. patents. Our issued patents expire between December 22, 2023 and April 22, 2036, subject to payment of required maintenance fees, annuities and other charges. The subset of our patent estate directed specifically to our ready-to-use glucagon consists of one U.S. composition of matter patent that is scheduled to expire in year 2036, two pending U.S. patent applications and 18 international patent applications. Patents that issue based on the foregoing international application would expire in year 2036.

Trade secret and other protection

In addition to patented intellectual property, we also rely on trade secrets and proprietary know-how to protect our technology and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual’s relationship with us except in limited circumstances. These agreements generally also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

Other intellectual property rights

We file trademark applications and pursue registrations in the United States and abroad when appropriate. We own a registered trademark for the mark Xeris Pharmaceuticals. We also own pending trademark applications for XERISOL, XERIJECT, GVOKE HYPOPEN and HYPOPEN in the United States; and XERISOL and XERIJECT in the EU for use in connection with our pharmaceutical research and development as well as products, as well as trade names that could be used with our potential products. The USPTO has allowed the following trademark applications which are awaiting Statements of Use: XERISOL, XERIJECT, GVOKE HYPOPEN, HYPOPEN and GLUCAPEN.

From time to time, we may find it necessary or prudent to obtain licenses from third-party intellectual property holders.

Grant Agreements

Through September 30, 2018, we have received $0.8 million out of an expected $0.9 million in grant proceeds for the development of a stable liquid glucagon for use in an artificial pancreas. Under the terms of the agreement, we will be required to pay up to four times the award received upon commercialization of glucagon for use in the artificial pancreas. If we undergo a change in control, then we will be required to pay a mid-single digit percentage of the gross proceeds, capped at four times the award amount less any amounts already paid. Additionally, if sales of glucagon for use in the artificial pancreas exceed $750 million in the first five years after the first commercial sale, then we would be required to make an additional payment equal to the original award amount.

Through September 30, 2018, we received $0.9 million in grant proceeds to help fund our EIH program. Under terms of this agreement, we will be required to pay up to two times the award amount upon the commercialization of an EIH product. These amounts are a low double-digit percentage of annual gross sales of an EIH product, capped at $0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, if sales exceed $1 billion, we will be required to pay an additional amount equal to two times the award amount.

Through September 30, 2018, we received $1.0 million in grant proceeds to help fund our T1D chronic glucagon programs. Under terms of this agreement we will be required to pay up to two times the award amount upon the commercialization of any chronic glucagon program. These amounts are a low double-digit percentage of annual gross sales of T1D all chronic glucagon programs, capped at $0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, for each chronic glucagon program where sales exceed $500 million, we will be required to pay an additional amount equal to two times the award amount.

We have also received awards from the NIH National Institute of Diabetes and Kidney Diseases, which awards are not subject to any repayment obligations. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” for additional details.

Loan and Security Agreement

In February 2018, we entered into the Loan and Security Agreement that provides a senior secured loan facility of up to an aggregate principal amount of $45.0 million. The first tranche was $20.0 million and was drawn down in February 2018. The second tranche was $15.0 million and was drawn down in September 2018. The third tranche is $10.0 million and is available beginning upon approval of our Gvoke HypoPen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Loan Agreement” for additional details.

Government Regulation

United States Drug and Biological Product Development

In the United States, the FDA regulates drugs, medical devices and combinations of drugs and devices, or combination products, under the federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Drugs, biologics, medical devices and combination products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory, and biologics under the FDCA, the Public Health Service Act, or PHSA, and their implementing regulations approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, requests for voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are subject to regulation as combination products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different Centers within the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its regulation based on a determination of the combination

product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our product candidates, the primary mode of action is attributable to the drug component of the product, or biological component of the product, which means that the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our product candidates. Accordingly, we plan to investigate our products through the IND framework and seek approval through the NDA or BLA pathway. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require a separate medical device authorization for the device, but this could change during the course of its review of any marketing application that we may submit. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with an applicable IND and other clinical study related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug or biologic for its proposed indication;
- submission to the FDA of a NDA or BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the FDA's current good manufacturing practice requirements, or cGMP;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA and payment of associated user fees;
- review by an FDA advisory committee, where appropriate or if applicable;
- FDA review and approval of the NDA or BLA prior to any commercial marketing or sale; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. An IND is an exemption from the FDCA that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance, and may be imposed on all drug or biological products within a certain class of drugs or biologics. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The

IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- Phase 2. Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials. Companies that conduct certain clinical trials also are required to register them and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk to humans exposed to the product, findings from animal or in vitro testing that suggest a significant risk to human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. The clinical trial sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review Process

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug or biologic, proposed labeling and other relevant information, are submitted to the FDA as part of a NDA or BLA, requesting approval to market the product. An NDA for a new drug must contain proof of the drug's safety and efficacy. A BLA is a request for approval to market a biologic for one or more specified indications and must contain proof of the biologic's safety, purity, and potency. Under federal law, the submission of most NDAs or BLAs is subject to an application user fee, which for federal fiscal year 2019 is $2,588,478 for a NDA or BLA requiring clinical data. The sponsor of an approved NDA or BLA is also subject to an annual program fee, which for fiscal year 2019 is $309,915. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing and may request additional information rather than accepting a NDA or BLA for filing. The FDA typically makes a decision on accepting a NDA or BLA for filing within 60 days of receipt. The decision to accept the NDA or BLA for filing means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal to complete its substantive review of a standard NDA and respond to the applicant is ten months from the receipt of the NDA or ten months from the filing date of an NDA for a new molecular entity or original BLA. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and may go through multiple review cycles.

After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a NDA or BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving a NDA or BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be

limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA or BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 clinical trials to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and effectiveness of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and effectiveness for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to a NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under a NDA, known as the reference-listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is the same as the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug. Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also

referred to as the “Orange Book.” Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety, which is the molecule or ion responsible for the physiological or pharmacological action of the drug substance, that has previously been approved by the FDA in any other NDA. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, which states that the proposed drug will not infringe the already approved product’s listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Pursuant to the Food and Drug Administration Reauthorization Act of 2017, the FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight (8) months for a drug that has three (3) or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA’s drug shortage list. The new legislation also authorizes FDA to expedite review of ‘‘competitive generic therapies’’ or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Marketing Exclusivity for Biological Products

An abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCI Act. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. ‘‘First licensure’’ typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of

administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of a NDA, including a 505(b)(2) NDA, or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant relies on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the applicant is not seeking approval).

If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or the 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components, that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the FDCA. In reviewing the NDA or 505(b)(2) application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System, or QS, regulations applicable to medical devices.

Drug-device combination products present unique challenges for competitors seeking approval of Abbreviated New Drug Applications, or ANDA, for generic versions of combination products. Generally, FDA reviews both the drug and device constituents of a proposed generic product to determine whether it is the same as the innovator product, including whether the basic design and operating principles of the device component are the same and whether minor differences require significant differences in labeling for safe and effective use. If FDA determines that the device component of the proposed generic product is not the same in terms of performance and critical design, or that the labeling is not the same, it generally will not approve the ANDA. Likewise, if FDA determines that certain clinical studies, such as clinical usability or human factors studies, are necessary to demonstrate the safety and/or effectiveness of the device component, FDA generally will not accept or approve an ANDA for a combination product and will instead require the submission of a full NDA or 505(b)(2) application.

Post-Marketing Requirements

Any products for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse events with the product, providing the applicable regulatory authorities with updated safety and efficacy information, and product sampling and distribution requirements in accordance with the Prescription Drug Marketing Act, or PMDA, a part of the FDCA, as well as the Drug Supply Chain Security Act, or DSCSA. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market. Moreover, each component of a combination product retains their regulatory status (as a drug or device, for example) and is subject to the requirements established by the FDA for that type of component. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market.

Prescription drug and biologic advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug and biologic promotion and advertising, including direct-to-consumer advertising. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. In addition, a pharmaceutical company must comply with restrictions on promoting drugs and biologics for uses or in patient populations that are not described in the drug's or biologic's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements

for promotional activities involving the internet. Although physicians may prescribe legally available drugs or biologics for off-label uses, manufacturers typically may not market or promote such off-label uses.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that combination products be manufactured in specific approved facilities and in accordance with cGMPs applicable to drugs, biologics and devices, including certain QS requirements. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug and biologics manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA or BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product’s approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory approval of our products under development and impact approved products already on the market.

Other Regulatory Matters

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, voluntary recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, exclusion from federal healthcare programs, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the voluntary recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. Alternatively, orphan drug designation may be available if the disease of the condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor’s marketing application for the same drug for the same condition for seven years, except in certain limited circumstances. Orphan exclusivity does not block the approval of a different drug for the same rare disease or condition, nor does it block the approval of the same drug for different conditions. If a drug designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Orphan drug exclusivity will not bar approval of another product with the same drug for the same condition under certain circumstances, including if a subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, as amended, a NDA or supplement thereto must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs. The requirements for pediatric data generally do not apply to drugs or biologics for an indication for which orphan designation has been granted.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent five-year and three-year and orphan exclusivity. This six-month exclusivity may be granted if a NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted. If reports of FDA-requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Regulations and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union, or EU, generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to the relevant competent authorities for clinical trials authorization and to the European Medicines Authority, or EMA, for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the EU.

European Orphan Designation and Exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect not more than five in 10,000 persons in the European Union Community, or when, without incentives, it is unlikely that sales of such products in the European Union would be sufficient to justify the necessary investment in developing the products. Additionally, orphan drug designation is only available where no satisfactory method of diagnosis, prevention, or treatment of the condition has been authorized (or the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity would not prevent the approval of a similar drug that is shown to be safer, more effective or otherwise clinically superior.

Other Healthcare Laws and Compliance Requirements

In addition to FDA restrictions on the marketing of pharmaceutical products and medical devices, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. Our activities are also subject to regulation by numerous regulatory authorities include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or DHHS, the Department of Justice, or DOJ, the Drug Enforcement Administration, or DEA, the Consumer Product Safety Commission, or CPSC, the Federal Trade Commission, or FTC, the Occupational Safety & Health Administration, or OSHA, the Environmental Protection Agency, or EPA, and state and local governments. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, or AKS, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, receive or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for, or intended to induce or reward, including arranging for or recommending, either the referral of an individual, or the purchase, lease, order, prescription or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (see below) or federal civil money penalties statute. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs;
- federal civil and criminal false claims laws and civil monetary penalties laws, such as the federal False Claims Act, which imposes criminal and civil penalties and authorizes civil whistleblower or qui tam actions,

against individuals or entities (including manufacturers) for, among other things: knowingly presenting, or causing to be presented, to a federal government healthcare program, claims for payment that are false or fraudulent; making, using or causing to be made or used, a false statement or record material to payment of a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Our marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products and any future product candidates, are subject to scrutiny under this law;

- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (including private payors) or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose specified requirements on certain covered healthcare providers, health plans, and healthcare clearinghouse ("covered entities") as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associate with pursing federal civil actions;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act, including the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- The Foreign Corrupt Practices Act, or FCPA, prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment.

Additionally, we may be subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and non-U.S. laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, disgorgement, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act, or the ACA, was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, Congressional, and Executive challenges. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate. However, the current presidential administration has indicated that enacting changes to the ACA is a legislative priority and has discussed repealing and replacing or amending the ACA. While Congress has not passed repeal legislation to date, the 2017 Tax Reform Act includes a provision repealing the individual mandate, effective January 1, 2019.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. In addition, other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2027. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Since 2016, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing or delaying penalties, starting

January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement could have on our business.

In addition, the Budget Control Act of 2011 and the Bipartisan Budget Act of 2015 led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will remain in effect through 2027 unless additional Congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Centers for Medicare & Medicaid Services, or CMS, has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization, or PA, and step therapy, or ST, for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" while a definition of "price concession" in the regulations. It is unclear whether these proposed changes we be accepted, and if so, what effect such changes will have on our business.

Moreover, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any product candidates for

which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product, we may need to conduct expensive clinical trials in order to demonstrate the medical necessity and cost-effectiveness of such product, in addition to the costs required to obtain regulatory approvals. Our products may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new methodology by which rebates owed by are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits (phased-in by 2014). Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D,

Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

However, on December 27, 2018, the District Court for the District of Columbia invalidated a recent reimbursement formula change instituted by CMS under the 340B program. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price, or ASP, plus 6% to ASP minus 22.5% on specified covered outpatient drugs, or SCODs. The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make, but was instead a fundamental change in the reimbursement calculation, and such a dramatic change was beyond the scope of the Secretary's authority. The court has not determined whether reimbursement rates should be retroactively returned to the ASP plus 6% rate and the difference in such reimbursement made to the covered facilities, or if some other remedy is more appropriate. It is unclear how the invalidation of the formula could affect pharmaceutical manufacturers and hospitals who prescribe their products. The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers, including:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes

included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.

- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. We expect that an increasing emphasis on cost containment measures in the United States will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs. Individual state legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Employees

As of January 31, 2019, we had 100 employees, 46 of whom were primarily engaged in product development and research, 43 of whom were primarily engaged in administration and finance, and 11 of whom were primarily engaged in sales and marketing. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

Our principal office is located in Chicago, Illinois. Our Chicago office occupies approximately 16,045 square feet of leased and sub-leased space, which we refer to as the existing premises. In November 2018, we signed an amendment to this lease to occupy an additional 40,850 square feet of space and expect to relocate from our

existing premises to this additional space in March 2019. The lease term expires on June 30, 2031. As part of this amendment, upon completing our relocation, we will return 8,899 square feet of the existing premises back to our landlord. We intend to sublease the remaining 7,146 square feet of existing premises by the end of 2019. We also maintain a product development site in San Diego, California. Our San Diego office occupies approximately 17,105 square feet of leased space under a 60-month lease term through June 2023. We believe that the Chicago office coupled with our San Diego office will be suitable and adequate to meet our current needs.

Legal Proceedings

We are not aware of any pending or threatened legal proceeding against us that could have a material adverse effect on our business, operating results or financial condition. Our industry is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various additional legal proceedings from time to time.

MANAGEMENT

The following table sets forth information about our current directors and executive officers.

NAME	AGE	POSITION(S)
Executive Officers		
Paul Edick	63	President, Chief Executive Officer and Chairman
Barry Deutsch	55	Chief Financial Officer
John Shannon	56	Executive Vice President, Chief Operating Officer
Steven Prestrelski	55	Chief Scientific Officer
Ken Johnson	56	Senior Vice President, Clinical Development, Regulatory, Quality Assurance and Medical Affairs
Beth Hecht	55	Senior Vice President, General Counsel and Corporate Secretary
Non-Employee Directors		
BJ Bormann (2)(3)	60	Director
Dawn Halkuff (2)(3)	48	Director
Marla Persky (1)(3)	62	Director
Jonathan Rigby (1)(3)	51	Director
John Schmid (1)(2)	56	Director
Jeffrey Sherman (2)	64	Director

(1) Member of our audit committee
(2) Member of our compensation committee
(3) Member of our nominating and corporate governance committee

Executive Officers

Paul Edick. Mr. Edick joined our company in January 2017 as President and Chief Executive Officer and was appointed as Chairman in June 2018. Previously, Mr. Edick was a founding partner of 3G Advisors, a consultancy firm to the pharmaceutical, healthcare and healthcare investor communities. From 2010 to 2014, Mr. Edick was the chief executive officer of Durata Therapeutics, Inc. prior to its acquisition in November 2014. Prior to that, Mr. Edick was chief executive officer of Ganic Pharmaceuticals, Inc., a Warburg Pincus investment search vehicle, from 2008 to 2010. Before that, from 2006 to 2008, Mr. Edick was chief executive officer of MedPointe Healthcare, Inc. and served as its president of pharmaceutical operations from 2002 to 2006.

Mr. Edick currently serves on the board of directors for Iterum Therapeutics Limited. Mr. Edick has also previously served on a number of pharmaceutical and healthcare company boards including Circassia Pharmaceuticals Plc, Sucampo Pharmaceuticals, Inc., Durata Therapeutics, NewLink Genetics Corp., Neos Therapeutics, Inc. and PDL BioPharma, Inc. Mr. Edick received a B.A. degree in psychology from Hamilton College. We believe Mr. Edick is qualified to serve on our board of directors because of his management and industry experience.

Barry Deutsch. Mr. Deutsch joined our company in July 2017 as our vice president, business development. In April 2018, Mr. Deutsch was appointed as our Chief Financial Officer. Previously, from 2007 to 2017, Mr. Deutsch was a vice president for the BioScience Division of Baxter Healthcare Corporation, Baxalta Incorporated following its spinoff from Baxter, and Shire plc following its acquisition of Baxalta. Mr. Deutsch's roles included serving as vice president of business development at Baxter BioScience and Baxalta and head of business development and public-private partnerships for the intercontinental region at Baxalta and Shire.

Mr. Deutsch received a B.S. in Economics degree in finance and accounting from The Wharton School of the University of Pennsylvania and an M.B.A. from the Kellogg School of Management at Northwestern University.

John Shannon. Mr. Shannon joined our company in February 2017 as Chief Operating Officer. Previously, from 2015 until its acquisition in 2016, Mr. Shannon served as chief executive officer and director for Catheter

Connections, Inc. Prior to that, from 2012 until its acquisition in 2014, Mr. Shannon served as chief commercial officer for Durata Therapeutics. From 2002 to 2012, he served as vice president and general manager of Baxter BioScience.

Mr. Shannon received a B.S. degree in biology with an emphasis in microbiology from Western Illinois University.

Steve Prestrelski, Ph.D. Dr. Prestrelski is one of our co-founders. He has served as our Chief Scientific Officer since 2005 and as our Interim Chief Executive Officer from 2013 to 2014. He also served on our board of directors from 2005 to 2015. Dr. Prestrelski is the inventor of our platform technologies. Prior to joining our company, from 2003 to 2011, Dr. Prestrelski was vice president of pharmaceutical R&D at Amylin Pharmaceuticals. At Amylin, from 2003 to 2005, he was the executive director of the Bydureon program. From 1998 to 2002, Dr. Prestrelski was vice president, biopharmaceuticals at PowderJect Technologies, Inc. Dr. Prestrelski serves on the board of directors of BaroFold, Inc. and on the scientific advisory board of iMEDD, Inc. Dr. Prestrelski served on the scientific advisory board of GIRx Metabolics from 2012 to 2014.

Dr. Prestrelski has a B.S. in nutrition science from Drexel University, a Ph.D. in molecular biophysics from the City University of New York and an M.B.A from Rady School of Management at the University of California, San Diego.

Ken Johnson, Pharm.D. Dr. Johnson joined our company in March 2017. Prior to that, from 2016 to 2017, Dr. Johnson served as executive director, U.S. medical affairs for hospital specialty products at Merck. Previously, Dr. Johnson served as vice president of global medical affairs at Circassia Pharmaceuticals from 2015 to 2016 and as vice president of corporate medical affairs at Durata Therapeutics from 2012 to 2015. Prior to his time at Durata, Mr. Johnson also held senior management positions in medical affairs at Horizon Pharma, Inc., Takeda Pharmaceuticals North America, NeoPharm, Inc., Searle/Pharmacia Pharmaceuticals and Bristol-Myers Squibb.

Dr. Johnson received a B.S. in pharmacy and Pharm.D. from the University of Minnesota and completed a post-doctoral fellowship at the University of Tennessee Health Sciences Center.

Beth Hecht. Ms. Hecht joined our company in January 2018 and serves as Senior Vice President, General Counsel and Corporate Secretary. Ms. Hecht has over twenty-five years of experience as a corporate executive in the life sciences industry, most recently serving from 2012 to 2018 as managing director and chief legal and administrative officer of Auven Therapeutics, a global biotechnology and pharmaceutical private equity firm. From November 2013 through November 2014, Ms. Hecht also served as corporate secretary and legal and compliance advisor at Durata Therapeutics. Prior to that, she was senior vice president, general counsel and corporate secretary at the Sun Products Corporation from March 2009 through September 2012, and prior to that executive vice president and general counsel of MedPointe Inc. Ms. Hecht has served on the board of directors of Neos Therapeutics, Inc. since September 2015 where she chairs the nominating and corporate governance committee. Ms. Hecht received a J.D. from Harvard Law School and a B.A. from Amherst College.

Non-Employee Directors

BJ Bormann, Ph.D. Dr. Bormann has served on our board of directors since April 2018. Dr. Bormann has served as chief executive officer and as a member of the board of directors of Pivot Pharmaceuticals Inc. since 2015. Dr. Bormann also serves as the interim chief executive officer of Supportive Therapeutics, LLC and was previously the chief executive officer of Harbour Antibodies from 2015 to 2017 and the chief business advisor for NanoMedical Systems, Inc. From 2007 to 2013, Dr. Bormann was a senior vice president, world-wide alliances, licensing and business development at Boehringer Ingelheim Pharmaceuticals, Inc. Dr. Bormann currently serves on the board of directors of various companies, including Supportive Therapeutics, LLC, the Institute for Pediatric Innovation and Bioline RX.

Dr. Bormann received her Ph.D. in biomedical science from the University of Connecticut Health Center and her B.Sc. from Fairfield University in biology. Dr. Bormann completed postdoctoral training at Yale Medical School in the department of pathology. We believe Dr. Bormann is qualified to serve on our board of directors because of her experience in the industry in which we operate.

Dawn Halkuff. Ms. Halkuff has served on our board of directors since April 2018. Since 2016, Ms. Halkuff has served as the chief commercial officer of TherapeuticsMD, Inc. Prior to that, Ms. Halkuff held numerous senior level

positions at Pfizer, Inc. and the Pfizer Consumer Healthcare Wellness Organization and was a member of its Consumer Global Leadership Team, including roles as senior vice president, global wellness, vice president, women's health sales and marketing and senior director, women's health products. Prior to that, Ms. Halkuff was the commercial lead for sales and marketing of the Pfizer's Women's Health Division. From 2005 to 2010, Ms. Halkuff was head of global innovation at Weight Watchers International.

Ms. Halkuff has a B.A. degree in psychology from University of Connecticut and an M.B.A from Pennsylvania State University. We believe Ms. Halkuff is qualified to serve on our board of directors because of her experience in the industry in which we operate.

Marla S. Persky. Ms. Persky has served on our board of directors since April 2018. Since 2014, Ms. Persky has served as the chief executive officer and president of WOMN, LLC, a consulting and coaching organization. From 2005 to 2013, Ms. Persky was senior vice president, general counsel and corporate secretary of Boehringer Ingelheim Corporation, a pharmaceutical company. Ms. Persky also serves on the board of advisors of Text IQ, Inc. and the board of directors of Ygeia Group, Inc.

Ms. Persky has a B.S.S. degree in speech sciences from Northwestern University and a J.D. from Washington University School of Law. We believe Ms. Persky is qualified to serve on our board of directors because of her experience in the industry in which we operate.

Jonathan Rigby. Mr. Rigby has served on our board of directors since March 2016. In 2011, Mr. Rigby founded SteadyMed Therapeutics Inc. and has since served as its president, chief executive officer and director. Prior to founding SteadyMed, Mr. Rigby cofounded Zogenix Inc., a specialty pharmaceutical company focused on the development and commercialization of central nervous system and pain products, where he served as its vice president of business development from 2006 until December 2011.

Mr. Rigby has a B.S. degree in biological sciences from Sheffield University (UK) and an M.B.A. from Portsmouth University (UK). We believe Mr. Rigby is qualified to serve on our board of directors because of his experience in the industry in which we operate.

John Schmid. Mr. Schmid has served on our board of directors since September 2017. Mr. Schmid currently serves as a member of the board of directors of Neos Therapeutics, Inc., AnaptysBio Inc., Forge Therapeutics, Inc., Patara Pharma, Inc., Speak, Inc. and Poseida Therapeutics Inc. Previously, he was the chief financial officer of Auspex Pharmaceuticals, Inc. from 2013 until its acquisition in 2015. Prior to joining Auspex Pharmaceuticals, Mr. Schmid co-founded Trius Therapeutics, Inc. in 2004, where he served as chief financial officer until its sale in 2013.

Mr. Schmid received a B.A. in economics from Wesleyan University and an M.B.A. from the University of San Diego. We believe Mr. Schmid is qualified to serve on our board of directors because of his experience, including financial experience, in the industry in which we operate.

Jeffrey Sherman, M.D., FACP. Dr. Sherman has served on our board of directors since April 2018. Since 2009, Dr. Sherman has served as the chief medical officer and executive vice president at Horizon Pharma plc. Dr. Sherman serves on the board of directors of Strongbridge Biopharma plc and is a member of a number of professional societies, a diplomat of the National Board of Medical Examiners and the American Board of Internal Medicine, and also serves on the Board of Advisors of the Center for Information and Study on Clinical Research Participation. He previously held positions at IDM Pharma Takeda Global Research and Development, NeoPharm, Searle/Pharmacia, and Bristol-Myers Squibb and is past president of the Drug Information Association.

Dr. Sherman received a B.A. in Biology from Lake Forest College and earned his M.D. from the Rosalind Franklin University of Medicine and Science/The Chicago Medical School. Dr. Sherman completed internship and residency programs at Northwestern University Feinberg School of Medicine, where he currently serves as an adjunct assistant professor, and a fellowship program at the University of California San Francisco. We believe Dr. Sherman is qualified to serve on our board of directors because of his experience in the industry in which we operate.

Board Composition

Our nominating and corporate governance committee and our board of directors may consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance

committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Staggered Board

In accordance with the terms of our amended and restated certificate of incorporation and our amended and restated bylaws, our board of directors is divided into three staggered classes of directors and each is assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2019 for Class I directors, 2020 for Class II directors and 2021 for Class III directors.

- Our Class I directors will be Jonathan Rigby and BJ Bormann;
- Our Class II directors will be Jeffrey Sherman and Dawn Halkuff; and
- Our Class III directors will be Paul Edick, John Schmid and Marla Persky.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Independence

Our common stock is listed on The Nasdaq Global Select Market. Under the rules of The Nasdaq Global Select Market, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, The Nasdaq Global Select Market rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under The Nasdaq Global Select Market rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In April 2018, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each

director concerning his background, employment and affiliations, including family relationships, our Board of Directors has determined that none of our non-employee directors has a material relationship with us that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” in accordance with the rules of The Nasdaq Global Select Market. In making that determination, our board of directors considered the relationships that each of those non-employee directors has with us and all other facts and circumstances the board of directors deemed relevant in determining independence, including the potential deemed beneficial ownership of our capital stock by each non-employee director, including non-employee directors that are affiliated with certain of our major stockholders. Mr. Edick is not an independent director under these rules because he is an executive officer of our company.

Our board of directors has adopted a policy that outlines a process for security holders to send communications to the Board.

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee.

Audit Committee

Our audit committee consists of John Schmid, Jonathan Rigby and Marla Persky and is chaired by John Schmid. The functions of the audit committee include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee’s review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and The Nasdaq Global Select Market. Our Board of Directors has determined that John Schmid qualifies as an audit committee financial expert within the meaning of applicable SEC regulations. In making this determination, our Board of Directors considered the nature and scope of experience that John Schmid has previously had with public reporting companies. Our Board of Directors has determined that all of the current members of our audit committee satisfy the relevant independence requirements for service on the audit committee set forth in the rules of the SEC and the listing requirements of The Nasdaq Global Select Market. Both our independent registered public accounting firm and management will periodically meet privately with our audit committee.

Our board of directors has adopted a written audit committee charter. We believe that the composition of our audit committee, and our audit committee's charter and functioning, complies with the applicable requirements of The Nasdaq Global Select Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

The full text of our audit committee charter is available on the investor relations portion of our website at https://www.xerispharma.com/. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Compensation Committee

Our compensation committee consists of BJ Bormann, John Schmid, Jeffrey Sherman and Dawn Halkuff, and is chaired by BJ Bormann. The functions of the compensation committee include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation (i) reviewing and determining the cash compensation of our Chief Executive Officer and (ii) reviewing and approving grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing our compensation committee report if and when required by SEC rules;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986. Furthermore, we believe that the composition of our compensation committee, and our compensation committee's charter and functioning, complies with the listing requirements of The Nasdaq Global Select Market and SEC rules and regulations.

Our board of directors has adopted a written compensation committee charter. We believe that the composition of our compensation committee, and our compensation committee's charter and functioning, complies with the applicable requirements of The Nasdaq Global Select Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

The full text of our compensation committee charter is available on the investor relations portion of our website at https://www.xerispharma.com/. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Jonathan Rigby, Marla Persky, BJ Bormann and Dawn Halkuff and is chaired by Jonathan Rigby. The functions of the nominating and corporate governance committee include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;

- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

Our board of directors has adopted a written nominating and corporate governance committee charter. We believe that the composition of our nominating and corporate governance committee, and our nominating and corporate governance committee's charter and functioning, complies with the requirements of The Nasdaq Global Select Market and SEC rules and regulations that will be applicable to us. We intend to comply with future requirements to the extent they become applicable to us.

The full text of our nominating and corporate governance committee charter is available on the investor relations portion of our website at https://www.xerispharma.com/. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is, or has at any time during the prior three years been, one of our officers or employees. None of our executive officers currently serve, or have in the past fiscal year served, as a member of the board of directors or compensation committee of any entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

Code of Business Conduct and Ethics

Our board of directors has adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants.

We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics and our Code of Ethics for our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer, or waivers of those provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified below or in a current report on Form 8-K. The full text of our Code of Business Conduct and Ethics and our Code of Ethics for our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer is posted on our website at http://www.xerispharma.com. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus, and you should not consider that information a part of this prospectus.

Limitations on Liability and Indemnification Agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into separate indemnification agreements with each of our directors and executive officers, which are broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Table of Contents

EXECUTIVE COMPENSATION

Executive Compensation Overview

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act. This section provides an overview of the compensation awarded to, earned by, or paid to each individual who served as our principal executive officer at any time during fiscal year 2018, and our next two most highly compensated executive officers in respect of their service to our company for our fiscal year ended December 31, 2018. We refer to these individuals as our named executive officers. Our named executive officers are:

- Paul Edick, our President and Chief Executive Officer effective January 10, 2017;
- John Shannon, our Executive Vice President and Chief Operating Officer; and
- Barry Deutsch, our Chief Financial Officer.

Our executive compensation program is based on a pay for performance philosophy. Compensation for our executive officers is composed primarily of the following main components: base salary; bonus; and equity incentives in the form of options. Our executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

2018 Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by, or paid to our named executive officers for services rendered to us in all capacities during the fiscal year ended December 31, 2018.

NAME AND PRINCIPAL POSITION	YEAR	SALARY ($)	BONUS ($) (1)	OPTION AWARDS ($) (2)	NON-EQUITY PLAN COMPENSATION $(3)	ALL OTHER COMPENSATION ($)	TOTAL ($)
Paul Edick,	2018	535,000	119,900	329,626	329,725	—	1,314,251
President and Chief Executive Officer (4)	2017	489,583	—	657,134	250,000	—	1,396,717
John Shannon,	2018	368,750	—	344,036	205,700	—	918,486
Executive Vice President and Chief Operating Officer (5)	2017	218,750	—	168,029	100,834	—	487,613
Barry Deutsch,	2018	276,095	—	448,144	132,000	—	856,239
Chief Financial Officer (6)							

(1) Amounts reported in the bonus column represent the amount of each bonus paid to our named executive officers that was discretionarily awarded above target under the cash bonus program and took into account individual and company achievements.

(2) Amounts reflect the grant date fair value of option awards granted or modified in 2017 or 2018, as applicable, in accordance with the Financial Accounting Standards Board’s Accounting Standards Codification Topic 718, or ASC 718. Such grant date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 2 to our financial statements and the discussion under “Management’s

Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and the Use of Estimates—Stock based compensation" included elsewhere in this prospectus. These amounts do not correspond to the actual value that may be recognized by the named executive officers upon vesting of applicable awards.

(3) The amounts reported reflect a cash bonus approved by our board of directors based on achievement of individual and company performance goals in 2017 or 2018, as applicable.

(4) Mr. Edick commenced his employment with us in January 2017.

(5) Mr. Shannon commenced his employment with us in February 2017.

(6) Mr. Deutsch was appointed as our Chief Financial Officer in April 2018.

Narrative to the 2018 Summary Compensation Table

Base Salary

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

Annual Bonus

We do not have a formal performance-based bonus plan. Our employment agreements with our named executive officers provide that the executive may be eligible to earn an annual performance bonus of up to a target percentage of the executive's base salary, as described further below under the section entitled "—Employment Arrangements and Severance Agreements with our Named Executive Officers". From time to time, our board of directors or compensation committee may approve annual bonuses for our named executive officers based on individual performance, company performance or as otherwise determined to be appropriate, including up to amounts in excess of 100% of an individual's target bonus.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

We typically grant stock option awards at the start of employment to each executive officer and our other employees as well as on an annual basis for retention purposes. We award our stock options on the date our board of directors approves the grant. We set the option exercise price and grant date fair value based on our per-share estimated valuation on the date of grant.

Employment Arrangements and Severance Agreements with our Named Executive Officers

We have entered into employment agreements with each of our named executive officers. These agreements set forth the initial terms and conditions of each executive's employment with us, including base salary, target annual bonus opportunity and standard employee benefit plan participation. In connection with this offering, we intend to enter into new employment agreements with each of our named executive officers.

These employment agreements provide for "at will" employment. The material terms of these employment agreements with our named executive officers are described below. The terms "cause" and "change in control" used in each existing employment agreement are defined in each employment agreement.

Paul Edick

We entered into an employment agreement with Mr. Paul Edick, our President and Chief Executive Officer, on January 9, 2017, pursuant to which Mr. Edick is entitled to receive an annual base salary of $500,000, an annual target bonus equal to 50% of his annual base salary based upon our board of directors' assessment of Mr. Edick's performance and our attainment of targeted goals approved by the board of directors, an equity grant and eligibility to participate in our benefit plans generally. This employment agreement also contains provisions related to confidentiality, inventions assignment and non-competition, pursuant to which Mr. Edick agrees to refrain from disclosing our confidential information, re-affirms the obligations contained in his Proprietary Information and Inventions Agreement and agrees not to compete with us during his employment.

Mr. Edick's employment agreement provides that, in the event that his employment is terminated by us without "cause" or by him upon a "material change" (as each term is defined in the employment agreement), subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (in addition to accrued compensation and benefits through the date of termination) (i) salary continuation based on his then-current base salary for 11 months and (ii) reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Edick had he remained employed with us for up to 11 months following termination.

Upon a "change in control," subject to the execution and effectiveness of a release, Mr. Edick shall be eligible to receive a lump sum amount equal to 18 months of his then-current base salary (but in no event less than $500,000), his annual target bonus reflective for a period of 18 months and 100% accelerated vesting of his outstanding stock options. Furthermore, the employment agreement provides that our board of directors may, in its sole discretion, consider providing Mr. Edick with a transaction bonus at the time of a "change in control". If he is terminated upon the effectiveness of the "change in control," he shall also receive reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Edick had he remained employed with us for up to 18 months following termination.

We have entered into an amended and restated employment agreement with Mr. Edick pursuant to which Mr. Edick is entitled to receive an annual base salary and an annual target bonus equal to a percentage of his annual base salary based upon our board of directors' assessment of Mr. Edick's performance and our attainment of targeted goals as set by the board of directors in its sole discretion. For the fiscal year ending December 31, 2019, Mr. Edick's annual base salary is $599,500 and his annual target bonus is 60% of his annual base salary. This employment agreement also contains provisions related to confidentiality, inventions assignment and non-competition, pursuant to which Mr. Edick re-affirmed the obligations contained in his Proprietary Information and Inventions Agreement. Mr. Edick's amended and restated employment agreement provides that, in the event that his employment is terminated by us without "cause" or by him for "good reason," subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (i) an amount equal to (x) 18 months of base salary payable on our normal payroll cycle if such termination is not in connection with a "change in control" or (y) 18 months of base salary plus his average target incentive compensation received for the three preceding fiscal years if such termination is in connection with a "change in control," and (ii) reimbursement of COBRA premiums for health benefit coverage for him in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Edick had he remained employed with us for up to 18 months. In addition, if within 12 months following a "change in control," Mr. Edick is terminated by us without "cause" or he resigns for "good reason," all time-based stock options and other time-based stock-based awards held by Mr. Edick issued after the date of the amended and restated employment agreement will accelerate and vest immediately.

John Shannon

We entered into an employment agreement with Mr. John Shannon, our Executive Vice President and Chief Operating Officer, on February 16, 2017 pursuant to which Mr. Shannon is entitled to receive an annual base salary of $250,000, an annual target bonus equal to 40% of his annual base salary based upon our board of directors' assessment of Mr. Shannon's performance and our attainment of targeted goals as approved by the board of directors, an equity grant and eligibility to participate in our benefit plans generally. This employment agreement

also contains provisions related to confidentiality, inventions assignment and non-competition agreement with us, pursuant to which Mr. Shannon agrees to refrain from disclosing our confidential information, re-affirms the obligations contained in his Proprietary Information and Inventions Agreement and agrees not to compete with us during his employment. Mr. Shannon's employment agreement provides that, in the event that his employment is terminated by us without "cause" or by him upon a "material change," subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (in addition to accrued compensation and benefits through the date of termination) (i) salary continuation based on his then-current base salary for 10 months and (ii) reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Shannon had he remained employed with us for up to 10 months following termination.

Upon a "change in control," subject to the execution and effectiveness of a release, Mr. Shannon shall be eligible to receive a lump sum amount equal to 12 months of his then-current base salary (but in no event less than $250,000), his annual target bonus and 100% accelerated vesting of his outstanding stock options. Furthermore, the employment agreement provides that our board of directors may, in its sole discretion, consider providing Mr. Shannon with a transaction bonus at the time of a "change in control". If he is terminated upon the effectiveness of the "change in control," he shall also receive reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Shannon had he remained employed with us for up to 12 months following termination.

We have entered into an amended and restated employment agreement with Mr. Shannon pursuant to which Mr. Shannon is entitled to receive an annual base salary and an annual target bonus equal to a percentage of his annual base salary based upon our board of directors' assessment of Mr. Shannon's performance and our attainment of targeted goals as set by the board of directors in its sole discretion. For the fiscal year ending December 31, 2019, Mr. Shannon's annual base salary is $446,250 and his annual target bonus is 40% of his annual base salary. This employment agreement also contains provisions related to confidentiality, inventions assignment and non-competition agreement with us, pursuant to which Mr. Shannon re-affirmed the obligations contained in his Proprietary Information and Inventions Agreement. Mr. Shannon's amended and restated employment agreement provides that, in the event that his employment is terminated by us without "cause" or by him for "good reason," subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (i) an amount equal to (x) 15 months of base salary payable on our normal payroll cycle if such termination is not in connection with a "change in control" or (y) 15 months of base salary plus his average target incentive compensation received for the three preceding fiscal years if such termination is in connection with a "change in control," and (ii) reimbursement of COBRA premiums for health benefit coverage for him in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Shannon had he remained employed with us for up to 15 months. In addition, if within 12 months following a "change in control," Mr. Shannon is terminated by us without "cause" or he resigns for "good reason," all time-based stock options and other time-based stock-based awards held by Mr. Shannon issued after the date of the amended and restated employment agreement will accelerate and vest immediately.

Barry Deutsch

We entered into an employment agreement with Mr. Barry Deutsch, our Chief Financial Officer, on June 6, 2018 pursuant to which Mr. Deutsch is entitled to receive an annual base salary and an annual target bonus equal to a percentage of his annual base salary based upon our board of directors' assessment of Mr. Deutsch's performance. For the fiscal year ending December 31, 2019, Mr. Deutsch's annual base salary is $349,500 and his annual target bonus is 40% of his annual base salary. This employment agreement also contains provisions related to confidentiality, inventions assignment and non-competition agreement with us, pursuant to which Mr. Deutsch re-affirmed the obligations contained in his Employee Confidentiality, Noncompetition and Assignment Agreement. Mr. Deutsch's employment agreement provides that, in the event that his employment is terminated by us without "cause" or by him for "good reason," subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (i) an amount equal to (x) 15 months of base salary payable on our normal payroll cycle if such termination is not in connection with a "change in control" or (y) 15 months of base salary plus

his average target incentive compensation received for the three preceding fiscal years if such termination is in connection with a “change in control,” and (ii) reimbursement of COBRA premiums for health benefit coverage for him in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Deutsch had he remained employed with us for up to 15 months. In addition, if within 12 months following a “change in control,” Mr. Deutsch is terminated by us without “cause” or he resigns for “good reason,” all time-based stock options and other time-based stock-based awards held by Mr. Deutsch issued after the date of the amended and restated employment agreement will accelerate and vest immediately.

Outstanding Equity Awards at 2018 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by our named executive officers as of December 31, 2018.

	OPTION AWARDS (1)					STOCK AWARDS	
NAME	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) UNEXERCISABLE	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE	NUMBER OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED (#)	MARKET VALUE OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED ($)
Paul Edick	2/1/2018 (2)	98,252	—	5.93	1/31/2028	—	—
	6/12/2017 (2)	69,822	—	1.55	6/11/2027	—	—
	1/9/2017 (2)	668,065	—	1.55	1/27/2027	—	—
John Shannon	5/15/2018 (2)	34,977	—	12.50	5/15/2028	—	—
	1/31/2018 (2)	28,072	—	5.93	1/31/2028	—	—
	6/12/2017 (3)	—	25,136	1.55	6/11/2027	—	—
	2/16/2017 (4)	129,067	31,268	1.55	2/3/2027	—	—
Barry Deutsch	5/15/2018 (2)	56,144	—	12.50	5/15/2028	—	—
	2/1/2018 (2)	14,036	—	5.93	1/31/2028	—	—
	7/17/2017 (2)	21,054	—	2.33	10/20/2027	—	—

(1) Each equity award was granted pursuant to our 2011 Stock Option/Stock Issuance Plan, as amended, or the 2011 Plan. The shares subject to each option vest with respect to 25% of the option on the one year anniversary of the applicable vesting commencement date and the remaining shares subject to each option vest in 36 equal installments on the corresponding day of each calendar month thereafter (or, if such calendar month does not have a corresponding day, on the last day of such month), in all cases subject to the optionee's continuous service to us through each vesting date. In addition, each option becomes exercisable as described in the footnotes below, where any unvested portion subject to a right of repurchase upon the optionee's termination of continuous service. Upon a change in control of the Company while the optionee is providing services to us, 100% of the shares subject to the option shall vest and become exercisable immediately prior to the effective date of the change in control.

(2) The shares subject to these options are early exercisable.

(3) All of the shares subject to this option become exercisable on January 1, 2019.

(4) 64,533 of the shares subject to the option became exercisable as of the grant date, an additional 64,534 shares became exercisable on January 1, 2018, and the remaining 31,268 shares shall become exercisable on January 1, 2019.

On January 31, 2019, our compensation committee granted equity awards to our named executive officers pursuant to our 2018 Plan. Mr. Edick received a restricted stock unit award for 125,000 shares of our common stock and an option award exercisable for 200,000 shares of our common stock. Mr. Shannon received an option award exercisable for 80,000 shares of our common stock. Mr. Deutsch received an option award exercisable for 25,000 shares of our common stock. The shares subject to each award vest with respect to 25% of the award on January 31, 2020 and the remaining shares subject to each award vest in 36 equal installments on the corresponding day of each calendar month thereafter (or, if such calendar month does not have a corresponding day, on the last day of such month), in all cases subject to the optionee's continuous service to us through each vesting date.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking.

This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Employee Benefit and Equity Compensation Plans

2011 Stock Option/Stock Issuance Plan

Our 2011 Plan was adopted by our board of directors and our stockholders in March 2011. The 2011 Plan was most recently amended in January 2018 with the approval of both our board of directors and our stockholders. Under the 2011 Plan, we reserved for issuance an aggregate of 4,714,982 shares of our common stock. The number of shares of common stock reserved for issuance is subject to adjustment in the event of any merger, consolidation, sale of all or substantially all of our assets, reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar transaction.

The shares of common stock underlying awards that (i) expire, are terminated or are canceled for any reason prior to the issuance of the underlying shares or (ii) are unvested and then repurchased at a price not greater than the option exercise or direct issue price paid per share shall be added back to the shares of common stock available for issuance under the 2011 Plan.

Our board of directors has acted as administrator of the 2011 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2011 Plan. Persons eligible to participate in the 2011 Plan are those employees, officers and directors of, and consultants and advisors to, our company as selected from time to time by the administrator in its discretion.

The 2011 Plan permits the granting of (1) options to purchase common stock, including options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, and (2) shares of common stock directly, either through the immediate purchase of such shares or as a bonus for services rendered or pursuant to restricted stock units or other share right awards which vest upon the completion of designated service periods of pre-established performance milestones. In addition, the 2011 Plan permits the granting of restricted shares of common stock. The per share option exercise price of each option will be determined by the administrator but may not be less than par value of the common stock on the date of grant. The term of each option will be fixed by the administrator. The administrator will determine at what time or times each option may be exercised.

The 2011 Plan provides that upon the occurrence of a “change in control,” as defined in the 2011 Plan, 100% of the shares subject to outstanding options shall vest and become exercisable immediately prior to the effective date of the change in control unless such option is assumed or continued or replaced with a cash retention program which preserves the spread existing on the unvested option shares at the time of the change in control. Immediately following the change in control, all outstanding options shall terminate and cease to be outstanding unless assumed or continued by the successor entity. Our board of directors has discretion to provide that all or some of the outstanding options shall vest and become exercisable in full immediately prior to a change in control event, even if such awards are not going to be assumed or continued. The 2011 Plan also provides that, upon the occurrence of a “change in control,” the right of repurchase and vesting conditions for restricted stock and restricted stock units shall immediately vest in full prior to the “change in control” unless such awards are assigned to a successor entity or continued pursuant to the terms of the transaction. Our board of directors has discretion to provide that all or some of the outstanding restricted stock or restricted stock units shall vest and become exercisable in full immediately prior to a change in control event, even if such awards are not going to be assumed or continued.

The administrator may amend or modify the 2011 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The administrator of the 2011 Plan may also amend or modify any outstanding award, provided that no amendment to an award may adversely affect a participant’s rights without his or her consent.

The 2011 Plan will terminate automatically upon the earlier of (i) 10 years from the date on which the 2011 Plan was adopted by our board of directors, (ii) the date on which all shares available for issuance under the 2011 Plan shall have been issued as vested shares or (iii) the action of board to terminate of all outstanding options in connection with a “change in control.” As of December 31, 2018, options to purchase 2,400,516 shares of common stock were outstanding under the 2011 Plan. Our board of directors has determined not to make any further awards under the 2011 Plan following the closing of this offering.

2018 Stock Option and Incentive Plan

Our 2018 Stock Option and Incentive Plan, or the 2018 Plan, was adopted by our board of directors in April 2018 and approved by our stockholders in June 2018 and became effective upon our IPO. The 2018 Plan has replaced the 2011 Plan as our board of directors has determined not to make additional awards under the 2011 Plan following the closing of our IPO. The 2018 Plan allows the compensation committee to make equity-based and cash-based incentive awards to our officers, employees, directors and other key persons (including consultants).

We initially reserved 1,822,000 shares of our common stock, or the Initial Limit, for the issuance of awards under the 2018 Plan. The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee, or the Annual Increase. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. On January 1, 2019, the number of shares of common stock available for issuance under the 2018 Plan was automatically increased by 835,728 shares.

The shares we issue under the 2018 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan and the 2011 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options shall not exceed the Initial Limit cumulatively increased on January 1, 2019 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 1,541,000 shares of common stock.

The 2018 Plan is administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2018 Plan. Persons eligible to participate in the 2018 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation committee in its discretion.

The 2018 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code, and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may generally not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of the common stock on the date of grant.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2018 Plan. Unrestricted stock may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant. Our compensation committee may grant cash bonuses under the 2018 Plan to participants, subject to the achievement of certain performance goals.

The 2018 Plan provides that in the case of, and subject to, the consummation of a “sale event” as defined in the 2018 Plan, all outstanding awards may be assumed, substituted or otherwise continued by the successor entity. To

the extent that the successor entity does not assume, substitute or otherwise continue such awards, then (i) all stock options and stock appreciation rights will automatically become fully exercisable and the restrictions and conditions on all other awards with time-based conditions will automatically be deemed waived, and awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the compensation committee's discretion and (ii) upon the effectiveness of the sale event, the 2018 Plan and all awards will automatically terminate. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) prior to the sale event; or (ii) we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights (to the extent then exercisable).

Our board of directors may amend or discontinue the 2018 Plan amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2018 Plan require the approval of our stockholders. No awards may be granted under the 2018 Plan after the date that is 10 years from the date of stockholder approval.

2018 Employee Stock Purchase Plan

Our board of directors adopted in April 2018, and our stockholders approved in June 2018, the 2018 Employee Stock Purchase Plan, or ESPP, which became effective upon our IPO. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of 193,000 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and each January 1 thereafter through January 1, 2028, by the least of (i) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31; (ii) 386,000 shares or (iii) such number of shares as determined by the ESPP administrator. On January 1, 2019, the number of shares of common stock available for issuance under the ESPP was automatically increased by 208,932 shares. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees who have completed at least three months of employment and whose customary employment is for more than 20 hours per week are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of stock is not eligible to purchase shares under the ESPP.

We will make one or more offerings each year to our employees to purchase shares under the ESPP. Unless otherwise determined by the compensation committee, offerings will usually begin on each January 1 and July 1 and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions of up to 15% of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

Equity Inducement Plan

Our Equity Inducement Plan, or the Inducement Plan, was adopted by our board of directors in February 2019. The Inducement Plan was adopted without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan allows us to make stock option or restricted stock unit awards to prospective employees of the company as an inducement to such individuals to commence employment with us. We intend to use this Inducement Plan to help us attract and retain prospective employees who are necessary to support the commercial launch of our Gvoke HypoPen and the expansion of the Company generally.

We have initially reserved 750,000 shares of our common stock for the issuance of awards under the Inducement Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the Inducement Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the Inducement Plan will be added back to the shares of common stock available for issuance under the Inducement Plan.

The Inducement Plan is administered by our board of directors or our compensation committee, or the administrator. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the Inducement Plan. Persons eligible to participate in the Inducement Plan will be those individuals whom are eligible to receive inducement awards pursuant to the exemption provided by NASDAQ Listing Rule 5635(c)(4).

The Inducement Plan permits the granting of options that do not qualify as incentive stock options under Section 422 of the Code. The option exercise price of each option will be determined by the administrator but may generally not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by the administrator and may not exceed 10 years from the date of grant. The administrator will determine at what time or times each option may be exercised.

The administrator may award restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period.

The Inducement Plan provides that in the case of, and subject to, the consummation of a “sale event” as defined in the Inducement Plan, all outstanding awards may be assumed, substituted or otherwise continued by the successor entity. To the extent that the successor entity does not assume, substitute or otherwise continue such awards, then (i) all stock options will automatically become fully exercisable and the restrictions and conditions on all other awards with time-based conditions will automatically be deemed waived, and awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the administrator’s discretion and (ii) upon the effectiveness of the sale event, the Inducement Plan and all awards will automatically terminate. In the event of such termination, (i) individuals holding options will be permitted to exercise such options (to the extent exercisable) prior to the sale event; or (ii) we may make or provide for a payment, in cash or in kind, to participants holding options equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options (to the extent then exercisable). The administrator may also, in its sole discretion, make or provide for a payment, in cash or in kind, to the holders of restricted stock units in an amount equal to the per share consideration payable to stockholders in the sale event and the exercise price of the options multiplied by the number of vested shares subject to such restricted stock units.

Our board of directors may amend or discontinue the Inducement Plan or amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder’s consent. In no event may the administrator, without stockholder consent, reduce the exercise price of any outstanding options, or effect repricing through cancellation and re-grants or cancellations of stock options in exchange for cash or other Awards.

Senior Executive Cash Incentive Bonus Plan

In April 2018, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

Our compensation committee may select corporate performance goals from among the following: cash flow (including, but not limited to, operating cash flow and free cash flow); research and development, publication, clinical and/or regulatory milestones; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of the Company's common stock; economic value added; acquisitions or strategic transactions, including licenses, collaborations, joint ventures or promotion arrangements; operating income (loss); return on capital, assets, equity, or investment; total stockholder returns; coverage decisions; productivity; expense efficiency; margins; operating efficiency; working capital; earnings (loss) per share of the Company's common stock; sales or market shares; number of prescriptions or prescribing physicians; revenue; corporate revenue; operating income and/or net annual recurring revenue.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion and provides the compensation committee with discretion to adjust the size of the award as it deems appropriate to account for unforeseen factors beyond management's control that affected corporate performance.

401(k) Plan

We maintain the Xeris Pharmaceuticals, Inc. 401(k) Plan, a tax-qualified retirement plan for our employees. The 401(k) plan is intended to qualify under Section 401(k) of the Code, so that contributions to the 401(k) plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn from the 401(k) plan, and so that contributions by us, if any, will be deductible by us when made. All employees are eligible to participate in the 401(k) plan as of the first day of the first full month of their employment. Participants have the option to make two kinds of Elective Deferral Contributions: Pre-Tax Elective Deferrals and Roth Elective Deferrals. Any initial election or change of election by an eligible employee may be made at any time. Participants are always 100% vested in their contributions. While we have discretion to make matching contributions, we have historically not provided such contributions.

DIRECTOR COMPENSATION

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2018. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2018. Paul Edick, our current President and Chief Executive Officer does not receive any compensation for his service as a member of our board of directors. Mr. Edick's compensation for service as an employee for fiscal year 2018 is presented in "Executive Compensation – 2018 Summary Compensation Table." We reimburse non-employee members of our board of directors for reasonable travel expenses.

Director Compensation Table—2018

NAME	FEES EARNED OR PAID IN CASH ($)	OPTION AWARDS ($) (1)	TOTAL ($)
Robert C. Faulkner (2)	—	—	—
Cary McNair (2)	—	—	—
John Schmid (3)	52,750	172,000	224,750
Jonathan Rigby (4)	48,250	76,575	124,763
BJ Bormann (5)	38,250	134,013	172,263
Marla Persky (6)	35,250	134,013	169,263
Dawn Halkuff (7)	33,750	134,013	167,763
Jeffrey Sherman (8)	30,750	134,013	164,763

(1) Each equity award was granted pursuant to our 2011 Plan and, unless otherwise described in the footnotes, the shares vest in 24 monthly equal installments commencing as of May 15, 2018, in all cases subject to the optionee's continuous service to us through each vesting date. The shares subject to the options are early exercisable. Upon a change in control of the Company while the optionee is providing services to us and where the option is not assumed, continued, or substituted, 100% of the shares subject to the option shall vest and become exercisable immediately prior to the effective date of the change in control.

(2) Investor-appointed directors did not receive fees or other compensation for their service on our board of directors. Messrs. Faulkner and McNair departed from our board of directors in April 2018.

(3) The amounts reported were granted pursuant to the offer agreement, dated August 31, 2017, by and between Mr. Schmid and us. On December 31, 2017, Mr. Schmid early exercised all 5,659 stock options, 1,887 of which remained unvested as of December 31, 2018. As of December 31, 2018, Mr. Schmid held unexercised options to purchase 25,220 shares of our common stock.

(4) The amounts reported were granted pursuant to the offer agreement, dated September 15, 2017, by and between Mr. Rigby and us. As of December 31, 2018, Mr. Rigby held unexercised options to purchase 39,344 shares of our common stock.

(5) The amounts reported were granted pursuant to the offer agreement, dated March 30, 2018, by and between Dr. Bormann and us. As of December 31, 2018, Dr. Bormann held unexercised options to purchase 19,650 shares of our common stock.

(6) The amounts reported were granted pursuant to the offer agreement, dated March 30, 2018, by and between Ms. Persky and us. As of December 31, 2018, Ms. Persky held unexercised options to purchase 19,650 shares of our common stock.

(7) The amounts reported were granted pursuant to the offer agreement, dated April 16, 2018, by and between Ms. Halkuff and us. As of December 31, 2018, Ms. Halkuff held unexercised options to purchase 19,650 shares of our common stock.

(8) The amounts reported were granted pursuant to the offer agreement, dated March 30, 2018, by and between Dr. Sherman and us. As of December 31, 2018, Dr. Sherman held unexercised options to purchase 19,650 shares of our common stock.

Table of Contents

Non-Employee Director Compensation Policy

Our board of directors adopted a non-employee director compensation policy following our IPO that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee is paid cash compensation, as set forth below:

	MEMBER ANNUAL FEE ($)	CHAIRMAN ADDITIONAL ANNUAL FEE ($)
Board of Directors	35,000	20,000
Audit Committee	8,000	8,000
Compensation Committee	6,000	6,000
Nominating and Corporate Governance Committee	4,000	4,000

In addition, each non-employee director elected or appointed to our board of directors will be granted 19,650 options on the date of such director's election or appointment to the board of directors, which will vest over three years, subject to continued service through such vesting date(s). On the date of each annual meeting of stockholders of our company, each non-employee director will be granted 11,228 options, which will vest in full upon the earlier to occur of the first anniversary of the date of grant or the date of the next annual meeting subject to continued service as a director through such vesting date(s).

Table of Contents

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a description of transactions or series of transactions since January 1, 2016, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds $120,000; and
- in which any of our executive officers, directors and principal stockholders, including their immediate family members, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under “Management—Director Compensation” and “Executive Compensation.”

Private Placements of Securities

Series C Preferred Stock Financing

In December 2015, with subsequent closings in December 2016, May 2017, December 2017 and February 2018, we sold an aggregate of 13,542,592 shares of our Series C preferred stock at a purchase price of $6.2705 per share for an aggregate principal amount of $84.9 million. The following table summarizes purchases of our Series C preferred stock by related persons:

STOCKHOLDER	SHARES OF SERIES C PREFERRED STOCK	TOTAL PURCHASE PRICE
Entities affiliated with Palmetto Partners, Ltd.	1,833,983	$ 11,499,996.41
Entities affiliated with Deerfield Management Company	3,114,584	$ 19,529,998.98
Entities affiliated with Redmile Group, LLC (1)	3,109,796	$ 19,499,995.82
Mérieux Participations 2 S.A.S.	1,562,873	$ 9,799,995.15
Paul Edick (2)	23,922	$ 150,002.91
Nora Brennan (3)	16,000	$ 100,328.00
John Shannon	16,000	$ 100,328.00
Ken Johnson	4,000	$ 25,082.00

(1) Robert Faulkner was a member of our board of directors from December 2015 to April 2018 and is a partner at Redmile Group, LLC.
(2) Represents 23,922 shares of Series C preferred stock held by the Paul R. Edick 2008 Revocable Trust.
(3) Ms. Brennan departed from her position as our Chief Financial Officer on April 24, 2018.

Agreements with Stockholders

In connection with our Series C preferred stock financing, we entered into investors’ rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our preferred stock and certain holders of our common stock. These stockholder agreements were terminated in connection with our IPO, except for the registration rights granted under our investors’ rights agreement, as more fully described in “Description of Capital Stock—Registration Rights.”

Indemnification Agreements

In connection with our IPO, we entered into agreements to indemnify our directors and executive officers. These agreements, among other things, require us to indemnify these individuals for certain expenses (including attorneys’ fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person’s status as a member of our board of directors to the maximum extent allowed under Delaware law.

Policies for Approval of Related Party Transactions

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with our IPO, we adopted a written related party transactions policy that such transactions must be approved by our audit committee. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which include transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

PRINCIPAL STOCKHOLDERS

The following table sets forth, as of December 31, 2018, information regarding the beneficial ownership of our common stock as adjusted to reflect the shares of common stock to be issued and sold in the offering assuming no exercise of the underwriters' option to purchase additional shares, by:

- each person, or group of affiliated persons, who is known by us to be the beneficial owner of five percent or more of our common stock;
- each of our directors;
- each of our named executive officers; and
- all our directors and executive officers as a group (11 persons).

We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Section 13(d) and 13(g) of the Exchange Act. Under these rules, the number of shares of common stock deemed outstanding includes shares issuable upon exercise of options and warrants held by the respective person or group which may be exercised or converted within 60 days after December 31, 2018. For purposes of calculating each person's or group's percentage ownership, stock options and warrants exercisable within 60 days after December 31, 2018 are included for that person or group but not the stock options or warrants of any other person or group. Certain options to purchase shares of our common stock included in the table below are early exercisable, and to the extent such shares are unvested as of a given date, such shares will remain subject to a right of repurchase held by us.

Applicable percentage ownership is based on 20,893,205 shares of common stock outstanding as of December 31, 2018, which includes 84,849 shares of unvested restricted stock.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over the shares listed. Unless otherwise noted below, the address of each person listed on the table is c/o Xeris Pharmaceuticals, Inc., 180 N. LaSalle Street, Suite 1810, Chicago, IL 60601.

	SHARES OF COMMON STOCK BENEFICIALLY OWNED	PERCENTAGE OF SHARES BENEFICIALLY OWNED	
		BEFORE OFFERING	AFTER OFFERING
5% Stockholders			
Entities affiliated with Deerfield Management Company (1)	2,498,666	11.96%	9.65%
Entities affiliated with Redmile Group, LLC (2)	2,412,642	11.55%	9.32%
Entities affiliated with FMR LLC (3)	2,213,898	10.60%	8.55%
Entities affiliated with Palmetto Partners, Ltd. (4)	2,121,289	10.15%	8.19%
Mérieux Participations 2 S.A.S. (5)	1,097,464	5.25%	4.24%
Directors, Named Executive Officers and Other Executive Officers			
Paul Edick (6)	849,569	3.91%	3.18%
Steven Prestrelski (7)	553,926	2.64%	2.13%
John Shannon (8)	257,503	1.22%	*
Barry Deutsch (9)	114,526	*	*
Ken Johnson (10)	80,844	*	*
Jonathan Rigby (11)	39,344	*	*
John Schmid (12)	30,879	*	*
BJ Bormann (13)	19,650	*	*
Jeffrey Sherman (14)	19,650	*	*
Marla Persky (15)	19,650	*	*
Dawn Halkuff (16)	19,650	*	*
All current executive officers and directors as a group (11 persons) (17)	2,005,191	9.07%	7.34%

* Less than one percent.

(1) Based upon information set forth in the Schedule 13G filed with the SEC on June 27, 2018, beneficial ownership consists of: (i) 1,498,666 shares of common stock held by Deerfield Private Design Fund III, L.P. and (ii) 1,000,000 shares of common stock held by Deerfield Special Situations Fund, L.P. Deerfield Mgmt, L.P. is the general partner of Deerfield Special Situations Fund, L.P., and Deerfield Mgmt III, L.P. is the general partner of Deerfield Private Design Fund III, L.P. (collectively with Deerfield Special Situations Fund, L.P., the "Deerfield Funds"). Deerfield Management Company, L.P. is the investment manager of each of the Deerfield Funds. James E. Flynn is the sole member of the general partner of Deerfield Mgmt, L.P., Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P. Deerfield Mgmt, L.P., Deerfield Management Company, L.P. and as such shares voting and investment control over the shares held by the Deerfield Funds. Mr. James E. Flynn may be deemed to beneficially own the securities held by Deerfield Special Situations Fund, L.P. Deerfield Mgmt III, L.P., Deerfield Management Company, L.P. and Mr. James E. Flynn may be deemed to beneficially own the securities held by Deerfield Private Design Fund III, L.P. The address of the Deerfield Funds is 780 Third Avenue, 37th Floor, New York, NY 10017.

(2) Based upon information set forth in the Schedule 13G filed with the SEC on June 27, 2018, beneficial ownership consists of: 2,412,642 shares of common stock held by certain private investment vehicles and separate managed accounts managed by Redmile Group, LLC, which shares may be deemed beneficially owned by Redmile Group, LLC as investment manager of such private investment vehicles and separately managed accounts. The shares may also be deemed beneficially owned by Jeremy C. Green as the principal of Redmile Group, LLC. Redmile Group, LLC and Mr. Green each disclaim beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any. The address of Redmile Group, LLC is One Letterman Drive, Building D, Suite D3-300, San Francisco, CA 94129.

(3) Based upon information set forth in the Schedule 13G filed with the SEC on November 13, 2018, beneficial ownership consists of 2,213,898 shares of common stock held by FMR LLC. Abigail P. Johnson is a Director, the Vice Chairman, the Chief Executive Officer and the President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment

companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.

(4) Based upon information set forth in the Form 4 filed by Palmetto Partners, Ltd. on June 25, 2018, consists of (i) 930,383 shares of common stock held by Palmetto Partners 2014, LP, (ii) 581,992 shares of common stock held by Palmetto Partners 2015, LP., (iii) 597,686 shares of common stock held by Palmetto Partners, Ltd. and (iv) 11,228 shares of common stock underlying options exercisable within 60 days of December 31, 2018 held by Palmetto Partners, Ltd. Palmetto Partners, Ltd. is the general partner of each of Palmetto Partners 2014, LP and Palmetto Partners 2015, LP and may be deemed to beneficially own the securities held by such funds. The address of Palmetto Partners, Ltd. is 109 N Post Oak Ln., Suite 600, Houston, TX 77024.

(5) Consists of 1,097,464 shares of common stock held by Mérieux Participants 2 S.A.S. Voting and investment power over the securities held by Mérieux Participants 2 S.A.S. is exercised by its board of directors. The address of Mérieux Participants 2 S.A.S. is 17 Rue Bourgelat, Lyon, France 69002.

(6) Consists of (i) 836,139 shares of common stock underlying options exercisable within 60 days of December 31, 2018 and (ii) 13,430 shares of common stock held by the Paul R. Edick 2008 Revocable Trust (the "2008 Trust Shares"). Mr. Edick may be deemed to beneficially own the 2008 Trust Shares. Mr. Edick disclaims beneficial ownership of the 2008 Trust Shares and this shall not be deemed an admission that he is the beneficial owner of the 2008 Trust Shares.

(7) Consists of (i) 489,324 shares of common stock, 23,603 of which are held by Steven Prestrelski and Tracy Yeo and (ii) 64,602 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(8) Consists of (i) 8,983 shares of common stock and (ii) 248,520 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(9) Consists of (i) 23,292 shares of common stock and (ii) 91,234 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(10) Consists of (i) 2,245 shares of common stock and (ii) 78,599 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(11) Consists of 39,344 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(12) Consists of (i) 5,659 shares of common stock and (ii) 25,220 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(13) Consists of 19,650 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(14) Consists of 19,650 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(15) Consists of 19,650 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(16) Consists of 19,650 shares of common stock underlying options exercisable within 60 days of December 31, 2018.

(17) Includes an aggregate of 1,442,608 shares of common stock underlying options exercisable within 60 days of December 31, 2018 held by eleven executive officers and directors.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated.

As of December 31, 2018, 20,893,205 shares of our common stock (which includes 84,839 shares of common stock issued upon the early exercise of stock options, which remain subject to vesting restrictions) were outstanding and held by 125 stockholders of record, and no shares of our preferred stock outstanding.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of December 31, 2018, options to purchase 2,315,677 shares of common stock were outstanding under our 2011 Plan (which excludes options to purchase 84,839 shares of common stock that were early exercised).

As of December 31, 2018, options to purchase 723,137 shares of common stock were outstanding under our 2018 Plan.

Warrants

As of December 31, 2018, we had outstanding warrants to purchase 8,635 shares of common stock at an exercise price of $5.912 per share and warrants to purchase 94,012 shares of common stock at an exercise price of $11.169 per share.

Registration Rights

The holders of 537,274 shares of our common stock are entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an investors' rights agreement between us, certain holders of our common stock and holders of our preferred stock. The investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

The holders of 537,274 shares of our common stock are entitled to demand registration rights. Under the terms of the investors' rights agreement, we will be required, upon the written request of holders of at least 20% of the securities eligible for registration then outstanding or such lesser percentage that would result in an aggregate offering price of at least $10.0 million, to file a registration statement and use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement.

Short-Form Registration Rights

Pursuant to the investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of majority in interest of these holders to sell registrable securities at an aggregate price of at least $1.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are not required to effect more than registrations that have been declared or ordered effective by the SEC pursuant to this provision of the investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback Registration Rights

Pursuant to the investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of 537,274 shares of our common stock are entitled to include their shares in the registration. Subject to certain exceptions contained in the investors' rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of Registration Rights

The demand registration rights and short form registration rights granted under the investors' rights agreement will terminate on the fifth anniversary of the completion of this offering or at such time after this offering when the holders' shares may be sold without restriction pursuant to Rule 144 within a three-month period.

Anti-Takeover Effects of Delaware Law and Certain Provisions of our Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however

occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders’ notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty by one or more of our directors, officers or employees, (iii) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. Our bylaws further provide that, unless we consent in writing to an alternate forum, the United States District Court for the Northern District of Illinois will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our bylaws. The Delaware Court of Chancery has ruled that federal forum selection provisions are invalid under Delaware law. That decision has been appealed to the Delaware Supreme Court. It is possible that the Delaware Supreme Court (or other courts) could find federal forum selection provisions to be invalid or unenforceable, in which case our board of directors will amend promptly our amended and restated bylaws to remove our federal forum selection provision.

Stock Exchange Listing

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol “XERS.”

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is Computershare Inc.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. Sales of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Following this offering, based on the number of shares of our common stock outstanding as of December 31, 2018, we will have a total of 25,893,205 shares of our common stock outstanding. Of these shares, 25,350,272 shares of common stock, including the shares of common stock sold in this offering will be freely tradable, except that any shares purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below, and restricted shares of common stock are subject to time-based vesting terms. All remaining shares of common stock will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, summarized below.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately 259,000 shares, immediately after this offering; or
- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares.

However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-Up Agreements

In connection with this offering, our directors and executive officers have signed lock-up agreements under which they have agreed not to sell or otherwise transfer or dispose of any of our securities for a period of 90 days from the date of this prospectus, subject to certain exceptions. The representatives of the underwriters in this offering may, in

their sole discretion, permit early release of shares subject to the lock-up agreements. See the section entitled “Underwriting” appearing elsewhere in this prospectus for more information.

Registration Rights

Holders of 537,274 shares of our common stock are entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act thereafter. See the section entitled “Description of Capital Stock—Registration Rights” appearing elsewhere in this prospectus for more information.

Equity Incentive Plans

We filed a registration statement on Form S-8 under the Securities Act to register all of our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement was filed on June 21, 2018. Accordingly, shares registered under such registration statement are available for sale in the open market, unless such shares are subject to vesting restrictions with us, the lock-up restrictions described above or Rule 144 in the case of our affiliates.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust the income of which is not subject to U.S. federal income tax on a net income basis and that (1) is not subject to the primary supervision of a court within the United States or over which no U.S. persons have authority to control all substantial decisions and (2) has not made an election to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any U.S. state, local or non-U.S. taxes, the alternative minimum tax, the Medicare tax on net investment income, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code, or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and

- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on Sale, or Other Taxable Disposition of Our Common Stock." Any such distributions will also be subject to the discussions below under the sections titled "Backup Withholding and Information Reporting" and "Withholding and Information Reporting Requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussions below under "Backup Withholding and Information Reporting" and "Withholding and Information Reporting Requirements—FATCA," a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;

  the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax

treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or

- we are, or have been, at any time during the five-year period preceding such sale of other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and Information Reporting Requirements—FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Such withholding may also apply to payments of proceeds from sales or other dispositions of our common stock, although under recently proposed U.S. Treasury Regulations no withholding would apply to payments of gross proceeds. The preamble to the proposed regulations specifies that taxpayers (including withholding agents) are permitted to rely on the proposed regulations pending finalization. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in

this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

Table of Contents

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2019, among us and Jefferies LLC and SVB Leerink LLC, as the representatives of the underwriters named below, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
SVB Leerink LLC	
RBC Capital Markets, LLC	
Mizuho Securities USA LLC	
Total	5,000,000

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock to certain brokers and dealers. After the offering, the public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $772,000. We have also agreed to pay the filing fees incident to, and the fees and disbursements of counsel for the underwriters in connection with, the required review by the Financial Industry Regulatory Authority, Inc.

Listing

Our common stock is listed on The Nasdaq Global Select Market under the trading symbol “XERS”.

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 750,000 shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter’s initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers and our directors have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open “put equivalent position” within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended, or
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus without the prior written consent of the representatives.

This restriction terminates after the close of trading of the common stock on and including the 90th day after the date of this prospectus.

The representatives may, in their sole discretion and at any time or from time to time before the termination of the 90-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time. The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Select Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters’ web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment

management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Canada

Resale Restrictions

The distribution of our shares of common stock in Canada is being made only in the provinces of Ontario, Quebec, Manitoba, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

Representations of Canadian Purchasers

By purchasing our shares of common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares without the benefit of a prospectus qualified under those securities laws as it is an “accredited investor” as defined under National Instrument 45-106—Prospectus Exemptions,
- the purchaser is a “permitted client” as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—*Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this document.

Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser of these

securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of our shares of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares in their particular circumstances and about the eligibility of the shares for investment by the purchaser under relevant Canadian legislation.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each referred to herein as a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, referred to herein as the Relevant Implementation Date, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the

Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or CO, or which do not constitute an offer to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with section 15A of the Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities,

directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated. Each such person is referred to herein as a Relevant Person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters relating to this offering will be passed upon for the underwriters by Wilmer Cutler Pickering Hale and Dorr LLP, New York, New York.

EXPERTS

The financial statements of Xeris Pharmaceuticals, Inc. as of December 31, 2016 and 2017, and for each of the years in the two-year period ended December 31, 2017, have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-   ) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

We are subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. You may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	F-2
Financial Statements	
Balance sheets as of December 31, 2016 and 2017	F-3
Statements of operations for the years ended December 31, 2016 and 2017	F-4
Statements of convertible preferred stock and stockholders' deficit for the years ended December 31, 2016 and 2017	F-5
Statements of cash flows for the years ended December 31, 2016 and 2017	F-6
Notes to financial statements	F-7
Unaudited Interim Financial Statements	
Condensed balance sheets as of December 31, 2017 and September 30, 2018	F-21
Condensed statements of operations and comprehensive loss for the nine months ended September 30, 2017 and 2018	F-22
Condensed statements of convertible preferred stock and stockholders' equity (deficit) for the nine months ended September 30, 2018	F-23
Condensed statements of cash flows for the nine months ended September 30, 2017 and 2018	F-24
Notes to condensed interim financial statements	F-25

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Xeris Pharmaceuticals, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Xeris Pharmaceuticals, Inc. (the Company) as of December 31, 2017 and 2016, the related statements of operation, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2016.

Chicago, Illinois
March 21, 2018 (except as to Note 15, as to which the date is June 11, 2018)

XERIS PHARMACEUTICALS, INC.

Balance Sheets
December 31, 2016 and 2017
(In thousands except share and par value data)

	2016	2017
Assets:		
Current assets:		
Cash and cash equivalents	$ 32,269	$ 42,045
Accounts receivable	101	1,199
Prepaid expenses and other current assets	804	809
Total current assets	33,174	44,053
Property and equipment, net	312	788
Other assets	47	157
Total assets	$ 33,533	$ 44,998
Liabilities, Convertible Preferred Stock and Stockholders' Deficit:		
Current liabilities:		
Accounts payable	$ 1,315	$ 1,976
Accrued expenses	902	2,557
Deferred grant award	263	234
Preferred stock warrants	47	93
Total current liabilities	2,527	4,860
Deferred rent—long term	42	90
Total liabilities	2,569	4,950
Convertible Preferred Stock:		
Series A Convertible Preferred Stock—par value $0.0001, 1,864,797 shares authorized; 1,843,965 shares issued and outstanding as of December 31, 2016 and 2017, respectively (liquidation preference of $1,881 at December 31, 2017)	1,945	1,945
Series B Convertible Preferred Stock—par value $0.0001, 5,732,338 authorized; 5,696,834 issued and outstanding as of December 31, 2016 and 2017, respectively (liquidation preference of $18,908 at December 31, 2017)	18,536	18,536
Series C Convertible Preferred Stock—par value $0.0001, 7,973,845 and 14,353,859 shares authorized; 7,177,398 and 12,834,912 issued and outstanding as of December 31, 2016 and 2017, respectively (liquidation preference of $80,481 at December 31, 2017)	42,417	77,397
Total convertible preferred stock	62,898	97,878
Stockholders' Deficit		
Common stock—par value $0.0001, 21,247,980 and 30,450,994 shares authorized; 1,927,237 and 2,159,068 shares issued and outstanding as of December 31, 2016 and 2017, respectively	1	1
Additional paid in capital	2,096	2,754
Accumulated deficit	(34,031)	(60,585)
Total stockholders' deficit	(31,934)	(57,830)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 33,533	$ 44,998

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.

Statements of Operations
Years Ended December 31, 2016 and 2017
(In thousands except share and per share data)

	2016	2017
Grant income	$ 1,022	$ 1,540
Service revenue	53	16
Cost of revenue	8	4
Gross profit	1,067	1,552
Operating expenses:		
Research and development	10,238	20,166
General and administrative	4,060	8,015
Expense from operations	14,298	28,181
Loss from operations	(13,231)	(26,629)
Other income (expense):		
Interest income	5	124
Interest expense	(2)	(2)
Change in fair value of warrants	24	(46)
Other expense	(5)	(1)
Total other income	22	75
Net loss	$ (13,209)	$ (26,554)
Net loss per share—basic and diluted	$ (7.17)	$ (13.09)
Weighted average shares outstanding, basic and diluted	1,842,416	2,028,224
Pro forma net loss per share basic and diluted—unaudited		$ (2.34)
Pro forma weighted average shares outstanding basic and diluted—unaudited		11,385,655

See Notes to Financial Statements.

Table of Contents

XERIS PHARMACEUTICALS, INC.

Statements of Convertible Preferred Stock and Stockholders' Deficit
Years Ended December 31, 2016 and 2017
(In thousands except share data)

	CONVERTIBLE PREFERRED STOCK						STOCKHOLDERS' DEFICIT					
	SERIES A		SERIES B		SERIES C		COMMON STOCK		ADDITIONAL PAID IN CAPITAL	SHAREHOLDER NOTES RECEIVABLE	ACCUMULATED DEFICIT	TOTAL
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance, January 1, 2016	1,796,174	$ 1,787	5,696,834	$18,536	6,539,490	$38,569	1,815,651	$ 1	$ 1,534	$ (90)	$ (20,822)	$(19,377)
Net loss	—	—	—	—	—	—	—	—	—	—	(13,209)	(13,209)
Exercise of Series A Warrants	47,791	49	—	—	—	—	—	—	—	—	—	—
Fair market value of preferred stock warrants charged to Series A Preferred stock	—	109	—	—	—	—	—	—	—	—	—	—
Issuance of Series C Preferred Stock, net of cost $152	—	—	—	—	637,908	3,848	—	—	—	—	—	—
Repayments on shareholder notes	—	—	—	—	—	—	—	—	—	17	—	17
Allowance on shareholder notes	—	—	—	—	—	—	—	—	—	73	—	73
Exercise and vesting of stock based awards	—	—	—	—	—	—	111,586	—	22	—	—	22
Stock based compensation	—	—	—	—	—	—	—	—	540	—	—	540
Balance, December 31, 2016	1,843,965	$ 1,945	5,696,834	$18,536	7,177,398	$42,417	1,927,237	$ 1	$ 2,096	$ —	$ (34,031)	$(31,934)
Net loss	—	—	—	—	—	—	—	—	—	—	(26,554)	(26,554)
Issuance of Series C Preferred Stock, net of cost $395	—	—	—	—	5,657,514	34,980	—	—	—	—	—	—
Exercise and vesting of stock based awards	—	—	—	—	—	—	231,831	—	159	—	—	159
Stock based compensation	—	—	—	—	—	—	—	—	499	—	—	499
Balance, December 31, 2017	1,843,965	$ 1,945	5,696,834	$18,536	12,834,912	$77,397	2,159,068	$ 1	$ 2,754	$ —	$ (60,585)	$(57,830)

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.

Statements of Cash Flows
Years Ended December 31, 2016 and 2017
(In thousands)

	2016	2017
Cash flows from operating activities:		
Net loss	$ (13,209)	$ (26,554)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	116	177
Impairment of fixed assets	—	48
Stock-based compensation	540	499
Change in fair value of warrants	(24)	46
Allowance for shareholder note receivable	73	—
Changes in operating assets and liabilities:		
Accounts receivable	204	(1,098)
Prepaid expenses and other current assets	(294)	(5)
Other assets	1	(111)
Accounts payable	(2,909)	661
Accrued expenses	(552)	1,703
Deferred grant award	(33)	(29)
Net cash used in operating activities	(16,087)	(24,663)
Cash flows from investing activities:		
Purchases of property and equipment	(35)	(700)
Net cash used in investing activities	(35)	(700)
Cash flows from financing activities:		
Proceeds from sale of Series C Preferred Stock	4,000	35,475
Payments of Series C Preferred Stock offering costs	(152)	(495)
Proceeds from exercise of preferred stock warrants	49	—
Proceeds from shareholder notes receivable	17	—
Repayments of capital lease	(32)	—
Proceeds from exercise of stock awards	22	159
Net cash provided by financing activities	3,904	35,139
Increase (decrease) in cash and cash equivalents	(12,218)	9,776
Cash and cash equivalents, beginning of year	44,487	32,269
Cash and cash equivalents, end of year	$ 32,269	$ 42,045
Supplemental cash flow information:		
Income taxes paid	$ —	$ —
Interest paid	$ 2	$ 2
Supplemental schedule of noncash investing and financing activities:		
Change in fair market value of expired warrants	$ 109	$ —

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.

Notes to financial statements

Note 1. Organization and Nature of the Business

Nature of business

Xeris Pharmaceuticals, Inc. ("Xeris" or the "Company") is a specialty pharmaceutical company that was incorporated in Delaware in 2005. Xeris is dedicated to the development of ready-to-use injectable and infusible drug formulations to address important unmet medical needs and that are easier to use by patients, caregivers and health practitioners, and reduce costs for payors and the healthcare system.

Basis of presentation

The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Since its inception, the Company has devoted substantially all of its efforts to research and development, regulatory and technical activities. The Company has financed its operation through the issuance of convertible preferred stock and other equity instruments and grants from the National Institutes of Health and other philanthropic organizations.

The Company has not generated any revenue from product sales. The Company has incurred operating losses since inception and had an accumulated deficit of $34.0 million and $60.6 million as of December 31, 2016 and 2017, respectively. The Company expects to continue to incur net losses for the next several years and is highly dependent on its ability to find additional sources of funding in the form of debt and/or equity financing and grant awards to fund its operations. The Company's ability to fund its planned clinical operations, including completion of its planned trials, and commercialization of its product candidates is expected to depend on the amount and timing of cash receipts from financing transactions and grant awards. Adequate additional funding may not be available to the Company on acceptable terms or at all. The failure to raise funds as and when needed could have a negative impact on the Company's financial condition and ability to pursue its business strategies. Based on the Company's current operating plans, existing working capital at December 31, 2017 combined with the $35.0 million in expected proceeds from the Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB) (collectively, the "Lenders") and $4.4 million in Series C Convertible Preferred Stock sold in February 2018, cash is sufficient to sustain operations beyond March 21, 2019. If additional funding is not secured when required, the Company may need to delay or curtail its operations until such funding is received. The Company is subject to a number of risks similar to other specialty pharmaceutical companies, including, but not limited to, successful development and commercialization of its drug candidates, raising additional capital, the development of new technological innovations by its competitors, protection of intellectual property and market acceptance of the Company's products.

Note 2. Summary of Significant Accounting Policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and contingent liabilities and expenses included in the financial statements and accompanying notes. Actual results could differ from those estimates.

Grant Income

The Company has received several grants from the National Institutes of Health and other philanthropic organizations for certain research and development projects the Company is currently performing. Grant income is recognized when these research and development activities are performed, and the Company has met criteria for reimbursement per the grant agreements. The Company also has grants where cash is received upfront. The Company defers these awards until the research and development expenses are incurred.

Revenue

The Company recognizes revenue when persuasive evidence of an arrangement exists, the related services have been performed, the price is fixed and determinable and collectability is reasonably assured. The Company generates revenue through the performance of research and development activities on behalf of others.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs include salaries, stock compensation and other personnel-related costs, consulting fees, fees paid for contract research services, laboratory equipment and facilities costs, and other external costs.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are received or the services are performed.

Stock-based compensation

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. The Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. The Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period. Restricted stock awards are valued based on the fair market value of the Company's common stock on the date they were granted. Restricted stock that vests and stock options that are authorized are issued out of authorized available shares.

The Company accounts for stock-based awards issued to non-employees by recognizing compensation expense based on the fair value of such awards when the services are completed over the vesting period of the award.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Accounting for Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2017, the Company does not have any significant uncertain tax positions.

Cash and cash equivalents

Cash and cash equivalents include demand deposits with financial institutions and liquid investments with original maturities of three months or less.

Concentrations of risk

The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

The Company is dependent on several key suppliers and third-party manufacturers. A failure or disruption by one of the Company's key suppliers or third-party manufacturers may have a material impact to its planned operations.

Prepaid expenses and other current assets

Prepaid expenses and other current assets include prepaid expenses for general business purposes, which are stated at cost and are amortized on a straight-line basis over the related period of benefit. Prepaid expenses also include supplies and materials used in several research projects. These supplies are expensed as they are consumed.

Property and equipment

Property and equipment are carried at cost less accumulated depreciation. Depreciation is calculated utilizing the straight-line method over the estimated useful lives of the respective assets:

Lab equipment	5 years
Computer equipment	5 years
Leasehold improvements	Lesser of useful life or lease term
Software	3-5 years
Furniture and fixtures	5 years
Office equipment	5 years

Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is recognized.

Impairment of long-lived assets

The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, *Property, Plant and Equipment*. Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company recognized impairment charges of $0 and $48,000 for the years ended December 31, 2016 and 2017, respectively. The impairment charge in 2017 was related to equipment that is no longer used in the Company's manufacturing of the Gvoke HypoPen due to process and formulation improvements.

Deferred rent

Certain of the Company's lease agreements provide for scheduled rent increases during the lease term and for rental payments commencing at a date after the initial occupancy date. Provisions are made for the excess of operating lease rentals, computed on a straight-line basis throughout the lease term, over cash rentals paid.

Preferred stock

The Company's Series A, B and C Convertible Preferred Stock (collectively known as "Preferred Stock") allows the holders to redeem their shares upon a change in control in the Company. As a result, the Company classifies its Preferred Stock as mezzanine equity. The Company charges specific incremental issuance costs incurred in the offering of Preferred Stock against the gross proceeds of the Preferred Stock.

Warrants

Warrants for the Company's convertible preferred stock are liability classified as they represent a financial instrument for a share of convertible preferred stock. The warrants are revalued each reporting period with the change in fair value recorded in the accompanying statements of operations until the warrants are exercised, expire, reclassified to permanent equity, or otherwise settled.

Fair value of financial instruments

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments are made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumption are used when estimating fair value. Items measured at fair value on a recurring basis include the Company's preferred stock warrants. The warrants are carried at their estimated fair value.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM") in making decisions

regarding resource allocation and assessing performance. The Company's chief executive officer uses summary financial information in determining how to allocate resources and assess performance. The Company has determined that it operates in one segment and all of the Company's assets are located in the United States.

Net loss per share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares during the period. For all periods presented, the outstanding shares of the Preferred Stock, preferred stock warrants, and stock awards have been excluded from the calculation because their effects would be anti-dilutive. Therefore the weighted-average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2016 and 2017, as they would be antidilutive:

	YEARS ENDED DECEMBER 31,	
	2016	2017
Convertible preferred stock	8,263,377	11,439,752
Warrants	19,931	19,931
Vested and unvested stock options	508,328	1,979,306
	8,791,636	13,438,989

Amounts in the table above reflect the common stock equivalents of the noted instruments.

The unaudited pro forma net loss per common share is computed using the weighted-average number of common shares outstanding and assumes the issuance of 11,459,683 shares of common stock issued to the holders of the Company's Preferred Stock and preferred stock warrants upon an initial public offering as if such conversion had occurred at the beginning of the period presented or the date of original issuance, if later.

The following table summarizes the calculation of unaudited pro forma basic and diluted net loss per common share:

(In thousands except share and per share data)	2017
Pro forma net loss per common share (unaudited)	
Numerator	
Net loss attributable to common stockholders	$ (26,554)
Pro forma adjustments to eliminate changes in fair value of preferred stock warrant liability	46
Net loss used to compute pro forma net loss per share	$ (26,508)
Denominator	
Weighted average of common shares outstanding	2,028,224

Recent accounting pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share Based Payment Accounting* ("ASU 2016-09") as part of the FASB simplification initiative. The new standard provides for changes to accounting for stock compensation including 1) excess tax benefits and tax deficiencies related to share-based payment awards will be recognized as income tax expense in the reporting period in which they occur; 2) excess tax benefits will be classified as an operating activity in the statement of cash flow; 3) the option to elect to estimate forfeitures or account for them when they occur; and 4) increase tax withholding requirements threshold to qualify for equity classification. ASU 2016-09 is effective for public companies with annual periods and interim periods beginning after December 15, 2016. Early adoption is permitted. The Company intends to adopt this standard on January 1, 2018 and continues to analyze and assess the impact, if any, of this standard on its financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The new standard requires the recognition of assets and liabilities arising from lease transactions on the balance sheet and the disclosure of key information about leasing arrangements. Accordingly, a lessee will recognize a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Both the asset and liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either a finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the asset. For leases with a term of twelve months or less, a lessee can make an accounting policy election by class of underlying asset to not recognize an asset and corresponding liability. Lessees will also be required to provide additional qualitative and quantitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. These disclosures are intended to supplement the amounts recorded in the financial statements and provide additional information about the nature of an organization's leasing activities. The new standard will be effective for public companies with annual periods and interim periods beginning after December 15, 2018. Early adoption is permitted. In transition, lessees are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The transition guidance also provides specific guidance for sale and leaseback transactions, build-to-suit leases and amounts previously recognized in accordance with the business combinations guidance for leases. The Company intends to adopt this standard on January 1, 2020 and continues to analyze and assess the impact, if any, of this standard on its financial statements.

In May 2014, the FASB issued ASU 2014-09 (ASC606), *Revenue from Contracts with Customers*. This ASU, as amended by ASU 2015-14, affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance in GAAP when it becomes effective. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for public companies with annual periods beginning after December 15, 2018 and for interim periods beginning after December 15, 2019. Early adoption is permitted. The Company intends to adopt this standard on January 1, 2019 and continues to analyze and assess the impact, if any, of this standard on its financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718):* Scope of Modification Accounting. ASU 2017-09 clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. ASU 2017-09 will be applied prospectively to awards modified on or after the adoption date. ASU 2017-09 is effective for public companies for annual and interim periods beginning after December 15, 2017. Early adoption is permitted. The Company intends to adopt this standard on January 1, 2019, and continues to analyze and assess the impact, if any, of this standard on its financial statements.

Table of Contents

Note 3. Property and Equipment

Property and equipment consisted of the following:

(In thousands)	DECEMBER 31, 2016	DECEMBER 31, 2017
Lab equipment	$ 375	$ 860
Furniture and fixtures	103	128
Computer equipment	50	100
Office equipment	26	78
Software	16	52
Leasehold improvements	10	10
	580	1,228
Less accumulated depreciation and amortization	(268)	(440)
Property and equipment, net	$ 312	$ 788

Depreciation and amortization expense relating to property and equipment was $116,000 and $177,000 for the years ended December 31, 2016 and 2017, respectively.

Note 4. Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	DECEMBER 31, 2016	DECEMBER 31, 2017
Accrued employee costs	$744	$1,581
Accrued research costs	70	566
Other	88	410
Accrued expenses	$902	$2,557

Note 5. Convertible Preferred Stock

The holders of the Company's Preferred Stock will be entitled to receive non-cumulative dividends at the rate of 8% of the purchase price per annum in preference to any dividends to the holders of the common stock, payable as and if when declared by the Board of Directors. The Board has not declared any dividends as of December 31, 2017. The holders of the Preferred Stock also will be entitled to participate pro rata in any dividends paid to the holders of the common stock on an as-converted basis.

Upon the liquidation of the Company, the holders of Preferred Stock will be entitled to receive, in preference to the holders of the common stock, an amount equal to $1.02 per share for Series A Convertible Preferred Stock, $3.319 per share for Series B Convertible Preferred Stock and $6.2705 per share for Series C Convertible Preferred Stock plus any declared but unpaid dividends (the "Liquidation Preference"). After the payment of the Liquidation Preference in full, the remaining assets or other property of the Company will be distributed ratably to the holders of the common stock and the Preferred Stock on an as converted basis. A merger or consolidation involving the Company, a sale of voting control of the Company or the sale of all or substantially all of the assets of the Company will be deemed to be a liquidation for this purpose.

The holders of the Preferred Stock will have the right to convert their shares (including declared, but unpaid dividends thereon) into shares of the Company's common stock at any time. The initial conversion rate will be 1:1.78112 subject to customary anti-dilution provisions.

The Preferred Stock will convert automatically into common stock upon the election of the holders of a majority of the outstanding Preferred Stock holders; or the closing of a firmly underwritten public offering of shares of the Company's common stock at a public offering price per share (prior to underwriter commissions and expenses) that is not less than $16.74 per share in an offering with aggregate proceeds to the Company of not less than $30,000,000.

Prior to completion of the Company's initial public offering, the holders of the Series C Convertible Preferred Stock are entitled to elect two board members and the holders of Series A and B Convertible Preferred Stock are entitled to elect two board members.

Note 6. Warrants

In 2013 the Company issued 69,000 Series A Convertible Preferred Stock warrants ("Series A Warrants"). The holder of each Series A Warrant was entitled to purchase one share of Series A Convertible Preferred Stock for $1.02. In 2016 47,791 warrants were exercised and the remaining Series A Warrants expired. There were no Series A Warrants outstanding as of December 31, 2016 and 2017.

In 2014 the Company issued 35,504 warrants ("Series B Warrants") to certain investors. The Series B Warrants allow each holder to purchase one share of Series B Preferred stock for $3.319 and they expire in August of 2020. There have been no exercises of Series B Warrants as of December 31, 2017 and as such all 35,504 warrants were outstanding as of December 31, 2016 and 2017.

Note 7. Commitments and Contingencies

Commitments

The Company has non-cancellable operating leases for office space and equipment, which expire at various times through 2024. The non-cancellable office lease agreements provide for monthly lease payments, which increase during the term of the lease. Future minimum lease payments under operating leases at December 31, 2017 are as follows:

(In thousands)	
2018	$ 730
2019	859
2020	834
2021	1,123
2022	1,148
Thereafter	701
Total minimum lease payments	$ 5,395

Total rent expense under these operating leases was approximately $268,000 and $526,000 for the years ended December 31, 2016 and 2017, respectively.

The Company has an outstanding letter of credit for $58,000 used to secure a lease in San Diego, California.

Through December 31, 2017, the Company has received $760,000 out of an expected $872,000 in grant proceeds for the development of a stable liquid glucagon for use in an artificial pancreas. Under the terms of the agreement, the Company will be required to pay up to four times the award received upon the commercialization of glucagon for use in the artificial pancreas. If the Company undergoes a change in control, then the Company will be required to pay a mid-single digit percentage of the gross proceeds, capped at four times the award amount less any amounts already paid. Additionally, if sales of glucagon for use in the artificial pancreas exceed $750 million in the first five years after the first commercial sale, then the Company would be required to make an additional payment equal to the original award amount.

The Company has received a grant for $929,000 to help fund its exercise induced hypoglycemia ("EIH") program. Under terms of this agreement and upon the commercialization of an EIH product, the Company will be required to

make royalty payments based on a low double-digit percentage of annual gross sales of an EIH product, capped at $500,000 annually. If the Company undergoes a change in control, the Company will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, if sales exceed $1 billion, the Company will be required to make a milestone payment equal to two times the award amount.

The Company has received a grant for $1,004,000 to help fund its Type 1 Diabetes chronic glucagon programs. Under terms of this agreement the Company will be required to pay up to two times the award amount upon the commercialization of any chronic glucagon program. These amounts are a low double-digit percentage of annual gross sales of all Type 1 Diabetes chronic glucagon programs, capped at $500,000 annually. If the Company undergoes a change in control, then it will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, for each chronic glucagon program where sales exceed $500 million, the Company will be required to pay an additional amount equal to two times the award amount.

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of December 31, 2016 and 2017, management was not aware of any existing, pending or threatened legal actions that would have a material impact on the financial position or results of operations of the Company.

Note 8. Shareholder Notes Receivables

In November 2014, the Company accepted Notes Receivables totaling $107,000 from its then Chief Executive Officer (CEO) and a member of the Company's Board of Directors, to exercise certain stock options. The Notes Receivables carried an interest rate of 1.93%, were payable in equal installments over 60 months and were collateralized by the underlying common stock purchased as a part of the stock option exercise and thus were recorded as a deduction to stockholder's equity. The Board member paid his Note Receivable in full upon his resignation from the Board in 2016. The Company agreed to forgive the unpaid portion of the CEO's Note Receivable as part of his severance package in connection with this separation from the Company in January 2017. As a result, the CEO's Note Receivable of $73,000 was fully reserved at December 31, 2016 and written off in January 2017.

Note 9. Stock Compensation Plan

In 2011 the Company adopted the 2011 Stock/Option Issuance Plan ("2011 Plan") and subsequently amended to authorize the Board of Directors to issue up to 4,378,116 incentive grant and non-statutory awards. Options and restricted stock granted to employees under the 2011 Plan typically vest over a 48-month period and options and restricted stock granted to non-employee directors vest over a 24-month period. All stock awards typically expire 10 years after they were issued. Subsequent to December 31, 2017 the shareholders approved an increase of 336,866 incentive grant and non-statutory awards allowed to be granted under the 2011 Plan.

The fair value of stock options was estimated with the following weighted average assumptions:

	YEARS ENDED DECEMBER 31,	
	2016	2017
Expected term	5.88	6.06
Expected volatility	61.46%	61.10%
Risk-free interest rate	1.48%	2.06%
Expected dividends	—	—

Stock option activity for employee awards for the year ended December 31, 2016 and 2017 is as follows:

	UNITS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)
Outstanding—January 1, 2016	364,612	$ 1.32	6.33
Issued	138,115	2.71	
Exercised	(12,538)	0.87	
Forfeited	(9,350)	1.23	
Outstanding—December 31, 2016	480,838	1.69	6.71
Issued	1,642,565	1.64	
Exercised	(117,318)	1.59	
Forfeited	(13,256)	1.83	
Expired	(46,599)	1.53	
Outstanding—December 31, 2017	1,946,230	$ 1.66	8.71
Exercisable—December 31, 2017	1,709,929	$ 1.64	8.70
Vested and expected to vest at December 31, 2017	1,735,470	$ 1.66	8.70

The weighted average grant date fair value of awards granted during the years ended December 31, 2016 and 2017 was $1.55 and $0.94 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2016 and 2017 was $9,000 and $1,258,000 respectively. The aggregate intrinsic value of awards vested and expected to vest as of December 31, 2016 and 2017 was $122,000 and $7,422,000, respectively.

Restricted stock awards for employees for the 2011 Plan for the years ended December 31, 2016 and 2017 is as follows:

	SHARES
Outstanding—January 1, 2016	96,849
Granted	103,867
Vested	(99,898)
Outstanding—December 31, 2016	101,118
Vested	(101,118)
Outstanding—December 31, 2017	—

The weighted average grant date fair value of awards issued in 2016 was $294,000 and the intrinsic fair value of shares vested and expected to vest during the year ended December 31, 2016 was $157,000. There were no awards granted during 2017 or outstanding as of December 31, 2017.

The following table summarizes the reporting of total stock-based compensation expense resulting from employee and non-employee stock options and restricted stock awards:

	YEARS ENDED DECEMBER 31,	
(In thousands)	**2016**	**2017**
Research and development	$ 78	$ 62
General and administrative	462	437
Total stock-based compensation	$ 540	$ 499

There was a total of $1,311,000 of unrecognized compensation expense that is expected to be recognized over a weighted average period of 1.34 years.

The Company also granted stock options to non-employees. These awards are marked to fair-value at the end of each reporting period. Stock option activity for these awards for the years ended December 31, 2016 and 2017 is as follows:

	UNITS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)
Outstanding—January 1, 2016	27,510	0.89	7.15
Issued	14,036	2.83	
Exercised	(12,866)	0.82	
Forfeited	(1,170)	0.82	
Outstanding—December 31, 2016	27,510	1.91	7.75
Issued	5,614	1.55	
Outstanding—December 31, 2017	33,124	$ 1.91	6.75
Exercisable—December 31, 2017	27,510	$ 1.91	6.75
Vested and expected to vest at December 31, 2017	27,510	$ 1.91	6.74

The aggregate intrinsic value of awards vested and expected to vest at December 31, 2016 and 2017 was $8,000 and $110,000 respectively. The aggregate intrinsic value of awards exercisable as of December 31, 2016 and 2017 was $8,000 and $111,000, respectively. The company recognized expense associated with these awards of $8,000 and $35,000 for the years ended December 31, 2016 and 2017, respectively.

Note 10. Defined Contribution Plan

The Company sponsors an employee retirement plan qualifying under Section 401(k) of the Internal Revenue Code for all eligible employees in the United States. Employees become eligible to contribute to the plan upon meeting certain age requirements and 30 days of service. Currently the company does not make any contributions to the plan.

Note 11. Income Taxes

Due to reported losses, the Company recorded no income tax expense for the years ended December 31, 2016 and 2017. A reconciliation of the expected income tax benefit computed using the federal statutory income tax rate of 34% to the Company's effective income tax rate is as follows:

	DECEMBER 31,	
(In thousands)	2016	2017
Income tax using the federal statutory tax rate	$ (4,491)	$ (9,028)
Impact of rate change	—	7,478
Research and development and orphan drug credit	(655)	(517)
Permanent adjustments to expenses	(3)	76
Stock compensation	145	42
Prior year adjustment	—	(100)
Changes in valuation allowance	5,004	2,049
Total income taxes	$ —	$ —

During the years ended December 31, 2016 and 2017, the Company had no interest and penalties related to income taxes.

Deferred income taxes reflect the net tax effects of temporary difference between the carrying amount of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established a valuation allowance due to the uncertainties regarding the realization of the deferred tax assets based on the Company's lack of earning's history. Significant components of the Company's deferred tax assets and liabilities are as follows:

	DECEMBER 31,	
(In thousands)	**2016**	**2017**
Deferred tax assets		
Net operating losses	$ 10,547	$ 11,715
Research credits	1,462	2,045
Stock compensation	5	49
Other temporary differences	202	349
Valuation allowance	(12,157)	(14,124)
Total assets	59	34
Deferred tax liabilities		
Fixed and intangible assets	(59)	(34)
Total liabilities	(59)	(34)
Net deferred tax assets	$ —	$ —

As of December 31, 2016 and 2017, the Company had federal net operating loss carryforwards ("NOL") of $31,011,000 and $55,786,000, respectively. As of December 31, 2016 and 2017, the Company had federal research and orphan drug credit carryforwards of $1,462,000 and $2,045,000, respectively. If not utilized, these NOLs and research and orphan drug credit carryforwards will expire between 2025 and 2036.

Impacts of the Tax Cuts and Jobs Act

On December 22, 2017, the Tax Cuts and Jobs Act (H.R. 1) (the "Tax Act") was signed into law. The Tax Act contains significant changes to corporate taxation, including (i) the reduction of the corporate income tax rate to 21%, (ii) the acceleration of expensing for certain business assets, (iii) the one-time transition tax related to the transition of U.S. international tax from a worldwide tax system to a territorial tax system, (iv) the repeal of the domestic production deduction, (v) additional limitations on the deductibility of interest expense, and (vi) expanded limitations on executive compensation. The key impacts of the Tax Act on the Company's financial statements for the year ended December 31, 2017, were the re-measurement of deferred tax balances to the new corporate tax rate. While the Company has not yet completed the assessment of the effects of the Tax Act, the Company was able to determine reasonable estimates for the impacts of the key items specified above, thus it reported provisional amounts for these items. In accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), the Company is providing additional disclosures related to these provisional amounts. In order to calculate the effects of the new corporate tax rate on its deferred tax balances, ASC 740 "*Income Taxes*" ("ASC 740") required the re-measurement of the Company's deferred tax balances as of the enactment date of the Tax Act, based on the rates at which the balances were expected to reverse in the future. The provisional amount determined, and recorded, for the re-measurement of its deferred tax balances resulted in a net reduction in deferred tax assets of $7,478,000 and a corresponding reduction in the valuation allowance of $7,478,000.

The aforementioned provisional amounts related to the deferred tax balances are based on information available at this time and may change due to a variety of factors, including, among others, (i) anticipated guidance from the U.S. Department of Treasury about implementing the Tax Act, (ii) potential additional guidance from the Securities and Exchange Commission or the FASB related to the Tax Act and (iii) management's further assessment of the Tax Act and related regulatory guidance. The Company is not complete in its assessment of the impact of the Tax Act on its business and financial statements. While the effective date of most of the provisions of the Tax Act do not apply until the Company's tax year beginning January 1, 2018 it will continue the assessment of the impact of the Tax Act on its business and financial statements throughout the one-year measurement period as provided by SAB 118.

Note 12. Fair Value Measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are classified and disclosed in one of the following categories:

Level 1: Measured using unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Measured using quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3: Measured based on prices or valuation models that required inputs that are both significant to the fair value measurement and less observable from objective sources (i.e., supported by little or no market activity).

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values stated below takes into account the market for its financial assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The carrying amounts of cash and cash equivalents, grants receivable, and accounts payables approximate their fair values due to the short-term maturities of these instruments.

The fair value of the Company's warrant liabilities at inception and for subsequent mark-to-market fair value measurements, are based on management's valuation model and expected methods and timing of settlement. These estimates are prepared using models that consider various inputs including: (a) the Company's estimated future cash flows, (b) time value, and (c) current market conditions, as well as other relevant economic measures. The Company has determined that the warrant liabilities fair values are Level 3 items within the fair value hierarchy. The following table presents the changes in the warrant liabilities:

(In thousands)	
Balance at January 1, 2016	$ 180
Fair value of Series A warrants expired/exercised	(109)
Changes in fair value of warrants	(24)
Balance at December 31, 2016	47
Changes in fair value of warrants	46
Balance at December 31, 2017	$ 93

Note 13. Related Party Transaction

During 2017 the Company paid a spouse of an officer $37,000 to help with the development of the Company's website.

Note 14. Subsequent Events

Management reviews events and transactions occurring after the balance sheet date for potential recognition and disclosure in the financial statements. Management has evaluated subsequent events through March 21, 2018, the date on which the financial statements were available to be issued.

In February 2018, the Company entered into a lease for office space in Chicago, Illinois that expires in November 2024, and entered into a letter of credit for $85,000 to secure the lease. Annual minimum lease payments for the next five years are included in the table below:

(In thousands)	
2018	$ 163
2019	202
2020	210
2021	219
2022	228
Thereafter	462
Total minimum lease payments	$ 1,484

In February 2018, the Company sold 707,680 shares of Series C Convertible Preferred Stock for $6.2705 per share resulting in proceeds of $4.4 million with the same rights and preferences as the Series C Preferred Stock disclosed in Note 5.

In February 2018, the Company entered into the Loan Agreement, providing a senior secured loan facility of up to an aggregate principal amount of $45.0 million, comprising a $20.0 million drawdown in February 2018, and an additional $25.0 million which can be borrowed in two additional tranches. The second tranche is $15.0 million and is available beginning upon our submission of our NDA for our Gvoke HypoPen until the earlier of September 30, 2018 or the 30th day following such NDA submission. The third tranche is $10.0 million and is available beginning upon approval of our Gvoke HypoPen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

The interest rate under the Loan Agreement is the thirty-day U.S. LIBOR rate plus 6.75%. Payments on the Loan Agreement are interest only for the first 24 months, which can be extended by an additional twelve months if the third tranche is drawn. The total term of the loan is 59 months and the principal payments will begin in either 36 or 24 months, contingent on the third tranche being drawn.

Pursuant to the Loan Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property and certain other assets, owned by us. There is a negative pledge on intellectual property owned by the Company.

The Company also issued warrants to the Lenders to purchase the Company's Series C Preferred stock at an exercise price of $6.2705. The number of warrants issued to Lenders is equal to the total principal of each funded tranche multiplied by 3.0%, which is then divided by $6.2705. As of March 1, 2018, a total of 95,686 warrants have been issued in connection with the Loan Agreement.

The Loan Agreement allows the Company to voluntarily prepay the outstanding amounts thereunder, but not less than $2.0 million of the outstanding principal at any time. A prepayment fee of 1.5% would be assessed on the prepaid principal through the interest-only period. A final payment fee of 6.5% multiplied by the original principal amount of each tranche drawn is due upon the earlier to occur of the maturity date of the Loan Agreement, the acceleration of the Loan Agreement or prepayment of such borrowings. The Loan Agreement includes a non-utilization fee of 2.0% multiplied by the principal amount of tranche three payable to lenders in October 2019, if the Company does not elect to draw the third Tranche.

Note 15. Reverse Stock Split

On June 8, 2018, the Company effectuated a 1-for-1.78112 reverse stock split of its outstanding common stock, which was approved by the Company's board of directors on May 22, 2018 and by the Company's stockholders on June 8, 2018. The reverse stock split resulted in an adjustment to the preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of $0.0001 per share. Accordingly, the stockholders' deficit reflects the reverse stock split by reclassifying from common stock to additional paid in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

[Table of Contents](#)

XERIS PHARMACEUTICALS, INC.

Condensed Balance Sheets

(In thousands except share and par value data)

	DECEMBER 31, 2017	SEPTEMBER 30, 2018 (unaudited)
Assets:		
Current assets:		
Cash and cash equivalents	$ 42,045	$ 75,745
Short-term investments	—	55,296
Accounts receivable, net	1,199	1,731
Prepaid expenses and other current assets	809	2,898
Total current assets	44,053	135,670
Property and equipment, net	788	1,826
Other assets	157	95
Total assets	$ 44,998	$ 137,591
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit):		
Current liabilities:		
Accounts payable	$ 1,976	$ 622
Accrued expenses and other current liabilities	2,557	6,260
Warrant liabilities	93	1,042
Deferred grant award	234	284
Total current liabilities	4,860	8,208
Long-term debt, net of deferred costs	—	31,642
Other long-term liabilities	90	2,621
Total liabilities	4,950	42,471
Commitments and Contingencies (Note 8)		
Convertible Preferred Stock:		
Series A Convertible Preferred Stock—par value $0.0001, 1,864,797 shares authorized and 1,843,965 shares issued and outstanding as of December 31, 2017	1,945	—
Series B Convertible Preferred Stock—par value $0.0001, 5,732,338 shares authorized and 5,696,834 shares issued and outstanding as of December 31, 2017	18,536	—
Series C Convertible Preferred Stock—par value $0.0001, 14,353,859 shares authorized and 12,834,912 shares issued and outstanding as of December 31, 2017	77,397	—
Total convertible preferred stock	97,878	—
Stockholders' Equity (Deficit):		
Preferred stock—par value $0.0001, 10,000,000 shares authorized as of September 30, 2018 and no shares issued and outstanding as of September 30, 2018	—	—
Common stock—par value $0.0001, 30,450,994 and 150,000,000 shares authorized as of December 31, 2017 and September 30, 2018, respectively; 2,159,068 and 20,755,666 actual shares issued and outstanding as of December 31, 2017 and September 30, 2018, respectively; pro forma shares issued and outstanding December 31, 2018	1	2
Additional paid in capital	2,754	195,422
Accumulated deficit	(60,585)	(100,246)
Accumulated other comprehensive loss	—	(58)
Total stockholders' equity (deficit)	(57,830)	95,120
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 44,998	$ 137,591

See Notes to Unaudited Condensed Interim Financial Statements.

Table of Contents

XERIS PHARMACEUTICALS, INC.

Condensed Statements of Operations and Comprehensive Loss
(In thousands except share and per share data)
(unaudited)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2017	2018
Grant income	$ 1,073	$ 1,611
Service revenue	16	53
Cost of revenue	4	42
Gross profit	1,085	1,622
Operating expenses:		
Research and development	13,588	28,264
General and administrative	4,917	12,388
Expense from operations	18,505	40,652
Loss from operations	(17,420)	(39,030)
Other income (expense):		
Interest income	45	796
Interest expense	(1)	(1,490)
Change in fair value of warrants	(32)	63
Total other income (expense)	12	(631)
Net loss	$ (17,408)	$ (39,661)
Net loss per share—basic and diluted	$ (8.63)	$ (4.36)
Other comprehensive loss, net of tax:		
Unrealized losses on short-term investments	—	(58)
Comprehensive loss	$ (17,408)	$ (39,719)
Weighted average shares outstanding, basic and diluted	2,016,112	9,104,491

See Notes to Unaudited Condensed Interim Financial Statements

Table of Contents

XERIS PHARMACEUTICALS, INC.

Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands except share data)
(unaudited)

	CONVERTIBLE PREFERRED STOCK						STOCKHOLDERS' EQUITY (DEFICIT)					
	SERIES A		SERIES B		SERIES C		COMMON STOCK		ADDITIONAL PAID IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE LOSS	ACCUMULATED DEFICIT	TOTAL
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance, January 1, 2018	1,843,965	$ 1,945	5,696,834	$ 18,536	12,834,912	$ 77,397	2,159,068	$ 1	$ 2,754	$ —	$ (60,585)	$ (57,830)
Net loss	—	—	—	—	—	—	—	—	—	—	(39,661)	(39,661)
Issuance of Initial Public Offering	—	—	—	—	—	—	6,555,000	—	88,952	—	—	88,952
Issuance of Series C Preferred Stock, net of cost $24	—	—	—	—	707,680	4,414	—	—	—	—	—	—
Exercise and vesting of stock based Awards	—	—	—	—	—	—	204,525	—	275	—	—	275
Conversion of convertible preferred stock into common stock	(1,843,965)	(1,945)	(5,696,834)	(18,536)	(13,542,592)	(81,811)	11,837,073	1	102,292	—	—	102,293
Stock based compensation	—	—	—	—	—	—	—	—	1,149	—	—	1,149
Comprehensive loss	—	—	—	—	—	—	—	—	—	(58)	—	(58)
Balance, September 30, 2018	—	$ —	—	$ —	—	$ —	20,755,666	$ 2	$ 195,422	$ (58)	$ (100,246)	$ 95,120

See Notes to Unaudited Condensed Interim Financial Statements.

Table of Contents

XERIS PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows
(In thousands)
(unaudited)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2017	2018
Cash flows from operating activities:		
Net loss	$ (17,408)	$ (39,661)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	123	146
Amortization of debt issuance costs	—	312
Stock-based compensation	351	1,149
Change in fair value of warrants	32	(63)
Changes in operating assets and liabilities:		
Accounts receivable	(635)	(532)
Prepaid expenses and other current assets	262	(2,089)
Other assets	(55)	62
Accounts payable	299	(1,354)
Accrued expenses	1,473	3,790
Deferred grant award	(25)	50
Deferred rent	20	246
Net cash used in operating activities	(15,563)	(37,944)
Cash flows from investing activities:		
Purchases of property and equipment	(464)	(1,260)
Purchases of short-term investments	—	(55,278)
Net cash used in investing activities	(464)	(56,538)
Cash flows from financing activities:		
Proceeds from Initial Public Offering	—	98,325
Payments for Initial Public Offering costs	—	(9,373)
Proceeds from sale of Series C Preferred Stock	30,050	4,438
Payments of Series C Preferred Stock offering costs	(434)	(24)
Proceeds from issuance of long-term debt	—	35,000
Payments for debt issuance costs	—	(333)
Proceeds from exercise of stock awards	56	149
Net cash provided by financing activities	29,672	128,182
Increase in cash and cash equivalents	13,645	33,700
Cash and cash equivalents, beginning of year	32,269	42,045
Cash and cash equivalents, end of year	$ 45,914	$ 75,745
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 1	$ 1,031
Supplemental schedule of noncash investing and financing activities:		
Allocation of debt costs to warrants	$ —	$ 1,012
Accrued debt issuance costs	$ —	$ 2,325
Vesting of early exercised awards	$ —	$ 127

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.

Notes to Unaudited Interim Financial Statements.

Note 1. Organization and Nature of the Business

Nature of business

Xeris Pharmaceuticals, Inc. (“Xeris” or the “Company”) is a specialty pharmaceutical company that was incorporated in Delaware in 2005. Xeris is dedicated to the development of ready-to-use injectable and infusible drug formulations that address important unmet medical needs, are easier to use by patients, caregivers and health practitioners, and reduce costs for payors and the healthcare system.

Basis of presentation

The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

Since its inception, the Company has devoted substantially all of its efforts to research and development, regulatory and technical activities. The Company has financed its operations through the issuance of common stock in its June 2018 initial public offering (“IPO”), issuance of convertible preferred stock and other equity instruments, issuance of debt and grant funding from the National Institutes of Health (“NIH”) and other philanthropic organizations.

The Company has not generated any revenue from product sales. The Company has incurred operating losses since inception and has an accumulated deficit of $100.2 million as of September 30, 2018. The Company expects to continue to incur net losses for the next several years. Based on the Company’s current operating plans and existing working capital at September 30, 2018, cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months. The Company is subject to a number of risks similar to other specialty pharmaceutical companies, including, but not limited to, successful development and commercialization of its drug candidates, the development of new technological innovations by its competitors, protection of intellectual property and market acceptance of the Company’s products.

Note 2. Summary of Significant Accounting Policies

The accompanying unaudited interim financial statements have been prepared in conformity with GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company’s financial position as of September 30, 2018 and its results of operations and cash flows for the nine months ended September 30, 2018 and 2017. Operating results for the nine month periods ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2017 included in the prospectus (Registration No. 333-225191) filed pursuant to Rule 424(b) on June 21, 2018 with the U.S. Securities and Exchange Commission.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, contingent liabilities and expenses included in the financial statements and accompanying notes. Actual results could differ from those estimates.

Impacts of the Tax Cuts and Jobs Act

On December 22, 2017, the Tax Cuts and Jobs Act (H.R. 1) (the “Tax Act”) was signed into law. The Tax Act contains significant changes to corporate taxation, including (i) the reduction of the corporate income tax rate to

21%, (ii) the acceleration of expensing for certain business assets, (iii) the one-time transition tax related to the transition of U.S. international tax from a worldwide tax system to a territorial tax system, (iv) the repeal of the domestic production deduction, (v) additional limitations on the deductibility of interest expense, and (vi) expanded limitations on executive compensation. The key impacts of the Tax Act on the Company's financial statements for the year ended December 31, 2017 were the re-measurement of deferred tax balances to the new corporate tax rate. While the Company has not yet completed the assessment of the effects of the Tax Act, the Company was able to determine reasonable estimates for the impact of the key items specified above and thus it reported provisional amounts for these items. In accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), the Company provides additional disclosures related to these provisional amounts. In order to calculate the effects of the new corporate tax rate on its deferred tax balances, ASC 740 "*Income Taxes*" ("ASC 740") required the re-measurement of the Company's deferred tax balances as of the enactment date of the Tax Act, based on the rates at which the balances were expected to reverse in the future. The provisional amount determined, and recorded as of December 31, 2017, for the re-measurement of its deferred tax balances resulted in a net reduction in deferred tax assets of $7,478,000 and a corresponding reduction in the valuation allowance of $7,478,000.

The aforementioned provisional amounts related to the deferred tax balances are based on information available at this time and may change due to a variety of factors, including, among others, (i) anticipated guidance from the U.S. Department of Treasury about implementing the Tax Act, (ii) potential additional guidance from the U.S. Securities and Exchange Commission or the FASB related to the Tax Act and (iii) management's further assessment of the Tax Act and related regulatory guidance. The Company is not complete in its assessment of the impact of the Tax Act on its business and financial statements. The effective date of most of the provisions of the Tax Act applies to the Company's tax year beginning January 1, 2018. The Company will continue the assessment of the impact of the Tax Act on its business and financial statements throughout the one-year measurement period as provided by SAB 118.

Debt issuance costs

Long-term debt is accounted for at amortized cost. Debt issuance costs incurred in connection with financing arrangements are amortized to interest expense over the life of the respective financing arrangement using the effective interest method. Debt issuance costs, net of related amortization, are deducted from the carrying value of the related debt.

Equity financing costs

The Company capitalizes costs that are directly associated with in-process equity financings until such financings are consummated, at which time such costs are recorded in the additional paid in capital line on the balance sheet against the gross proceeds of the equity financings. As of September 30, 2018, the Company incurred $9.4 million in costs associated with the IPO.

Fair value of financial instruments

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments be made. Additionally, fair value is used on a non-recurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, and accounts payable, are shown at cost, which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Loan and Security Agreement approximates fair value due to the variable interest rate on the debt. Items measured at fair value on a recurring basis include the Company's short-term investments and warrants.

Net loss per common share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. For all periods presented, the outstanding shares of the preferred stock, warrants, and stock awards have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted average common shares outstanding used to calculate both basic and diluted loss per common share are the same.

The following potentially dilutive securities (shown below in common stock equivalent shares) were excluded from the computation of diluted weighted average common shares outstanding due to their anti-dilutive effect:

	SEPTEMBER 30, 2017	SEPTEMBER 30, 2018
Convertible preferred stock	10,954,012	—
Warrants	19,931	113,943
Vested and unvested stock options	1,902,997	2,753,208
	12,876,940	2,867,151

Recent accounting pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share Based Payment Accounting* ("ASU 2016-09"), as part of the FASB simplification initiative. The new standard provides for changes to accounting for stock compensation including 1) excess tax benefits and tax deficiencies related to share-based payment awards being recognized as income tax expense in the reporting period in which they occur; 2) excess tax benefits being classified as an operating activity in the statement of cash flow; 3) the option to elect to estimate forfeitures or account for them when they occur; and 4) increased tax withholding requirements threshold to qualify for equity classification. ASU 2016-09 is effective for public companies with annual periods and interim periods beginning after December 15, 2016. Early adoption is permitted. The Company adopted this standard on January 1, 2018, and it did not have an impact on the financial statements.

Note 3. Reverse Stock Split and Initial Public Offering

On June 8, 2018, the Company effectuated a 1-for-1.78112 reverse stock split of its outstanding common stock, which was approved by the Company's board of directors on May 22, 2018 and by the Company's stockholders on June 8, 2018. The reverse stock split resulted in an adjustment to the preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of $0.0001 per share. Accordingly, the stockholders' deficit reflects the reverse stock split by reclassifying from common stock to additional paid in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

On June 25, 2018, the Company closed the IPO of its common stock pursuant to a registration statement on Form S-1, as amended. The Company sold an aggregate of 6,555,000 shares of common stock under the registration statement at a public offering price of $15.00 per share, including 855,000 shares of common stock pursuant to the exercise of the underwriters' option to purchase additional shares. Net proceeds from the offering were approximately $89.0 million, after deducting underwriting discounts and commissions, as well as other offering expenses.

Upon closing the IPO, all outstanding shares of the Company's Series A, B and C convertible preferred stock were converted into 11,837,073 shares of common stock.

Note 4. Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	DECEMBER 31, 2017	SEPTEMBER 30, 2018
Accrued employee costs	$ 566	$ 2,759
Accrued research costs	1,581	2,739
Other	410	762
Accrued expenses	$ 2,557	$ 6,260

Note 5. Long-term Debt

Senior Secured Loan Facility

In February 2018, the Company entered into the Loan and Security Agreement that provides a senior secured loan facility of up to an aggregate principal amount of $45.0 million. The first tranche was $20.0 million and was drawn down in February 2018 ("Term A Loan"). The second tranche was $15.0 million and was drawn down in September 2018 ("Term B Loan"). The third tranche is $10.0 million and is available beginning upon approval of the Company's Gvoke HypoPen New Drug Application ("NDA") by the U.S. Food & Drug Administration ("FDA") until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

The interest rate under the Loan and Security Agreement is the thirty-day U.S. LIBOR rate plus 6.75%, which was approximately 8.86% as of September 30, 2018. Payments on the Loan and Security Agreement are interest only for the first 24 months, which can be extended by an additional twelve months if the third tranche is drawn. The total term of the loan is fifty-nine months, and the principal payments will begin in either 36 months or 24 months, contingent on the third tranche being drawn.

Pursuant to the Loan and Security Agreement, the Company provided a first priority security interest in all existing and future-acquired assets, excluding intellectual property and certain other assets, owned by the Company. The Loan and Security Agreement contains a negative pledge on intellectual property owned by the Company. The Company also issued warrants to the Lenders to purchase common stock, which is further discussed in Note 7, "Warrants," of the notes to unaudited condensed financial statements.

The Loan and Security Agreement allows the Company to voluntarily prepay the outstanding amounts thereunder, but not less than $2.0 million of the outstanding principal at any time. Prior to April 1, 2020, the Company is subject to a prepayment penalty equal to 1.50% of the principal amount being prepaid. In the event the Company draws on the third tranche, the period subject to 1.50% prepayment is extended to April 1, 2021. No prepayment fee exists for prepayments made after April 1, 2020, or April 1, 2021 in the event the third tranche is issued. A final payment fee of 6.5% multiplied by the original principal amount of each tranche drawn is due upon the earlier to occur of the maturity date of the Loan and Security Agreement, the acceleration of the Loan and Security Agreement or prepayment of such borrowings. The Loan and Security Agreement includes a non-utilization fee of 2.0% multiplied by the principal amount of tranche three payable to Lenders in October 2019, if the Company elects not to draw the third tranche.

The Loan and Security Agreement also contains customary indemnification obligations and customary events of default, including, among other things, failure to fulfill certain obligations under the Loan and Security Agreement and the occurrence of a material adverse change in the Company's business, operations or condition, a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of the Lenders' lien in the collateral or in the value of such collateral. In the event of default under the Loan and Security Agreement, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 5%. All such interest would be payable on demand and in cash. Further, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Loan and Security Agreement.

The Loan and Security Agreement includes certain restrictions on, among other things, the Company's ability to incur additional indebtedness, change the name or location of the business, merge with or acquire other entities, pay dividends or make other distributions to holders of the Company's capital stock, make certain investments, engage in transactions with affiliates, create liens, open new deposit accounts, sell assets or pay subordinated debt.

The components of debt are as follows:

(in thousands)	DECEMBER 31, 2017	SEPTEMBER 30, 2018
Term A Loan	$ —	$ 20,000
Term B Loan	—	15,000
Less unamortized deferred cost	—	(3,358)
Long-term debt	$ —	$ 31,642

The following table sets forth the Company’s future minimum principal payments (in thousands):

2018	$ —
2019	—
2020	9,000
2021	12,000
2022	12,000
2023	2,000
	$ 35,000

The Company incurred total debt issuance costs of $3.7 million, which are reflected as a direct reduction to the term loan balance and are being amortized into interest expense over the life of the loan using the effective interest method. For the nine months ended September 30, 2018, the Company recognized interest expense of $1,490,000, of which $312,000, was related to the amortization of debt issuance costs.

Note 6. Convertible Preferred Stock

In February 2018, the Company issued an additional 707,680 shares of Series C convertible preferred stock for net proceeds of $4.4 million.

During the second quarter of 2018, a majority of the holders of the Company’s convertible preferred stock elected to have their shares converted into common stock, therefore, all outstanding shares of preferred stock were converted into 11,837,073 shares of common stock at a conversion rate of 1:1.78112 upon the closing of the Company’s IPO on June 25, 2018.

Prior to the conversion of the convertible preferred stock into common stock; the holders of the Company’s convertible preferred stock were entitled to receive non-cumulative dividends at the rate of 8% of the purchase price per annum in preference to any dividends to the holders of the common stock, payable as and if when declared by the Board of Directors. No such dividends were declared by the Company’s Board of Directors. The holders of the convertible preferred stock also were entitled to participate pro rata in any dividends paid to the holders of the common stock on an as-converted basis. No dividends were declared by the Company’s Board of Directors.

Note 7. Warrants

In 2014 the Company issued 19,931 warrants (“2014 Warrants”) to certain investors. The 2014 Warrants allow each holder to purchase one share of common stock for $5.912. There have been no exercises of 2014 Warrants and as such all 19,931 warrants were outstanding as of September 30, 2018.

As part of the Loan and Security Agreement discussed in Note 5, “Long-term Debt,” in the notes to unaudited condensed financial statements, the Lenders receive warrants equal to 3.0% of the principal borrowing amounts concurrent with the borrowing. The warrants represent a right for the lender to purchase shares of the Company’s common stock at an initial exercise price of $11.169 per share. The Company issued 53,720 warrants (“Term A Warrants”) upon the drawdown of the Term A Loan in February 2018 and the Company issued 40,292 warrants

("Term B Warrants") upon the drawdown of the Term B Loan in September 2018. There have been no exercises of Term A Warrants or Term B Warrants and as such all 53,720 warrants and 40,292 warrants were outstanding as of September 30, 2018, respectively.

Because the warrants are a freestanding instrument, indexed to the Company's stock, they do not meet the criteria for equity classification. Therefore warrants are liability classified and subject to remeasurement at each reporting period until they are exercised, expired, or otherwise settled. The initial fair value of the warrant liability was recorded with a corresponding offset to deferred debt cost which is a reduction to the notional value of the debt.

The Company recognized a gain (loss) of $(149,000), $(131,000) and $343,000 upon the change in fair value of the warrants during the nine months ended September 30, 2018 related to the 2014 Warrants, the Term A Warrants and the Term B Warrants, respectively. The Company recognized a loss of $(32,000) upon the change in fair value of the 2014 Warrants during the nine months ended September 30, 2017.

As of September 30, 2018, the following warrants were outstanding:

	OUTSTANDING SHARES	EXERCISE PRICE PER SHARE	EXPIRATION DATE
2014 Warrants	19,931	$ 5.912	August 2020
Term A Warrants	53,720	$ 11.169	February 2025
Term B Warrants	40,292	$ 11.169	September 2025
	113,943		

Note 8. Commitments and Contingencies

Commitments

The Company has non-cancellable operating leases for office space, which expire at various times through 2024. The non-cancellable office lease agreements provide for monthly lease payments, which increase during the term of each lease agreement. In the first quarter of 2018, the Company signed a new lease for office space in Chicago, Illinois with remaining future minimum lease payments of approximately $49,000 in 2018, $84,000 in 2019, $210,000 in 2020, $219,000 in 2021, $228,000 in 2022, and $524,000 in 2023 and thereafter.

Total rent expense under these operating leases was approximately $841,000 and $304,000 for the nine months ended September 30, 2018 and 2017, respectively.

Note 9. Stock Compensation Plan

In 2011 the Company adopted the 2011 Stock Option Issuance Plan ("2011 Plan") and subsequently amended it to authorize the Board of Directors to issue up to 4,714,982 incentive grant and non-statutory awards.

The 2018 Stock Option and Incentive Plan ("2018 Plan") was adopted by our Board of Directors in April 2018 and approved by our stockholders in June 2018 to award up to 1,822,000 shares of our common stock. This plan became effective on the date immediately prior to the effectiveness of the Company's IPO registration statement. The 2018 Plan replaced the 2011 Plan as our Board of Directors determined not to make additional awards under the 2011 Plan following the closing of our IPO, which occurred in June 2018. The 2018 Plan allows the compensation committee to make equity-based and cash-based incentive awards to our officers, employees, directors and other key persons (including consultants). As of September 30, 2018, there were 1,539,190 awards available for future issuance.

Stock options are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Stock option awards typically vest over either two years or four years after the grant date and expire ten years from the grant date.

The fair value of each option is estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions noted in the following table. The expected life of options represents the period of time that

options granted are expected to be outstanding. The risk-free interest rate for periods during the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. For fiscal 2018, the expected volatility is based on the historical volatility of certain peer companies over the most recent period corresponding to the expected life as of the grant date. The expected dividend yield is based on the expected annual dividend as a percentage of the market value of the Company's ordinary shares as of the grant date. The Company uses historical data to estimate option exercises and employee terminations within the valuation model.

The fair value of stock options granted was estimated with the following weighted average assumptions:

	NINE MONTHS ENDED SEPTEMBER 30,	
	2017	2018
Expected term	6.1	6.0
Risk-free interest rate	2.05%	2.80%
Expected volatility	61.23%	58.55%
Expected dividends	—	—

Stock option activity for employee awards for the nine months ended September 30, 2018 was as follows:

	UNITS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)
Outstanding—January 1, 2018	1,946,230	$ 1.66	8.70
Issued	1,167,077	12.13	
Exercised	(181,884)	1.42	
Forfeited	(185,003)	1.94	
Outstanding—September 30, 2018	2,746,420	$ 6.26	8.74
Exercisable—September 30, 2018	2,347,080	$ 4.54	8.60
Vested and expected to vest at September 30, 2018	2,470,131	$ 6.07	8.70

The weighted average fair value of awards granted during the nine months ended September 30, 2018 was $6.53 per share. The total intrinsic value of options exercised during the nine months ended September 30, 2018 was $1.7 million. The aggregate intrinsic value of awards vested and expected to vest as of September 30, 2018 was $29.3 million.

The Company also granted stock options to non-employees. These awards are marked to fair value at the end of each reporting period until they vest. Stock option activity for these awards for the nine months ended September 30, 2018 was as follows:

	UNITS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)
Outstanding—January 1, 2018	33,125	$ 1.91	6.75
Issued	—	—	
Exercised	(26,337)	2.17	
Forfeited	—	—	
Outstanding—September 30, 2018	6,788	$ 1.09	4.89
Exercisable—September 30, 2018	6,737	$ 1.09	4.89
Vested and expected to vest at September 30, 2018	6,737	$ 1.09	4.89

The aggregate intrinsic value of awards vested and expected to vest at September 30, 2018 was $111,000. The aggregate intrinsic value of awards exercisable as of September 30, 2018 was $111,000. The company recognized expense associated with these awards of $114,000 and $12,000 for the nine months ended September 30, 2018 and 2017, respectively.

The following table summarizes the reporting of total stock-based compensation expense resulting from employee and non-employee stock options:

(in thousands)	NINE MONTHS ENDED SEPTEMBER 30, 2017	NINE MONTHS ENDED SEPTEMBER 30, 2018
Research and development	$ 46	$ 398
General and administrative	305	751
Total stock-based compensation	$ 351	$ 1,149

At September 30, 2018, there was a total of $6.9 million of unrecognized compensation expense that is expected to be recognized over a weighted average period of 1.51 years.

Note 10. Fair Value Measurements

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are classified and disclosed in one of the following categories:

Level 1: Measured using unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Measured using quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Measured based on prices or valuation models that required inputs that are both significant to the fair value measurement and less observable from objective sources (i.e., supported by little or no market activity).

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values stated below takes into account the market for its financial assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The following tables present the Company's fair value hierarchy for those assets and liabilities measured at fair value as of December 31, 2017 and September 30, 2018:

(in thousands)	TOTAL AS OF DECEMBER 31, 2017	LEVEL 1	LEVEL 2	LEVEL 3
Current Assets				
Money market funds (a)	$ 39,124	$ 39,124	$ —	$ —
Other current liabilities				
Warrant liabilities	$ 93	$ —	$ —	$ 93

Table of Contents

(in thousands)	TOTAL AS OF SEPTEMBER 30, 2018	LEVEL 1	LEVEL 2	LEVEL 3
Current Assets				
Cash and cash equivalents:				
Money market funds	$ 72,746	$72,746	$ —	$ —
Commercial paper	2,999	2,999	—	—
Total cash and cash equivalents	$ 75,745	$75,745	$ —	$ —
Short-term investments:				
U.S. government securities	$ 32,212	$32,212	$ —	$ —
Corporate securities	12,156	—	12,156	—
Agency securities	10,928	—	10,928	—
Total short-term investments	$ 55,296	$32,212	$23,084	$ —
Other current liabilities				
Warrant liabilities	$ 1,042	$ —	$ —	$ 1,042

(a) The money market funds noted above are included in cash and cash equivalents.

There were no investments in commercial paper or short-term investments as of December 31, 2017.

The fair value of the Company's warrant liabilities at inception and for subsequent mark-to-market fair value measurements is based on management's valuation model and expected methods and timing of settlement. These estimates are prepared using models that consider various inputs including: (a) the Company's estimated future cash flows, (b) time value, (c) current market conditions, and (d) other relevant economic measures.

The Company has determined that the warrant liabilities' fair values are Level 3 items within the fair value hierarchy. The following table presents the changes in the warrant liabilities:

(in thousands)	
Balance at December 31, 2017	$ 93
Fair value of Term A Warrants issued under the Loan and Security Agreement	326
Fair value of Term B Warrants issued under the Loan and Security Agreement	686
Change in fair value of warrants	(63)
Balance at September 30, 2018	1,042

There were no transfers between any of the levels of the fair value hierarchy during the nine months ended September 30, 2018.

Note 11. Short-Term Investments

The Company classifies its short-term investments as available-for-sale. Short-term investments comprise highly liquid investments with minimum "A" rated securities and as of September 30, 2018 consist of U.S. Treasury and agency bonds and corporate entity commercial paper and securities with maturities of more than three months but less than one year at the date of purchase. Short-term investments as of September 30, 2018 have an average maturity of 0.58 years. The investments are reported at fair value with unrealized gains or losses recorded in accumulated other comprehensive loss in the condensed balance sheets. Any differences between the cost and fair value of investments are represented by unrealized gains or losses. Refer to Note 10, "Fair Value Measurements," of the notes to unaudited condensed financial statements for information related to the fair value measurements and valuation methods utilized.

The following table represents the Company's available for sale short-term investments by major security type as of September 30, 2018:

(in thousands)	AMORTIZED COST	GROSS UNREALIZED LOSSES	TOTAL FAIR VALUE
Short-term investments:			
Agency securities	$ 10,938	$ (10)	$10,928
Corporate securities	12,166	(10)	12,156
U.S. government securities	32,250	(38)	32,212
Total short-term investments	$ 55,354	$ (58)	$55,296

There were no investments in short-term securities as of December 31, 2017.

We review our available-for-sale investments for other-than-temporary impairment loss quarterly. We consider factors such as the duration, severity and the reason for the decline in value, the potential recovery period and our intent to sell. For debt securities, we also consider whether (i) it is more likely than not that we will be required to sell the debt securities before recovery of their amortized cost basis and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the quarter ended September 30, 2018, we did not recognize any other-than-temporary impairment losses. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

Table of Contents

5,000,000 Shares

Common Stock

Prospectus

Joint Book-Running Managers

Jefferies **SVB Leerink** **RBC Capital Markets**

Mizuho Securities

, 2019

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the estimated costs and expenses, other than underwriting discounts and commissions, to be paid by us in connection with the sale of the shares of common stock being registered hereby.

SEC registration fee	$ 10,245
FINRA filing fee	13,231
Printing and engraving expenses	200,000
Legal fees and expenses	300,000
Accounting fees and expenses	150,000
Blue Sky fees and expenses (including legal fees)	5,000
Transfer agent and registrar fees and expenses	3,500
Miscellaneous	90,024
Total	**$ 772,000**

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

Our certificate of incorporation and bylaws contain provisions that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director or executive officer in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities

Since February 11, 2016, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Capital Stock

In December 2016, May 2017, December 2017 and February 2018, we sold an aggregate of 7,070,761 shares of our Series C preferred stock at a purchase price of $6.2705 per share.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Grants and Exercises of Stock Options

Between September 30, 2015 and the filing of our registration statement on Form S-8 on June 21, 2018, we granted stock options to purchase an aggregate of 2,212,537 shares of our common stock, with exercise prices ranging from $1.55 to $12.50 per share, to employees, directors and consultants pursuant to the 2011 Stock Option Plan, or the 2011 Plan. Between December 31, 2017, and the filing of our registration statement on Form S-8 on June 21, 2018, 88,274 shares of common stock were issued upon the exercise of stock options pursuant to the 2011 Plan.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

(c) Issuances of Warrants

On February 28, 2018, the Company issued warrants to purchase 53,720 shares of its common stock at an exercise price of $11.169 per share. On September 7, 2018, the Company issued warrants to purchase 40,292 shares of its common stock at an exercise price of $11.169 per share.

Table of Contents

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

EXHIBIT NUMBER	EXHIBIT TABLE
1.1	Form of Underwriting Agreement
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant, and currently in effect
3.2(2)	Amended and Restated By-laws of the Registrant, as currently in effect
4.1(3)	Form of Specimen Common Stock Certificate
5.1	Opinion of Goodwin Procter LLP
10.1#(4)	2011 Stock Option and Incentive Plan and forms of award agreements thereunder
10.2#(5)	2018 Stock Option and Incentive Plan and forms of award agreements thereunder
10.3#(6)	Senior Executive Cash Incentive Bonus Plan
10.4#(7)	Form of Director Indemnification Agreement
10.5#(8)	Form of Officer Indemnification Agreement
10.6(9)	Lease Agreement, dated as of September 29, 2017, by and between Are-SD Region No. 30, LLC and the Registrant
10.7#(10)	Amended and Restated Employment Agreement, by and between the Registrant and Paul Edick
10.8#(11)	Amended and Restated Employment Agreement, by and between the Registrant and John Shannon
10.9#(12)	Amended and Restated Employment Agreement, by and between the Registrant and Steven Prestrelski
10.10#(13)	Amended and Restated Employment Agreement, by and between the Registrant and Ken Johnson
10.11#(14)	Employment Agreement, by and between the Registrant and Barry Deutsch
10.12#	Employment Agreement, by and between the Registrant and Beth Hecht
10.13#	First Amendment to Employment Agreement, by and between the Registrant and Beth Hecht
10.14+(15)	API Supply Agreement, dated as of January 1, 2018, by and between the Registrant and Bachem Americas, Inc.
10.15+(16)	Quality Assurance Agreement, dated as of November 20, 2015, by and between Bachem AG and the Registrant, as amended by (i) Amendment 1 to the Quality Assurance Agreement, dated as of October 31, 2016, by and between Bachem AG and the Registrant and (ii) Amendment 2 to the Quality Assurance Agreement, dated as of January 26, 2017, by and between Bachem AG and the Registrant.
10.16+(17)	Commercial Supply Agreement, dated as of May 14, 2018, by and between Pyramid Laboratories Inc. and the Registrant
10.17+(18)	Joint Development Agreement, dated as of January 29, 2016, by and between the Registrant and Scandinavian Health Limited
10.18(19)	Loan and Security Agreement, dated as of February 28, 2018, by and between Oxford Finance LLC, Silicon Valley Bank and the Registrant
10.19+(20)	Quality Agreement, dated as of November 16, 2016, by and between Pyramid Laboratories Inc. and the Registrant

EXHIBIT NUMBER	EXHIBIT TABLE
10.20(21)	2018 Employee Stock Purchase Plan
10.21+(22)	Product Supply Agreement by and between SHL Pharma, LLC and the Registrant, dated August 1, 2018
10.22	First Amendment to Office Lease Agreement, dated as of November 20, 2018, by and between 180 N LaSalle Property Owner LLC and the Registrant
10.23+	Inducement Equity plan(23)
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm
23.2	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page)
101	The following materials from Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations and Comprehensive Loss, (iii) the Condensed Statements of Cash Flows and (iv) Notes to Unaudited Condensed Financial Statements
+	The Securities and Exchange Commission has granted confidential treatment of certain provisions. Omitted material for which confidential treatment has been granted has bene filed separately with the Securities and Exchange Commission.
#	Indicates a management contract or any compensatory plan, contract or arrangement

(1) Incorporated by reference to Exhibit 3.1 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38293) filed on June 28, 2018).
(2) Incorporated by reference to Exhibit 3.2 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38293) filed on June 28, 2018).
(3) Incorporated by reference to Exhibit 4.2 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(4) Incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(5) Incorporated by reference to Exhibit 10.2 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(6) Incorporated by reference to Exhibit 10.3 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(7) Incorporated by reference to Exhibit 10.4 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(8) Incorporated by reference to Exhibit 10.5 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(9) Incorporated by reference to Exhibit 10.3 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(10) Incorporated by reference to Exhibit 10.7 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(11) Incorporated by reference to Exhibit 10.8 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(12) Incorporated by reference to Exhibit 10.9 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(13) Incorporated by reference to Exhibit 10.10 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(14) Incorporated by reference to Exhibit 10.11 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(15) Incorporated by reference to Exhibit 10.12 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).

(16) Incorporated by reference to Exhibit 10.13 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(17) Incorporated by reference to Exhibit 10.14 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(18) Incorporated by reference to Exhibit 10.15 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(19) Incorporated by reference to Exhibit 10.16 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(20) Incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (SEC File No. 333-225191) filed on May 24, 2018).
(21) Incorporated by reference to Exhibit 10.18 to Xeris Pharmaceuticals, Inc.'s Amendment No. 1 to Registration Statement on Form S-1 (SEC File No. 333-225191) filed on June 11, 2018).
(22) Incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc. Quarterly Report on Form 10-Q (File No. 001-38537) filed on November 8, 2018.
(23) Incorporated by reference to Exhibit 99.1 to Xeris Pharmaceuticals, Inc. Registration Statement on Form S-8 (File No. 333-229587) filed on February 8, 2019.

(b) Financial Statement Schedules.

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the consolidated financial statements or the notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, Xeris Pharmaceuticals, Inc. has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chicago, State of Illinois, on the 11th day of February, 2019.

Xeris Pharmaceuticals, Inc.

By: /s/ Paul Edick
Paul Edick
President, Chief Executive Officer and Chairman

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul Edick and Barry Deutsch, and each of them, either of whom may act without the joinder of the other, as his or her true and lawful attorneys-in-fact and agents with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by the registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities indicated on the 11th day of February, 2019.

SIGNATURE	TITLE
/s/ Paul Edick Paul Edick	President, Chief Executive Officer and Chairman (Principal Executive Officer)
/s/ Barry Deutsch Barry Deutsch	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ BJ Bormann BJ Bormann	Director
/s/ Dawn Halkuff Dawn Halkuff	Director
/s/ Marla Persky Marla Persky	Director
/s/ Jonathan Rigby Jonathan Rigby	Director
/s/ John Schmid John Schmid	Director
/s/ Jeffrey Sherman Jeffrey Sherman	Director

[●] Shares of Common Stock

Xeris Pharmaceuticals, Inc.

UNDERWRITING AGREEMENT

[●], 2019

JEFFERIES LLC
SVB LEERINK LLC
As Representatives of the several Underwriters

c/o JEFFERIES LLC
520 Madison Avenue
New York, New York 10022

SVB LEERINK LLC
1301 Avenue of the Americas, 12th Floor
New York, New York 10019

Ladies and Gentlemen:

Introductory. Xeris Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), proposes to issue and sell to the several underwriters named in Schedule A (the "**Underwriters**") an aggregate of [●] shares of its common stock, par value $0.0001 per share (the "**Shares**"). The [●] Shares to be sold by the Company are called the "**Firm Shares**." In addition, the Company has granted to the Underwriters an option to purchase up to an additional [●] Shares as provided in Section 2. The additional [●] Shares to be sold by the Company pursuant to such option are collectively called the "**Optional Shares**." The Firm Shares and, if and to the extent such option is exercised, the Optional Shares are collectively called the "**Offered Shares**." Jefferies LLC ("**Jefferies**") and SVB Leerink LLC ("**SVB Leerink**") have agreed to act as representatives of the several Underwriters (in such capacity, the "**Representatives**") in connection with the offering and sale of the Offered Shares. To the extent there are no additional underwriters listed on Schedule A, the term "Representatives" as used herein shall mean you, as Underwriters, and the term "Underwriters" shall mean either the singular or the plural, as the context requires.

The Company has prepared and filed with the Securities and Exchange Commission (the "**Commission**") a registration statement on Form S-1, File No. 333-[●] which contains a form of prospectus to be used in connection with the public offering and sale of the Offered Shares. Such registration statement, as amended, including the financial statements, exhibits and schedules thereto, in the form in which it became effective under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Securities Act**"), including any information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430A under the Securities Act, is called the "**Registration Statement**." Any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offer and sale of the Offered Shares is called the "**Rule 462(b) Registration Statement**," and from and after the date and time of filing of any such Rule 462(b) Registration Statement the term "Registration Statement" shall include the Rule 462(b) Registration Statement. The prospectus, in the form first used by the Underwriters to confirm sales of the Offered Shares or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act, is called the "**Prospectus**." The preliminary

prospectus dated [●], 2019 describing the Offered Shares and the offering thereof is called the "**Preliminary Prospectus**," and the Preliminary Prospectus and any other prospectus in preliminary form that describes the Offered Shares and the offering thereof and is used prior to the filing of the Prospectus is called a "**preliminary prospectus**." As used herein, "**Applicable Time**" is [●] [a][p].m. (New York City time) on [●], 2019. As used herein, "**free writing prospectus**" has the meaning set forth in Rule 405 under the Securities Act, and "**Time of Sale Prospectus**" means the Preliminary Prospectus together with the free writing prospectuses, if any, identified in Schedule B hereto. As used herein, **"Road Show"** means a "road show" (as defined in Rule 433 under the Securities Act) relating to the offering of the Offered Shares contemplated hereby that is a "written communication" (as defined in Rule 405 under the Securities Act). As used herein, "**Section 5(d) Written Communication**" means each written communication (within the meaning of Rule 405 under the Securities Act) that is made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company to one or more potential investors that are qualified institutional buyers ("**QIBs**") and/or institutions that are accredited investors ("**IAIs**"), as such terms are respectively defined in Rule 144A and Rule 501(a) under the Securities Act, to determine whether such investors might have an interest in the offering of the Offered Shares; "**Section 5(d) Oral Communication**" means each oral communication, if any, made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company made to one or more QIBs and/or one or more IAIs to determine whether such investors might have an interest in the offering of the Offered Shares; "**Marketing Materials**" means any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Offered Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically); and "**Permitted Section 5(d) Communication**" means the Section 5(d) Written Communication(s) and Marketing Materials listed on Schedule C attached hereto.

All references in this Agreement to (i) the Registration Statement, any preliminary prospectus (including the Preliminary Prospectus), or the Prospectus, or any amendments or supplements to any of the foregoing, or any free writing prospectus, shall include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System ("**EDGAR**") and (ii) the Prospectus shall be deemed to include any "electronic Prospectus" provided for use in connection with the offering of the Offered Shares as contemplated by Section 3(o) of this Agreement.

The Company hereby confirms its agreements with the Underwriters as follows:

Section 1. Representations and Warranties.

The Company hereby represents, warrants and covenants to each Underwriter, as of the date of this Agreement, as of the First Closing Date (as hereinafter defined) and as of each Option Closing Date (as hereinafter defined), if any, as follows:

(a) ***Compliance with Registration Requirements*.** The Registration Statement has become effective under the Securities Act. The Company has complied, to the Commission's satisfaction with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission.

(b) ***Disclosure*.** Each preliminary prospectus and the Prospectus when filed complied in all material respects with the Securities Act and, if filed by electronic transmission pursuant to EDGAR, was identical (except as may be permitted by Regulation S-T under the Securities Act) to the copy thereof delivered to the Underwriters for use in connection with the offer and sale of the Offered Shares. Each of

the Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Applicable Time, the Time of Sale Prospectus (including any preliminary prospectus wrapper) did not, and at the First Closing Date (as defined in Section 2) and at each applicable Option Closing Date (as defined in Section 2), will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus (including any Prospectus wrapper), as of its date, did not, and at the First Closing Date and at each applicable Option Closing Date, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement or any post-effective amendment thereto, or the Prospectus or the Time of Sale Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with written information relating to any Underwriter furnished to the Company in writing by the Representatives expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 9(b) below. There are no contracts or other documents required to be described in the Time of Sale Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which have not been described or filed as required.

(c) ***Free Writing Prospectuses; Road Show.*** As of the determination date referenced in Rule 164(h) under the Securities Act, the Company was not, is not or will not be (as applicable) an "ineligible issuer" in connection with the offering of the Offered Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Each free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Offered Shares did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Prospectus or any preliminary prospectus and not superseded or modified. Except for the free writing prospectuses, if any, identified in Schedule B, and electronic road shows, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior written consent, prepare, use or refer to, any free writing prospectus. Each Road Show, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(d) ***Distribution of Offering Material By the Company.*** Prior to the later of (i) the expiration or termination of the option granted to the several Underwriters in Section 2 and (ii) the completion of the Underwriters' distribution of the Offered Shares**,** the Company has not distributed and will not distribute any offering material in connection with the offering and sale of the Offered Shares other than the Registration Statement, the Time of Sale Prospectus, the Prospectus or any free writing prospectus reviewed and consented to by the Representatives, the free writing prospectuses, if any, identified on Schedule B hereto and any Permitted Section 5(d) Communications.

(e) ***The Underwriting Agreement.*** This Agreement has been duly authorized, executed and delivered by the Company.

(f) ***Authorization of the Offered Shares*.** The Offered Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Offered Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Offered Shares.

(g) ***No Applicable Registration or Other Similar Rights*.** There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(h) ***No Material Adverse Change*.** Except as otherwise disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement, the Time of Sale Prospectus and the Prospectus: (i) there has been no material adverse change, or any development that could be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company, (any such change being referred to herein as a "**Material Adverse Change**"); (ii) the Company has not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company or has entered into any transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company and there has been no dividend or distribution of any kind declared, paid or made by the Company, or any repurchase or redemption by the Company of any class of capital stock.

(i) ***Independent Accountants*.** KPMG LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus, is (i) an independent registered public accounting firm as required by the Securities Act, the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Exchange Act**"), and the rules of the Public Company Accounting Oversight Board ("**PCAOB**"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(j) ***Financial Statements*.** The financial statements filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus present fairly in all material respects the financial position of the Company as of the dates indicated and the results of their operations, changes in stockholders' equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with U.S. generally accepted accounting principles applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto and except in the case of unaudited financial statements, which are subject to normal and recurring year-end adjustments and do not contain certain footnotes as permitted by the applicable rules of the Commission. The interactive data in eXtensible Business Reporting Language included in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines. No other financial statements or supporting schedules are required to be included in the Registration Statement, the Time of Sale Prospectus or the Prospectus. The financial

data set forth in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus under the captions "Prospectus Summary—Summary Financial Data," "Selected Financial Data" and "Capitalization" fairly present in all material respects the information set forth therein on a basis consistent with that of the audited financial statements contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(k) ***Company's Accounting System.*** The Company makes and keeps books and records that are accurate in all material respects and maintains a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v)_the interactive data in eXtensible Business Reporting Language included in the Registration Statement, the Time of Sale Prospectus and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto.

(l) ***Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting.*** The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared (it being understood that neither subsection (k) nor this subsection (l) requires the Company to comply with Section 404 of the Sarbanes Oxley Act of 2002 as of an earlier date than it would otherwise be required to so comply under applicable law). Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, since the end of the Company's most recent audited fiscal year, there have been no significant deficiencies or material weakness in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(m) ***Incorporation and Good Standing of the Company.*** The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the States of California, Illinois and Texas and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so qualified or be in good standing would not reasonably be expected, individually or in the aggregate, to result in a material adverse effect on the condition (financial or other), earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company (a "**Material Adverse Effect**").

(n) ***Subsidiaries.*** The Company has no subsidiaries (as defined in Rule 405 under the Securities Act).

(o) ***Capitalization and Other Capital Stock Matters.*** The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Capitalization" (other than for subsequent issuances, if any, pursuant to employee benefit plans, or upon the exercise of outstanding options or warrants, in each case described in the Registration Statement, the Time of Sale Prospectus and the Prospectus). The Shares (including the Offered Shares) conform in all material respects to the description thereof contained in the Time of Sale Prospectus. All of the issued and outstanding Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all applicable federal and state securities laws. None of the outstanding Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company other than those described in the Registration Statement, the Time of Sale Prospectus and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

(p) ***Stock Exchange Listing.*** The Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on The Nasdaq Global Select Market (the "**NASDAQ**"), and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Shares under the Exchange Act or delisting the Shares from the NASDAQ, nor has the Company received any notification that the Commission or the NASDAQ is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the NASDAQ.

(q) ***Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required.*** The Company is not in violation of its charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company is a party or by which it may be bound, or to which any of its properties or assets are subject (each, an "**Existing Instrument**"), except for such Defaults as would not be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect. The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus and the issuance and sale of the Offered Shares (including the use of proceeds from the sale of the Offered Shares as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Use of Proceeds") (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, of the Company, (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company, except for such conflicts, breaches, Defaults, liens, charges, encumbrances or violations specified to subsections (ii) and (iii) above that would not reasonably be

expected, individually or in the aggregate, to have a Material Adverse Effect. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or FINRA. As used herein, a "**Debt Repayment Triggering Event**" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company.

(r) ***Compliance with Laws.*** The Company has been and is in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(s) ***No Material Actions or Proceedings*****.** There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company, which if determined adversely to the Company would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company is a party or of which any of its properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Effect. No material labor dispute with the employees of the Company exists or, to the knowledge of the Company, is threatened or imminent.

(t) ***Intellectual Property Rights*****.** The Company owns, or has obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as being owned or licensed by them or which are necessary for the conduct of its business as currently conducted or as currently proposed to be conducted as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, except where the failure to own or license such rights would not, individually or in the aggregate, have a Material Adverse Effect (collectively, "**Intellectual Property**"). To the Company's knowledge: (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus as licensed to the Company; and (ii) there is no infringement by third parties of any Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the Time of Sale Prospectus or the Prospectus as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. The Company has complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company, and all such agreements are in full force and effect. The product candidates described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as under development by the Company fall within the scope of the claims of one or more patents owned by, or licensed to, the Company.

(u) ***All Necessary Permits, etc*****.** The Company possesses, or qualifies for applicable exemptions to, such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the Registration Statement, the Time of Sale Prospectus or the Prospectus ("**Permits**"), except where the failure to possess or obtain the same or so qualify would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company is not in violation of, nor is it in default under, any of the Permits nor has it received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any of the Permits, except for any such violations, defaults, or proceedings relating to the revocation or modification of, or non-compliance with, any such Permits that would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(v) ***Title to Properties*****.** Except as described in the Registration Statement, the Time of Sale Prospectus or the Prospectus, the Company has good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in Section 1(j) above (or elsewhere in the Registration Statement, the Time of Sale Prospectus or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The real property, improvements, equipment and personal property held under lease by the Company are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company.

(w) ***Tax Law Compliance*****.** The Company has filed all necessary federal, state and foreign income and franchise tax returns or has properly requested extensions thereof and has paid all material taxes required to be paid by it and, if due and payable, any related or similar assessment, fine or penalty levied against it except as may be being contested in good faith and by appropriate proceedings. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 1(j) above in respect of all material federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company has not been finally determined.

(x) ***Insurance*****.** The Company is insured by recognized and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary for its business including, but not limited to, policies covering real and personal property owned or leased by the Company against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company for product liability claims and clinical trial liability claims. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company has not been denied any insurance coverage which it has sought or for which it has applied.

(y) ***Compliance with Environmental Laws*****.** Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) the Company is not in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata)

or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "**Hazardous Materials**") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "**Environmental Laws**"); (ii) the Company has all permits, authorizations and approvals required under any applicable Environmental Laws and is in compliance with their requirements; (iii) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company; and (iv) there are no events or circumstances that might reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company relating to Hazardous Materials or any Environmental Laws.

(z) ***ERISA Compliance*****.** The Company and any "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "**ERISA**")) established or maintained by the Company or its "ERISA Affiliates" (as defined below) are in compliance in all material respects with ERISA. "**ERISA Affiliate**" means, with respect to the Company, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "**Code**") of which the Company is a member. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, (i) no "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates; (ii) no "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates, if such "employee benefit plan" were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA); and (iii) neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any liability under (x) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (y) Sections 412, 4971, 4975 or 4980B of the Code. Each employee benefit plan established or maintained by the Company or any of its ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code has received a favorable determination or opinion letter from the Internal Revenue Service or has time remaining to do so and, to the knowledge of the Company, nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.

(aa) ***Company Not an "Investment Company."*** The Company is not, and will not be, either after receipt of payment for the Offered Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus or the Prospectus, required to register as an "investment company" under the Investment Company Act of 1940, as amended (the "**Investment Company Act")**.

(bb) ***No Price Stabilization or Manipulation; Compliance with Regulation M*****.** The Company has not taken, directly or indirectly, without giving effect to activities by the Underwriters, any action designed to or that might reasonably be expected to cause or result in stabilization or manipulation of the price of the Shares or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("**Regulation M**")) with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(cc) ***Related-Party Transactions*****.** There are no business relationships or related-party transactions involving the Company or any other person required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus that have not been described as required.

(dd) ***FINRA Matters.*** All of the information provided to the Underwriters or to counsel for the Underwriters by the Company, its officers and directors and, to the knowledge of the Company, its counsel and the holders of any securities (debt or equity) or options to acquire any securities of the Company, in connection with the offering of the Offered Shares is true, complete, correct and compliant with FINRA's rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct.

(ee) ***Parties to Lock-Up Agreements.*** The Company has furnished to the Underwriters a letter agreement in the form attached hereto as Exhibit A (the "**Lock-up Agreement**") from each of the persons listed on Exhibit B. Such Exhibit B lists under an appropriate caption the directors and officers of the Company. If any additional persons shall become directors or officers of the Company prior to the end of the Company Lock-up Period (as defined below), the Company shall cause each such person, prior to or contemporaneously with their appointment or election as a director or officer of the Company, to execute and deliver to the Representatives a Lock-up Agreement.

(ff) ***Statistical and Market-Related Data.*** All statistical, demographic and market-related data included in the Registration Statement, the Time of Sale Prospectus or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

(gg) ***No Unlawful Contributions or Other Payments.*** Neither the Company nor, to the knowledge of the Company, any employee or agent of the Company, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any applicable law or of the character required to be disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus.

(hh) ***Foreign Corrupt Practices Act.*** Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company has, in the course of its actions for, or on behalf of, the Company (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic government official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "**FCPA**") or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any applicable non-U.S. anti-bribery statute or regulation; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any domestic government official, such foreign official or employee; and the Company and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(ii) ***Money Laundering Laws.*** The operations of the Company are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(jj) ***OFAC.*** Neither the Company nor, to the knowledge of the Company any director, officer, agent, employee, affiliate or person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or in any country or territory, that currently is the subject to any U.S. sanctions administered by OFAC or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of U.S. sanctions administered by OFAC.

(kk) ***Brokers.*** Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(ll) ***Forward-Looking Statements.*** Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that is was false or misleading.

(mm) ***Emerging Growth Company Status***. From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged in any Section 5(d) Written Communication or any Section 5(d) Oral Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**").

(nn) ***Communications***. The Company (i) has not alone engaged in communications with potential investors in reliance on Section 5(d) of the Securities Act other than Permitted Section 5(d) Communications with the consent of the Representatives with entities that are QIBs or IAIs and (ii) has not authorized anyone other than the Representatives to engage in such communications; the Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Marketing Materials, Section 5(d) Oral Communications and Section 5(d) Written Communications; as of the Applicable Time, each Permitted Section 5(d) Communication, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Permitted Section 5(d) Communication, if any, does not, as of the date hereof, conflict with the information contained in the Registration Statement, the Preliminary Prospectus and the Prospectus; and the Company has filed publicly on EDGAR at least 15 calendar days prior to any "road show" (as defined in Rule 433 under the Act), any confidentially submitted registration statement and registration statement amendments relating to the offer and sale of the Offered Shares.

(oo) ***Clinical Data and Regulatory Compliance.*** The preclinical tests and clinical trials, and other studies (collectively, "studies") that are described in, or the results of which are referred to in, the Registration Statement, the Time of Sale Prospectus or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures and all applicable laws and regulations, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, 312 and 812; each

description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company has no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Time of Sale Prospectus or the Prospectus; the Company has made all such filings and obtained all such approvals as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "**Regulatory Agencies**"); the Company has not received any written notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or material modification of any clinical trials that are described or referred to in the Registration Statement, the Time of Sale Prospectus or the Prospectus; and the Company has operated and currently is in compliance in all material respects with all applicable rules and regulations of the Regulatory Agencies.

(pp) ***No Rights to Purchase Preferred Stock.*** The issuance and sale of the Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of preferred stock of the Company.

(qq) ***No Rated Securities.*** There are no debt securities or preferred stock of, or guaranteed by, the Company that are rated by a "nationally recognized statistical rating organization" as that term is used in Rule 15c3-1(c)(2)(vi)(F) under the Exchange Act.

(rr) ***Cybersecurity***. There has been no security breach or other compromise of or relating to any of the information technology and computer systems, networks, hardware, software, data (including the data of its customers, employees, suppliers, vendors and any third party data maintained by or on behalf of the Company), equipment or technology owned, held or used by or for the Company (collectively, the "**IT Systems and Data**"), except for those that have been remedied without material cost or liability or the duty to notify any other person, nor are there any incidents under internal review or investigations relating to the same and (y) the Company has not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to the IT Systems and Data; (ii) the Company is presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to (x) the collection, use, transfer, storage, protection, disposal and/or disclosure of personally identifiable information collected from or provided by third parties, (y) the privacy and security of the IT Systems and Data and (z) the protection of the IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of this clause (ii), individually or in the aggregate, have a Material Adverse Effect; and (iii) the Company has taken commercially reasonable steps to protect the IT Systems and Data, including by implementing backup, security and disaster recovery plans, procedures and technology consistent with industry standards and practices.

(ss) ***Recognition of the U.S. Special Resolution Regimes.***

(i) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(ii) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

(iii) Definitions. For purposes of this paragraph:

"BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).

"Covered Entity" means any of the following:

(i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);

(ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or

(iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

"Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

"U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

Any certificate signed by any officer of the Company and delivered to any Underwriter or to counsel for the Underwriters in connection with the offering, or the purchase and sale, of the Offered Shares shall be deemed a representation and warranty by the Company (and not by such officer in his or her personal capacity) to each Underwriter as to the matters covered thereby.

The Company has a reasonable basis for making each of the representations set forth in this Section 1. The Company acknowledges that the Underwriters and, for purposes of the opinions to be delivered pursuant to Section 6 hereof, counsel to the Company and counsel to the Underwriters, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 2. Purchase, Sale and Delivery of the Offered Shares.

(a) ***The Firm Shares*.** Upon the terms herein set forth, the Company agrees to issue and sell to the several Underwriters an aggregate of [●] Firm Shares. On the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Underwriters agree, severally and not jointly, to purchase from the Company the respective number of Firm Shares set forth opposite their names on Schedule A. The purchase price per Firm Share to be paid by the several Underwriters to the Company shall be $[●] per share.

(b) ***The First Closing Date.*** Delivery of certificates for the Firm Shares to be purchased by the Underwriters and payment therefor shall be made at the offices of Wilmer Cutler Pickering Hale and Dorr LLP (or such other place as may be agreed to by the Company and the Representatives) at 9:00 a.m. New York City time, on [●], 2019, or such other time and date not later than 1:30 p.m. New York City time, on [●], 2019 as the Representatives shall designate by notice to the Company (the time and date of such closing are called the "**First Closing Date**"). The Company hereby acknowledges that circumstances under which the Representatives may provide notice to postpone the First Closing Date as originally scheduled include, but are not limited to, any determination by the Company or the Representatives to recirculate to the public copies of an amended or supplemented Prospectus or a delay as contemplated by the provisions of Section 11.

(c) ***The Optional Shares; Option Closing Date.*** In addition, on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to an aggregate of [●] Optional Shares from the Company at the purchase price per share to be paid by the Underwriters for the Firm Shares, less an amount per share equal to any dividend or distribution declared by the Company and payable on the Firm Shares but not payable on Optional Shares. The option granted hereunder may be exercised at any time and from time to time in whole or in part upon notice by the Representatives to the Company, which notice may be given at any time within 30 days from the date of this Agreement. Such notice shall set forth (i) the aggregate number of Optional Shares as to which the Underwriters are exercising the option and (ii) the time, date and place at which certificates for the Optional Shares will be delivered (which time and date may be simultaneous with, but not earlier than, the First Closing Date; and in the event that such time and date are simultaneous with the First Closing Date, the term "**First Closing Date**" shall refer to the time and date of delivery of certificates for the Firm Shares and such Optional Shares). Any such time and date of delivery, if subsequent to the First Closing Date, is called an "**Option Closing Date**," shall be determined by the Representatives and shall not be earlier than three or later than five full business days after delivery of such notice of exercise. If any Optional Shares are to be purchased, each Underwriter agrees, severally and not jointly, to purchase the number of Optional Shares (subject to such adjustments to eliminate fractional shares as the Representatives may determine) that bears the same proportion to the total number of Optional Shares to be purchased as the number of Firm Shares set forth on Schedule A opposite the name of such Underwriter bears to the total number of Firm Shares. The Representatives may cancel the option at any time prior to its expiration by giving written notice of such cancellation to the Company.

(d) ***Public Offering of the Offered Shares.*** The Representatives hereby advise the Company that the Underwriters intend to offer for sale to the public, initially on the terms set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, their respective portions of the Offered Shares as soon after this Agreement has been executed and the Registration Statement has been declared effective as the Representatives, in their sole judgment, have determined is advisable and practicable.

(e) ***Payment for the Offered Shares.*** (i) Payment for the Offered Shares shall be made at the First Closing Date (and, if applicable, at each Option Closing Date) by wire transfer of immediately available funds to the order of the Company.

(ii) It is understood that the Representatives have been authorized, for their own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Shares and any Optional Shares the Underwriters have agreed to purchase. Each of Jefferies and SVB Leerink, individually and not as the Representatives of the Underwriters, may (but shall not be obligated to) make payment for any Offered Shares to be purchased by any Underwriter whose funds shall not have been received by the Representatives by the First Closing Date or the applicable Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

(f) ***Delivery of the Offered Shares.*** The Company shall deliver, or cause to be delivered through the book entry facilities of the Depository Trust Company ("**DTC**") to the Representatives for the accounts of the several Underwriters the Firm Shares at the First Closing Date, against release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Company shall also deliver, or cause to be delivered, through the book entry facilities of DTC, to the Representatives for the accounts of the several Underwriters, the Optional Shares the Underwriters have agreed to purchase at the First Closing Date or the applicable Option Closing Date, as the case may be, against the release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Offered Shares shall be delivered to such accounts and in such denominations as the Representatives shall have requested at least two full business days prior to the First Closing Date (or the applicable Option Closing Date, as the case may be) and shall be made available for inspection on the business day preceding the First Closing Date (or the applicable Option Closing Date, as the case may be) at a location in New York City as the Representatives may designate. Time shall be of the essence, and delivery at the time and place specified in this Agreement is a further condition to the obligations of the Underwriters.

Section 3. Additional Covenants of the Company.

The Company further covenants and agrees with each Underwriter as follows:

(a) ***Delivery of Registration Statement, Time of Sale Prospectus and Prospectus.*** The Company shall furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) ***Representatives' Review of Proposed Amendments and Supplements.*** During the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), the Company (i) will furnish to the Representatives for review, a reasonable period of time prior to the proposed time of filing of any proposed amendment or supplement to the Registration Statement, a copy of each such amendment or supplement and (ii) will not amend or supplement the Registration Statement without the Representatives' prior written consent, which consent shall not be unreasonably withheld. Prior to amending or supplementing any preliminary prospectus, the Time of Sale Prospectus or the Prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the time of filing or use of the proposed amendment or supplement, a copy of each such proposed amendment or supplement. The Company shall not file or use any such proposed amendment or supplement without the Representatives' prior written consent, which consent shall not be unreasonably withheld. The Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) ***Free Writing Prospectuses.*** The Company shall furnish to the Representatives for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto prepared by or on behalf of, used by, or referred to by the Company, and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Representatives' prior written consent, which consent shall not be unreasonably withheld. The Company shall furnish to each Underwriter, without charge, as many copies of any free writing prospectus prepared by or on behalf of, used by or referred to by the Company as such Underwriter may reasonably request. If at any time when a prospectus is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172

under the Securities Act or any similar rule) in connection with sales of the Offered Shares (but in any event if at any time through and including the First Closing Date) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, as the case may be; *provided, however*, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus, and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Representatives' prior written consent, which consent shall not be unreasonably withheld.

(d) ***Filing of Underwriter Free Writing Prospectuses.*** The Company shall not take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been required to file thereunder.

(e) ***Amendments and Supplements to Time of Sale Prospectus.*** If the Time of Sale Prospectus is being used to solicit offers to buy the Offered Shares at a time when the Prospectus is not yet available to prospective purchasers, and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus so that the Time of Sale Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, the Company shall (subject to Section 3(b) and Section 3(c) hereof) promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the information contained in the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) ***Certain Notifications and Required Actions*****.** After the date of this Agreement, the Company shall promptly advise the Representatives in writing of: (i) the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus; (iii) the time and date that any post-effective amendment to the Registration Statement becomes effective; and (iv) the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus or the Prospectus or of any order preventing or suspending the use of any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus,

or of any proceedings to remove, suspend or terminate from listing or quotation the Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with all applicable provisions of Rule 424(b), Rule 433 and Rule 430A under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(g) ***Amendments and Supplements to the Prospectus and Other Securities Act Matters.*** During the Prospectus Delivery Period, if any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading, or if in the opinion of the Representatives or counsel for the Underwriters it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, the Company agrees (subject to Section 3(b) and Section 3(c)) hereof to promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law. Neither the Representatives' consent to, nor delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 3(b) or Section 3(c). As used herein, the term "**Prospectus Delivery Period**" means such period of time after the first date of the public offering of the Shares as in the opinion of counsel for the Underwriters a prospectus relating to the Shares is required by law to be delivered (or required to be delivered but for Rule 172 under the Securities Act) in connection with sales of the Shares by any Underwriter or dealer.

(h) ***Blue Sky Compliance*****.** The Company shall cooperate with the Representatives and counsel for the Underwriters to qualify or register the Offered Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws (or other foreign laws) of those jurisdictions designated by the Representatives, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Offered Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Representatives promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Offered Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof at the earliest possible moment.

(i) ***Use of Proceeds*****.** The Company shall apply the net proceeds from the sale of the Offered Shares sold by it in the manner described under the caption "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(j) ***Transfer Agent*****.** The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(k) ***Earnings Statement*.** The Company will make generally available to its security holders and to the Representatives as soon as practicable an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company commencing after the date of this Agreement that will satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(l) ***Continued Compliance with Securities Laws*.** The Company will comply with the Securities Act and the Exchange Act so as to permit the completion of the distribution of the Offered Shares as contemplated by this Agreement**,** the Registration Statement, the Time of Sale Prospectus and the Prospectus. Without limiting the generality of the foregoing, the Company will, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), file on a timely basis with the Commission and the NASDAQ all reports and documents required to be filed under the Exchange Act.

(m) ***Listing*.** The Company will use its best efforts to list, subject to notice of issuance, the Offered Shares on the NASDAQ.

(n) ***Company to Provide Copy of the Prospectus in Form That May be Downloaded from the Internet*.** If requested by the Representatives, the Company shall cause to be prepared and delivered, at its expense, within the time period a Prospectus is required by the rules of the Commission to be filed, to the Representatives or any other Underwriter with the consent of the Representatives, an "**electronic Prospectus**" to be used by the Underwriters in connection with the offering and sale of the Offered Shares. As used herein, the term "**electronic Prospectus**" means a form of Time of Sale Prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, satisfactory to the Representatives, that may be transmitted electronically by the Representatives and the other Underwriters to offerees and purchasers of the Offered Shares; (ii) it shall disclose the same information as the paper Time of Sale Prospectus, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic Prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, satisfactory to Jefferies, that will allow investors to store and have continuously ready access to the Time of Sale Prospectus at any future time, without charge to investors (other than any fee charged for subscription to the Internet as a whole and for on-line time). The Company hereby confirms that it has included or will include in the Prospectus filed pursuant to EDGAR or otherwise with the Commission and in the Registration Statement at the time it was declared effective an undertaking that, upon receipt of a request by an investor or his or her representative, the Company shall transmit or cause to be transmitted promptly, without charge, a paper copy of the Time of Sale Prospectus.

(o) ***Agreement Not to Offer or Sell Additional Shares*.** During the period commencing on and including the date hereof and continuing through and including the 90th day following the date of the Prospectus (such period being referred to herein as the "**Lock-up Period**"), the Company will not, without the prior written consent of the Representatives (which consent may be withheld in their sole discretion), directly or indirectly: (i) sell, offer to sell, contract to sell or lend any Shares or Related Securities (as defined below); (ii) effect any short sale, or establish or increase any "put equivalent position" (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any "call equivalent position" (as defined in Rule 16a-1(b) under the Exchange Act) of any Shares or Related Securities; (iii) pledge, hypothecate or grant any security interest in any Shares or Related Securities; (iv) in any other way transfer or dispose of any Shares or Related Securities; (v) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or

otherwise; (vi) announce the offering of any Shares or Related Securities; (vii) file any registration statement under the Securities Act in respect of any Shares or Related Securities (other than as contemplated by this Agreement with respect to the Offered Shares); or (viii) publicly announce the intention to do any of the foregoing; *provided*, *however*, that the Company may (A) effect the transactions contemplated hereby, (B) issue Shares or options to purchase Shares, or issue Shares upon exercise of options or warrants, pursuant to any stock option, warrants, stock bonus or other stock plan or arrangement described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, provided the recipients thereof provide to the Representatives a signed Lock-Up Agreement substantially in the form of Exhibit A hereto, (C) file a registration statement on Form S-8 with respect to any securities issued or issuable pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, (D) assist any stockholder of the Company in the establishment of a trading plan by such stockholder pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock; provided (x) that such plan does not provide for the transfer of shares of Common Stock during the Lock-up Period, (y) the establishment of such plan does not require or otherwise result in any public filing or other public announcement of such plan during such Lock-up Period and (z) such plan is otherwise permitted to be implemented during the Lock-up Period pursuant to the terms of the lock-up agreement between such stockholder and the Underwriters in connection with the offering of the Offered Shares, (E) issue shares of Common Stock in connection with the acquisition by the Company of the securities, business, property or other assets of another person or business entity or pursuant to any employee benefit plan assumed by the Company in connection with any such acquisition or (F) issue shares of Common Stock, warrants, or restricted stock awards or of options to purchase shares of Common Stock, in each case, in connection with joint ventures, commercial relationships, lending relationships or other strategic transactions; provided that, in the case of immediately preceding clauses (E) and (F), (x) the aggregate number of restricted stock awards and shares of Common Stock issued in connection with, or issuable pursuant to the exercise of any options or warrants issued in connection with, all such acquisitions and other transactions does not exceed 5% of the aggregate number of shares of Common Stock outstanding immediately following the offering of the Offered Shares pursuant to this Agreement and (y) the recipients of the shares of Common Stock or Related Securities provide to the Representatives a signed Lock-Up Agreement in the form set forth as Exhibit A hereto. For purposes of the foregoing, "**Related Securities**" shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for, or convertible into, Shares.

(p) ***Future Reports to the Representatives.*** During the period of five years hereafter for so long as the Company is subject to the reporting requirements of the Exchange Act during that time, the Company will furnish to the Representatives, c/o Jefferies, at 520 Madison Avenue, New York, New York 10022, Attention: Global Head of Syndicate and c/o SVB Leerink, at 1301 Avenue of the Americas, 12th Floor, New York, New York 10019, Attention: Syndicate Department: (i) as soon as practicable after the end of each fiscal year, copies of the Annual Report of the Company containing the balance sheet of the Company as of the close of such fiscal year and statements of income, stockholders' equity and cash flows for the year then ended and the opinion thereon of the Company's independent public or certified public accountants; (ii) as soon as practicable after the filing or furnishing thereof, copies of each proxy statement, Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other report filed by the Company with the Commission or any securities exchange; and (iii) as soon as available, copies of any report or communication of the Company furnished or made available generally to holders of its capital stock; *provided*, *however*, that the requirements of this Section 3(p) shall be satisfied to the extent that such reports, statement, communications, financial statements or other documents are available on EDGAR.

(q) ***Investment Limitation.*** The Company shall not invest or otherwise use the proceeds received by the Company from its sale of the Offered Shares in such a manner as would require the Company to register as an investment company under the Investment Company Act.

(r) ***No Stabilization or Manipulation; Compliance with Regulation M.*** The Company will not take, and will ensure that no affiliate of the Company will take, directly or indirectly, without giving effect to activities by the Underwriters, any action designed to or that might reasonably be expected to cause or result in stabilization or manipulation of the price of the Shares or any reference security with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply with all applicable provisions of Regulation M.

(s) ***Enforce Lock-Up Agreements.*** During the Lock-up Period, the Company will enforce all agreements between the Company and any of its security holders that restrict or prohibit, expressly or in operation, the offer, sale or transfer of Shares or Related Securities or any of the other actions restricted or prohibited under the terms of the form of Lock-up Agreement. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such "lock-up" agreements for the duration of the periods contemplated in such agreements, including, without limitation, "lock-up" agreements entered into by the Company's officers and directors pursuant to Section 6(i) hereof.

(t) ***Company to Provide Interim Financial Statements.*** Prior to the First Closing Date and each applicable Option Closing Date, the Company will furnish the Underwriters, as soon as they have been prepared by or are available to the Company, a copy of any unaudited interim financial statements of the Company for any period subsequent to the period covered by the most recent financial statements appearing in the Registration Statement and the Prospectus.

(u) ***Amendments and Supplements to Permitted Section 5(d)Communications***. If at any time following the distribution of any Permitted Section 5(d) Communication, during the Prospectus Delivery Period, there occurred or occurs an event or development as a result of which such Permitted Section 5(d) Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Permitted Section 5(d) Communication to eliminate or correct such untrue statement or omission.

(v) ***Emerging Growth Company Status***. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) the time when a prospectus relating to the Offered Shares is not required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) and (ii) the expiration of the Lock-Up Period (as defined herein).

The Representatives, on behalf of the several Underwriters, may, in their sole discretion, waive in writing the performance by the Company of any one or more of the foregoing covenants or extend the time for their performance.

Section 4. Payment of Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Offered Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all necessary issue, transfer and other stamp taxes in

connection with the issuance and sale of the Offered Shares to the Underwriters, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Time of Sale Prospectus, the Prospectus, each free writing prospectus prepared by or on behalf of, used by, or referred to by the Company, and each preliminary prospectus, each Permitted Section 5(d) Communication, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, reasonable and documented attorneys' fees and expenses incurred by the Company or the Underwriters in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Offered Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Representatives, preparing and printing a "Blue Sky Survey" or memorandum and a "Canadian wrapper", and any supplements thereto, advising the Underwriters of such qualifications, registrations and exemptions, (vii) the costs, fees and expenses incurred by the Underwriters in connection with determining their compliance with the rules and regulations of FINRA related to the Underwriters' participation in the offering and distribution of the Offered Shares, including any related filing fees and the legal fees of, and disbursements by, counsel to the Underwriters, (viii) the costs and expenses of the Company relating to investor presentations on any "road show", any Permitted Section 5(d) Communication or any Section 5(d) Oral Communication undertaken in connection with the offering of the Offered Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and any such consultants, and 50% of the cost of any aircraft chartered in connection with the road show, with the other 50% being paid by the Underwriters, (ix) the fees and expenses associated with listing the Offered Shares on the NASDAQ, and (x) all other fees, costs and expenses of the nature referred to in Item 13 of Part II of the Registration Statement; provided that the fees and expenses of counsel with respect to clauses (vi) and (vii) above shall not exceed $40,000 in the aggregate. Except as provided in this Section 4 or in Section 7, Section 9 or Section 10 hereof, the Underwriters shall pay their own expenses, including the fees and disbursements of their counsel and their own travel and lodging expenses.

Section 5. Covenant of the Underwriters. Each Underwriter severally and not jointly covenants with the Company not to take any action that would result in the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not, but for such actions, be required to be filed by the Company under Rule 433(d).

Section 6. Conditions of the Obligations of the Underwriters. The respective obligations of the several Underwriters hereunder to purchase and pay for the Offered Shares as provided herein on the First Closing Date and, with respect to the Optional Shares, each Option Closing Date, shall be subject to the accuracy of the representations and warranties on the part of the Company set forth in Section 1 hereof as of the date hereof and as of the First Closing Date as though then made and, with respect to the Optional Shares, as of each Option Closing Date as though then made, to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) ***Comfort Letter*****.** On the date hereof, the Representatives shall have received from KPMG LLP, independent registered public accountants for the Company, a letter dated the date hereof addressed to the Underwriters, in form and substance satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus, and each free writing prospectus, if any.

(b) ***Compliance with Registration Requirements; No Stop Order; No Objection from FINRA.***

(i) The Company shall have filed the Prospectus with the Commission (including the information required by Rule 430A under the Securities Act) in the manner and within the time period required by Rule 424(b) under the Securities Act; or the Company shall have filed a post-effective amendment to the Registration Statement containing the information required by such Rule 430A, and such post-effective amendment shall have become effective.

(ii) No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment to the Registration Statement shall be in effect, and no proceedings for such purpose shall have been instituted or, to the knowledge of the Company, threatened by the Commission.

(iii) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(c) ***No Material Adverse Change.*** For the period from and after the date of this Agreement and through and including the First Closing Date and, with respect to any Optional Shares purchased after the First Closing Date, each Option Closing Date, in the judgment of the Representatives there shall not have occurred any Material Adverse Change.

(d) ***Opinion of Counsel for the Company.*** On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of Goodwin Procter LLP, counsel for the Company, dated as of such date, in form and substance satisfactory to the Underwriters, which opinion shall include opinions with respect to regulatory matters.

(e) ***Opinion of Intellectual Property Counsel for the Company.*** On each of the First Closing Date and each Option Closing Date, the Representatives shall have received the opinion of Norton Rose Fulbright US LLP, counsel for the Company with respect to intellectual property matters, dated as of such date, in form and substance satisfactory to the Underwriters, and to such further effect as the Representatives shall reasonably request.

(f) ***Opinion of Counsel for the Underwriters.*** On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of Wilmer Cutler Pickering Hale and Dorr LLP, counsel for the Underwriters in connection with the offer and sale of the Offered Shares, in form and substance satisfactory to the Underwriters, dated as of such date, with executed copies for each of the other Underwriters named on the Prospectus cover page.

(g) ***Officers' Certificate.*** On each of the First Closing Date and each Option Closing Date, the Representatives shall have received a certificate executed by the Chief Executive Officer or President of the Company and the Chief Financial Officer of the Company, on behalf of the Company and not in their individual capacities, dated as of such date, to the effect set forth in Section 6(b)(ii) and further to the effect that:

(i) for the period from and including the date of this Agreement through and including such date, there has not occurred any Material Adverse Change;

(ii) the representations, warranties and covenants of the Company set forth in Section 1 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such date; and

(iii) the Company has complied with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such date.

(h) ***Bring-down Comfort Letter.*** On each of the First Closing Date and each Option Closing Date the Representatives shall have received from KPMG LLP, independent registered public accountants for the Company, a letter dated such date, in form and substance satisfactory to the Representatives, which letter shall: (i) reaffirm the statements made in the letter furnished by them pursuant to Section 6(a), except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be; and (ii) cover certain financial information contained in the Prospectus.

(i) ***Lock-Up Agreements.*** On or prior to the date hereof, the Company shall have furnished to the Representatives an agreement in the form of Exhibit A hereto from each of the persons listed on Exhibit B hereto, and each such agreement shall be in full force and effect on each of the First Closing Date and each Option Closing Date.

(j) ***Certificate of Chief Financial Officer***. On the date hereof, the First Closing Date and each Option Closing Date, the Representatives shall have received a written certificate of the chief financial officer of the Company, dated such date, in form and substance satisfactory to the Representatives, which letter shall cover certain financial information contained in the Registration Statement and the Prospectus, as applicable.

(k) ***Rule 462(b) Registration Statement.*** In the event that a Rule 462(b) Registration Statement is filed in connection with the offering contemplated by this Agreement, such Rule 462(b) Registration Statement shall have been filed with the Commission on the date of this Agreement and shall have become effective automatically upon such filing.

(l) ***Approval of Listing***. At the First Closing Date, the Offered Shares shall have been approved for listing on the NASDAQ, subject only to official notice of issuance.

(m) ***Additional Documents***. On or before each of the First Closing Date and each Option Closing Date, the Representatives and counsel for the Underwriters shall have received such information, documents and opinions as they may reasonably request for the purposes of enabling them to pass upon the issuance and sale of the Offered Shares as contemplated herein, or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the conditions or agreements, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Shares as contemplated herein and in connection with the other transactions contemplated by this Agreement shall be satisfactory in form and substance to the Representatives and counsel for the Underwriters.

If any condition specified in this Section 6 is not satisfied when and as required to be satisfied, this Agreement may be terminated by the Representatives by notice from the Representatives to the Company at any time on or prior to the First Closing Date and, with respect to the Optional Shares, at any time on or prior to the applicable Option Closing Date, which termination shall be without liability on the part of any party to any other party, except that Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination.

Section 7. Reimbursement of Underwriters' Expenses. If this Agreement is terminated by the Representatives pursuant to Section 6, Section 11 or Section 12, or if the sale to the Underwriters of the Offered Shares on the First Closing Date is not consummated because of any refusal, inability or failure on the part of the Company to perform any agreement herein or to comply with any provision hereof, the Company agrees to reimburse the Representatives and the other Underwriters (or such Underwriters as have terminated this Agreement with respect to themselves), severally, upon demand for all out-of-pocket expenses that shall have been reasonably incurred by the Representatives and the Underwriters in connection with the proposed purchase and the offering and sale of the Offered Shares, including, but not limited to, fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges; provided, however, that in the event any such termination is effected after the First Closing Date, but prior to any Option Closing Date with respect to the purchase of any Optional Shares, the Company shall only reimburse the Underwriters for all of their out-of-pocket expenses reasonably incurred after the First Closing Date in connection with the proposed purchase of any such Optional Shares.

Section 8. Effectiveness of this Agreement. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

Section 9. Indemnification.

(a) ***Indemnification of the Underwriters*****.** The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors, officers, employees and agents, and each person, if any, who controls any Underwriter within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which such Underwriter or such affiliate, director, officer, employee, agent or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (A) (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing), or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading, or (B) the violation of any laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold; and to reimburse each Underwriter and each such affiliate, director, officer, employee, agent and controlling person for any and all reasonable and documented expenses (including the fees and disbursements of counsel) as such expenses are incurred by such Underwriter or such affiliate, director, officer, employee, agent or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; *provided*, *however*, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company by the Representatives in writing expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any such free writing prospectus, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information consists of the information described in Section 9(b) below. The indemnity agreement set forth in this Section 9(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) ***Indemnification of the Company, its Directors and Officers***. Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, against any loss, claim, damage, liability or expense, as incurred, to which the Company, or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus, that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433 of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement) or the omission or alleged omission to state therein a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, such preliminary prospectus, the Time of Sale Prospectus, such free writing prospectus, such Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement), in reliance upon and in conformity with information relating to such Underwriter furnished to the Company by the Representatives in writing expressly for use therein; and to reimburse the Company, or any such director, officer or controlling person for any and all expenses (including the fees and disbursements of counsel) as such expenses are incurred by the Company, or any such director, officer or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The Company hereby acknowledges that the only information that the Representatives have furnished to the Company expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing) are the first sentence of the 3rd paragraph under the caption “Underwriting” regarding market making, the concession and reallowance figures in the first sentence of the 5th paragraph under the caption “Underwriting,” the first sentence of the 14th paragraph under the caption “Underwriting” regarding stabilizing activities and the first sentence of the 20th paragraph under the caption “Underwriting” regarding internet distribution in the Preliminary Prospectus and the Prospectus. The indemnity agreement set forth in this Section 9(b) shall be in addition to any liabilities that each Underwriter may otherwise have.

(c) ***Notifications and Other Indemnification Procedures*****.** Promptly after receipt by an indemnified party under this Section 9 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 9, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve the indemnifying party from any liability which it may have to any indemnified party to the extent the indemnifying party is not materially prejudiced as a proximate result of such failure and shall not in any event relieve the indemnifying party from any liability that it may have otherwise than on account of this indemnity agreement. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly

with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; *provided*, *however*, that if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 9 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate law firm (together with one law firm as local counsel in each relevant jurisdiction and special counsel), representing the indemnified parties who are parties to such action), which counsel (together with one law firm as local counsel in each relevant jurisdiction and special counsel) for the indemnified parties shall be selected by the Representatives (in the case of counsel for the indemnified parties referred to in Section 9(a) above) or by the Company (in the case of counsel for the indemnified parties referred to in Section 9(b) above)) or (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) ***Settlements.*** The indemnifying party under this Section 9 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 9(c) hereof, the indemnifying party shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and does not include an admission of fault or culpability or a failure to act by or on behalf of such indemnified party.

Section 10. **Contribution**. If the indemnification provided for in Section 9 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the

Underwriters, on the other hand, from the offering of the Offered Shares pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Offered Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total proceeds from the offering of the Offered Shares pursuant to this Agreement (before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth on the front cover page of the Prospectus, bear to the aggregate initial public offering price of the Offered Shares as set forth on such cover. The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriters, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 9(c), any reasonable and documented legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 9(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 10; *provided, however*, that no additional notice shall be required with respect to any action for which notice has been given under Section 9(c) for purposes of indemnification.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 10 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 10.

Notwithstanding the provisions of this Section 10, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by such Underwriter in connection with the Offered Shares underwritten by it and distributed to the public. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute pursuant to this Section 10 are several, and not joint, in proportion to their respective underwriting commitments as set forth opposite their respective names on Schedule A. For purposes of this Section 10, each affiliate, director, officer, employee and agent of an Underwriter and each person, if any, who controls an Underwriter within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 11. Default of One or More of the Several Underwriters. If, on the First Closing Date or any Option Closing Date any one or more of the several Underwriters shall fail or refuse to purchase Offered Shares that it or they have agreed to purchase hereunder on such date, and the aggregate number of Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase does not exceed 10% of the aggregate number of the Offered Shares to be purchased on such date, the Representatives may make arrangements satisfactory to the Company for the purchase of

such Offered Shares by other persons, including any of the Underwriters, but if no such arrangements are made by such date, the other Underwriters shall be obligated, severally and not jointly, in the proportions that the number of Firm Shares set forth opposite their respective names on Schedule A bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as may be specified by the Representatives with the consent of the non-defaulting Underwriters, to purchase the Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date. If, on the First Closing Date or any Option Closing Date any one or more of the Underwriters shall fail or refuse to purchase Offered Shares and the aggregate number of Offered Shares with respect to which such default occurs exceeds 10% of the aggregate number of Offered Shares to be purchased on such date, and arrangements satisfactory to the Representatives and the Company for the purchase of such Offered Shares are not made within 48 hours after such default, this Agreement shall terminate without liability of any party to any other party except that the provisions of Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination. In any such case either the Representatives or the Company shall have the right to postpone the First Closing Date or the applicable Option Closing Date, as the case may be, but in no event for longer than seven days in order that the required changes, if any, to the Registration Statement and the Prospectus or any other documents or arrangements may be effected.

As used in this Agreement, the term "**Underwriter**" shall be deemed to include any person substituted for a defaulting Underwriter under this Section 11. Any action taken under this Section 11 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

Section 12. Termination of this Agreement. Prior to the purchase of the Firm Shares by the Underwriters on the First Closing Date, this Agreement may be terminated by the Representatives by notice given to the Company if at any time: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the NASDAQ, or trading in securities generally on either the NASDAQ or the NYSE shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges; (ii) a general banking moratorium shall have been declared by any of federal, New York, Illinois or Texas authorities; (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Representatives is material and adverse and makes it impracticable to market the Offered Shares in the manner and on the terms described in the Time of Sale Prospectus or the Prospectus or to enforce contracts for the sale of securities; (iv) in the judgment of the Representatives there shall have occurred any Material Adverse Change; or (v) the Company shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Representatives may interfere materially with the conduct of the business and operations of the Company regardless of whether or not such loss shall have been insured. Any termination pursuant to this Section 12 shall be without liability on the part of (a) the Company to any Underwriter, except that the Company shall be obligated to reimburse the expenses of the Representatives and the Underwriters pursuant to Section 4 or Section 7 hereof or (b) any Underwriter to the Company; *provided, however,* that the provisions of Section 9 and Section 10 shall at all times be effective and shall survive such termination.

Section 13. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering contemplated hereby and the

process leading to such transaction, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) and no Underwriter has any obligation to the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

Section 14. Representations and Indemnities to Survive Delivery. The respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the several Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Offered Shares sold hereunder and any termination of this Agreement.

Section 15. Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Representatives:

Jefferies LLC
520 Madison Avenue
New York, New York 10022
Facsimile: (646) 619-4437
Attention: General Counsel

SVB Leerink LLC
1301 Avenue of the Americas, 12th Floor
New York, New York 10019
Facsimile: (646) 499-7051
Attention: Stuart Nayman

with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, New York 10007
Facsimile: (212) 230-8888
Attention: Lisa Firenze

If to the Company:

Xeris Pharmaceuticals, Inc.
180 North LaSalle Street
Suite 1800
Chicago, IL 60601
Facsimile: (312) 276-4497
Attention: Barry Deutsch

with a copy to: Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Facsimile: (617) 801-8864
Attention: Joseph Theis

Any party hereto may change the address for receipt of communications by giving written notice to the others.

Section 16. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, including any substitute Underwriters pursuant to Section 11 hereof, and to the benefit of the affiliates, directors, officers, employees, agents and controlling persons referred to in Section 9 and Section 10, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "**successors**" shall not include any purchaser of the Offered Shares as such from any of the Underwriters merely by reason of such purchase.

Section 17. Partial Unenforceability. The invalidity or unenforceability of any section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph or provision hereof. If any section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

Section 18. Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("**Related Proceedings**") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a "**Related Judgment**"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

Section 19. General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 9 and the contribution provisions of Section 10, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Section 9 and Section 10 hereof fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, each free writing prospectus and the Prospectus (and any amendments and supplements to the foregoing), as contemplated by the Securities Act and the Exchange Act.

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

XERIS PHARMACEUTICALS, INC.

By: ______________________________
Name:
Title:

The foregoing Underwriting Agreement is hereby confirmed and accepted by the Representatives in New York, New York as of the date first above written.

JEFFERIES LLC
SVB LEERINK LLC
Acting individually and as Representatives
of the several Underwriters named in
the attached Schedule A.

JEFFERIES LLC

By: ______________________________
Name:
Title:

SVB LEERINK LLC

By: ______________________________
Name:
Title:

Schedule A

Underwriters	Number of Firm Shares to be Purchased
Jefferies LLC	[●]
SVB Leerink LLC	[●]
RBC Capital Markets, LLC	[●]
Mizuho Securities USA LLC	[●]
Total	[●]

Schedule B

Free Writing Prospectuses Included in the Time of Sale Prospectus

[None.]

Schedule C

Permitted Section 5(d) Communications

[None.]

Exhibit A

Form of Lock-up Agreement

[Date]

Jefferies LLC
Leerink Partners LLC
As Representatives of the Several Underwriters

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

and

SVB Leerink LLC
1301 Avenue of the Americas, 12th Floor
New York, NY 10019

RE: Xeris Pharmaceuticals, Inc. (the "**Company**")

Ladies & Gentlemen:

The undersigned is an executive officer or director of the Company or owner of shares of common stock, par value $0.0001 per share, of the Company ("**Shares**") or of securities convertible into or exchangeable or exercisable for Shares. The Company proposes to conduct a public offering of Shares (the "**Offering**") for which Jefferies LLC ("**Jefferies**") and SVB Leerink LLC ("**Leerink**") will act as the representatives of the several underwriters. The undersigned recognizes that the Offering will benefit each of the Company and the undersigned. The undersigned acknowledges that the underwriters are relying on the representations and agreements of the undersigned contained in this letter agreement in conducting the Offering and, at a subsequent date, in entering into an underwriting agreement (the "**Underwriting Agreement**") and other underwriting arrangements with the Company with respect to the Offering.

Annex A sets forth definitions for capitalized terms used in this letter agreement that are not defined in the body of this agreement. Those definitions are a part of this agreement.

In consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby agrees that, during the Lock-up Period, the undersigned will not (and will cause any Family Member not to), subject to the exceptions set forth in this letter agreement without the prior written consent of Jefferies and Leerink, which may withhold their consent in their sole discretion:

- Sell or Offer to Sell any Shares or Related Securities currently or hereafter owned either of record or beneficially (as defined in Rule 13d-3 under the Exchange Act) by the undersigned or such Family Member,

- enter into any Swap,
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any Shares or Related Securities, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or
- publicly announce any intention to do any of the foregoing.

The foregoing will not apply to the registration of the offer and sale of the Shares, and the sale of the Shares to the underwriters, in each case as contemplated by the Underwriting Agreement. In addition, the foregoing restrictions shall not apply to (a) the transfer of Shares or Related Securities by gift, or by will or intestate succession to a Family Member or to a trust whose beneficiaries consist exclusively of one or more of the undersigned and/or a Family Member, (b) pursuant to a court order in respect of, or by operation of law as a result of, a divorce, or (c) if the undersigned is a non-individual, transfer of Shares or Related Securities to any affiliate (as such term is defined in Rule 405 of the Securities Act), limited partners, general partners, limited liability company members, trust beneficiaries or stockholders of the undersigned, or, if the undersigned is a corporation, to any wholly owned subsidiary of such corporation, if, in any case, such transfer is not for value; provided, however, that for any of (a), (b) or (c), it shall be a condition to such transfer or disposition that:

- each transferee executes and delivers to Jefferies and Leerink an agreement in form and substance satisfactory to Jefferies and Leerink stating that such transferee is receiving and holding such Shares and/or Related Securities subject to the provisions of this letter agreement and agrees not to Sell or Offer to Sell such Shares and/or Related Securities, engage in any Swap or engage in any other activities restricted under this letter agreement except in accordance with this letter agreement (as if such transferee had been an original signatory hereto), and
- prior to the expiration of the Lock-up Period, no public disclosure or filing under the Exchange Act, other than any required filing on Schedule 13G, Schedule 13G/A or Form 13F, by any party to the transfer (donor, donee, transferor or transferee) shall be required, or made voluntarily, reporting a reduction in beneficial ownership of Shares in connection with such transfer unless the undersigned shall include a statement describing the transaction as being a transfer to any affiliate (as such term is defined in Rule 405 of the Securities Act).

Furthermore, notwithstanding the restrictions imposed by this letter agreement, the undersigned may (i) transfer Shares to the Company upon the exercise of options or warrants during the Lock-up Period to cover tax withholding obligations in connection with such exercise or for the primary purpose of paying the exercise price of options or warrants to acquire Shares, in each case pursuant to a stock option, stock bonus or other stock plan or arrangement or warrants existing as of the date hereof or described in the Prospectus (as defined in the Underwriting Agreement) and any Shares acquired upon such exercise shall remain subject to this letter agreement, *provided* that if the undersigned is required to file a report under the Exchange Act related thereto, such report shall include a statement to the effect that the filing relates to the "net" or "cashless" exercise of options to purchase shares of common stock for the purpose of exercising such options, including, if applicable, the payment of taxes due as a result of such exercise, (ii) establish a trading plan pursuant to Rule 10b5-1 of the Exchange Act, *provided* that no sales or other dispositions of Shares or Related Securities may occur under such plan during the Lock-up Period and no public announcement or filing under the Exchange Act regarding the establishment of such plan shall be required or made during the Lock-up Period, (iii) the transfer of the undersigned's Shares or Related Securities pursuant to a bona fide third-party offer for all outstanding voting stock of the Company, whether pursuant to a merger, tender offer or otherwise, to a third party or group of third parties, *provided*

that in the event that such merger, tender offer or other transaction is not consummated, such Shares or Related Securities held by the undersigned shall remain subject to the restrictions on transfer set forth herein, (iv) transfer or dispose of Shares or Related Securities acquired in open market transactions after the completion of the Offering, (v) transfer or dispose of Shares or Related Securities acquired in the Offering or (vi) transfers of Shares or Related Securities by the undersigned pursuant to sales in the public market undertaken by the undersigned under a trading plan pursuant to Rule 10b5-1 under the Exchange Act, *provided* that such trading plan shall have been in effect prior to the date hereof; *provided* that in the case of (i) and (vi) above, if the undersigned is required to make a filing under the Exchange Act reporting a reduction in beneficial ownership of Shares during the Lock-up Period, the undersigned shall include a statement describing the purpose of the transaction and/or that the sale was made pursuant to a trading plan pursuant to Rule 10b5-1 under the Exchange Act, *provided further*, that in the case of (iv) and (v) above, no public announcement or filing under the Exchange Act, other than any required filing on Schedule 13G, Schedule 13G/A or Form 13F, shall be required or voluntarily made by the undersigned in connection with such transfer during the Lock-up Period.

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any Company-directed Shares the undersigned may purchase or otherwise receive in the Offering (including pursuant to a directed share program).

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of Shares or Related Securities held by the undersigned and the undersigned's Family Members, if any, except in compliance with the foregoing restrictions.

With respect to the Offering only, the undersigned waives any registration rights relating to registration under the Securities Act of the offer and sale of any Shares and/or any Related Securities owned either of record or beneficially by the undersigned, including any rights to receive notice of the Offering.

The undersigned confirms that the undersigned has not, and has no knowledge that any Family Member has, directly or indirectly, taken any action designed to or that might reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale of the Shares. The undersigned will not, and will cause any Family Member not to take, directly or indirectly, any such action.

Whether or not the Offering occurs as currently contemplated or at all depends on market conditions and other factors. The Offering will only be made pursuant to the Underwriting Agreement, the terms of which are subject to negotiation between the Company and the underwriters.

This letter agreement shall automatically terminate and be of no further effect upon the earliest to occur, if any, of (i) Jefferies and Leerink, on the one hand, or the Company, on the other hand, advising the other party in writing, prior to the execution of the Underwriting Agreement, that it has determined not to proceed with the Offering, (ii) the termination of the Underwriting Agreement before the sale of Shares to the underwriters, (iii) the registration statement filed with the Securities and Exchange Commission with respect to the Offering is withdrawn, and (iv) February 28, 2019, in the event that the Underwriting Agreement has not been executed by such date (provided that the Company may by written notice to the undersigned prior to February 28, 2019, extend such date for a period of up to three additional months).

The undersigned hereby represents and warrants that the undersigned has full power, capacity and authority to enter into this letter agreement. This letter agreement is irrevocable and will be binding on the undersigned and the successors, heirs, personal representatives and assigns of the undersigned.

This letter agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

Signature

Printed Name of Person Signing

(Indicate capacity of person signing if signing as custodian or trustee, or on behalf of an entity)

Certain Defined Terms
Used in Lock-up Agreement

For purposes of the letter agreement to which this Annex A is attached and of which it is made a part:

- "**Call Equivalent Position**" shall have the meaning set forth in Rule 16a-1(b) under the Exchange Act.
- "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended.
- "**Family Member**" shall mean the spouse of the undersigned, an immediate family member of the undersigned or an immediate family member of the undersigned's spouse, in each case living in the undersigned's household or whose principal residence is the undersigned's household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or otherwise). "**Immediate family member**" as used above shall have the meaning set forth in Rule 16a-1(e) under the Exchange Act.
- "**Lock-up Period**" shall mean the period beginning on the date hereof and continuing through the close of trading on the date that is 90 days after the date of the Prospectus (as defined in the Underwriting Agreement).
- "**Put Equivalent Position**" shall have the meaning set forth in Rule 16a-1(h) under the Exchange Act.
- "**Related Securities**" shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for or convertible into Shares.
- "**Securities Act**" shall mean the Securities Act of 1933, as amended.
- "**Sell or Offer to Sell**" shall mean to:
    - sell, offer to sell, contract to sell or lend,
    - effect any short sale or establish or increase a Put Equivalent Position or liquidate or decrease any Call Equivalent Position
    - pledge, hypothecate or grant any security interest in, or
    - in any other way transfer or dispose of,

  in each case whether effected directly or indirectly.
- "**Swap**" shall mean any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise.

Capitalized terms not defined in this Annex A shall have the meanings given to them in the body of this lock-up agreement.

Exhibit B

Directors and Officers Signing Lock-Up Agreement

Directors:

BJ Bormann

Dawn Halkuff

Marla Persky

Jonathan Rigby

John Schmid

Jeffrey Sherman

Officers:

Paul Edick

Barry Deutsch

John Shannon

Steven Prestrelski

Ken Johnson

Beth Hecht

Exhibit 5.1

February 11, 2019

Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1810
Chicago, Illinois 60601

Re: Securities Registered under Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-1 (as amended or supplemented, the "Registration Statement") with the Securities and Exchange Commission in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offering by Xeris Pharmaceuticals, Inc., a Delaware corporation (the "Company") of up to 5,750,000 shares (the "Shares") of the Company's Common Stock, $0.0001 par value share, including 750,000 shares purchasable by the underwriters upon their exercise of an over-allotment option granted to the underwriters by the Company. The Shares are being sold to the several underwriters named in, and pursuant to, an underwriting agreement among the Company and such underwriters (the "Underwriting Agreement").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers of the Company.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that the Shares have been duly authorized and, upon issuance and delivery against payment therefor in accordance with the terms of the Underwriting Agreement, the Shares will be validly issued, fully paid and non-assessable.

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Goodwin Procter LLP

GOODWIN PROCTER LLP

Exhibit 10.12

XERIS PHARMACEUTICALS, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of the 10th day of June, 2018, between Xeris Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and Beth Hecht (the "Executive") and is effective as of the closing of the Company's first underwritten public offering of its equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date").

WHEREAS, the Company and the Executive are parties to an employment agreement, dated January 16, 2018 (the "Prior Agreement"); and

WHEREAS, the parties intend to replace the Prior Agreement with this Agreement, effective as of the Effective Date.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Executive's employment with the Company will continue to be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Executive shall serve as the General Counsel and Corporate Secretary of the Company, and shall have supervision and control over and responsibility for the day-to-day business and affairs of the Company and shall have such other powers and duties as may from time to time be prescribed by the Board of Directors of the Company (the "Board"), the Chief Executive Officer of the Company (the "CEO") or other authorized executive. The Executive shall devote approximately 30 hours per week to the business and affairs of the Company. Notwithstanding the foregoing, the Executive shall be permitted to (i) serve as an outside director on the Neos Therapeutics Inc. Board of Directors; (ii) continue to serve as a Managing Director and CLO & CAO of Auven Therapeutics, and (ii) serve on other boards of directors, with the approval of the Board, or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not materially interfere with the Executive's performance of her duties to the Company as provided in this Agreement.

(c) Location. The Executive shall perform her duties at her home office in Florida. The executive shall be available for travel for the performance of the Executive's job duties from time to time.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Executive's annual base salary shall be $273,000 and shall be proportionally increased in the event Executive increases her time commitment to the Company in excess of 30 hours per week. The Executive's base salary shall be reviewed annually by the Board or the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for executive officers.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Executive's initial target annual incentive compensation shall be 40 percent of her Base Salary (the "Target Annual Incentive Compensation"). Except as otherwise provided herein, to earn incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by her during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

(d) Other Benefits. During the Term, the Executive shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Vacations. During the Term, the Executive shall be entitled to paid vacation in accordance with the Company's policies and procedures. The Executive shall also be entitled to all paid holidays given by the Company to its executive officers.

3. Termination. During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon her death.

(b) Disability. The Company may terminate the Executive's employment if she is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such

certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by the Executive constituting a material act of misconduct in connection with the performance of her duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Executive of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Executive that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries or affiliates if she were retained in her position; (iii) continued non-performance by the Executive of her duties hereunder (other than by reason of the Executive's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non- performance from the CEO; (iv) a breach by the Executive of any of the provisions contained in Section 7 of this Agreement; (v) a material violation by the Executive of the Company's written employment policies; or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(d) Termination Without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate her employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Executive's responsibilities, authority or duties; (ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location at which the Executive provides services to the Company; or (iv) the material breach of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Executive terminates her employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(f) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(g) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by her death, the date of her death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company under Section 3(d), the date on which a Notice of Termination is given; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) without Good Reason, 30 days after the date on which a Notice of Termination is given, and (v) if the Executive's employment is terminated by the Executive under Section 3(e) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

4. Compensation Upon Termination.

(a) Termination Generally. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to her authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Executive's Date of Termination; and (ii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Executive with Good Reason. During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates her employment for Good Reason as provided in Section 3(e), then the Company shall pay the Executive her Accrued Benefit. In addition, subject to the Executive signing a separation agreement containing, among other provisions, a general release of claims in favor of the Company and related persons and entities, confidentiality, return of property and non-disparagement, in a form and manner satisfactory to the Company (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Executive an amount equal to 1.25 times the Executive's Base Salary (the "Severance Amount"). Notwithstanding the foregoing, if the Executive breaches any of the provisions contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease;

(ii) Reserved;

(iii) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Executive a monthly cash payment for 15 months or the Executive's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company; and

(iv) the amounts payable under Section 4(b)(i) and (iii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice over 15 months commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A- 2(b)(2).

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Executive and the Company regarding the Executive's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Executive's continued attention and dedication to her assigned duties and her objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 12 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 12 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if within 12 months after a Change in Control, the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates her employment for Good Reason as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Executive and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to 1.25 times the sum of (A) the Executive's current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher) [plus (B) the Executive's Average Incentive Compensation. (For purposes of this Agreement, "Average Incentive Compensation" shall mean the average of the Target Annual Incentive Compensation received by the Executive for the three immediately preceding fiscal years. In no event shall "Average Incentive Compensation" include any sign-on bonus, retention bonus or any other special bonus.);

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time- based stock-based awards held by the Executive issued after the date hereof shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination;

(iii) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Executive a monthly cash payment for 15 months or the Executive's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following

order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity- based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A- 24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of

the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation. The terms of the Employee Confidentiality, Noncompetition and Assignment Agreement (the "Restrictive Covenant Agreement"), between the Company and the Executive, attached hereto as Exhibit A, shall continue to be in full force and effect and are incorporated by reference in this Agreement. The Executive hereby reaffirms the terms of the Restrictive Covenant Agreement as material terms of this Agreement.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Executive's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Chicago, Illinois in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Executive or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be

submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the Superior Court of the State of Illinois and the United States District Court for the Northern District of Illinois. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement.

11. Withholding. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Executive. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Executive's death after her termination of employment but prior to the completion by the Company of all payments due to her under this Agreement, the Company shall continue such payments to the Executive's beneficiary designated in writing to the Company prior to her death (or to her estate, if the Executive fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

18. Governing Law. This is a Illinois contract and shall be construed under and be governed in all respects by the laws of the State of Illinois, without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

XERIS PHARMACEUTICALS, INC.

By: Paul Edick

Its: Chairman and CEO

EXECUTIVE

Beth Hecht

Beth Hecht

FIRST AMENDMENT TO THE
EMPLOYMENT AGREEMENT BETWEEN BETH P. HECHT ("EXECUTIVE")
AND XERIS PHARMACEUTICALS, INC. ("COMPANY")

THIS FIRST AMENDMENT (this "Amendment") to the Employment Agreement dated June 10, 2018 between Executive and the Company (the "Employment Agreement") is made effective as of January 1, 2019. Capitalized terms used herein, and not otherwise defined shall have the meanings ascribed thereto in the Employment Agreement.

RECITALS

WHEREAS, the parties desire to amend the Employment Agreement as set forth herein.

NOW, THEREFORE, the Agreement is hereby amended and modified as follows:

1. **Amendments.**

a) Sections 1(b) and (c) are hereby deleted in their entirety and replaced with the following:

"(b) Position and Duties. During the Term, the Executive shall serve as the Senior Vice President, General Counsel and Corporate Secretary of the Company, and shall have supervision and control over and responsibility for the day-to-day business and affairs of the Company and shall have such other powers and duties as may from time to time be prescribed by the Board of Directors of the Company (the "Board"), the Chief Executive Officer of the Company (the "CEO") or other authorized executive. The Executive shall devote her full working time to the business and affairs of the Company. Notwithstanding the foregoing, the Executive shall be permitted to (i) serve as an outside director on the Neos Therapeutics Inc. Board of Directors; (ii) continue to serve as a consultant to Auven Therapeutics, and (iii) serve on other boards of directors, with the approval of the Board, or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not materially interfere with the Executive's performance of her duties to the Company as provided in this Agreement.

(c) Location. The Executive shall perform her duties at her home office in Delray Beach, Florida or a workspace provided by the Company in Delray Beach, Florida. The Executive shall be available for travel for the performance of the Executive's job duties from time to time."

b) The first sentence in Section 2(a) is hereby deleted in its entirety and replaced with the following: "During the Term, the Executive's annual base salary shall be $364,000." The remainder of Section 2(a) shall remain unchanged.

2. **Miscellaneous.**

a) Except for the specific amendments set forth in Section 1 above, the other terms of the Employment Agreement remain unchanged and in full force and effect.

b) This Amendment may be executed in two or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first set forth above.

XERIS PHARMACEUTICALS, INC.

By: Paul R. Edick
7F44A398D7412826EBC33F15BB1E1D27 contractworks

Name: Paul Edick
Title: Chairman and CEO

EXECUTIVE

By: Beth Hecht
C8F5609B4061BE2A3519AA0B725DCDFB contractworks

Name: Beth P. Hecht

FIRST AMENDMENT TO OFFICE LEASE AGREEMENT

THIS FIRST AMENDMENT TO OFFICE LEASE AGREEMENT (this "**Amendment**") is made and entered into as of the 20th day of November, 2018 (the "**Effective Date**"), by and between **180 N LASALLE PROPERTY OWNER LLC**, a Delaware limited liability company ("**Landlord**"), and **XERIS PHARMACEUTICALS, INC.**, a Delaware corporation ("**Tenant**").

A. Landlord and Tenant entered into that certain Office Lease Agreement dated January 26, 2018 (the "**Lease**"), pursuant to which Tenant currently leases certain premises designated as Suite 1810, containing approximately 8,899 rentable square feet (the "**Existing Premises**") of the building located at 180 N. LaSalle Street, Chicago, Illinois (the "**Building**").

B. The Term is currently scheduled to expire on November 30, 2024 ("**Prior Expiration Date**").

C. Landlord and Tenant desire to relocate and expand the Existing Premises, extend the Term, and otherwise modify the Lease as set forth below.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Recitals. The recitals set forth above are hereby incorporated into and made a material part of this Amendment. Capitalized terms used but not otherwise defined herein shall have the same meanings ascribed to them in the Lease.

2. Relocation and Expansion. Landlord leases to Tenant, and Tenant leases from Landlord, Suite 1500 and Suite 1600, containing approximately 40,850 rentable square feet in total, consisting of all leasable space on the 15th and 16th floors of the Building ("**Relocation Premises**"). Suite 1500 contains 20,425 rentable square feet and Suite 1600 contains 20,425 rentable square feet. Landlord shall tender possession of the Relocation Premises to Tenant so that Tenant may perform the Tenant Work in the Relocation Premises within fifteen (15) business days after full execution of this Amendment provided Tenant has delivered the Letter of Credit required below (the "**Delivery Date**"). Landlord shall remove all furniture from the Relocation Premises, except those items identified on Exhibit D-1 attached hereto (the "**Remaining Furniture**"), which shall remain in the Relocation Premises on the Delivery Date. Landlord shall be deemed to have conveyed the Remaining Furniture to Tenant as of the Delivery Date. The Relocation Premises is shown on Exhibit A-1 attached hereto and made a part hereof. The "**Relocation Premises Commencement Date**" or "**RPCD**" shall mean July 1, 2019, subject to extension on a day by day basis for each day of Landlord Delay. "**Landlord Delay**" means (a) Landlord fails to deliver the Relocation Premises to Tenant on the Delivery Date or (b) Landlord fails to respond to any request for Landlord's approval in the time period required in Exhibit B-1 attached hereto and such failure continues for three (3) business days after Landlord receives a second notice from Tenant advising that Landlord failed to respond within the required time period and notifying that a Landlord Delay will occur if Landlord fails to respond within three (3) business days of receipt of the second notice. The second notice may be sent by email to ryan.moore@us-mgt.ivanhoecambridge.com, Julie.welter@us-mgt.ivanhoecambridge.com, and meshon.chase@us-mgt.ivanhoecambridge.com. Prior to the Give-Back Date (defined below), Tenant may enter the Relocation Premises only to perform the Tenant Work. Tenant shall be entitled to beneficial occupancy of the Relocation Premises between the Give-Back Date and the Relocation Premises Commencement Date. Prior to the Relocation Premises Commencement Date, Tenant shall be required to comply with the terms and conditions of the Lease other than the requirement to pay Base Rent, Taxes or Expenses for the Relocation Premises; provided, however, Tenant shall be responsible for the cost of services requested by Tenant (e.g. after hours HVAC service) and electricity.

3. Return of Existing Premises. No later than March 31, 2019, subject to extension on a day by day basis for each day of Landlord Delay (“**Give Back Date**”), Tenant shall surrender the Existing Premises as if the Lease had naturally expired with respect thereto. Upon Tenant’s surrender of the Existing Premises as required, the Existing Premises shall no longer be part of the Premises and all references to the Premises in the Lease shall mean the Relocation Premises. Except as set forth in this Amendment, provided Tenant surrenders the Existing Premises as required by the Give-Back Date, Tenant shall not be required to pay Base Rent, Taxes or Expenses for the Existing Premises for March, 2019 or any date thereafter (and Landlord shall credit or repay any Base Rent, Taxes and Expenses previously paid by Tenant for the Existing Premises for March 2019 and after), and the Lease shall be deemed expired with respect to the Existing Premises as of the Give-Back Date, except with respect to liabilities that accrued prior to Give-Back Date and other obligations which, by the terms of the Lease, survive expiration. Except as otherwise set forth in this Amendment, Tenant must surrender the Existing Premises in accordance with the end of term requirements of the Lease. If Tenant does not surrender the Existing Premises as required by the Lease by the Give-Back Date, Tenant shall be a holdover tenant in such space, subject to Section 22 of the Lease.

4. Extension of Term. Notwithstanding the Prior Expiration Date, the Term is hereby extended (the “**Extended Term**”) such that the Expiration Date (herein called the “**Extended Expiration Date**”) for the Relocation Premises shall be June 30, 2031, unless sooner terminated or renewed in accordance with the terms of the Lease, as amended hereby. All of the terms and conditions of the Lease shall be applicable during the Extended Term, except as is otherwise provided in this Amendment.

5. Base Rent for the Relocation Premises. Tenant shall pay Base Rent for the Relocation Premises in the following monthly installments at the following times and in the same manner and place as is required under the Lease, as amended hereby, commencing on the Relocation Premises Commencement Date:

Time Period:	Annual Base Rent Per Rentable Square Foot	Monthly Installments of Base Rent
RPCD – 6/30/20	$ 25.50	$ 86,806.25
7/1/20 – 6/30/21	$ 26.20	$ 89,193.42
7/1/21 – 6/30/22	$ 26.92	$ 91,646.24
7/1/22 – 6/30/23	$ 27.66	$ 94,166.51
7/1/23 – 6/30/24	$ 28.42	$ 96,756.09
7/1/24 – 6/30/25	$ 29.20	$ 99,416.88
7/1/25 – 6/30/26	$ 30.01	$ 102,150.85
7/1/26 – 6/30/27	$ 30.83	$ 104,960.00
7/1/27 – 6/30/28	$ 31.68	$ 107,846.40
7/1/28 – 6/30/29	$ 32.55	$ 110,812.17
7/1/29 – 6/30/30	$ 33.45	$ 113,859.51
7/1/30 – 6/30/31	$ 34.37	$ 116,990.64

Notwithstanding the foregoing or anything to the contrary contained in Section 4 of the Lease, and provided Tenant is not then in Monetary Default under the Lease beyond any applicable notice and grace periods, Tenant's obligation to pay monthly Base Rent and Tenant's Pro Rata Share of Expenses and Taxes shall be abated for eight (8) months from the RPCD (expected to be July 1, 2019 through February 28, 2020) for Suite 1600, for eleven (11) months from the RPCD (expected to be July 1, 2019 through May 31, 2020) for Suite 1500, and for one (1) additional month (expected to be June, 2020) for 5,487 rentable square feet of the Relocation Premises (the "**Abatement Period**"). The total amount of Base Rent and Tenant's Pro Rata Share of Expenses and Taxes abated during the Abatement Period shall be herein referred to as the "**Relocation Premises Abated Rent**". If Tenant defaults at any time during the Term in any material respect and fails to cure such material default within any applicable notice and cure period and Landlord elects to terminate the Lease or Tenant's possession of the Premises, all unamortized Relocation Premises Abated Rent theretofore abated (i.e. based upon the amortization of the Relocation Premises Abated Rent in equal monthly amounts during the Extended Term, without interest) shall immediately become due and payable and Tenant shall not be entitled to any further Relocation Premises Abated Rent. The payment by Tenant of such unamortized Relocation Premises Abated Rent shall not limit or affect any of Landlord's other rights, pursuant to the Lease or at law or in equity. During the Abatement Period, only Base Rent and Tenant's Pro Rata Share of Expenses and Taxes shall be abated and all other costs and charges specified in the Lease shall remain as due and payable pursuant to the provisions of the Lease.

6. Additional Rent. Tenant shall continue to pay Additional Rent in the manner and at the times required under Section 4 of the Lease for the balance of the Term, as hereby extended, except that effective as of the Relocation Premises Commencement Date, Tenant's Pro Rata Share shall be increased to 5.3118% being the 40,850 rentable square feet in the Relocation Premises divided by the rentable square footage of the Building (i.e., 769,038 rentable square feet).

7. Security Deposit. As a condition to the effectiveness of this Amendment, Tenant shall deliver a new Letter of Credit that meets the requirements of Section 6 of the Lease in the amount of One Million Dollars ($1,000,000.00) ("**Replacement LOC**"). Upon receipt of the Replacement LOC, Landlord shall return to Tenant the existing Letter of Credit in the amount of Eighty-Five Thousand Dollars ($85,000.00). Section 6 of the Lease shall continue to govern with respect to the Letter of Credit except that the required amount of the Letter of Credit shall be One Million Dollars ($1,000,000.00) and cash may not be substituted for the Letter of Credit. Notwithstanding the foregoing, provided no Default (beyond applicable notice and cure periods) has occurred under the Lease and, not earlier than 60 and not later than 30 days prior to each reduction date set forth below, Tenant has delivered to Landlord a written request for Landlord to acknowledge (and Landlord has made such acknowledgement in writing on such form as is reasonably required by the issuing bank, and Landlord agrees to so acknowledge, if true, within ten (10) days after request therefor) that no Default (beyond applicable notice and cure periods) has occurred under the Lease, Tenant may reduce the amount of the Letter of Credit by One Hundred Thousand Dollars ($100,000) on each anniversary of the Relocation Premises Commencement Date until the Letter of Credit amount is One Hundred Thousand Dollars ($100,000), with no further reduction thereafter.

8. Condition of Premises. Landlord shall deliver the Relocation Premises to Tenant on the Delivery Date in its current “AS-IS” “WHERE-IS” condition, subject to Landlord’s maintenance obligations set forth in the Lease, in order for Tenant to construct the Tenant Work therein in accordance with Exhibit B-1 attached hereto and made a part hereof.

9. Renewal Option. Tenant is hereby granted one (1) option (“**Extension Option**”) to extend the term of the Lease for the entire Premises then under Lease for five (5) years (“**Extension Term**”). The Extension Option may be exercised only by giving Landlord irrevocable and unconditional written notice thereof no earlier than fifteen (15) months and no later than twelve (12) months prior to the commencement of the Extension Term. Tenant may not exercise the Extension Option if Tenant is in Monetary Default under the Lease beyond the expiration of any applicable cure period either at the date of said notice or at the commencement of the Extension Term. Upon exercise of the Extension Option, all references in the Lease to the Term shall be deemed to be references to the Term as extended pursuant to the Extension Option. The Extension Term shall be on the same terms, covenants and conditions as are contained in the Lease, except that (i) no additional extension option shall be conferred by the exercise of the Extension Option, (ii) Base Rent applicable to the Premises for the Extension Term shall be determined as provided below, (iii) any rent abatement, concession or allowance (including, without limitation, the Construction Allowance) which are in the nature of economic concessions or inducements contained in the Lease shall not be again applicable to any Extension Term because new concessions shall be determined in connection with determination of the Current Market Rate, and (iv) Tenant shall accept the Premises in its “as-is, where is” condition. In addition to Base Rent, Tenant shall pay Additional Rent and other Rent during the Extension Term as provided in this Lease. Base Rent per annum per rentable square foot of the Premises for the Extension Term shall be one hundred percent (100%) of the Current Market Rate for lease terms commencing on or about the date of commencement of the Extension Term. The term “**Current Market Rate**” means the prevailing rental rate per rentable square foot and concession package for comparable renewals recently executed for comparable space in the Building and in buildings of comparable age and quality in the Building’s submarket for renewing tenants of similar size, credit quality and stature. The determination of Current Market Rate shall take into consideration net versus gross lease; differing base years if applicable; any differences in the size of space being leased, the location of space in the applicable building and the length of lease terms; the use of the applicable premises; any differences in definitions of rentable square feet or rentable area with respect to which rental rates are computed; the value of rent abatements, allowances (for demolition, space planning, architectural and engineering fees, construction, moving expenses, commissions, or other purposes), leasing commissions, the creditworthiness of Tenant; the location and condition of the building, the location and condition of the applicable premises within the applicable building, and other pertinent factors. The Current Market Rate may include an escalation of a fixed base rental rate (based on a fixed step or index) then prevailing in the market. Within thirty (30) days after receipt of Tenant’s notice to extend Landlord shall deliver to Tenant written notice of the Current Market Rate and shall advise Tenant of the required adjustment to Base Rent, if any. Tenant shall, within thirty (30) days after receipt of Landlord’s notice, notify Landlord in writing whether Tenant (a) accepts Landlord’s determination of the Current Market Rate; or (b) requests that the Current Market Rate be determined by brokers (“**Arbitration Request**”). If Tenant requests that the Current Market Rate be determined by brokers, Landlord and Tenant, within ten (10) days after the date of the Arbitration Request, shall each simultaneously submit to the other, in a sealed envelope, its good faith estimate of the Current Market Rate (collectively referred to as the “**Estimates**”). If the higher of such Estimates is not more than one hundred five percent (105%) of the lower of such Estimates, then Current Market Rate shall be the average of the two Estimates. If the Current Market Rate is not resolved by the exchange of Estimates, Landlord and Tenant, within seven (7) days after the exchange of Estimates, shall each select a commercial real estate broker to determine which of the two Estimates most closely reflects the Current Market Rate. Each commercial real estate broker selected pursuant hereto shall (a) be a licensed commercial real estate broker in good standing, (b) have had at least ten (10) years’ experience within the previous fifteen (15) years as a commercial real estate broker working in the Building’s particular marketplace, (c) have working knowledge of current office rental rates and practices, and (d) not be affiliated with either Landlord or Tenant. Upon selection, Landlord’s and Tenant’s brokers shall work

together in good faith to agree upon which of the two Estimates most closely reflects the Current Market Rate. The Estimate chosen by such brokers shall be binding on both Landlord and Tenant as the Current Market Rate. If either Landlord or Tenant fails to appoint a broker within the seven day period referred to above, the broker appointed by the other party shall be the sole broker for the purposes hereof. If the two brokers cannot agree upon which of the two Estimates most closely reflects the Current Market Rate within the twenty (20) days after their appointment, then, within ten (10) days after the expiration of such twenty (20) day period, the two (2) brokers shall select a third broker meeting the aforementioned criteria. Once the third broker has been selected as provided for above, then, as soon thereafter as practicable but in any case within fourteen (14) days, the third broker shall make his determination of which of the two Estimates most closely reflects the Current Market Rate and such Estimate shall be binding on both Landlord and Tenant as the Current Market Rate. The parties shall share equally in the costs of the third broker. Any fees of any broker, counsel or experts engaged directly by Landlord or Tenant, however, shall be borne by the party retaining such broker, counsel or expert. In the event that the Current Market Rate has not been determined by the commencement date of the Extension Term at issue, Tenant shall pay the most recent Base Rent set forth in the Lease until such time as the Current Market Rate has been determined. Upon such determination, Base Rent shall be retroactively adjusted. If such adjustment results in an underpayment of Base Rent by Tenant, Tenant shall pay Landlord the amount of such underpayment within thirty (30) days after the determination thereof. If such adjustment results in an overpayment of Base Rent by Tenant, Landlord shall credit such overpayment against the next installment of Base Rent due under the Lease and, to the extent necessary, any subsequent installments until the entire amount of such overpayment has been credited against Base Rent. Tenant must timely exercise the Extension Option or the Extension Option shall terminate. Tenant's exercise of the Extension Option shall not operate to cure any default by Tenant of any of the terms or provisions in the Lease, nor to extinguish or impair any rights or remedies of Landlord arising by virtue of such default. If the Lease or Tenant's right to possession of the Premises shall terminate in any manner whatsoever before Tenant shall exercise the Extension Option, or if Tenant shall have subleased (other than to an Affiliate) more than twenty five percent (25%) of the Premises, then immediately upon such termination or sublease of more than 25%, the Extension Option shall simultaneously terminate and become null and void. The Extension Option is personal to Tenant, Tenant's Affiliates, and any successor Tenant after any Business Transfer in accordance with Section 11.04 of the Lease.

10. Termination Option. Provided: (a) the Lease is then in full force and effect and (b) Tenant is not in Monetary Default under the Lease beyond applicable notice and cure periods, Tenant shall have the one time right and option to terminate the Lease ("**Termination Option**") effective June 30, 2027 ("**Termination Date**"). The Termination Option shall be exercised, if at all, by Tenant by giving written notice of the exercise to Landlord ("**Termination Notice**") no later than June 30, 2026. It shall be a condition to the exercise of Tenant's Termination Option that Tenant pay to Landlord a termination fee ("**Termination Fee**") in the sum of (x) $3,534,441.52 , plus (y) three (3) months Base Rent, Taxes and Expenses payable by Tenant at the Termination Date. Notwithstanding the foregoing, in the event the Premises are expanded at any time during the Extended Term (pursuant to Tenant's exercise of its rights under this Amendment or otherwise), part (x) of the Termination Fee shall be revised to add Landlord's unamortized transaction costs with respect to the expansion space including Landlord's brokerage costs, legal fees, construction allowances, and rent abatement, all amortized as of the expansion space rent commencement date through the Extended Term of this Lease with eight percent (8%) per annum interest, and part (y) of the Termination Fee shall be deemed to include Base Rent, Taxes and Expenses due for the Premises and the expansion space. Half of the Termination Fee shall be payable contemporaneously with Tenant's transmittal to Landlord of the Termination Notice; the balance shall be payable no later than thirty (30) days prior to the Termination Date. At Tenant's request, Landlord will provide information necessary to calculate the Termination Fee. Provided Tenant properly and timely exercises the Termination Option and timely and properly pays Landlord the Termination Fee, then the Lease shall terminate effective as of the Termination Date, as if said Termination Date were set forth in the Lease as

the Expiration Date of the Term of the Lease. Tenant shall vacate and deliver possession of the Premises to Landlord in the manner required by the Lease on or before 11:59 p.m. on the Termination Date. Tenant shall also pay to Landlord on or before the Termination Date, and be responsible for, all sums due under the Lease that accrue under the Lease on or prior to the Termination Date. Tenant's rights under this Section are personal to the Tenant named in this Lease, its Affiliates, and any successor Tenant after any Business Transfer in accordance with Section 11.04 of the Lease.

11. Expansion Option. Provided no Default exists beyond applicable notice and cure periods and the Lease is in full force and effect, provided Tenant (or an Affiliate) is leasing and occupying the entire Relocation Premises, by giving Landlord written notice, if at all, on or before July 1, 2021, subject to existing rights of other tenants of the Building listed on Schedule 1 attached hereto, Tenant shall have the option to expand the Premises (the "**Expansion Option**"), as provided herein. Tenant may exercise the Expansion Option, if at all, by giving Landlord timely written notice ("**Expansion Notice**"). If Tenant exercises the Expansion Option, the "**Expansion Space**" shall be Suite 1822 containing 1,801 rentable square feet, Suite 1810 containing approximately 9,132 rentable square feet, and Suite 1801 containing approximately 2,629 rentable square feet. The Expansion Space is shown on Exhibit C-1 attached hereto and made a part hereof. In the event that Tenant timely exercises the Expansion Option, then (a) Landlord shall tender possession of the Expansion Space to Tenant in an "as-is, where is" condition so that Tenant may perform any Tenant Work in the Expansion Space on or before April 1, 2022 (the "**Expansion Delivery Date**") and (b) effective as of July 1, 2022, subject to extension on a day by day basis for each day of Landlord Delay [for purposes of this reference to Landlord Delay, Delivery Date shall be replaced with the Expansion Delivery Date and Relocation Premises shall be replaced with Expansion Space] (the "**Expansion Space Commencement Date**"), the Expansion Space shall be added to, and constitute part of, the "Premises" leased hereunder, and the same shall be leased upon and subject to the same terms, provisions and conditions as are applicable to the other portions of the Premises for the remainder of the Term of the Lease, except that Base Rent, rent abatement, and concessions for the Expansion Space shall be at the Current Market Rate, determined in accordance with the procedure set forth above in this Amendment. Promptly after Tenant exercises the Expansion Option and the parties determine the Current Market Rate, Landlord and Tenant shall execute an amendment to the Lease confirming the increase in the square footage of the Premises and all matters incident thereto (such as an increase in Tenant's Pro Rata Share and Base Rent and a workletter to address payment of the construction allowance, if any); however, the failure of the parties to timely execute such amendment shall not defer the Expansion Space Commencement Date or otherwise invalidate this Lease or affect the parties' rights or obligations hereunder. In the event demising work is necessary to accommodate Tenant's exercise of its Expansion Option, then Landlord shall build a Building standard multi-tenant corridor (including without limitation construction of a demising wall and separation of the corridor from electrical, fire/life safety, HVAC, and other systems serving the Premises). Such demising work shall be at Tenant's expense, provided that Tenant may use the construction allowance to pay for such work. Furthermore, Tenant (and not Landlord) shall be responsible for drywall and finish on the side of the corridor located within the Premises. In no event shall Landlord be obligated to pay a commission with respect to any space leased by Tenant under this Section other than pursuant to a written commission agreement with Tenant's designated broker who is actively involved in negotiations on Tenant's behalf at the time and Tenant and Landlord shall each indemnify the other against all costs, expenses, attorneys' fees, and other liability for commissions or other compensation claimed by any other broker or agent claiming the same by, through, or under the indemnifying party. Tenant's rights under this Section are personal to the above-named Tenant, its Affiliates, and any successor Tenant after any Business Transfer in accordance with Section 11.04 of the Lease.

12. <u>Right of First Refusal</u>. Subject to existing renewal options, expansion options, and other preferential rights in the leases of other tenants as of the Effective Date, provided no Default then exists beyond applicable notice and cure periods, provided Tenant (or an Affiliate) is occupying the entire Relocation Premises, provided the Lease is then in full force and effect, provided that Tenant's interest in this Lease has not been assigned other than to an Affiliate or pursuant to a Business Transfer in accordance with Section 11.04 of the Lease, and provided that there will be at least three (3) years of rent-paying term for the Landlord's ROFR Notice Space, Tenant shall have the right of first refusal ("**Right of First Refusal**") as hereinafter described, to lease any space that Landlord desires to make available for lease on the seventeenth or eighteenth floor of the Building ("**Right of First Refusal Space**"), for a term beginning on the ROFR Effective Date (as hereinafter defined). This Right of First Refusal is exercisable at the following times and upon the following conditions. Landlord shall not voluntarily lease the Right of First Refusal Space to a third party (other than to the then-current tenant or subtenant of such space) without making such proposed new lease (a "**New Lease**") subject to Tenant's Right of First Refusal. Upon agreement on a bona fide proposal for a New Lease that Landlord is willing to accept, Landlord shall provide written notice to Tenant ("**Landlord's ROFR Notice**") of the significant business terms of the bona fide proposal including, without limitation, a description of that portion of the Right of First Refusal Space being offered (which may include space in excess of the Right of First Refusal Space) ("**Landlord's ROFR Notice Space**"), the rent, the commencement date, the term, and any allowances to be given. Landlord shall provide a redacted copy of the bona fide proposal. Tenant shall have a period of ten (10) days after the date of delivery of Landlord's ROFR Notice to notify Landlord ("**Tenant's ROFR Notice**"), whether Tenant elects to exercise the right granted hereby to lease the entire Landlord's ROFR Notice Space on the terms set forth in Landlord's ROFR Notice, provided that the term of Tenant's lease of the Landlord's ROFR Notice Space shall end contemporaneously with the expiration date of the Term of this Lease (as it may be renewed or extended), unless sooner terminated as provided in the Lease. Landlord may prorate concessions in the Landlord's ROFR Notice if the Term of the Lease will be shorter than the proposed New Lease Term. If Tenant elects to exercise its right to lease the Landlord's ROFR Notice Space, the term thereof shall commence as of the commencement date set forth in the bona fide proposal (the "**ROFR Effective Date**"). If Tenant fails to give Tenant's ROFR Notice to Landlord within the required ten (10) day period, Tenant shall be deemed to have refused its right to lease such space. If Tenant fails to or does not elect to exercise its right to lease the Landlord's ROFR Notice Space, Tenant's rights under this Section shall be deemed waived as to such space and Landlord shall have the right to lease said space on terms not materially more favorable than the terms contained in the Landlord's ROFR Notice. However, if the Landlord fails to execute a New Lease within nine (9) months of Tenant's waiver or refusal, then Tenant shall retain the Right of First Refusal. Subject to the foregoing provisions, the parties intend that this Right of First Refusal shall be a continuing right throughout the Term. For purposes of this paragraph, the phrase "materially more favorable" shall mean that Landlord's new deal terms are 7% or more lower on a net effective basis than Landlord's offer to Tenant. In the event that Tenant shall exercise its Right of First Refusal as provided herein, Landlord and Tenant promptly after Tenant gives Tenant's ROFR Notice, shall enter into a written agreement modifying and supplementing the Lease to confirm the addition of the Landlord's ROFR Notice Space to the Premises in accordance with the terms and provisions of the Lease, except as otherwise provided in Landlord's ROFR Notice, but the effectiveness of the addition of Landlord's ROFR Notice Space to the Premises shall not be conditioned upon the execution and delivery of such instrument. If Tenant exercises its Right of First Refusal, Landlord shall terminate the New Lease (or bona fide proposal) for the Landlord's ROFR Notice Space. In no event shall Landlord be obligated to pay a commission with respect to any space leased by Tenant under this Section other than pursuant to a written commission agreement with Tenant's designated broker who is actively involved in negotiations on Tenant's behalf at the time and Tenant and Landlord shall each indemnify the other against all costs, expenses, attorneys' fees, and other liability for commissions or other compensation claimed by any other broker or agent claiming the same by, through, or under the indemnifying party.

13. Fire Stairs. To the extent permitted by law, Tenant may use the Building's fire stairs connecting multiple floors of the Premises as convenience stairs for inter-floor access within the Premises. At no cost to Landlord, Landlord agrees to use reasonable commercial efforts to assist Tenant obtaining any necessary permits and authorizations to use the Building's fire stairs. To the extent permitted by law and provided that Landlord is given access, Tenant may install an internal key card system as part of this right at Tenant's expense provided, Tenant may use the Construction Allowance set forth in Exhibit B-1 attached hereto to pay for such expenses. Landlord may require that any key card system so installed by Tenant be compliant, compatible, and installed in a coordinated manner with Landlord's fire and security systems, including giving the main Building system the ability to lock or unlock the doors in the event of an emergency or test. Tenant must comply with Exhibit B-1 or Section 9 of the Lease in connection with any alterations or improvements that Tenant desires to install in the fire stairs including, without limitation, installation of any key card system. Tenant shall be solely responsible for all costs associated with Tenant's system and any necessary modifications to the Building security system to accommodate Tenant's system provided, Tenant may use the Construction Allowance set forth in Exhibit B-1 attached hereto to pay for such expenses. The parties intend that Tenant will be able to use Tenant's security system and the Building security system in such a manner that Landlord and Tenant (and their respective employees and others who have authorized access to the Premises) shall each only be required to carry one (1) security keycard (as opposed to a building card and a premises card) for access to the Building and the Premises and Landlord and Tenant shall work together and use commercially reasonable efforts to achieve this goal in the most cost-effective manner possible, provided that Landlord shall not be required to replace the Building's system or incur any expense and further provided that no other tenant of the Building shall be impacted or burdened. Tenant's improvements in the fire stairs must comply with code and Tenant shall indemnify and hold Landlord harmless from any loss, cost, expense, damage or liability incurred by Landlord as a result of Tenant's modifications to the fire stairwells. The cost of the on-going maintenance and cleaning of such stairs, to the extent such costs are equal to those for the same stairs without any such Tenant's usage, shall be considered as part of the normal Expenses of the Building. Any above standard maintenance or cleaning costs shall be paid by solely by Tenant.

14. Signage.

(a) Landlord shall provide Tenant, at Landlord's expense, with Building standard suite entry, elevator lobby directional, and lobby directory signage. Tenant may also install at Tenant's expense elevator lobby signage on each full floor leased and occupied by Tenant, such signage to be subject to Landlord's approval not to be unreasonably withheld, conditioned or delayed.

(b) So long as Tenant is not in Monetary Default, provided Tenant is leasing and occupying at least two (2) full floors in the Building, and provided Tenant obtains and maintains at Tenant's expense all necessary permits, licenses and approvals, Tenant shall have the non-exclusive right to install and maintain, at its sole cost and expense, one (1) tenant identification exterior sign on the Building beneath one of the Byline Bank signs in the location depicted on Exhibit E attached hereto), subject to the following terms and conditions:

(i) The design of Tenant's exterior sign shall be as approved by Landlord. The location, design, construction, size and all other aspects of such signage and the installation thereof shall be subject to Landlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

(ii) The expense of installing, constructing, maintaining, replacing and removing the sign shall be the sole cost and expense of Tenant and shall be paid directly by Tenant. Tenant shall be responsible for all costs and expenses associated with such signage and Tenant shall promptly repair any damage to the Building resulting from the installation, construction, maintenance or removal of such signage, normal wear and tear excepted. Tenant shall maintain such signage in a first class manner. If Tenant does not so maintain such signage, Landlord shall do so on Tenant's behalf and Tenant shall pay Landlord for such maintenance at Building-standard rates.

(iii) Tenant's sign contractor shall be subject to Landlord's approval (not to be unreasonably withheld) and Tenant's sign contractor must comply with Landlord's rules and regulations for the Building. Alternatively, Landlord may elect to require the use of Landlord's sign contractor.

(iv) Tenant hereby agrees to indemnify and hold Landlord harmless for any cost, expense, loss or other liability associated with the installation, construction, maintenance and removal of the sign.

(v) If Tenant requests any assignment or subletting of this Lease, Tenant's rights with respect to the sign as contained herein shall not be transferable or assignable to an assignee or subtenant without the express prior written consent of Landlord which consent may be granted, withheld or conditioned in Landlord's sole and absolute discretion. Notwithstanding the foregoing, Tenant, Tenant's Affiliates, and any successor Tenant after any Business Transfer in accordance with Section 11.04 of the Lease may exercise Tenant's rights with respect to the sign.

(vi) Upon the expiration or earlier termination of the Lease or Tenant's signage right, Tenant shall promptly remove the signage, restore the Building's façade to remove any trace of Tenant's signage, and reimburse Landlord for all costs and expenses associated with any damage to the Building caused by such removal.

(vii) Tenant's exterior signage right shall expire if Tenant fails to install exterior signage within six (6) months of the Relocation Premises Commencement Date.

(viii) Landlord reserves the right to temporarily remove, to replace, and/or to relocate Tenant's signage in connection with any renovation of the Building by Landlord. Furthermore, Landlord reserves the right to refresh and modify the appearance of Tenant's signage to be aesthetically consistent with renovations. Tenant's signage shall not be less visible post-renovation compared to pre-renovation. Modifications to Tenant's signage made by Landlord pursuant to this subsection shall be at Landlord's expense.

(c) Landlord makes no representation or warranty whether the City of Chicago may approve exterior signage for Tenant. Tenant's exterior signage right is personal to the above-named Tenant, Tenant's Affiliates, and any successor Tenant after any Business Transfer in accordance with Section 11.04 of the Lease.

15. Amendments to Existing Lease.

(a) Section 4.03(a)(xi)(2) of the Lease is hereby deleted.

(b) Section 4.03(b) of the Lease is hereby revised to add the following as an exclusion from Expenses: management fees for the Building in excess of three percent (3%) of the gross annual Revenue for the Property.

(c) The eighth sentence of Section 5.01 of the Lease is hereby deleted and replaced with "Tenant shall not have more persons in the Premises than permitted by applicable code."

(d) Section 11.02(c) of the Lease is hereby deleted and replaced with "in the event of an assignment of this Lease or subletting of a full floor or more, other than to an Affiliate or any successor Tenant after any Business Transfer in accordance with Section 11.04, recapture the portion of the Premises that Tenant is proposing to Transfer; provided that within 10 days after Tenant's receipt of notice under this clause (c), Tenant may withdraw Tenant's request for consent, in which case this Lease will continue in effect."

(e) The third sentence of Section 11.03 of the Lease is hereby amended and restated as follows: "In determining the excess due Landlord, Tenant may first deduct from the excess all reasonable and customary expenses (including any attorneys' fees, commissions, and improvement costs) directly incurred by Tenant attributable to the Transfer."

(f) Section 18(a) of the Lease is hereby revised to replace 3 days with 5 days.

(g) Landlord shall not require Tenant to provide a payment or performance bond in connection with the Tenant Work performed in accordance with Exhibit B-1.

16. Brokers. Tenant represents that Tenant has not dealt with any broker, agent or finder in connection with this Amendment other than CBRE, Inc., whose right to a commission shall be paid by Landlord pursuant to separate written agreement, and Tenant agrees to indemnify and hold Landlord harmless from all damages, judgments, liabilities and expenses (including reasonable attorneys' fees) arising from any claims or demands of any other broker, agent or finder with whom Tenant has dealt for any commission or fee alleged to be due in connection with its participation in the procurement of Tenant or the negotiation with Tenant of this Amendment.

17. Existing Lease Rent Abatement & Allowance. Tenant shall not be entitled to an abatement of Base Rent, Taxes and Expenses for the Existing Premises during months 13-19 of the Term pursuant to Section 4.05 of the Lease. Any Construction Allowance provided by Section 9 of Exhibit C of the Lease that has not been used by Tenant prior to execution of this Amendment shall no longer be available to Tenant. Without limitation, Tenant may not use any of the Lease Exhibit C, Section 9 Construction Allowance as Rent credit after the date hereof.

18. Binding Effect. This Amendment shall not be binding until executed and delivered by both Landlord and Tenant.

19. Electronic Counterparts. This Amendment may be executed in any number of electronic (facsimile or PDF) counterparts, any one of which shall be an original, but all of which together shall be one and the same instrument.

20. Estoppel. Tenant hereby represents, warrants and agrees that: to the best of Tenant's knowledge, (i) there exists no breach, default or event of default by Landlord under the Lease, or any event or condition which, with the giving of notice or passage of time or both, would constitute a breach, default or event of default by Landlord under the Lease; (ii) the Lease continues to be a legal, valid and binding agreement and obligation of Tenant; and (iii) Tenant has no current offset or defense to its performance or obligations under the Lease. Nothing in this Section 20 shall be deemed to impair or deny Tenant's right to audit or review Landlord's books and records and to receive recompense for overpayments by Tenant disclosed by such audit or review.

21. SNDA. With respect to future Mortgages (as defined in Section 23.01 of the Lease) of the Property, Landlord shall use reasonable efforts to obtain and deliver to Tenant a reasonable Subordination Non-Disturbance and Attornment Agreement (“**SNDA**”) from Landlord’s future Mortgagees (as defined in Section 23.031 of the Lease) on such Mortgagee’s customary form as negotiated by Tenant, but receipt of SNDAs from future Mortgagees shall not be a condition to the Lease or Tenant’s subordination to the future Mortgage. Tenant may be required to execute each such SNDA before Landlord or the Mortgagee will execute the SNDA. Tenant shall be responsible to pay Landlord’s Mortgagee’s SNDA reasonable and documented out-of-pocket processing and legal fees and Tenant shall reimburse Landlord for same within thirty (30) days of receipt of an invoice therefor. Landlord shall not be in default in the event Tenant desires to negotiate the SNDA and the parties are unable to agree upon a final form of SNDA.

22. Exhibits. Each Exhibit attached hereto is made a part hereof for all purposes.

23. No Representations. Landlord and Landlord’s agents have made no representations or promises, express or implied, in connection with this Amendment, except as expressly set forth herein, and Tenant has not relied on any representations except as expressly set forth herein.

24. OFAC. Tenant represents and warrants to Landlord that (1) Tenant is not acting, directly or indirectly, for or on behalf of any person, group, entity, or nation named by any Executive Order or the United States Treasury Department as a terrorist, “Specially Designated National,” “Blocked Person,” or other banned or blocked person, entity, nation, or transaction pursuant to any law, order, rule, or regulation that is enforced or administered by the Office of Foreign Assets Control; and (2) Tenant is not engaged in this transaction, directly or indirectly on behalf of, or instigating or facilitating this transaction, directly or indirectly on behalf of, any such person, group, entity or nation. Tenant agrees to defend, indemnify, and hold harmless Landlord from and against any and all claims, damages, losses, risks, liabilities, and expenses (including reasonable attorney’s fees and costs) arising or related to any breach of the foregoing representation and warranty.

25. Miscellaneous. This Amendment sets forth the entire agreement with respect to the matters set forth herein. There have been no additional oral or written representations or agreements. As modified by this Amendment, the Lease is hereby ratified and confirmed, and shall remain in full force and effect. In the event of any inconsistency between the provisions of the Lease and this Amendment, the provisions of this Amendment shall control. Headings used in this Amendment are for convenience only and shall not serve to limit, expand or otherwise alter the terms of this Amendment.

26. Notice Address. Landlord’s addresses set forth in Section 1.12 of the Lease is hereby amended to substitute the following current notice addresses for Landlord:

180 N LaSalle Property Owner LLC
c/o IC US Capital Properties LLC
10 S. Riverside Plaza, Suite 2050
Chicago, Illinois 60606
Attention: Todd W. Hartman, SVP – Asset Management

with a copy to:

180 N LaSalle Property Owner LLC
180 N LaSalle Street, Suite LL-020
Chicago, Illinois 60601
Attention: Building Manager

and

180 N LaSalle Property Owner LLC
c/o IC US Capital Properties LLC
10 S. Riverside Plaza, Suite 2050
Chicago, Illinois 60606
Attention: Bansari Shah, SVP – General Counsel

and

Ivanhoé Cambridge
95 Wellington Street West, Suite 600
Toronto (Ontario) M5J 2R2
Attention: Sunita Mahant, Senior Director, Legal Affairs

and

Levenfeld Pearlstein, LLC
2 N. LaSalle St. Suite 1300
Chicago, Illinois 60602
Attention: Brian K. Kozminski

Tenant's notice addresses set forth in Section 1.12 of the Lease is hereby amended to substitute the following current notice addresses for Tenant:

Xeris Pharmaceuticals, Inc.
180 N LaSalle Street, Suite 1600
Chicago, Illinois 60601
Attention: Steve Pieper

with a copy to:

Xeris Pharmaceuticals, Inc.
180 N LaSalle Street, Suite 1600
Chicago, Illinois 60601
Attention: Legal Department

[***remainder of page intentionally left blank; signature page follows***]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment to Office Lease as of the date first above written.

LANDLORD:

180 N LASALLE PROPERTY OWNER LLC,
a Delaware limited liability company

By: 180 N LaSalle REIT, its sole member

By: IC US Capital Properties LLC, its Asset Manager

By: /s/ Todd W. Hartman
Name: Todd W. Hartman
Title: Senior Vice President – Asset Management

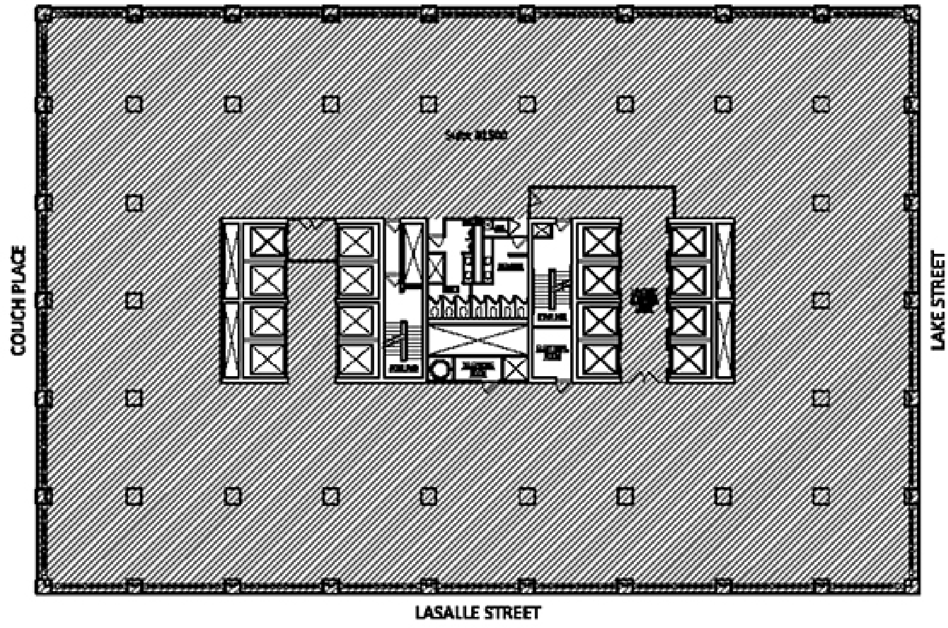
TENANT:

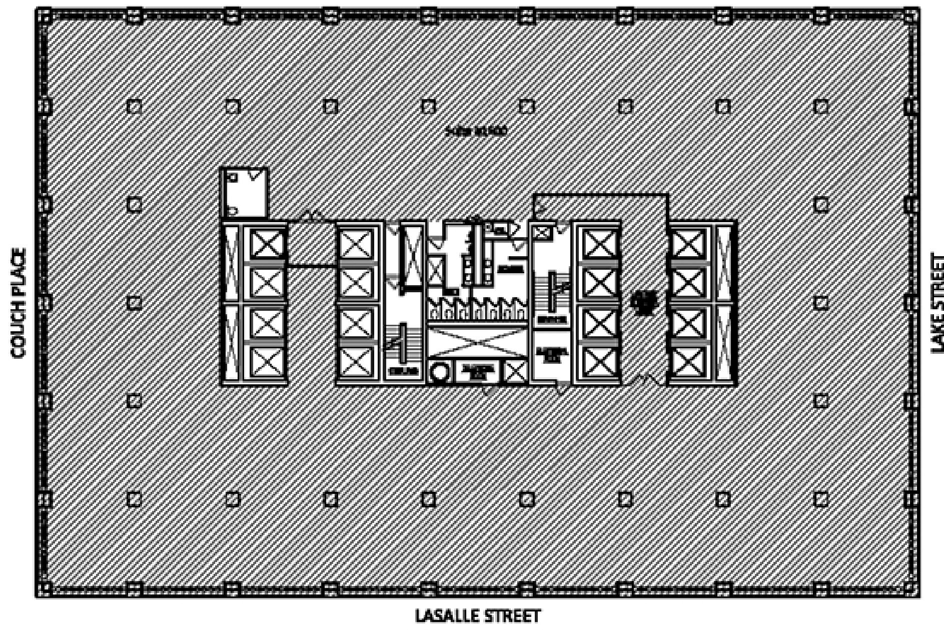
XERIS PHARMACEUTICALS, INC.,
a Delaware corporation

By: /s/ Paul R. Edick
Name: Paul R. Edick
Its: Chief Executive Officer

EXHIBIT A-1

RELOCATION PREMISES





180 NORTH LASALLE STREET - CHICAGO, ILLINOIS
FLOOR 16 - LEASE EXHIBIT A-1 RELOCATION PREMISES SUITE 1600

November 6, 2018

EXHIBIT B-1

WORKLETTER

This Exhibit is attached to and made a part of the Amendment to Office Lease by and between **180 N LASALLE PROPERTY OWNER LLC**, a Delaware limited liability company ("**Landlord**"), and **XERIS PHARMACEUTICALS, INC.**, a Delaware corporation ("**Tenant**"), for space in the Building located at 180 N. LaSalle Street, Chicago, Illinois. Capitalized terms used but not defined herein shall have the meanings given in the Lease.

1. Acceptance of Relocation Premises. Except as set forth in this Exhibit, Tenant accepts the Relocation Premises in its "**AS-IS**" condition on the Effective Date of this Amendment, subject to Landlord's maintenance obligations set forth in the Lease.

2. Working Drawings.

   (a) Preparation and Delivery. Landlord has approved Tenant's space plans attached as **Exhibit A** to this Workletter. Tenant shall provide to Landlord for its approval final working drawings (architectural and MEP drawings), prepared by an architect (the "**Architect**") reasonably acceptable to Landlord (Landlord hereby approving Partners By Design), of all improvements that Tenant proposes to install in the Relocation Premises; such working drawings shall be delivered in PDF and CAD format along with a hard copy thereof and shall include the partition layout, ceiling plan, electrical outlets and switches, telephone outlets, drawings for any modifications to the mechanical and plumbing systems of the Building, and detailed plans and specifications for the construction of the improvements called for under this Exhibit in accordance with all applicable laws.

   (b) Approval Process. Landlord shall notify Tenant whether it approves of the submitted working drawings within ten business days after Tenant's submission thereof. If Landlord disapproves of such working drawings, then Landlord shall notify Tenant thereof specifying in reasonable detail the reasons for such disapproval, in which case Tenant shall, within five business days after such notice, revise such working drawings in accordance with Landlord's objections and submit the revised working drawings to Landlord for its review and approval. Landlord shall notify Tenant in writing whether it approves of the resubmitted working drawings within five business days after its receipt thereof. This process shall be repeated until the working drawings have been finally approved by Tenant and Landlord.

   (c) Landlord's Approval; Performance of Work. Landlord's approval of such working drawings shall not be unreasonably withheld, provided that (1) they comply with all laws, (2) the improvements depicted thereon do not adversely affect (in the reasonable discretion of Landlord) the Building's structure or the Building's systems, the exterior appearance of the Building, or the appearance of the Common Area, (3) such working drawings are sufficiently detailed to allow construction of the improvements in a good and workmanlike manner, and (4) the improvements depicted thereon conform to the rules and regulations promulgated from time to time by Landlord for the construction of tenant improvements and delivered to Tenant. As used herein, "**Working Drawings**" shall mean the final working drawings approved by Landlord, as amended from time to time by any approved changes thereto, and "**Tenant Work**" shall mean all improvements to be constructed in accordance with and as indicated on the Working Drawings. Landlord's approval of the Working Drawings shall not be a representation or warranty of Landlord that such drawings are adequate for any use or comply

with any law, but shall merely be the consent of Landlord thereto. Tenant and Landlord shall, at the other's request, sign the Working Drawings to evidence their review and approval thereof. After the Working Drawings have been approved, Tenant shall cause the Tenant Work to be performed in accordance with the Working Drawings. Tenant may not commence construction of the Tenant Work until necessary permits have been obtained.

3. Contractors; Performance of Tenant Work. The Tenant Work shall be performed only by licensed contractors and subcontractors approved in writing by Landlord, which approval shall not be unreasonably withheld. Landlord hereby approves Skender as general contractor. Tenant may competitively bid the Tenant Work. All contractors and subcontractors shall be required to procure and maintain insurance against such risks, in such amounts, and with such companies as Landlord may reasonably require. Certificates of such insurance, with paid receipts therefor, must be received by Landlord before the Tenant Work is commenced. The Tenant Work shall be performed in a good and workmanlike manner free of defects, shall conform strictly with the Working Drawings, and shall be performed in such a manner and at such times as and not to unreasonably interfere with the operation of the Building, and the occupancy thereof by other tenants. All contractors and subcontractors shall contact Landlord and schedule time periods during which they may use Building facilities in connection with the Tenant Work (e.g., elevators, excess electricity, etc.). Tenant must use union contractors.

4. Construction Contracts

(a) Tenant's General Contractor. Tenant shall enter into a construction contract with a general contractor selected by Tenant and approved by Landlord (such approval not to be unreasonably withheld, conditioned or delayed) in a form acceptable to Tenant's representative for the Tenant Work, which shall comply with the provisions of this Section 4 and provide for, among other things, (1) a one-year warranty for all defective Tenant Work; (2) a requirement that Tenant's Contractor maintain general commercial liability insurance of not less than a combined single limit of $5,000,000 (which may be satisfied by an umbrella policy), naming Landlord, Landlord's property management company, Landlord's mortgagee and Tenant as additional insureds; (3) a requirement that the contractor perform the Tenant Work in substantial accordance with the Working Drawings and in a good and workmanlike manner; (4) a requirement that the contractor is responsible for daily cleanup work and final clean up (including removal of debris); and (5) those items described in Section 4.(b) below (collectively, the "**Approval Criteria**"). Landlord shall have three business days to notify Tenant whether it approves the proposed construction agreements. If Landlord disapproves of the proposed construction agreements, then it shall specify in reasonable detail the reasons for such disapproval, in which case Tenant shall revise the proposed construction agreements to correct the objections and resubmit them to Landlord within five business days after Landlord notifies Tenant of its objections thereto, following which Landlord shall have two business days to notify Tenant whether it approves the revised construction agreements. Landlord shall not unreasonably withhold, condition or delay its approval. Tenant must deliver to Landlord a true, correct and complete copy of the executed construction contract between Tenant and Tenant's general contractor and all amendments thereto promptly after execution thereof.

(b) All Construction Contracts. Unless otherwise agreed in writing by Landlord and Tenant, each of Tenant's construction contracts shall: (1) provide a schedule and sequence of construction activities and completion reasonably acceptable to Landlord, (2) be in a contract form that satisfies the Approval Criteria, and (3) be assignable following an uncured default by Tenant under the Lease to Landlord and Landlord's mortgagee.

5. Change Orders. Tenant may initiate changes in the Tenant Work. Each material change must receive the prior written approval of Landlord, such approval not to be unreasonably withheld, conditioned or delayed; however, if such requested change would adversely affect (in the reasonable discretion of Landlord) (i) the Building's structure or the Building's systems, (ii) the exterior appearance of the Building, or (iii) the appearance of the Common Area, Landlord shall have the right to approve or disapprove the change in its sole and absolute discretion. Landlord shall respond to a change order request within three (3) business days. Tenant shall, upon completion of the Tenant Work, furnish Landlord with an accurate architectural "as-built" plan of the Tenant Work as constructed in PDF and CAD format (together with a hard copy thereof), which plan shall be incorporated into this Exhibit by this reference for all purposes. If Tenant requests any changes to the Tenant Work described in the Working Drawings, then such increased costs and any additional design costs incurred in connection therewith as the result of any such change shall be added to the Total Construction Costs.

6. Definitions. As used herein "**Substantial Completion**," "**Substantially Completed**," and any derivations thereof mean the Tenant Work in the Relocation Premises is substantially completed (as reasonably determined by Tenant's Architect) in accordance with the Working Drawings, and Tenant has obtained a Certificate of Occupancy if required by applicable law. Substantial Completion shall have occurred even though minor details of construction, decoration, and mechanical adjustments remain to be completed.

7. Walk-Through; Punchlist. When Tenant considers the Tenant Work in the Relocation Premises to be Substantially Completed, Tenant will notify Landlord and within three business days thereafter, Landlord's representative and Tenant's representative shall conduct a walk-through of the Relocation Premises and identify any necessary touch-up work, repairs and minor completion items that are necessary for final completion of the Tenant Work. Neither Landlord's representative nor Tenant's representative shall unreasonably withhold his or her agreement on punchlist items. Tenant shall use reasonable efforts to cause the contractor performing the Tenant Work to complete all punchlist items within 60 days after agreement thereon.

8. Excess Costs. The entire cost of performing the Tenant Work (including design of the Tenant Work and preparation of the Working Drawings, any fees of the Architect or any engineers, costs of construction labor and materials, electrical usage during construction, and related taxes and insurance costs, all of which costs are herein collectively called the "**Total Construction Costs**") in excess of the Construction Allowance (hereinafter defined) shall be paid by Tenant. Upon approval of the Working Drawings, selection of a contractor and determination of the estimated Total Construction Costs, Tenant shall promptly execute a work order agreement which identifies such drawings and itemizes the Total Construction Costs and sets forth the Construction Allowance.

9. Construction Allowance.

(a) Landlord shall provide to Tenant a construction allowance not to exceed $135.00 per rentable square foot in the Relocation Premises (the "**Construction Allowance**") to be applied toward the Total Construction Costs, as adjusted for any changes to the Tenant Work. If the Total Construction Costs are estimated to exceed the Construction Allowance by more than $5.00 per rentable square foot of the Relocation Premises, then no advance of the Construction Allowance shall be made by Landlord until Tenant has first paid to the contractor from its own funds (and provided reasonable evidence thereof to Landlord) the anticipated amount by which the projected Total Construction Costs exceed the amount of the Construction Allowance. Thereafter, Landlord shall pay to Tenant (or at Tenant's request directly to Tenant's general contractor) the Construction Allowance in multiple disbursements (but not

more than once in any calendar month) following the receipt by Landlord of the following items: (i) a request for payment and sworn statements of Tenant and contractor, (ii) final or partial lien waivers, as the case may be, from all persons performing work or supplying or fabricating materials for the Tenant Work, fully executed, acknowledged and in recordable form, which waivers may be conditioned upon receipt of payment, (iii) the Architect's certification that the Tenant Work for which reimbursement has been requested has been finally completed, including (with respect to the last application for payment only) any punch-list items, on the appropriate AIA form or another form approved by Landlord, and, (iv) with respect to the disbursement of the last 10% of the Construction Allowance, (1) the permanent certificate of occupancy issued for the Relocation Premises, if required by applicable law, (2) the record drawing in CAD format, PDF format and hard copy required by Section 5 above, and (3) an estoppel certificate confirming such factual matters as Landlord or Landlord's Mortgagee may reasonably request (collectively, a "**Completed Application for Payment**"). Landlord shall pay the amount requested in the applicable Completed Application for Payment to Tenant within 30 days following Tenant's submission of the Completed Application for Payment. If, however, the Completed Application for Payment is incomplete or incorrect, Landlord shall promptly notify Tenant of the same and Landlord's payment of such request shall be deferred until 30 days following Landlord's receipt of the corrected Completed Application for Payment. Notwithstanding anything to the contrary contained in this Exhibit, Landlord shall not be obligated to make any disbursement of the Construction Allowance during the pendency of any of the following: (1) Landlord has received written notice of any unpaid claims relating to any portion of the Tenant Work or materials in connection therewith covered by previously funded applications for payment, (2) there is an unbonded lien outstanding against the Building or the Relocation Premises or Tenant's interest therein by reason of work done, or claimed to have been done, or materials supplied or specifically fabricated, claimed to have been supplied or specifically fabricated, to or for Tenant or the Relocation Premises, (3) the conditions to the advance of the Construction Allowance are not satisfied, or (4) Tenant is in Default under the Lease.

(b) **The Construction Allowance must be used on Tenant Work performed within the Relocation Premises and the Total Construction Costs and may not be used to pay for furniture, fixtures or equipment or as rent abatement, HOWEVER, notwithstanding the foregoing, provided Tenant is not in Default, Tenant may use a portion of the Construction Allowance, not to exceed an amount equal to $35.00 per rentable square foot of the Relocation Premises, to pay for furniture, fixtures or equipment, moving costs, cabling costs, and other soft costs associated with the Relocation Premises. Should Tenant elect to use a portion of the Construction Allowance to pay for such soft costs, at Landlord's request Tenant shall execute and deliver a letter to Landlord confirming the exact amount of the Construction Allowance used to pay for such soft costs. Should Tenant elect to use a portion of the Construction Allowance to pay for such costs, Tenant shall provide Landlord with a written request that includes copies of paid invoices or receipts for reimbursement of such costs, and Landlord shall reimburse Tenant for such amounts within 30 days of receipt of Tenant's request. Tenant shall provide lien waivers as appropriate. No portion of the Construction Allowance may be used as a credit against Rent due under the Lease.**

(c) **The Construction Allowance must be used (i.e. work performed and invoices submitted to Landlord) by June 30, 2020, or the Construction Allowance shall be deemed forfeited with no further obligation by Landlord with respect thereto.**

(d) **If Landlord defaults in Landlord's obligation to pay the Construction Allowance pursuant to Section 9 of this Exhibit B-1, or any portion thereof, within five (5) days after the date the same is due, then Tenant shall have the right to give Landlord a second written notice ("Offset Exercise Notice") requesting payment of such unpaid amounts and notifying Landlord that Tenant intends to offset against rent if not paid. In the event that Landlord fails to contest in good faith or fully pay such amounts within ten (10) business days after such Offset Exercise Notice is received by Landlord, then provided no Default exists Tenant may withhold and offset such unpaid sums from and against 25% of Base Rent next due until paid.**

10. Demolition Allowance. In addition to the Construction Allowance, Landlord shall provide Tenant a "Demolition Allowance" not to exceed $3.50 per rentable square foot of the Relocation Premises. The Demolition Allowance may be used only to pay for costs of demolition of existing conditions in the Relocation Premises. Landlord shall disburse the Demolition Allowance in the same manner as the Construction Allowance, except that Section 9(a)(iv) above shall not be required and the Demolition Allowance must be used by June 30, 2019 or shall be deemed forfeited with no further obligation by Landlord with respect thereto.

11. Construction Cost Reimbursement. Tenant shall reimburse Landlord for all reasonable, actual out of pocket costs incurred by Landlord in connection with plan review and supervision of Tenant's work. "Supervision" costs in this context are out of pocket costs of third party contractors and engineers that Landlord may engage to ensure that work has been constructed in accordance with approved plans. In addition, Tenant shall be responsible for Building standard charges for work orders, after hours HVAC, and other services required in connection with Tenant's performance of the Tenant Work.

12. Construction Representatives. Landlord's and Tenant's representatives for coordination of construction and approval of change orders will be as follows, provided that either party may change its representative upon written notice to the other:

Landlord's Representative:

Ryan Moore
Project Manager
Jones Lang LaSalle
10 S. Riverside Plaza, Suite 850
Chicago, Illinois 60606
Phone: (312) 930- 9890
Email: ryan.moore@us-mgt.ivanhoecambridge.com

Tenant's Representative:

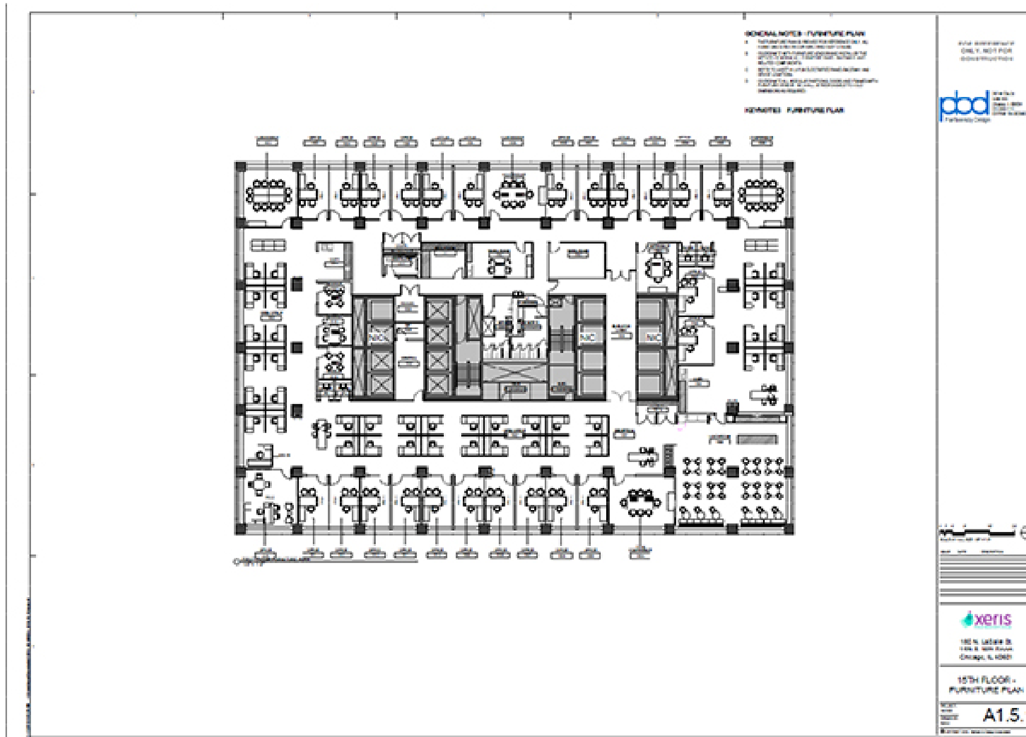
Steve Pieper
c/o Xeris Pharmaceuticals, Inc.
180 North LaSalle Street, Suite 1810
Chicago, Illinois 60601
Telephone: (312) 517-1384
Email: SPieper@xerispharma.com

Tenant will coordinate construction and changes with Landlord's Representative. Other than Landlord's Representative, Tenant will not make any inquiries of or requests to, and will not give any instructions or authorizations to, any other employee or agent of Landlord, including Landlord's architect, engineers and contractors or any of their agents or employees, with regard to matters covered by this Work Letter.

13. Miscellaneous. To the extent not inconsistent with this Exhibit, the Lease shall govern the performance of the Tenant Work and Landlord's and Tenant's respective rights and obligations regarding the improvements installed pursuant thereto. Initial and subsequent construction in the Relocation Premises by Tenant shall comply with the building's environmental and energy efficiency initiatives in effect at the time of construction. Such initiatives may include, but shall not be limited to, usage of low VOC construction materials (including, without limitation, low VOC paint and carpet); energy efficient lighting (and controls), equipment, and appliances; HVAC efficiencies; water use reduction; CFC reduction; recycling; construction waste management; usage of locally manufactured materials; usage of rapidly renewable materials; and usage of recycled materials. Landlord shall provide Tenant the specific requirements for the foregoing upon Tenant's request.

EXHIBIT A TO EXHIBIT B-1

SPACE PLANS



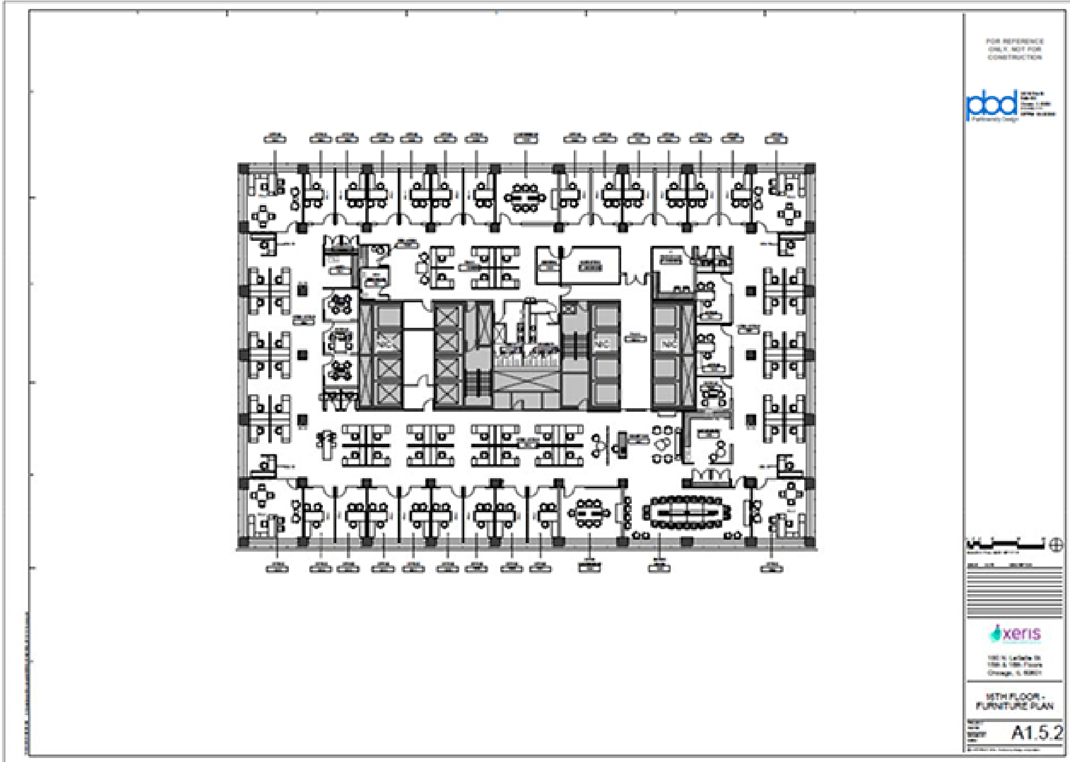
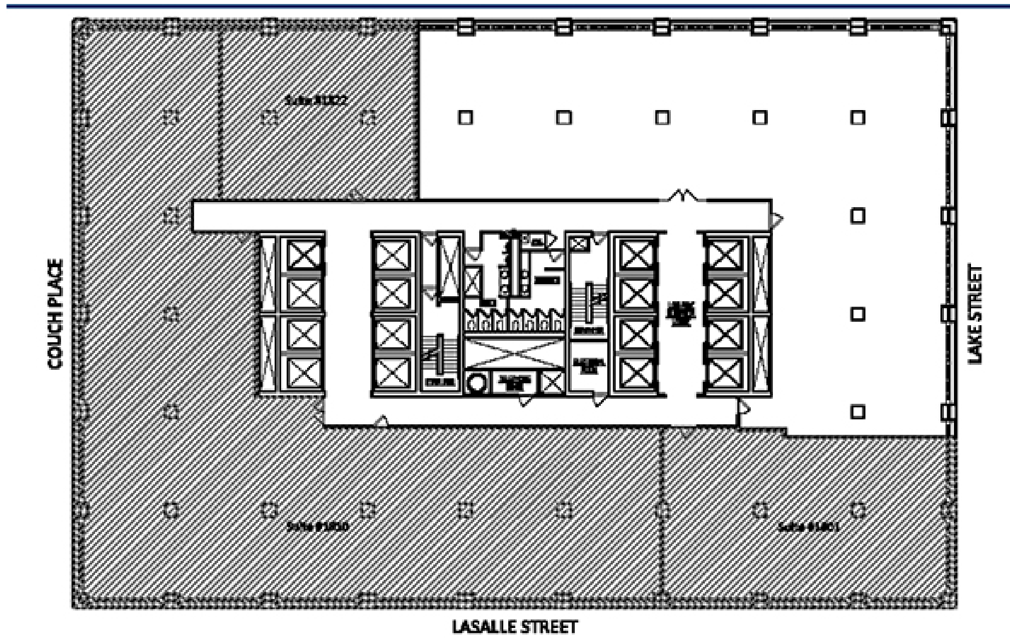

FOR REFERENCE ONLY. NOT FOR CONSTRUCTION
pbd
xeris
180 N. LaSalle St.
15th & 16th Floors
Chicago, IL 60601
16TH FLOOR - FURNITURE PLAN
A1.5.2

EXHIBIT C-1

EXPANSION SPACE



180 NORTH LASALLE STREET - CHICAGO, ILLINOIS
FLOOR 18 - LEASE EXHIBIT C EXPANSION SPACE SUITES 1801, 1810 AND 1822

November 6, 2018

EXHIBIT D-1

REMAINING FURNITURE

EXHIBIT D-1

REMAINING FURNITURE

Xeris Furniture Walk-through
Date: November 15, 2018
Location: 180 N LaSalle 15th & 16th Floors
Attendees: Xeris
CBRE
PBD

Below is a list of items that Xeris would like to keep for Re-use from suites 1500 and 1600.

15th Floor:

(11) Training tables- 24x60 - Training Tables on site: 5 silver w/gray top and 6 w/white top

(12) White boards

(6) Wood grain laminate top Dining tables- 36" Dia.

(24) Blackish/Gray dining chairs

(1) TV in conference room off of reception

16th Floor:

(1) White high top table and (3) barstools from café

(2) Lounge chairs + (1) coffee table from corner office - 1638

(1) TV from 1632

(3) TVs from café

(6) TVs from 1601 + IT rack + camera (1) TV + camera from 1614

(1) TV from 1646

(1) TV from 1638

(10) Task chairs Herman Miller Aeron

EXHIBIT E

TENANT’S EXTERIOR SIGNAGE LOCATION CHOICES

SCHEDULE 1

RIGHTS SUPERIOR TO TENANT'S EXPANSION OPTION

- The tenant under the Building's ABM Janitorial Services lease has a superior right of first offer on 18th floor space.
- The tenant under the Building's Donald A. Shapiro, Ltd. Lease has a renewal option on Suite 1801, exercisable if at all by notice given on or before November 30, 2018.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Xeris Pharmaceuticals, Inc.:

We consent to the use of our report included herein and to the reference to our firm under the heading “Experts” in the prospectus.

/s/ KPMG LLP

Chicago, Illinois
February 11, 2019