UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-40880

XERIS BIOPHARMA HOLDINGS, INC.

(Exact name of the registrant as specified in its charter)

Delaware	**87-1082097**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1375 West Fulton Street, Suite 1300 Chicago, Illinois	**60607**
(Address of principal executive offices)	(Zip Code)

(844) 445-5704

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**XERS**	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2023, the aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant was approximately $361.6 million based on the closing sales price as reported on the Nasdaq Stock Market.

As of February 29, 2024, 140,453,467 shares, par value $0.0001 per share, of common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the Registrant's Definitive Proxy Statement to be filed with the Commission in connection with the Registrant's 2023 Annual Meeting of Shareholders. Such Definitive Proxy Statement will be filed not later than 120 days after the conclusion of the Registrant's fiscal year ended December 31, 2023.

Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- As a company, we have a limited operating history and limited experience commercializing pharmaceutical products and have incurred significant losses since inception.
- We may never be profitable or be able to sustain revenues or, if achieved, sustain profitability in the future and we may not be able to continue operations without additional fundings.
- 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 could force us to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our business depends entirely on the commercial success of our products and product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed.
- We operate in a competitive business environment, which may have an adverse impact on our revenue. If we are unable to compete successfully against our existing or future competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our products or product candidates, even if approved.
- If we are unable to establish or do not maintain sufficient marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our products on terms acceptable to us, we may not be able to generate product revenue and our business, results of operations, and financial condition will be materially adversely affected.
- Our reliance on third-party suppliers, including single-source suppliers, together with a limited number of possible suppliers and long development lead-times for alternate sources for Gvoke, Recorlev and Keveyis or our product candidates could harm our ability to develop our product candidates or to continue to commercialize Gvoke, Recorlev, Keveyis, or any product candidates that are approved.
- Reimbursement decisions by third-party payors and consolidation within the healthcare industry and among competitors 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 and pricing pressure may impact our ability to sell our products at prices necessary to support our current business strategies.
- 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 Food and Drug Administration ("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.
- Gvoke, Recorlev, Keveyis and 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.
- Our failure to successfully identify, develop and market additional product candidates, or acquire additional product candidates or enter into collaborations or other commercial agreements could impair our ability to grow.
- Our success depends on our ability to protect our intellectual property and proprietary formulation science, as well as the ability of our collaborators to protect their intellectual property and proprietary formulation science.
- Our stock price has been and will likely continue to be volatile, and you may lose part or all of your investment.
- Our data collection and processing activities are governed by restrictive regulations governing the use, processing and, in certain jurisdictions, cross-border transfer of personal information.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled "Risk Factors" and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the United States Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

XERIS BIOPHARMA HOLDINGS, INC.

Index to Annual Report on Form 10-K

Year Ended December 31, 2023

Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K (this "Annual Report") are referred to without the ® and ™ symbols, but absence of such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. The trademarks, trade names, and service marks appearing in this Annual Report are the property of their respective owners.

Cautionary Statements for Forward-Looking Information

This Annual Report on Form 10-K 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 Annual Report on Form 10-K include, but are not limited to, statements about:

- the rate and degree of market acceptance and clinical utility of Gvoke, Recorlev and Keveyis;
- the pricing and reimbursement of Gvoke, Recorlev and Keveyis or any of our product candidates, if approved;
- our estimates regarding the market opportunities for Gvoke, Recorlev and Keveyis and our product candidates;
- the commercialization, marketing and manufacturing of Gvoke, Recorlev and Keveyis and our product candidates, if approved;
- our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of components and drug product for commercialization of Gvoke, Recorlev and Keveyis or any of our product candidates, if approved;
- our expectations related to the collaboration and partnerships with other pharmaceutical companies regarding the development of formulations of their proprietary therapeutics using our formulation science;
- the rate and degree of market acceptance and clinical utility of any of our product candidates for which we receive marketing approval in the future;
- 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 our public offerings and borrowings in ways that increase the value of your investment;
- our expectations related to the use of proceeds from our public offerings and borrowings and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- 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; and
- other risks and uncertainties, including those listed under the section entitled "Risk Factors" (refer to Part 1, Item 1A, of this Annual Report on Form 10-K).

In some cases, forward-looking statements can be identified by terminology such as "will," "would," "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" and terms of similar meaning. 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". 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.

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 Annual Report on Form 10-K.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for Gvoke, Recorlev and Keveyis and 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.

PART I

ITEM 1. BUSINESS

As used herein, the "Company", "Xeris", "we" or "our" refers to Xeris Biopharma Holdings, Inc. ("Xeris Biopharma"). Throughout this document, unless otherwise noted, references to Gvoke include Gvoke PFS, Gvoke HypoPen, Gvoke Kit and Ogluo.

Overview

We are focused on building an innovative, self-sustaining, growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing clinically meaningful products across a range of therapies. We are uniquely positioned to achieve this through our three commercial products and our proprietary formulation science (XeriSol and XeriJect), which generates partnerships and enhances our product candidates.

Commercial Products

Our top priority is maximizing the potential of our three commercial products:

- *Gvoke* is a ready-to-use, liquid-stable glucagon for the treatment of severe hypoglycemia. The product is indicated for use in pediatric and adult patients with diabetes age two years and above and can be administered in two simple steps. The estimated total addressable market for this drug is approximately $5.0 billion in the United States.
- *Recorlev* is a cortisol synthesis inhibitor approved for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative. Endogenous Cushing's syndrome is a rare but serious and potentially fatal endocrine disease caused by chronic elevated cortisol exposure. The estimated total addressable market for this therapy is approximately $3.0 billion in the United States.
- *Keveyis* is the first therapy approved in the United States to treat hyperkalemic, hypokalemic, and related variants of Primary Periodic Paralysis ("PPP"). PPP is a rare genetic, neuromuscular disorder that can cause extreme muscle weakness and/or paralysis; some forms are also commonly associated with myotonia or muscle stiffness. The estimated total addressable market for this therapy is greater than $0.5 billion in the United States.

Our Proprietary Formulation Capabilities

Our company name, Xeris, is derived from the ancient Greek word xērós meaning 'dry' or 'without water/non-aqueous'. Our proprietary, non-aqueous formulation capabilities are designed to enable the convenient injection of medicines previously uninjectable or poorly injectable when utilizing aqueous approaches. Both XeriSol and XeriJect offer the opportunity to create ready-to-use, room-temperature stable, highly concentrated, injectable formulations of both small and large molecules. These proprietary formulation capabilities can enable subcutaneous (SC) or intramuscular (IM) administration in lieu of intravenous (IV) infusion, allow for convenient, cost-effective storage, and provide an improved patient, caregiver, and healthcare provider experience. XeriSol and XeriJect have broad applications and enable us to develop our own internal product development candidates in endocrinology, neurology and other therapeutic areas. They also enable us to pursue formulation and development partnerships pursuant to which our proprietary formulation science is applied with the goal of enhancing the product formulation, delivery and clinical profile of other companies' proprietary drugs and biologics.

Our Strategy

Our goal is to build a growth-oriented, self-sustaining biopharmaceutical company by developing and commercializing differentiated and innovative products across a range of therapies that improve patients' lives. To achieve our goal, we are pursuing the following strategies:

- ***Drive revenue growth through effective commercial execution of our innovative products.*** We have three innovative commercial assets (Gvoke, Recorlev and Keveyis) all of which fill unique, unmet needs. Additionally, Gvoke and Recorlev are in the early stages of their product lifecycles and both leverage our experienced and growing leadership presence in the endocrinology community. Executing against the opportunities made possible by Gvoke, Recorlev, and Keveyis should maintain our momentum of growth and enable the financial self-sufficiency of our Company.
- ***Continue to leverage our proprietary formulation science and expertise to develop our internal new product candidates.*** We have established a proven capability to bring new and innovative products through the development and regulatory process to successful commercialization. XeriSol and XeriJect have broad application and have the potential to be utilized across a range of potential product candidates in multiple therapeutic areas. Our immediate focus is on developing XP-8121, a once weekly subcutaneous injection of levothyroxine and eventually generating significant benefits for patients and value for our company.
- ***Collaborate with pharmaceutical and biotechnology companies to apply our proprietary formulation science to enhance the formulations of their proprietary products and candidates.*** We are pursuing formulation and development partnerships to apply our XeriJect and XeriSol formulation platforms to enhance the drug delivery and clinical profile of other companies' proprietary drugs and biologics. We are currently collaborating with several major pharmaceutical companies on the development of formulations of their proprietary therapeutics with XeriJect. Our strategic goal is to ultimately enter into commercial licensing agreements with these partners upon successful completion of formulation development.

We believe these three pillars of our strategy can bring new products to market and transform the lives of patients with life-impacting diseases and ultimately drive value for Xeris' shareholders. Pursuing these strategies provides Xeris with a range of value driving opportunities that are incremental to the value already realized by the Xeris enterprise.

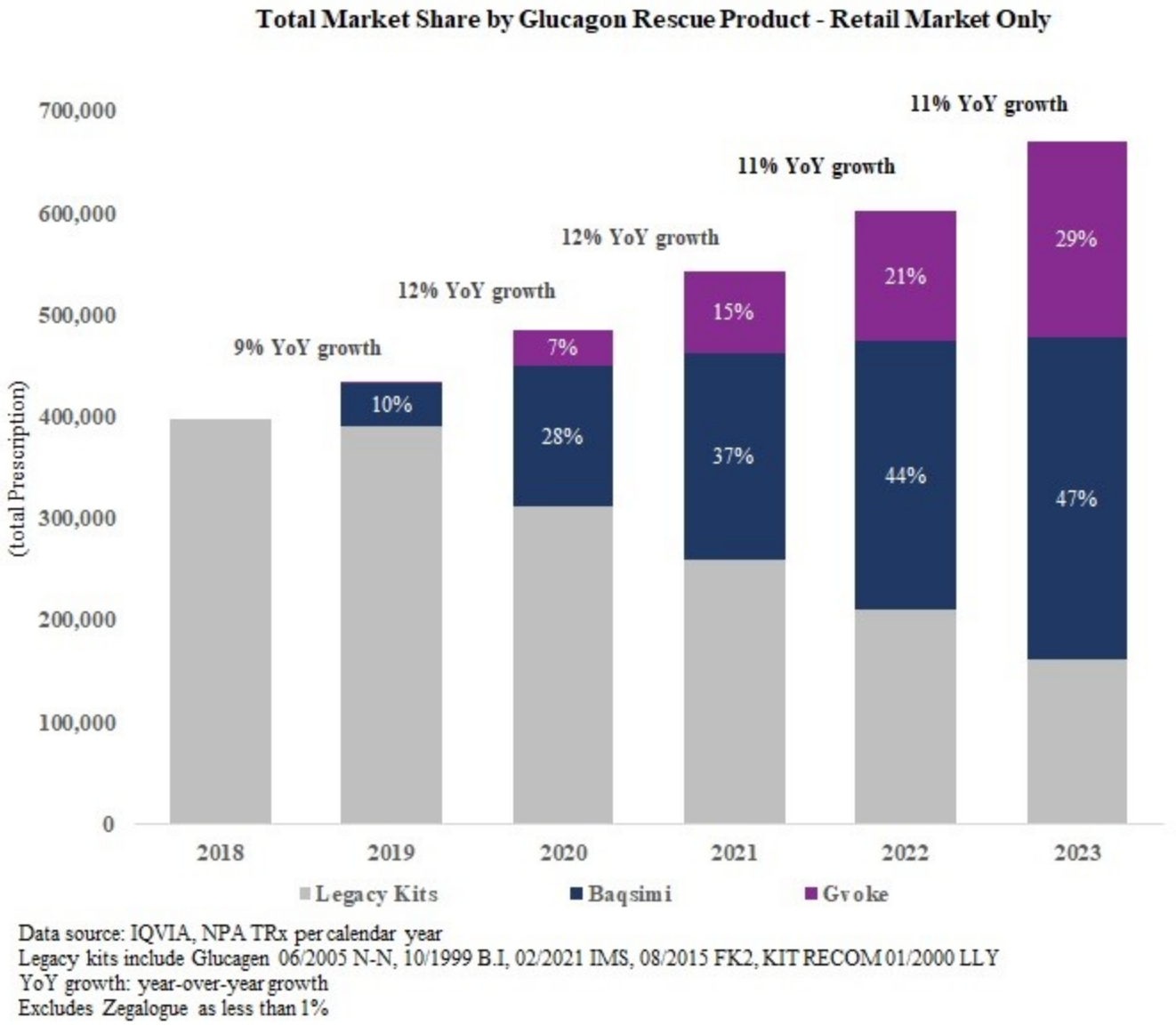
Our Products

Gvoke

Gvoke is our ready-to-use, room-temperature stable, liquid glucagon product. Available since late 2019, Gvoke is a potentially life-saving rescue product that is designated to be reliably administrated by the individual with diabetes or their caregivers during low blood sugar emergencies (e.g., a severe hypoglycemic episode). Gvoke is available in three presentation types - HypoPen (auto-injector), PFS (pre-filled syringe), and Kit (pre-filled vial and administration syringe). Our most widely prescribed presentation, HypoPen, is designed to be administered subcutaneously in a simple two-step process requiring no dose calibration.

The marketplace for Gvoke and other ready-to-use glucagon products is significant, owing to the widespread and growing prevalence of diabetes, the large proportion of people with diabetes at risk of experiencing a severe hypoglycemic event, and the still limited awareness of the availability of innovative, ready-to-use glucagon.

We participate in this market primarily with Baqsimi, a ready-to-use nasally administered glucagon powder, which was launched in mid-2019 and acquired by Amphastar Pharmaceuticals, Inc. in June 2023. Our promotional efforts to create awareness of Gvoke have helped expand the market for rescue glucagon by more than 60%, enabled us to capture an over 30% share of the overall glucagon rescue retail market as of December 31, 2023, and generated approximately a quarter million prescriptions since launch.



Data source: IQVIA, NPA TRx per calendar year
Legacy kits include Glucagen 06/2005 N-N, 10/1999 B.I, 02/2021 IMS, 08/2015 FK2, KIT RECOM 01/2000 LLY
YoY growth: year-over-year growth
Excludes Zegalogue as less than 1%

The most recent Standards of Care established by the American Diabetes Association, the American Academy of Clinical Endocrinologists, and the Endocrine Society, all advise that patients at increased risk of dangerously low blood sugar should be prescribed a ready-to-use glucagon. We estimate that at least half of the approximately 30 million people with diabetes in the United States fall into this at-risk category and should be prescribed and have handy, a ready-to-use rescue glucagon, like the Gvoke HypoPen for use during a potential severe hypoglycemic episode. Current prescription volumes suggest that approximately 1 million people with diabetes are adequately protected today, leaving a significant number of people without protection as recommended by the latest guidelines. If all at risk persons were adequately protected, the market potential is estimated to be nearly $5.0 billion annually.

Our commercial team and sales force are focused on driving awareness and adoption of Gvoke by healthcare professionals, patients and caregivers.

Recorlev

Recorlev is our new therapy approved in 2022 for the treatment of Cushing's syndrome, a rare condition which is the result of sustained, elevated levels of cortisol in the body (hypercortisolism). Cushing's syndrome affects approximately 25,000 people in the United States of which approximately two-thirds are cured by surgery. Pharmacologic products like Recorlev are used for the balance of patients for whom surgery was not curative or was not indicated. Recorlev has received orphan drug exclusivity status in the United States through December 30, 2028.

We believe that the Cushing's syndrome market in the United States is approximately $3.0 billion annually. Recorlev competes primarily with other established medications and therapies, including older generic drugs that are used off-label for Recorlev's approved indication. Signifor (pasireotide) Injection and Isturisa (osilodrostat) are approved for Cushing's Disease, a subset of Cushing's syndrome and sold by Recordati S.p.A. Korlym (mifepristone) is approved for the treatment of hyperglycemia secondary to

hypercortisolism in Cushing's syndrome patients and sold by Corcept Therapeutics. Because of the complex nature of Cushing's syndrome, many patients are inadequately treated with currently available medicines.

Our experienced commercial organization focuses on educating prescribing clinicians and patients to raise awareness of the benefits of normalizing cortisol with Recorlev. Xeris' Care Connection program provides direct, dedicated support to treating clinicians and patients throughout their Recorlev journey. In addition, our efforts include the support of a single, highly experienced specialty pharmacy that provides logistical assistance in the securing of coverage from third-party payors and then subsequent distribution of Recorlev to the patients.

Keveyis

Keveyis (dichlorphenamide) is the first FDA-approved therapy for the treatment of the ultra-rare condition of PPP. PPP is an inherited group of neuromuscular conditions that are characterized by interference with the electrical-chemical communications between nerve cells and skeletal muscles that can cause paralytic attacks.

PPP is estimated to affect approximately 4,000 to 5,000 people in the United States. Our promotional efforts are aimed at bringing awareness of this condition to both the healthcare professionals and patient communities.

Patient identification, capture, and retention in ultra-rare markets is extremely difficult and time-consuming. To address this, we have built an extensive set of patient support processes and proprietary analytics to identify patients affected by PPP and suitable for Keveyis therapy treatment. We also employ a specialty pharmacy to assist with the navigation of complex payer, healthcare professionals and patient support requirements for this ultra-rare disease.

Since our purchase of Keveyis through the acquisition of Strongbridge, we have been planning and projecting for the loss of orphan drug exclusivity status, which occurred in August 2022. We also continue to seek patents to restore our exclusive rights. We currently have two United States patent applications pending with claims protecting therapeutic uses of Keveyis. Both of these patent applications are on appeal at the United States Court of Appeals for the Federal Circuit. In late 2022, the FDA approved a generic version of our Keveyis product.

Our proprietary Formulation Platforms

Overview

In the presence of water, many drugs have poor solubility and stability. Our proprietary non-aqueous formulation science is designed to address the challenges associated with formulating certain drugs and overcome the inherent limitations of conventional aqueous-based formulation approaches. Injectable pharmaceuticals have conventionally been developed using aqueous formulations. 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 an aqueous diluent. This is typically associated with a challenging multi-step procedure with significant potential for error. Furthermore, these drugs can begin to break down once combined with water, which requires the reconstituted product to be used immediately or otherwise be refrigerated. In addition, many of these drugs 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 products can be difficult or painful to administer and have limited portability, resulting in an overall poor experience for patients and caregivers.

Our proprietary non-aqueous XeriSol and XeriJect technologies 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 and other routes of administration. We believe these present distinct advantages over existing aqueous formulation approaches for currently marketed products and development-stage product candidates.

The proprietary XeriSol non-aqueous formulation platform is designed to address the limitations of aqueous formulations for peptide and small molecule drugs. The solutions are formulated using biocompatible, non-aqueous solutions that impart high stability and solubility to drugs allowing for development of room temperature stable, ready-to-use formulations. XeriSol formulations have been used extensively in global commercial products (Gvoke/Ogluo) and clinical trials.

The proprietary XeriJect non-aqueous formulation platform is designed as an innovative, ready-to-use, viscoelastic pharmaceutical suspension that has the potential to improve drug delivery, lower treatment burden and improve patients' lives across a broad range of therapeutic categories. XeriJect suspensions maximize drug loadings at >400mg/mL, enable small volume subcutaneous injections and do not settle on storage. The suspensions use FDA-approved excipients and leverage known manufacturing processes. XeriJect formulation science is well suited for drugs and biologics including large molecules such as proteins, monoclonal antibodies, and vaccines.

The formulation science associated with both the XeriSol and XeriJect technologies is protected by an extensive patent estate, trade secrets and know-how, and it is available for licensing. We believe that our scientific formulation capabilities can lead to products that will improve outcomes and enable easier administration while reducing costs for payors and the healthcare system.

Our Product Candidates

Once Weekly Subcutaneous Injection of Levothyroxine (XP-8121)

XP-8121 is a novel formulation for subcutaneous administration that could potentially mitigate many of the challenges associated with oral formulations, such as identification of an ideal dose due to absorption variation and medication adherence for patients who have difficulty maintaining a stable, therapeutic serum level. Preclinical studies of XP-8121 showed a sustained plasma exposure profile

and similar highest concentration of a drug in the blood, or Cmax, when compared with equivalent doses of the oral formulation. We conducted a Phase 1 study of XP-8121 to evaluate the pharmacokinetics, safety and tolerability, and potential for weekly dosing in the treatment of hypothyroidism.

Levothyroxine and Hypothyroidism

The thyroid gland is responsible for the synthesis, storage, and release of metabolic hormones including thyroxine (T4) and triiodothyronine (T3). These hormones are crucial in the regulation of critical metabolic processes and are vital for normal growth and development during fetal life, infancy, and childhood.

Therapeutically, levothyroxine is administered as a replacement for deficient thyroid hormones. The goal of the therapy is restoration of the euthyroid state which can reverse the clinical manifestations of hypothyroidism and significantly improve quality of life. The treatment of choice for correction of hypothyroidism is currently continuous daily oral administration of levothyroxine. It is one of the most widely prescribed drug products in the United States, but the complexity of maintaining biochemical and clinical euthyroidism in patients undergoing treatment with oral levothyroxine is challenging. It has been reported that nearly 40% of patients undergoing treatment with oral levothyroxine are either over- or under-treated due to factors that include, but are not limited to, drug formulation, use of the drug with food, adherence to the drug, use of concomitant medications, and pre-existing medical conditions. Many patients failing to reach target thyroid stimulating hormone ("TSH") levels are managed by simply increasing their levothyroxine daily dose. However, levothyroxine is a drug with a narrow therapeutic index, meaning that relatively small deviations from the proper dose can cause a clinically meaningful shift in pharmacological effects when administered to a patient; thus, the titration of levothyroxine oral drug may be a tailored and incremental process.

The Phase 1 clinical study was a single ascending dose crossover design in 30 healthy participants to compare matching doses of oral levothyroxine (Synthroid) and subcutaneous XP-8121. The primary endpoints of the study were to characterize the absorption and elimination kinetics of XP-8121 and compare bioavailability of XP-8121 to oral levothyroxine. Secondary endpoints were safety and tolerability of XP-8121.

In October 2022, we reported positive topline Phase 1 data of XP-8121. The data showed that subjects receiving XP-8121 subcutaneous had slower absorption, lower peak plasma, and higher extended exposure compared to Synthroid PO at the comparable dose of 600 µg. In addition, exposure was proportional over the range of ascending XP-8121 doses studied. Simulations based on a population pharmacokinetic model indicated that exposure from weekly XP-8121 1200 µg SC doses overlapped daily Synthroid PO 300 µg suggesting a dose conversion factor of 4x. Importantly, single SC doses of XP-8121 at all doses were well-tolerated and the XP-8121 doses studied were generally comparable to Synthroid 600 µg PO with respect to the safety findings. In June 2023, we initiated a non-randomized, open-label, single arm, self-controlled Phase 2 study to determine a target dose conversion factor from stably dosed oral levothyroxine to XP-8121 in patients with hypothyroidism and also assess the safety and tolerability after once-weekly subcutaneous injections. In November 2023, the study was over 85% enrolled and should be completed in the first half of 2024.

Market Opportunity

Hypothyroidism affects approximately 20 million people in the United States. For nearly 100 years, the only available option to treat patients with hypothyroidism has been with oral levothyroxine. The prescription category comprised of oral levothyroxine in its various branded and generic forms is the second largest prescription category in the United States with more than one hundred million prescriptions written annually. Complications associated with a requirement to take medicines by mouth, every day, are well-documented and include difficulties in swallowing, gastrointestinal malabsorption or intolerance, potential interactions with other orally administered medications, and general non-adherence given the daily regimen. Any of these complications can contribute to suboptimal treatment requiring higher dosing, generally poor control over TSH levels, or complete treatment failure. We believe XP-8121 to be well-suited to address these challenges. XP-8121 is designed to be a once-weekly, small-volume, subcutaneous injection which, given its route of administration, bypasses the gastrointestinal tract and could avoid many of the therapeutic complications associated with the use of oral forms of levothyroxine. We believe that our novel approach to treatment has the potential to establish a new standard of care for hypothyroidism. Given the size of the impacted patient population and the challenges faced by certain patients, we estimate the potential market opportunity for XP-8121 to be $2.0 to $3.0 billion dollars annually.

Collaboration and Partnerships

We believe that our proprietary XeriSol and XeriJect formulation capabilities could be broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To enhance and further exploit our core formulation science, we will continue to collaborate with other pharmaceutical companies on the development of formulations of their proprietary therapeutics with XeriSol or XeriJect. This strategy is designed to broaden our revenue stream and enhance the formulation, delivery and clinical profile of other companies' proprietary drugs and biologics. Our strategic goal is to ultimately enter into commercial licensing agreements with our partners upon successful completion of formulation development.

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 ("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. The standard operating procedures and quality systems in place at Xeris and our CMOs are designed to ensure compliance with the FDA's Current Good Manufacturing Practice ("CGMP") regulations and provide a framework for effective regulatory communications. We selected our CMOs for specific competencies, and they have met our development, manufacturing, quality and regulatory requirements and have all been involved in manufacturing our clinical supplies, commercial registration batches, and commercial products.

Glucagon is the active pharmaceutical ingredient ("API") used in Gvoke and our ready-to-use glucagon product candidates. Bachem Americas, Inc., ("Bachem") is our primary commercial source for glucagon API. Bachem holds a United States 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. We believe that Bachem has sufficient capacity to satisfy our long-term glucagon API requirements for Gvoke and other ready-to-use glucagon product candidates.

Manufacturing drug product for Gvoke requires an aseptic fill/finish facility capable of handling solvents and a cyclic olefinic polymer syringe. Pyramid Laboratories, Inc. ("Pyramid") has been actively involved in the development and manufacturing of Gvoke. Its facility in California is our primary source for drug product. We have entered into a non-exclusive supply agreement with Pyramid. We believe that Pyramid has sufficient capacity to satisfy our demand requirements for at least three to five years.

The auto-injector used to deliver drug product in Gvoke HypoPen is a proprietary multi-product device platform developed by SHL Medical AG and SHL Pharma, LLC (collectively "SHL"). SHL produces device sub-assemblies at its facility in Taiwan and performs final drug product/device assembly operations at its facility in Florida. We have entered into a supply agreement with SHL.

We have a supply agreement with Taro Pharmaceuticals North America, Inc. ("Taro") to produce Keveyis including all packaging. If the supply agreement is terminated by Taro at the conclusion of the renewal term, we have the right to manufacture the product on our own or have the product manufactured by a third party on our behalf.

Levoketoconazole is the API used in Recorlev. Regis Technologies, Inc. ("Regis") has been actively involved in the development and manufacturing of levoketoconazole and its facility in Illinois is our sole source for API. We have entered into a supply agreement with Regis. We believe that Regis has sufficient capacity to satisfy our demand requirements for at least three to five years.

Manufacturing Recorlev drug product requires a conventional solid oral dosage form manufacturing facility. Lonza Tampa, LLC (f/k/a Xcelience, LLC, "Lonza") has been actively involved in the development and manufacturing of Recorlev and its facility in Florida is our sole source for drug product. We have entered into a supply agreement with Lonza. We believe that Lonza has sufficient capacity to satisfy our demand requirements for at least three to five years.

We believe that a number of CMOs can provide suitable secondary packaging services for Gvoke and Recorlev, and we have entered into commercial supply agreements with one vendor. A number of third-party logistic providers can provide commercial order processing and finished goods distribution services to the United States specialty pharmacies and wholesale customers, and we have a commercial distribution agreement with one such vendor for Gvoke, Recorlev and Keveyis.

Competition

Our industry is characterized by intense competition and a strong emphasis on proprietary products. While we believe that our employees, products, product candidates, formulation science, development expertise, intellectual property 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.

- **Gvoke:** Two traditional emergency glucagon kits are currently available to treat severe hypoglycemia: Fresenius Kabi's Glucagon Emergency Kit and Amphastar's generic Glucagon for Injection Emergency Kit. In addition to Gvoke, two ready-to-use glucagon products are currently available to treat severe hypoglycemia. The first is Amphastar's intranasal glucagon dry powder, Baqsimi, and the second is Zealand Pharma's dasiglucagon auto-injector, Zegalogue, which is currently commercialized by Novo Nordisk. We are not aware of any drugs or additional treatments currently in development.
- **Recorlev:** A number of therapies are currently approved or in various stages of development for endogenous Cushing's syndrome. Currently, there are no therapies broadly marketed for the treatment of endogenous Cushing's syndrome patients in the United States. Korlym (mifepristone), marketed by Corcept Therapeutics Incorporated, is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. In addition, Teva Pharmaceutical Industries Limited initiated the launch of a generic version of mifepristone in early 2024. Signifor (pasireotide) and Signifor LAR are marketed by Recordati in the United States and are indicated for the treatment of adult patients with Cushing's disease (a subset of Cushing's syndrome) for whom pituitary surgery is not an option or has not been curative. Isturisa (osilodrostat), a cortisol synthesis inhibitor indicated for adult patients with Cushing's disease (a subset of Cushing's syndrome) for whom pituitary surgery is not an option or has not been curative, is also marketed by Recordati. A number of products, including ketoconazole, metyrapone, cabergoline, mitotane and etomidate are used off-label for the treatment of Cushing's syndrome in the United States. Ketoconazole, metyrapone and mitotane are marketed by HRA Pharma in certain European countries. We are also facing potential competition from a number of pipeline products in development, such as Relacorilant (CORT125134), AZD-4017 and SPI-62.
- **Keveyis:** In late 2022, the FDA approved a generic version of our Keveyis product, which is marketed by Torrent Pharmaceuticals Ltd. Another product, acetazolamide, an oral carbonic anhydrase inhibitor, is used frequently off-label for the prophylactic and sometimes acute treatment of PPP. Potassium supplements are indicated for use in hypokalemic periodic paralysis in the United States and are frequently used either chronically or for emergency treatment of episodes in the form of PPP. Several other types of drugs have been reported to have benefits for chronic or acute use in one or more than one PPP variant, including potassium-sparing diuretics, beta receptor agonists, mexelitine and other sodium channel blockers, and others.

Intellectual Property

Proprietary Protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our products and product candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing our proprietary rights. We have been building and continue to build our intellectual property portfolio relating to our product candidates and formulation science. We seek to protect our proprietary position by, among other methods, filing United States and certain foreign patent applications related to our proprietary formulation science, inventions and improvements that are important to the development and implementation of our business. We also intend to rely on trade secrets, know-how, formulation science innovation and 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 formulation science.

Patent Rights

We currently own 170 patents issued globally, including composition of matter patents covering our ready-to-use glucagon formulation that expire in 2036. Included in the total patents, we have 60 granted patents globally related to our platform technologies and 8 patents granted in the United States and listed in the United States FDA Orange Book covering proprietary formulations of levoketoconazole (the active pharmaceutical ingredient in Recorlev) and the uses of such formulations in treating certain endocrine-related diseases and syndromes. The latter includes United States Patent Nos. 11,020,393, 11,278,547 and 11,903,940, which were granted on June 1, 2021, March 22, 2022, and February 22, 2024, respectively, and which provide patent protection through 2040 for the use of Recorlev in the treatment of certain patients with persistent or recurrent Cushing's syndrome.

Trade Secrets and Other Protection

In addition to patented intellectual property, we also rely on trade secrets and proprietary know-how to protect our formulation science 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 own all inventions conceived and/or reduced to practice by the individual in the course of their employment with us or 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 registered trademarks for the mark Xeris Pharmaceuticals in the United States, for the marks GVOKE, GVOKE HYPOPEN and HYPOPEN in the United States and several ex-United States countries, the registered trademark for OGLUO in the EU and the UK, and the registered trademarks for XERIJECT in the United States, Australia, the EU, the UK, Japan and Mexico. We also own pending trademark applications for XERISOL in the United States and a number of ex-US countries, and for the marks GVOKE, GVOKE HYPOPEN and XERIJECT in a number of ex-United States countries, all for use in connection with our pharmaceutical research and development and products, as well as trade names that could be used with our product candidates.

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

Regulation

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 ("FDCA") and its implementing regulations and biologics under the FDCA and the Public Health Service Act ("PHSA") and their 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 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 United States 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.

Certain of our products and product candidates are subject to regulation as combination products, which means that they are composed of both a drug product and device product. If our drug products, along with our combination product, 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 Gvoke and some 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 ("CDER") or FDA's Center for Biologics Evaluation and Research ("CBER") has primary jurisdiction over the premarket development, review and approval of the combination product. Accordingly, we plan to continue to investigate our products through the Investigational New Drug ("IND") framework and seek approval through the New Drug Application ("NDA") or Biologics License Applications ("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 component of our combination products, 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 ("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 ("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 FDA's Clinical Practices ("GCPs") regulations, to establish the safety and efficacy of the proposed drug or biologic for its proposed indication;
- submission to the FDA of an 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 CGMP regulations;
- potential FDA inspection of Xeris, the clinical trial sites, or other vendors that generated the data in support of the NDA or BLA;
- 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 ("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. Preclinical 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 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 are also 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. In addition, for certain combination products it may be necessary to conduct Human Factors studies prior to NDA or BLA submission to ascertain the usability of the product by patients in real-world settings.

FDA Review Process

The results of product development, preclinical studies, Human Factors studies (when required), 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 an 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, most NDAs or BLAs must be accompanied by a significant application user fee to the FDA. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. 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 which we utilized for Gvoke.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA or BLA for filing. The FDA typically makes a decision on accepting an 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 ("PDUFA"), the FDA's goal to complete its substantive review and respond to the applicant is ten months from the receipt of a standard 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 an 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 an NDA or BLA, the FDA may 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 an 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 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 at least two adequate and well-controlled clinical studies and 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 authorized, however, 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 approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternative 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 ("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 an NDA, known as the reference-listed drug ("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 an 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 RLD. 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 ("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.

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 ("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 an 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 provide a Paragraph IV certification against 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, 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, 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 the 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 also has 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 ("QS") regulations applicable to medical devices.

Drug-device combination products present unique challenges for competitors seeking approval of an ANDA for generic versions of combination products. Generally, the 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 the 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, the 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 ("PDMA"), a part of the FDCA, as well as the Drug Supply Chain Security Act ("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 its 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 are prohibited from marketing or promoting 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 or 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 or 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, an 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 ("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.

A biological product or drug can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and, for drugs, patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection and, for drugs, patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Expedited Review and Approval Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address

unmet medical needs for that disease or condition. For a Fast Track product, the FDA may consider sections of the NDA or BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met.

A product candidate may also qualify for priority review, under which the FDA generally sets the target date for FDA action on the NDA or BLA that is subject to PDUFA goals at six months after the FDA accepts the application for filing, or for drugs that are not new chemical entities, six months after the FDA receives the application. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA PDUFA review period of ten months after the FDA accepts the application for filing, or for drugs that are not new chemical entities, ten months after FDA receives the application. Priority review designation does not change the scientific or medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve an NDA or BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after regulatory approvals are generally required to verify the drug or biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product.

The FDA also may designate a product candidate as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy designation is a distinct status from both accelerated approval and priority review, which also can be granted to the same drug or biologic if relevant criteria are met. If a product is designated as Breakthrough Therapy, the FDA will work to expedite the development and review of such product.

Fast Track designation, Breakthrough Therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Regulations and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside 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, pricing, 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-United States 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 EU generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, pre-clinical 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 such competent authorities or the European Medicines Agency ("EMA") of a marketing authorisation application ("MAA") and granting of a marketing authorization before the product can be marketed and sold in the EU. Similar requirements are necessary to conduct clinical trials in the United Kingdom, with the submission of an MAA to the Medicines and Healthcare Products Regulatory Agency ("MHRA"), the UK medicines regulator for marketing authorization.

Clinical Trial Approval

In April 2014, the EU adopted the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which replaced the previous Clinical Trials Directive. The CTR entered into application on January 31, 2022. The transitory provisions of the CTR provide that, by January 31, 2025, all ongoing clinical trials must have transitioned to the CTR. The CTR overhauled the system of approvals for clinical trials in the EU. Specifically, the new legislation, which is directly applicable in all EU Member States (meaning no national implementing legislation in each Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. For instance, the CTR provides for a streamlined application procedure via a single-entry point (through the Clinical Trials Information System ("CTIS")) and strictly defined deadlines for the assessment of clinical trial applications. Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the EU through the CTIS.

Marketing Authorization

To obtain a marketing authorization for a product in the EU, an applicant must submit an MAA either under a centralized procedure administered by the EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EU, and in the additional Member States of the European Economic Area ("EEA") (i.e. Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines), and products with a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National marketing authorizations, which are issued by the competent authorities of the Member States of the EU and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this national authorization can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Now that the UK has left the EU, Great Britain is no longer covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations currently continue to be recognized in Northern Ireland). A separate marketing authorization is therefore required to market products in Great Britain. On January 1, 2024, a new international recognition framework was put in place by the MHRA, under which the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators when determining an application for a new Great Britain marketing authorization. The MHRA also has the power to have regard to marketing authorizations approved in EU Member States through decentralized or mutual recognition procedures with a view to more quickly granting a marketing authorization in the UK or Great Britain.

Data and Market Exclusivity

In the EU, innovative medicinal products approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. Data exclusivity, if granted, prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During an additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted and authorized, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained a marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA (for a centrally authorized product) or by the competent authority of the relevant EU Member State (for a nationally authorized product). To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in respect of the centralized procedure) or on the market of the authorizing EU Member State (for a nationally authorized product) within three years after authorization, or if the product is removed from the market for three consecutive years, ceases to be valid (the so-called sunset clause).

Regulatory Requirements After a Marketing Authorization has been Obtained

Where an authorization for a medicinal product in the EU is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive (EU) 2017/1572, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.
- The marketing and promotion of authorized medicinal products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of medicinal products and/or the general public, are strictly regulated in the EU notably under Directive 2001/83/EC, as amended, and are also subject to EU Member State national laws. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

The aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

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. Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from Medicare, Medicaid or other third-party payors for our products, we are subject to broadly applicable healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business. Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the Department of Health and Human Services ("HHS"), the Department of Justice ("DOJ"), the Drug Enforcement Administration ("DEA"), the Consumer Product Safety Commission ("CPSC"), the Federal Trade Commission ("FTC"), the Occupational Safety & Health Administration ("OSHA"), the Environmental Protection Agency ("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 the federal government and the states in which we conduct our business as well as in foreign jurisdictions in which we may conduct trials or where we may otherwise be subject to local regulation. The laws that may affect our ability to operate include:

- Anti-Kickback Statute ("AKS"). 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 program;

- The federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act ("FCA"), prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using or causing to be made or used a false statement or record material to 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. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Companies that submit claims directly to payors also may be liable under the FCA for the direct submission of such claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- 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;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health 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 associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-United States laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In addition, HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program 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, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; 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.
- 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 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 HHS information regarding any payment or other "transfer of value" made or distributed to healthcare professionals (currently defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other licensed healthcare practitioners and teaching hospitals, as well as ownership and investment interests held by the healthcare professionals and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission.
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- The Foreign Corrupt Practices Act ("FCPA"), which prohibits companies and their intermediaries from making, or offering or promising to make, improper payments to non-United States officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment.

Additionally, we may be subject to state and non-United States 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 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-United States 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 United States government. In addition, private individuals have the ability to bring actions on behalf of the United States 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, 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 also will likely subject us to non-United States equivalents of the healthcare laws mentioned above, among other non-United States 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 also may adversely affect our business.

We may also 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.

In the United States, to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs ("PAPs") and copay coupon programs for eligible patients. PAPs are regulated by and subject to guidance from CMS Office of Inspector General's ("OIG"). In addition, at least one insurer has directed its network pharmacies to no longer accept copay coupons for certain specialty drugs the insurer identified. Our copay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using copay coupons. Accordingly, companies exclude these Part D beneficiaries from using copay coupons.

Healthcare Reform

A primary trend in the United States 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 ("ACA") was enacted in the United States. The ACA includes measures that have significantly changed,

and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that 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.
- Imposed a requirement on manufacturers of branded drugs to provide a 70% point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i.e., "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D.
- Extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.
- Expanded the entities eligible for discounts under the 340B Drug Discount Program.
- Imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs.
- Established a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The United States Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year through 2031.
- On January 2, 2013, the United States American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives 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 May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- In August 2022, the Inflation Reduction Act of 2022, or IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs in Medicare Part D, allow the United States government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it will not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program The effects of the IRA on our business and the healthcare industry in general is not yet known.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At a federal level, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented 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.

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 or product candidates, 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 products or 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 pharmaceutical drug product or service does not ensure that other payors will also provide coverage for the pharmaceutical drug 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. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of pharmaceutical drug 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 healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, 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, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("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. 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. 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.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On November 3, 2023, the U.S. District Court of South

Carolina issued an opinion in Genesis Healthcare Inc. v. Becerra et al. that may lead to an expansion of the scope of patients eligible to access prescriptions at 340B pricing. The outcome of this judicial proceeding is uncertain. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. We continue to review developments impacting the 340B program.

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 HHS, 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 drugs, if any such drug or the condition that they are intended to treat are the subject of a trial. It also is possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drugs after approval. 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.

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 of our products or product candidates for which we may obtain regulatory approval or the frequency with which any such product 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 of our products or product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Human Capital Resources

As of December 31, 2023, we had 377 full-time employees in the United States, 216 of whom were primarily engaged in sales and marketing, 121 of whom were primarily engaged in general administration, and 40 of whom were primarily engaged in product development and research.

We believe our success will depend on, among other things, our ability to continue to hire and retain the necessary qualified personnel across all departments in our organization, as we expand the commercialization of our products. Our President and Chief Operating Officer and Vice President, Human Resources are responsible for developing and executing our human capital strategy. This includes the attraction, acquisition, development and engagement of talent to deliver on the Company's strategy. The executive management team regularly updates our board of directors and its committees on the operation and status of our human capital trends and activities.

Diversity, Equity and Inclusion

We are committed to building a company that provides an inclusive environment where we invite and encourage diverse perspectives, ideas, and people. With that goal in mind, we have established a committee comprised of employees and sponsored by key executive team members to continue building a strategic plan designed to promote a diverse and inclusive work environment. We believe these initiatives and a workforce with diverse backgrounds, experiences and viewpoints will continue to help the Company achieve innovative solutions to the business challenges. In addition, we have sought to implement recruiting practices and to work with recruiting partners who can help us best identify and attract diverse candidates. We continue to expand our systems to track key human capital metrics such as demographics, diversity, compensation and benefits, and engagement and to think of new ways to best support our female and underrepresented employees to help advance their careers.

Training and Talent Development

We believe that our employees are the key to our success, and we believe their development is what drives our growth and prosperity as a company. To support employee development, as well as plan for short- and long-term business success, we review and update a company succession plan regularly and we offer a number of development opportunities for our employees through various methods. Our succession plan is reviewed with the board annually. In addition, upon joining the company, all new employees are required to become familiar with our policies, including our Code of Business Conduct and Ethics and Employee Handbook, and complete compliance training, and existing employees are required to acknowledge current policies annually.

Compensation and Benefits

An important part of attracting and retaining key talent is competitive pay and benefits. To ensure our compensation and benefits programs are competitive, we engage nationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our programs and to provide benchmarking against our peers within the industry. Our pay for performance philosophy seeks to motivate and reward employees while accomplishing the Company's short and long-term strategic goals. As part of a robust performance management process, employees are evaluated both on what they accomplished and how they

demonstrated our values. Annual salary increases and incentive bonuses are based on both individual and corporate performance factors.

As a long-term incentive, to encourage our employees to think like owners and share in the Company's long-term success, employees are granted equity in the form of stock options or restricted stock units and can elect to participate in our employee stock purchase plan. Employees are generally eligible for health insurance, paid and unpaid leaves including paid parental leave, paid caregiver leave, retirement plans with an employer contribution match, life and disability/accident coverage, parking or commuter assistance, an employee assistance program providing mental health, legal and financial health resources, and a wellness reimbursement benefit.

Health and Safety

We are committed to the safety of our employees and the communities we serve. We provide regular health and safety training programs for employees, which includes, upon on-boarding, an overview during new hire orientation, as well as ongoing training throughout the year. Employees are trained on workplace safety, including security and inspection, work related injuries and emergency protocols as applicable for their role and work location. In addition, special health and safety training is conducted for laboratory staff.

Corporate Information

We were incorporated under the laws of the State of Delaware in 2005. Our principal offices are located at 1375 West Fulton Street, Chicago, Illinois, 60607, and our telephone number is (844) 445-5704. We completed our initial public offering of common stock in June 2018, and our common stock is listed on The Nasdaq Global Select Market under the symbol "XERS." Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

Available Information

Our website address is www.xerispharma.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act") are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at *http://www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Our code of conduct, corporate governance guidelines and the charters of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are available through our website at www.xerispharma.com.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Careful consideration should be given to the following risk factors, in evaluating us and our business. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized and described below are not intended to be exhaustive and are not the only risks facing us. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks Related to our Financial Position and Need for Financing

Risks Related to Our Operating History

As a company, we have a limited operating history and limited experience commercializing pharmaceutical products and have incurred significant losses since inception.

Historically, we have funded our operations primarily through private placements of convertible preferred stock, public offerings of common stock and convertible notes, and debt issuances. We have five pharmaceutical products that were commercially launched in the past six years, i.e., Keveyis (2017), Gvoke PFS (2019), Gvoke HypoPen (2020), Recorlev (2022) and Gvoke Kit (2022). We are in the early stages of commercializing our biopharmaceutical products and have a limited operating history.

We have incurred significant losses in every fiscal year since inception. For the years ended December 31, 2023, 2022 and 2021, we reported a net loss of $62.3 million, $94.7 million and $122.7 million, respectively. In addition, our accumulated deficit as of December 31, 2023 was $617.0 million.

We expect to continue to incur significant operating expenses as we continue the commercialization of Gvoke, Recorlev and Keveyis, develop, enhance and commercialize new products, and incur additional operational and reporting costs associated with being a public company. In particular, we anticipate that we will continue to incur significant expenses as we:

- execute our Gvoke, Recorlev and Keveyis commercial strategies in the United States;
- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements; and
- continue to operate as a public company.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies prior to and at the early stages of commercialization of any product candidates, especially biopharmaceutical 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 biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to successfully execute our commercialization strategy and may not be successful in doing so. 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 may never be profitable or be able to sustain revenues or, if achieved, sustain profitability in the future and we may not be able to continue operations without additional fundings.

Our ability to generate revenue from Gvoke, Recorlev and Keveyis, and our product candidates, if successfully developed and approved, depends on a number of factors, including, but not limited to, our ability to:

- obtain commercial quantities of our products at acceptable cost levels;
- successfully manage inventory;
- sell and distribute our products on terms acceptable to us;
- achieve an adequate level of market acceptance of our products 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;
- obtain and maintain third-party coverage and adequate reimbursement for our products;
- compete effectively against our competitors; and
- launch and commercialize our products utilizing our own sales force or by entering into partnership or co-promotion arrangements with third parties.

We have incurred and expect to continue to incur significant sales and marketing costs as we commercialize Gvoke, Recorlev and Keveyis. Regardless of these expenditures, our products and our product candidates, if developed and approved, may not be commercially successful. Although we generate revenue from Gvoke, Recorlev and Keveyis, if we are unable to generate sufficient product revenue, we will not become profitable. 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.

Risks Related to Future Financial Condition

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 could force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Biopharmaceutical development is a time consuming, expensive and uncertain process that takes years to complete. We are incurring significant commercialization expenses related to product sales, marketing, manufacturing, packaging and distribution of Gvoke, Recorlev and Keveyis and expect to continue to incur such expenses for our products, as well as for any of our product candidates, if approved. We expect to require additional capital to complete the clinical trials associated with our product candidates and begin commercialization efforts, if approved. Accordingly, we may need additional funding in connection with our continuing operations. In the future, 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 and/or sales and marketing activities. Market volatility, including due to geopolitical instability, rising interest rates, fluctuations in inflation rates, the tightening of lending standards, any further deterioration in the macroeconomic economy or financial services industry resulting from actual or potential bank failures, or other factors could also materially and adversely impact our ability to access capital as and when needed and increase our cost of capital even if available.

We may be required to or choose 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 significant interest expense or other costs, 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. Under our existing credit facility dated March 8, 2022, as amended (the "Hayfin Loan Agreement"), with the lenders from time to time parties thereto (the "Lenders"), Hayfin Services LLP, as administrative agent for the Lenders, Xeris Pharmaceuticals, Inc., Xeris Biopharma Holdings, Inc. and our subsidiaries party thereto, we are restricted in our ability to incur additional indebtedness and to pay dividends. Any additional debt financing that we may secure in the future could include similar or more restrictive covenants relating to our capital raising activities, buying or selling assets and other financial and operational matters, which may make it more difficult for us to obtain additional capital, manage our business and pursue business opportunities. We may also be required to secure any such debt obligations with some or all of our assets. For example, our Hayfin Loan Agreement is secured by substantially all of our property and assets, including our intellectual property assets, subject to certain exceptions.

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 commercialization of our products and 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. 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, or to repurchase our Convertible Notes for cash following a fundamental change, if required, and our existing and future indebtedness may limit our ability to repurchase the Convertible Notes.

On June 30, 2020, we completed a public offering of $86.3 million aggregate principal amount of our 5.00% Convertible Senior Notes due 2025 (the "2025 Convertible Notes"), including $11.3 million pursuant to the underwriters' option to purchase additional notes which was exercised in July 2020. A total principal amount of $39.1 million of Convertible Notes converted into equity in the second half of 2020. On September 29, 2023, we completed the exchange of $31,975,000 in aggregate principal amount of the 2025 Convertible Notes for $33,574,000 in aggregate principal amount of new 8.00% Convertible Senior Notes due 2028 (the "2028 Convertible Notes" and together with the 2025 Convertible Notes, the "Convertible Notes"). As of December 31, 2023, the outstanding balance of the 2025 Convertible Notes was $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million. The 2025 Convertible Notes are governed by the terms of a base indenture for senior debt securities dated June 30, 2020 (the "2025 Base Indenture"), as supplemented by the first supplemental indenture thereto dated June 30, 2020 and the second supplemental indenture thereto dated October 5, 2021 (collectively, the "2025 Supplemental Indentures" and together with the 2025 Base Indenture, the "2025 Indenture"), each between us and U.S. Bank Trust Company, National Association (f/k/a U.S. Bank National Association) ("U.S. Bank"), as trustee. The 2028 Convertible Notes are governed by the terms of an indenture for senior debt

securities dated September 29, 2023 (the "2028 Indenture" and together with the 2025 Indenture, the "Indentures") between us and U.S. Bank, as trustee. Failure to satisfy our current and future debt obligations under the Indentures could result in an event of default and, as a result, all of the amounts outstanding could immediately become due and payable. In the event of an acceleration of amounts due under the Indentures 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.

Noteholders may require us to repurchase their Convertible Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change includes certain acquisition transactions and the failure of our common stock to be listed on the Nasdaq Global Select Market or certain similar national securities exchanges. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Convertible Notes. In addition, applicable law, regulatory authorities and the agreements governing our existing and future indebtedness may restrict our ability to repurchase the Convertible Notes. Our failure to repurchase the Convertible Notes when required will constitute a default under the Indentures that govern the Convertible Notes. A default under the Indentures or the fundamental change itself could also lead to a default under agreements governing our other existing or future indebtedness, which may result in that other indebtedness becoming immediately payable in full. For instance, a fundamental change without lender consent would constitute an event of default under our Hayfin Loan Agreement. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Convertible Notes.

In addition, we have $150.0 million of term loans outstanding under our Hayfin Loan Agreement as of December 31, 2023. All obligations under our Hayfin Loan Agreement are secured by substantially all of our property and assets, including our intellectual property assets, subject to certain limited exceptions. The term loans and the Convertible Notes 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 Hayfin Loan Agreement could result in an event of default thereunder and, as a result, our lenders could accelerate all amounts due. Events of default also include our failure to comply with customary affirmative and negative covenants as well as a default under any indenture or other agreement governing convertible indebtedness permitted by the Hayfin Loan Agreement, including the Indentures. The Hayfin Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict our ability to incur additional indebtedness, grant liens, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. In the event of an acceleration of amounts due under our Hayfin Loan 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. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

Our PPP Loan, which we repaid in full in June 2020, was subject to the terms and conditions applicable to loans administered by the SBA under the CARES Act, and we may be subject to an audit or enforcement action related to the PPP Loan.

On April 21, 2020, we entered into the United States Small Business Administration (the "SBA") PPP Note (the "Note") with Silicon Valley Bank (the "PPP Lender") for a loan in the amount of $5.1 million (the "PPP Loan") enabled by the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act"). We received the full amount of the PPP Loan on April 22, 2020. On May 4, 2020, we repaid $0.9 million of the PPP Loan. In June 2020, we repaid the remaining amount outstanding under the PPP Loan in connection with the concurrent 2025 Convertible Notes and equity offerings.

We may be subject to CARES Act-specific lookbacks and audits until May of 2026 that may be conducted by other federal agencies, including several oversight bodies created under the CARES Act. These bodies have the ability to coordinate investigations and audits and refer matters to the Department of Justice for civil or criminal enforcement and other actions. Complying with such SBA audit could divert management resources and attention and require us to expend significant time and resources, which could have an adverse effect on our business, financial condition and results of operations.

Greater than expected product returns may exceed our reserve for returns.

We use various factors to estimate the provision for returns, including the launch date of products, historical customer return rates, third-party industry data for comparable products in the market and estimated channel inventory data. In a reporting period, we may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels, inventory dating, prescription data, the expiration dates of product, price changes of competitive products and introductions of generic products. Any significant increase in returns that exceeds our reserves could adversely affect our revenue and operating results.

We use data from third parties as part of our return reserves calculation. We are reliant on these third parties to ensure that the data they provide is accurate. Inaccurate data could cause us to estimate our return reserves incorrectly and could have an adverse impact on our results of operations and financial condition.

Risks Related to the Commercialization and Marketing of our Products and Product Candidates

Risks Related to Commercialization and Marketing

Our business depends entirely on the commercial success of our products and 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 recently has been and will continue to be focused on marketing and commercializing our approved products, Gvoke, Recorlev and Keveyis, in the United States. Our business and future success are substantially dependent on our ability to generate and increase product revenue in the near term. Our estimates of the potential market opportunity for Gvoke, Recorlev, Keveyis, and 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. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, the actual market for our product and product candidates could be smaller than our estimates of our potential market opportunity. Our product candidates are in various stages of development and subject to the risks of failure inherent in developing drug products. Any delay or setback in the regulatory approval, product launch, commercialization or distribution of any of our product candidates will adversely affect our business. The infrastructure, systems, processes, policies, relationships and materials we have built for the commercialization of Gvoke, Recorlev and Keveyis may not be sufficient for us to achieve success at the levels we expect. Further, our products may contain undetected manufacturing defects, including mislabeling, which might require product replacement, re-labeling or product recalls, which could further harm our business. For more information, see the section entitled, "*Business — Coverage and Reimbursement*".

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

- a covered benefit under health plans;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Additionally, if, after obtaining marketing approval of any of our products or product candidates, 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 product, 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, contraindications or the issuance of field alerts to physicians and pharmacies;
- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy ("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 a 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 products 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 product candidates, 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.

We operate in a competitive business environment, which may have an adverse impact on our revenue. If we are unable to compete successfully against our existing or future competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our products or 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, 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. 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 or product candidates, if approved, could be negatively affected and our results of operations could suffer. Because of the size of the potential market for certain of our products and product candidates, we anticipate that companies will dedicate significant resources to developing products competitive to such products and product candidates.

For example, Gvoke has numerous competitors in the severe hypoglycemia market, which currently include Amphastar's Baqsimi, an intranasal glucagon dry powder, Zealand Pharma's Zegalogue, a dasiglucagon outlicensed to Novo Nordisk, Novo Nordisk's GlucaGen HypoKit, Fresenius Kabi's glucagon emergency kit for low blood sugar, and Amphastar's generic Glucagon for Injection Emergency Kit. 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 Gvoke.

Keveyis (dichlorphenamide) is an oral carbonic anhydrase inhibitor that was approved in the United States to treat hyperkalemic, hypokalemic, and related variants of PPP for which orphan drug exclusivity ended on August 7, 2022. Torrent Pharmaceuticals Limited's ANDA for generic dichlorphenamide was approved on December 29, 2022 and now competes with Keveyis, which may adversely impact our revenue. In addition, due to the end of orphan drug exclusivity, we expect that additional generic competitors could emerge which may also contribute to the erosion of Keveyis sales. Acetazolamide, another oral carbonic anhydrase inhibitor, is used frequently off-label for the prophylactic and sometimes acute treatment of PPP. Potassium supplements are indicated for use in hypokalemic periodic paralysis in the United States and are frequently used either chronically or for emergency treatment of episodes in that form of PPP. Several other types of drugs have been reported to have benefits for chronic or acute use in one or more than one PPP variant, including potassium-sparing diuretics, beta receptor agonists, mexelitine and other sodium channel blockers, and others. We are not aware of drugs currently in development for prophylactic chronic treatment of PPP.

We are also currently aware of various companies that are marketing existing drugs that may compete with Recorlev, such as Corcept Therapeutics and Recordati. The treatment of endogenous Cushing's syndrome patients who fail or are ineligible for surgery in the United States and Europe are: Korlym (mifepristone) marketed by Corcept Therapeutics in the United States; Signifor LAR (pasireotide) and Isturisa (osilodrostat), both marketed by Recordati in the United States and EU; and ketoconazole, metyrapone and mitotane marketed by HRA in the EU. Corcept is developing relacorilant, a second-generation glucocorticoid receptor modulator; currently in Phase 3. Ketoconazole is used off-label for treatment of Cushing's syndrome in the United States. Regulatory approval of ketoconazole for the treatment of endogenous Cushing's syndrome in the United States, which is not currently being sought by any sponsor to our knowledge, could significantly increase competition for Recorlev due to the similar mechanisms of action between the drug products.

If we are unable to establish or do not maintain sufficient marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our products on terms acceptable to us, we may not be able to generate product revenue and our business, results of operations, and financial condition will be materially adversely affected.

We have developed our commercial infrastructure for the sales, marketing and distribution of Gvoke, Recorlev and Keveyis. In order to successfully commercialize our product candidates, we will need to maintain and may need to expand our marketing, sales, distribution, managerial and other non-technical capabilities and/or make arrangements with third parties to perform some or all of these services. We have established our sales force to market our products in the United States. In order to maintain and, if needed, expand our sales force, we will compete with other companies to recruit, hire, train and retain sales and marketing personnel. There are significant expenses and risks involved with maintaining and, if needed, expanding, our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, obtain access to an adequate number of physicians and persuade them to prescribe our products and any product candidates that receive regulatory approval, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in our ability to maintain or expand, if needed, our internal sales, marketing and distribution capabilities would adversely impact the commercialization of Gvoke, Recorlev and Keveyis and the launch and commercialization of our product candidates, if approved. Even if we are able to recruit, hire and retain a sufficient number of sales representatives, they may not be effective at promoting our products.

We intend to leverage the sales and marketing capabilities that we have established for our approved products to commercialize additional product candidates for the management of other 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 the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of our product candidates could be delayed which would negatively impact our ability to generate product revenue.

In addition, we intend to continue to establish collaborations to commercialize our product candidates outside the United States, if approved by the relevant regulatory authorities. Therefore, our future success outside the United States will depend, in part, on our ability to enter into and maintain collaborative relationships, 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 or exert the level of effort that we would if we were marketing and selling the product ourselves.

Risks Related to Third-Parties Actions and Market Acceptance

Our reliance on third-party suppliers, including single-source suppliers, together with a limited number of possible suppliers and long development lead-times for alternate sources for Gvoke, Recorlev and Keveyis or our product candidates could harm our ability to develop our product candidates or to continue to commercialize Gvoke, Recorlev, Keveyis, or any product candidates that are approved.

We do not currently own or operate any manufacturing facilities for the production of Gvoke, Recorlev, or Keveyis for commercial supply or our product candidates for use in clinical trials. We rely on third-party suppliers to manufacture and supply our products and our product candidates. For Gvoke, we currently rely on a number of single-source suppliers, such as Bachem Americas, Inc. and certain of its affiliates ("Bachem") for active pharmaceutical ingredient ("API"), Pyramid Laboratories Inc. ("Pyramid") for drug product and SHL Pharma, LLC ("SHL Pharma") for auto-injector and final product assembly, and we have entered into several supply agreements including with Bachem, Pyramid and SHL Pharma. Taro produces all of our requirements for Keveyis pursuant to a supply agreement. If the agreement were to be terminated by Taro prior to the next renewal in March of 2027, we will need to find a new third party to manufacture Keveyis or manufacture the product ourselves. Similarly, for Recorlev, we rely on a number of single-source suppliers, such as Regis Technologies, Inc. for API and Xcelience, LLC ("Lonza") for finished drug product. We rely on other third parties to manufacture our product candidates for use in clinical trials. If any of these vendors are unable or unwilling to meet our future requirements, we may not be able to manufacture and/or supply our products in a timely manner. Our current arrangements with these manufacturers are terminable by such manufacturers, subject to certain notice provisions. In addition, Taro maintains certain reversion rights in the purchased assets, including the regulatory approval for Keveyis, enabling Taro to elect to have the purchased assets returned to it and to terminate its agreement with us should we be materially in non-compliance with any reversion condition such as breaching certain of the assignment restrictions or failing to meet our marketing commitments after receiving notice thereof and failing to cure such material non-compliance.

Our third-party suppliers may not be able to produce sufficient inventory to meet commercial demand in a timely manner, or at all, and we continue to experience long lead times for certain components and materials used in the production of our products and product candidates. 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, we may not obtain sufficient quantities of products, components or other key materials in the future, which could have a material adverse effect on our business as a whole. Any disruption to the facilities or operations of our third-party suppliers resulting from weather-related events, epidemics, including global health concerns, fire, acts of terrorism, political instability, war, labor or geopolitical issues, or any other cause could materially impair our ability to manufacture our products and to distribute our products to customers. We have a global supply chain and manufacture some components of our products outside the United States, including without limitation, Taiwan and Israel. The current war between Israel and Hamas could directly and indirectly affect our operations. For example, the Israel-Hamas war could result in damage, destruction or disruptions to the facilities or operations of our third-party suppliers, including, but not limited to, our supplier of Keveyis, longer lead times for ours products or product candidates, export delays or restrictions or other adverse events which adverse events we cannot predict with any certainty. Any interruption or other delay in the production or delivery of our supplies could reduce sales of our products and increase our costs and any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

Gvoke and some of our product candidates are drug-device combination products that are regulated under the drug regulations of the Federal Food, Drug, & Cosmetic Act ("FDCA") based on their primary mode of action as a drug. Third-party manufacturers may fail to comply with the current Good Manufacturing Practice ("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 Quality System Regulation (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 our products and product candidates, re-labeling or re-packaging of our products, operating restrictions and criminal prosecutions, any of which could significantly affect the supply of our products and product candidates. The facilities used by our contract manufacturers to manufacture our products and product candidates must be registered with the FDA and are subject to inspections conducted by the FDA to ensure compliance with CGMPs. Other foreign regulatory authorities may also require manufacturers to register manufacturing facilities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with CGMPs and the QSR. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or circumstances where the contractor may not be able to maintain compliance with the applicable CGMP or the QSR. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications, CGMP and/or the QSR 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 such foreign regulatory authorities do not approve these facilities for the manufacture of our products or product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to market our products or develop, obtain regulatory approval for or market our product candidates, if approved.

There are a limited number of third-party suppliers that are compliant with CGMP and/or the QSR, as required by the FDA, the EU, 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. On February 23, 2022, the FDA proposed to amend its Quality System Regulation ("QSR") requirements to align more closely with the international consensus standards for medical devices. Specifically, the FDA proposed to do so primarily by incorporating by reference the 2016 edition of the International Organization of Standardization ("ISO"), ISO 13485 standard. We do not have certainty on when or if the proposed rule will be finalized or even if it is finalized, whether it will be finalized in its current proposed form. While the ISO 13485 standard and the FDA's QSR requirements are similar in certain aspects, it is possible that we may need to revise our compliance system and processes to be in line with the requirements established by any final rule to amend the QSR requirements.

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 due to terms within long-term supply arrangements with suppliers or lack of long-term supply arrangements for key materials and products;
- given the long lead times to change suppliers, existing suppliers may utilize that as leverage in negotiations with us in a manner that is adverse to our business;
- our suppliers may lose access to critical services or sustain damage to a facility, including losses due to natural disasters, accidents, terrorism, geo-political events, or epidemics that may result in a sustained interruption in the manufacture and
- 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 necessary raw materials or components become unavailable;
- 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; and
- the possibility of breach or termination of a manufacturing agreement or purchase order by the third party.

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.

If any CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our products or product candidates which license we may not be able to obtain on favorable terms or at all. In addition, in the case of the CMOs that supply our products or product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Additionally, under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.

Reimbursement decisions by third-party payors and consolidation within the healthcare industry and among competitors 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 and pricing pressure may impact our ability to sell our products at prices necessary to support our current business strategies.

Our future revenues and profitability will be adversely affected if the United States 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 on behalf of patients. If these entities do not 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 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 products or product candidates for which we obtain marketing approval. 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 and other terms favorable to them. 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 or other 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. For more information, see the sections entitled, "*Business — Coverage and Reimbursement*" and "*Business — Healthcare Reform*".

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.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree.

New requirements by third-party payors include: (i) net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States and (ii) third-party payors are increasingly requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement; and many pharmaceutical manufacturers must calculate and report certain price metrics to the government, such as average manufacturer price, or AMP, and Best Price. Penalties may apply when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

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. 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.

At the state level, legislatures have increasingly passed legislation and implemented 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.

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, these factors 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 or product candidates, and if we are unable to obtain adequate coverage and reimbursement by third-party payors, our ability to successfully commercialize our products or product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price, including through increased discounting, of our products will have a material adverse effect on our ability to achieve profitability.

The success of Gvoke, Recorlev, Keveyis and our product candidates will be dependent on their proper use by patients, healthcare practitioners and caregivers. Additionally, individual devices may fail.

We have designed our products to be operable by patients, caregivers, and healthcare practitioners. We cannot control the successful use of the product by patients, caregivers, and healthcare practitioners. If we are not successful in promoting the proper use of our products by patients, healthcare practitioners, and caregivers, we may not be able to achieve market acceptance or effectively commercialize our products. In addition, even in the event of proper use of our products such as Gvoke, 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 tablet or device that is produced, and it is possible that individual product may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of any of our products, result in negative press coverage, or increase the risk that we may be sued.

A small number of major customers account for a high percentage of our revenue, thus, the loss of any of these customers and our inability to enter into new customer relationships could negatively impact our business.

We depend on a relatively small number of customers for the majority of our revenue. As further discussed in "Note 2 - Basis of presentation and summary of significant accounting policies and estimates" to our consolidated financial statements, for the years ended December 31, 2023, 2022 and 2021, four customers accounted for over 90% of the Company’s gross product revenue. At December 31, 2023 and December 31, 2022, the same four customers accounted for over 90% of the trade accounts receivable, net. We expect to continue to depend upon a relatively small number of customers for a high percentage of our revenue. If we lose any of these customers and are unable to establish new customer relationships of similar magnitude, our business, prospects, financial condition and results of operations could be materially and adversely affected. Additionally, if one or more of our major customers experiences financial difficulties, the adverse impact on us could be substantial.

Risk Related to our Dependence on Third Parties for Clinical Trials

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, clinical research organizations ("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. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. 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. Further, conducting clinical trials in foreign countries, as we have done and may 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. 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. Our clinical trial vendors are required to monitor and report to us issues with the conduct of our clinical trials, and we monitor our clinical trial vendors through our clinical, regulatory, and quality assurance staff and other service providers. Our clinical trial vendors or

personnel may not timely and fully discover and report any fraud or abuse or other issues that may occur in connection with our clinical trials to us. Such fraud or abuse or other issues, if they occur and are not successfully remediated, could have a material adverse effect on our research, development, and commercialization activities and results.

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

Risks Related to Regulatory Approval

We cannot be certain that our product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our product candidates.

We have devoted significant financial resources and business efforts to the development of our product candidates. We cannot be certain that any of our 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 and other regulatory authorities 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 a New Drug Application ("NDA") or Biologics License Application ("BLA") 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, conditions for approval, regulations, standards of care, 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 and BLAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs and BLAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. Any delay or setback in the regulatory approval or commercialization of any of our 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 or other pathways we have selected, as applicable, 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 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, including any findings that the clinical and other benefits of our product candidates do not 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 we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for any of our 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 any of our 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 or implementation of a REMS;
- may change its criteria for 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.

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 (e.g., boxed warnings) or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators in 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.

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.

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 of our product candidates. Any delay in, or termination of, our clinical trials will delay the submission of the applicable NDA or BLA to the FDA, the Marketing Authorisation Application ("MAA") to the European Medicines Agency ("EMA") or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate revenue.

We intend to utilize the 505(b)(2) pathway for the regulatory approval of certain of our product candidates. If the FDA does not conclude that such 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 FDCA for the approval of certain of our product candidates, 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 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, former 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 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. Specifically, on March 23, 2020, a small subset of "biological products" approved under the FDCA, such as insulin, which historically were approved as drugs, transitioned to being regulated as biological products. Being regulated as biological products enables transition products to serve as the reference product for biosimilar or interchangeable products approved through the abbreviated licensure pathway. The transition is a regulatory action in which the approved drug application for a transition biological product will be "deemed" to be a biologics license application. If our other product candidates do not meet the requirements of Section 505(b)(2) or are otherwise ineligible or become 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, our product candidates may not 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 has 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 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.

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

Certain of our product candidates 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.

Gvoke, Recorlev, Keveyis and 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.

Patients treated in clinical trials with our ready-to-use glucagon have experienced drug-related side effects typically observed with glucagon products, including nausea, vomiting and headaches. In our clinical trials of Recorlev, the most common adverse reactions (incidence > 20%) were nausea/vomiting, hypokalemia, hemorrhage/contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain/dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia/sleep disturbances, and peripheral edema. In the Keveyis clinical trial, the most common adverse reactions (incidence > 10%) were paresthesia, cognitive disorder, dysgeusia, and confusional state. These adverse events can be dose-dependent and may increase in frequency and severity if we increase the dose to increase efficacy.

For our product candidates in development, 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 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, and for our approved products, the emergence of new or more serious side effects may cause regulatory authorities to impose additional requirements on our marketing and monitoring of these products. The range and potential severity of possible side effects from systemic therapies are significant. Recent developments in the pharmaceutical industry have prompted heightened government focus on safety reporting during both pre- and post-approval time periods and pharmacovigilance. For example, at the request of the FDA we are conducting an enhanced pharmacovigilance program for all cases of hepatotoxicity reported with patients taking Recorlev tablets, for a period of 5 years from the date of approval. Global health authorities may impose regulatory requirements to monitor safety that may burden our ability to commercialize our drug products. In addition, drug-related side effects of our product candidates could affect patient recruitment or the ability of enrolled patients to complete the trial or could also adversely affect physician or patient acceptance thereof. Any of these occurrences may harm our business, financial condition and prospects.

Even if our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by one of our 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 products 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 Keveyis, Recorlev and certain of our product candidates with respect to certain indications and may 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 five indications for our products and product candidates, which are our ready-to-use glucagon for post-bariatric hypoglycemia ("PBH") and Congenital Hyperinsulinism ("CHI"), and for Recorlev, for the treatment of adult patients with endogenous Cushing's syndrome for whom surgery is not an option or has not been curative. We may pursue such designation for others in specific orphan indications in which there is an unmet medical need. We relied on orphan drug exclusivity in the marketing and sale of Keveyis until it expired on August 7, 2022 and with respect to the marketing and sale of Recorlev, intend to rely on orphan drug exclusivity through December 30, 2028. 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 may 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. 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. In assessing whether a drug provides a "major contribution to patient care" over and above the currently approved drugs, which is evaluated by the FDA on a case-by-case basis, there is no one objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration. However, such a demonstration to overcome the seven-year market exclusivity may be difficult to establish with limited precedents and there can be no assurance that we will be successful in these efforts if and where we pursue them. 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 the European Union, the period of orphan market 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 designation are no longer met, including if it is shown on the basis of

available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. Legislation has been proposed by the European Commission that, if implemented, has the potential in some cases to shorten the ten-year period of orphan market exclusivity. We have received orphan designation from the EMA for our ready-to-use glucagon for the treatment of CHI and NIPHS, which includes patients with PBH.

Even with the FDA approval of Gvoke, Recorlev and Keveyis in the United States, and the EMA and MHRA approval of Ogluo in the European Union ("EU") and the United Kingdom ("UK"), we may not be able to obtain or maintain foreign regulatory approvals to market our products in other countries.

We do not have any products other than Gvoke, Recorlev, and Keveyis approved for sale in the United States, nor any products or product candidates other than Ogluo approved for sale in any international markets, and we do not have experience in obtaining regulatory approval in international markets outside of the EU and the UK. 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, 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 products and 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, restrict or regulate post-approval activities and affect our ability to profitably sell any products or product candidates for which we obtain marketing approval. For more information, see the section entitled, "*Business — Healthcare Reform*".

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable debate, and members of Congress have indicated that they will address such costs through new legislative measures. To date, there have been several recent United States 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. There has recently been intense publicity regarding the pricing of pharmaceutical products generally, including publicity and pressure resulting from the prices charged for new products as well as price increases for older products that the government and public deem excessive. We may experience downward pricing pressure on the price of our products due to social or political pressure to lower the cost of drugs, which could reduce our revenue and future profitability. Many companies in our industry have received governmental requests for documents and information relating to drug pricing and patient support programs. We could incur significant expense and experience reputational harm as a result of these or other similar future inquiries, as well as reduced market acceptance and demand for our products, which could harm our ability to market our products in the future. These factors could also result in changes in our product pricing and distribution strategies, reduced demand for our products and/or reduced reimbursement of products, including by federal health care programs such as Medicare and Medicaid and state health care programs.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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 products and product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval of those product candidates for which we seek marketing approval, as well as subject us to more stringent labeling and post-marketing testing and other requirements.

Risks Related to our Industry and Ongoing Legal and Regulatory Requirements

Risks Related to Ongoing Regulatory Obligations

Even after approval of our products and product candidates, we may still face future development and regulatory difficulties. If we fail to comply with continuing United States and non-United States regulations or new adverse safety data arise, we could lose our marketing approvals and our business would be seriously harmed.

Our approved products and 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. Approved products, third-party suppliers and their facilities are required to comply with extensive FDA requirements and requirements of other regulatory authorities even after approval, including ensuring that quality control and manufacturing procedures conform to CGMPs and applicable QSRs and applicable product tracking and tracing requirements. 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 the QSR. Accordingly, we and our third-party suppliers 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 events and production problems, if any, to the FDA and other regulatory authorities and to comply with certain requirements concerning advertising and promotion of 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 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. Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA, the Federal Trade Commission and other agencies and government entities, including the Department of Justice ("DOJ") and the Office of Inspector General of the United States Department of Health and Human Services, 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 warning or enforcement action for off-label marketing, government investigations, or litigation. 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. On June 7, 2023, we received an untitled letter from FDA's Office of Prescription Drug Promotion ("OPDP") regarding specific sections of the Recorlev consumer website. The letter raised concerns that the webpages made false or misleading claims about the safety and efficacy of Recorlev that misbrand Recorlev within the meaning of the FDCA. We submitted a response to the FDA regarding our plan to revise those sections of the webpages at issue.

The FDA completed evaluation of our response and issued a close-out letter in August 2023 stating that it appears that we have addressed all the concerns contained in the untitled letter.

If our products or 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 or require modification of or revision to 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 third party inspection and/or monitoring costs, corrective action plans with 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-United States 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.

Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse, transparency, privacy, 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 play a primary role in the recommendation and prescription use of any products for which we obtain marketing approval. Our 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. For more information, see the section entitled, "*Business — Other Healthcare Laws and Compliance Requirements*".

Efforts to ensure that our business arrangements with third parties, and our business generally, 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, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement, deferred prosecution agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. 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 are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. The United States government has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide copay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded

pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, copay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance. Further, it is possible that changes in insurer policies regarding copay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule ("FSS"), pricing program, and the Tricare Retail Pharmacy program, which require us to disclose average manufacturer pricing, and, in the future may require us to report the average sales price for certain of our drugs to the Medicare program.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. Furthermore, regulatory and legislative changes, and judicial rulings relating to these programs and policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation. For example, in the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the revised data for up to three years after those data originally were due. Such restatements increase our costs and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our government prices, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. Additionally, our agreement to participate in the 340B program or our Medicaid drug rebate agreement could be terminated, in which case federal payments may not be available under Medicaid or Medicare Part D for our covered outpatient drugs.

Additionally, if we overcharge the government in connection with our arrangements with FSS or Tricare Retail Pharmacy, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid unit rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, certain pharmaceutical manufacturers are involved in ongoing litigation regarding contract pharmacy arrangements under the 340B program. The outcome of those judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain.

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 the United States and require us to develop and implement costly compliance programs.

We currently have operations in the United States and in Ireland, and we maintain relationships with CMOs in certain parts of Europe, Asia and the United States for the manufacture of our products and product candidates. The Foreign Corrupt Practices Act ("FCPA") prohibits any United States 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 ("SEC") is involved with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from having its securities traded on United States exchanges for violations of the FCPA's accounting provisions.

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

The creation and implementation of international business practices compliance programs, particularly FCPA compliance, are 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 United States 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 foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. 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. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. 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.

Risks Related to Industry Competition

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the sales of our products and 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 ("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 products or product candidates, 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 products or product candidates. In some cases, even this limited bioequivalence testing can be waived by the FDA. Laws have also been enacted to facilitate the development of generic drugs and biologics based off recently approved NDAs and BLAs. The Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act") was enacted in 2019 requiring sponsors of approved NDAs and BLAs to provide sufficient quantities of product

samples on commercially reasonable, market-based terms to eligible product developers. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. Providing product samples and allocating additional resources to respond to such requests or any legal challenges under this law, could adversely impact our business. Competition from generic equivalents to our products or product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products or product candidates. For example, Amphastar's ANDA for generic Glucagon for Injection Emergency Kit was approved by the FDA on December 29, 2020 for the treatment of severe hypoglycemia and while we previously relied on orphan drug exclusivity in the marketing and sale of Keveyis through the expiration of orphan drug exclusivity, Torrent Pharmaceuticals Limited's ANDA for generic dichlorphenamide was approved on December 29, 2022. We intend to rely on orphan drug exclusivity and if available, NCE exclusivity in the marketing and sale of Recorlev. While we applied for NCE exclusivity for Recorlev under section 505(u) of the FDCA, the FDA may determine that the Recorlev application does not meet the eligibility criteria under 505(u) for NCE exclusivity.

Risks Related to Product Development

Our failure to successfully identify, develop and market additional product candidates, or acquire additional product candidates or enter into collaborations or other commercial agreements 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 science, and evaluate other commercial relationships through collaborations or other strategic agreements. 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. Gvoke, which delivers ready-to-use glucagon via a pre-filled syringe or auto-injector, was approved by the FDA in 2019 for the treatment of severe hypoglycemia in pediatric (aged two years and above) and adult patients with diabetes. While we have identified several additional potential applications of our ready-to-use glucagon, there is no guarantee that we will be able to utilize our formulation science to obtain approval of additional product candidates.

In the future, we may be dependent upon other 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. In addition, we expect to seek one or more collaborators for the development and commercialization of one or more of our products or product candidates, particularly with respect to our pipeline product candidates or foreign geographies. We face significant competition in seeking appropriate collaborators. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies or enter into collaborations or other strategic arrangements 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 or approved products 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 or retain 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 Our Intellectual Property

Risks Related to Protecting Our Intellectual Property

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

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 the use, formulation and structure of our proprietary 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. 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 patents or applications owned 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. Moreover, 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.

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 are 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 products or 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 products or product candidates is not sufficiently broad to exclude such competition, our ability to successfully commercialize our products or 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 pre-issuance 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 exclude others from using or commercializing similar or identical technology and products, or may 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 future development partners will be successful in protecting our product candidates by obtaining, maintaining 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 United States 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 United States 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.

We have entered into a license agreement with a third party (and may, in the future, enter into additional such license agreements with other 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 licensees and cannot guarantee that we would receive it and on what terms. We cannot be certain that those licensees 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 take 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.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

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 patent applications and patents, in any future licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any claim(s) in any of our patent applications will be found to be patentable, including over our own prior art patents, or that any such patent applications 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 instituted 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 and/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 the United States 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. 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.

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.

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.

Thus, 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 markets 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 objections. 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.

Risks Related to Intellectual Property Litigation

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 depends in part on our ability to develop, manufacture, market and sell our products that have been approved for sale, and to use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we will market products and are developing product candidates. Some claimants, who may include our competitors in both the United States and abroad, may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of Gvoke, Recorlev, Keveyis, or our product candidates. 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. Because patent applications can take up to 18 months after filing to become public, and many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any compositions formed during the manufacturing process or any final product itself, the

holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

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 lawsuits, 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 exclude the other party from making, using or selling 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 exclude the other party from making, using or selling the invention at issue on the grounds that our patent claims do not cover the invention or the other party's manufacture, use or sale of it. 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.

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. A third party could 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. Furthermore, 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.

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. 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.

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.

We may also 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 our products and product candidates, which could have an adverse effect on our business, results of operations and financial condition.

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 candidates.

We expect to submit NDAs under Section 505(b)(2) of the FDCA for most of our product candidates. 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 or 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 Gvoke, 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).

However, 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 candidates.

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.

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

We may not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on our products and 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 products and 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 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 the ability to control 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.

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.

Risk Related to Intellectual Property Laws

Changes to the patent law in the United States and other jurisdictions could diminish the value of our 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 involve both technological and legal complexity and are therefore costly, time consuming and inherently uncertain. Changes in patent statutes, regulations promulgated under them, and court holdings interpreting the statutes and regulations 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. Depending on future actions by the United States Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Further, 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. Alternatively, a petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired. 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 the United States patents in lawsuits in the United States federal courts and uses a lower burden of proof than used in litigation in the United States federal courts. Therefore, it is generally considered easier and less costly for a competitor or third party to have a United States patent invalidated in a USPTO post-grant review or inter partes review proceeding than in a litigation in a United States 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 could result in a loss of the challenged patent right to us.

Risks Related to Employee Matters, Managing Growth and Ongoing Operations

Risks Related to Potentially Under-resourced Regulatory Authorities

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns 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 or other similar regulatory agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, global health concerns, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. 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.

For example, over the last several years the United States 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, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, 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, 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.

Risk Related to Employment Matters

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, Steven Pieper, our Chief Financial Officer, John Shannon, our President and Chief Operating Officer, Ken Johnson, our Senior Vice President, Global Development and Medical Affairs, and Beth Hecht, our Chief Legal Officer 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 commercialize our products and to develop and commercialize our product candidates will be limited.

Risks Related to Our Common Stock

Risks Related to Investment in Securities

Our stock price has been and will likely continue to be volatile, and you may lose part or all of your investment.

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

- our ability to successfully commercialize Gvoke, Recorlev, and Keveyis;
- regulatory actions with respect to our products and 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 Gvoke, Recorlev, Keveyis or any of our 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 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, including impacts from inflation, interest rate increases, major bank failure or sustained financial market illiquidity; and
- any public health crisis, such as a resurgence of the COVID-19 pandemic.

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.

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 in connection with 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. On March 4, 2024, the closing price of a share of our common stock was $3.04 per share.

The conversion of any of the Convertible Notes or other convertible securities into shares of common stock could have a material dilutive effect that could cause our share price to decline.

We have a number of convertible securities outstanding, including Contingent Value Rights ("CVRs"), Convertible Notes and warrants, and the conversion of such securities into shares of our common stock could have a material dilutive effect that could cause our share price to decline.

The Convertible Notes are convertible into shares of common stock at any time at the option of the holder subject to certain conditions. We have reserved a sufficient number of shares of common stock for issuance upon conversion of the Convertible Notes, CVRs and warrants. During the second half of 2020, $39.1 million in principal amount of Convertible Notes were converted into 13,171,791 shares of our common stock. As of December 31, 2023, the outstanding balance of Convertible Notes was $48.8 million. If

any more or all of the Convertible Notes are converted into shares of common stock, our existing shareholders will experience immediate dilution of voting rights and the price of shares of our common stock may decline. Furthermore, the perception that such dilution could occur may cause the market price of our common stock to decline. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders of Convertible Notes may convert their Convertible Notes at their option into shares of our common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The conversion rate for the Convertible Notes is 326.7974 shares of our common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $3.06 per share of common stock, and is subject to adjustment under the terms of the Convertible Notes. In the event of certain circumstances, we will increase the conversion rate, provided that the conversion rate will not exceed 367.6470 shares of our common stock per $1,000 principal amount of Convertible Notes in the case of the 2025 Convertible Notes and 549.4505 shares of our common stock per $1,000 principal amount of Convertible Notes in the case of the 2028 Convertible Notes. As a result of the conversion rates of the Convertible Notes adjusting upward upon the occurrence of certain events, our existing shareholders may experience more dilution if any or all of the Convertible Notes are converted into shares of common stock after the adjusted conversion rate became effective.

Each CVR is worth up to $1.00, payable to CVR holders if future performance milestones are achieved, and settleable in cash, common stock, or a combination of cash and common stock, at our sole election. If the performance milestones are met and we elect to pay the CVR consideration in common stock, it could have a dilutive effect to our earnings per share and cause our share price to decline. As of December 31, 2023, a performance milestone worth $0.25 has been achieved, and performance milestones worth $0.50 remain outstanding.

Upon completion of the acquisition of Strongbridge, each outstanding and unexercised Strongbridge warrant (except private placement warrants) was assumed by the Company such that, upon exercise, the applicable holders will have the right to have delivered to them the reference property (as such term is defined in the Strongbridge assumed warrants). We also assumed the outstanding and unexercised Strongbridge private placement warrants and they expired in June 2022. The conversion of these assumed Strongbridge warrants (except the private placement warrants) into shares of our common stock could have a dilutive effect that could cause our share price to decline.

We do not anticipate paying any cash dividends in the foreseeable future, and accordingly, our stockholders' ability to achieve a return on their 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 Hayfin Loan Agreement, we are generally 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.

Risks Related to Tax

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, 2023, we had federal net operating loss carryforwards of $494.3 million and various state net operating loss carryforwards of $352.2 million. If not utilized, the federal net operating losses generated in taxable years beginning on or before December 31, 2017 will expire in 2037, and these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Federal net operating losses generated in taxable years beginning after December 31, 2017 can be carried forward indefinitely; however, such net operating losses may only offset up to 80% of taxable income in taxable years beginning after December 31, 2023. As of December 31, 2023, we had $6.9 million and $3.7 million of federal and state income tax credits, respectively, to reduce future tax liabilities. If not utilized, the $6.9 million in federal income tax credits will begin to expire in 2038, and the $3.7 million of state economic development and research and development credits will begin to expire in 2024. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Code") 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 future ownership changes, many of which may be outside of our control, our ability to utilize our net operating losses or credits could be further limited by 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.

Changes in tax law may adversely affect us or our investors.

The rules dealing with the United States federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service ("IRS") and the United States Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the United States will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any

adverse effects of changes in tax law.

Risks Related to our Indentures for our Convertible Notes, Charter and Bylaws

Provisions in the Indentures for our Convertible Notes and 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; and 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; and
- establish a Delaware Forum Provision (as defined below) or a Federal Forum Provision (as defined below).

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 our stockholders' best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

In addition, certain provisions in the Indentures governing our Convertible Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the notes and the indentures could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that noteholders or holders of our common stock may view as favorable.

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 and may discourage such lawsuits with respect to such claims.

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, or a claim based on, a breach of or based on a fiduciary duty owed by any of our current or former 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 (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended. In addition, our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision").

This forum selection provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable or cost-efficient for disputes with us or any of our directors, officers, employees or agents, which may discourage such lawsuits, or increase the costs to a shareholder of bringing such lawsuits, against us and such persons.

The enforceability of forum selection provisions in other companies' articles of incorporation, bylaws or similar governing documents has been challenged in legal proceedings, and it is possible that in connection with any action a court could find the forum selection provisions contained in our bylaws to be inapplicable or unenforceable in such action. If a court were to find these forum selection provisions inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely impact our operating or financial condition or performance.

General Risk Factors

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. 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 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 are vulnerable to damages from computer viruses, natural disasters, unauthorized access, cyber-attack, including ransomware, and other similar disruptions. Any system failure, accident or cybersecurity incident, compromise, or breach could result in disruptions to our operations. For example, third parties may attempt to hack into systems and may obtain our proprietary information or other sensitive information, which could cause significant damage to our reputation, lead to claims or government enforcement action against the Company and ultimately harm our business. To the best of our knowledge, no risks from cybersecurity threats, including those resulting from any previous cybersecurity incidents, have materially affected, and we do not believe they are reasonably likely to materially affect, us, our business strategy, results of operations, or financial condition. We may expend significant resources to try to protect against these threats to our Systems. In addition, a cybersecurity incident involving one of our customers, including an incident involving their customers or vendors, could materially affect our business strategy, results of operations, or financial condition if our customers or their customers or vendors are unable to conduct their regular operations. For example, in February 2024, UnitedHealth Group announced that its Change Healthcare information technology systems that process payment claims for payors was being taken offline for an undefined period due to a cybersecurity incident, such incident could reduce demand for our products and harm our revenues as physician providers are unable to use such systems to submit electronic prescriptions and pharmacies are unable to fill electronic prescriptions for our products.

If products 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 products and product candidates. These claims may be expensive to defend and may result in large judgments against us. During the course of treatment, patients using our products and product candidates could suffer adverse medical effects for reasons that may or may not be related to our products and 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 products liability claims against us. We maintain total products liability insurance coverage of $15.0 million.

Although we maintain products liability insurance for claims arising from the use of our products after FDA approval and for claims arising from the use of our product candidates in clinical trials prior to 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 products and product candidates in the future. Also, our insurance coverage and resources may not be sufficient to satisfy any liability resulting from products liability claims, which could materially harm our business, financial condition or results of operations. In addition, we have in the past and may in the future agree to indemnify counterparties from losses arising from claims relating to the products, processes or services made, used, sold or performed.

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 the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Products liability claims could result in an FDA or other regulatory authority investigation into 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. Products liability claims could also result in investigation, prosecution or enforcement action by the DOJ or other federal or state government agencies.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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, as amended, 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 costs associated with our public company reporting requirements, and we expect those costs may increase in the future, , particularly since we determined we have ceased to qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act enacted in April 2012, as of December 31, 2023 and as a “smaller reporting company” as of June 30, 2023. For example, we are no longer able to take advantage of certain exemptions and relief from various reporting requirements that are applicable to public companies that are not “emerging growth companies”. In particular and amongst other requirements, we are required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley and are subject to the full disclosure obligations regarding executive compensation in our periodic reports and proxy statements which rules and regulations have increased our legal and financial compliance costs relative to prior years and will make some activities more time-consuming and costly. We may also need to hire more employees in the future or engage additional outside consultants to comply with these requirements, which will increase our costs and expenses.

During the course of our ongoing review and testing of our internal controls, we may identify deficiencies and may incur significant costs to remediate such deficiencies, including material weaknesses, if any, that we identify through these efforts. 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.

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. Analysts who publish information about our common stock may have relatively little experience covering 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.

Our data collection and processing activities are governed by restrictive regulations governing the use, processing and, in certain jurisdictions, cross-border transfer of personal information.

We may be subject to the United States federal and state, European, UK and other foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). We have personnel located in Ireland and have conducted and may in the future conduct clinical trials in the European Economic Area ("EEA") and/or the UK subjecting us to additional privacy restrictions and data protection requirements. The collection and use of personal data (including health data) in the EEA and the UK are governed by the provisions of the EU General Data Protection Regulation ("EU GDPR") as well as other national data protection legislation in force in relevant Member States, with respect to the EEA, and the UK General Data Protection Regulation (the "UK GDPR," together with the EU GDPR the "GDPR") and the UK Data Protection Act 2018 with respect to the UK. These laws impose a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the EEA or the UK, providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data

processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals' requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR 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 the EEA and UK data protection regimes. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

The GDPR prohibits the international transfer of personal data to countries outside of the EEA or the UK ("third countries") which are not deemed as adequate for the transfers of personal data by competent authorities, unless a derogation exists or adequate safeguards (for example, the European Commission approved Standard Contractual Clauses ("EU SCCs") and the UK International Data Transfer Agreement/Addendum ("UK IDTA")) are implemented in compliance with EEA and UK data protection laws. Where relying on the EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments on transfers made pursuant to the EU SCCs and the UK IDTA, on a case-by-case basis to ensure the law in the data importer's country and the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR. This assessment includes assessing whether third party vendors can also ensure these guarantees. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data from the EEA and UK to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position.

The EU commission has adopted its adequacy decision for the EU-U.S. Data Privacy Framework ("Framework") agreed with the U.S., which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EEA and the U.S. is comparable to that offered in the EEA. This Framework provides a further avenue to ensure transfers to the U.S. are carried out in line with GDPR. Where we rely on the Framework as a transfer mechanism for international transfers of personal data to the U.S., the Framework's validity could be challenged and the Framework subsequently invalidated as a mechanism for transferring personal data to the U.S. like its predecessor Privacy Shield and Safe Harbor frameworks.

Although the UK is regarded as a third country under the EU's GDPR, the European Commission has issued an adequacy decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. Likewise, the UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK government has introduced a Data Protection and Digital Information Bill ("UK Bill") into the UK legislative process. The aim of the UK Bill is to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK adequacy decision from the European Commission.

The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of European personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA.

In addition, EEA Member States have adopted national laws to implement the EU GDPR that may partially deviate from the EU GDPR and competent authorities in the EEA Member States may interpret the EU GDPR obligations slightly differently from country to country. Therefore, we do not expect to operate in a uniform legal landscape in the EEA.

If we are investigated by a European or UK data protection authority, we may face fines and other penalties, including bans on processing and transferring personal data. EEA and UK data protection authorities have the power to impose administrative fines for violations of the GDPR of up to a maximum of €20 (£17.5 under the UK GDPR) million or 4% of our total worldwide global turnover for the preceding fiscal year, whichever is higher, and violations of the GDPR may also lead to damages claims by data controllers and data subjects. Such penalties are in addition to any civil litigation claims by data controllers, clients, and data subjects. As such, we will need to take steps to cause our processes to continue to be compliant with the applicable portions of the GDPR, but we cannot assure you that we will be able to implement changes in a timely manner or without significant disruption to our business, or that such steps will be effective, and we may face the risk of liability under the GDPR.

Many jurisdictions outside of Europe where we may do business or conduct trials in the future are also considering and/or have enacted comprehensive data protection legislation. In addition, we also continue to see jurisdictions imposing data localization laws. These and similar regulations may interfere with our intended business activities, inhibit our ability to expand into those markets, require modifications to our products or services or prohibit us from continuing to offer services or conduct trials in those markets without significant additional costs.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing

or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Our employees, independent contractors, consultants, collaborators and CROs 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 CROs may engage in fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-United States regulatory authorities, to provide accurate information to the FDA or comparable non-United States 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-United States 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.

Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflicts between Russia and Ukraine and Israel and Hamas, or other events could adversely affect our business and financial performance.

Economic uncertainty in various global markets caused by political instability and conflict and economic challenges has in the past resulted, and may continue to result, in weakened demand for our products. Political developments impacting government spending and international trade, including potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-economic conditions. The effects of these events may continue due to potential United States government shutdowns and the transition in administrations, and the United States' ongoing trade disputes with China and other countries. In addition, the current military conflicts between Russia and Ukraine and Israel and Hamas could disrupt or otherwise adversely impact our operations and related sanctions, export controls or other actions that may be initiated by nations including the United States, the EU, Russia or countries or actors in the Middle East (e.g., potential cyberattacks, disruption of energy flows, etc.) could adversely affect our business and/or our supply chain or those of our third party service providers. The United States and other countries could take other actions that may adversely affect our business should the conflicts further escalate. It is not possible to predict the broader consequences of these conflicts, which could include further sanctions, embargoes, regional instability, prolonged periods of higher inflation, international trade disruptions, supply disruptions, geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations. The continuing effect of any or all of these events could adversely impact demand for our products, harm our operations and weaken our financial results.

Our operations are subject to the effects of a rising rate of inflation.

The United States has recently experienced historically high and fluctuating levels of inflation. If the inflation rate continues to increase, for example due to increases in the costs of labor and supplies, or remain at a historically high rate, it will affect our expenses, such as employee compensation, supply costs and research and development expenses. In addition, elevated and fluctuating inflation and increasing interest rates has contributed to potential economic uncertainty in the larger economy. To the extent inflation continues to result in rising interest rates and has other adverse effects on the market, it may adversely affect our financial condition and results of operations.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations, ability to pay operational expenses or make other payments, and its financial condition and results of operations.

Our cash held in non-interest bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") limits and is predominantly held at one institution, Wells Fargo Bank, N.A. If such banking institution or any future banking institutions where we maintain our cash were to fail, we could lose all or a portion of those amounts held in excess of such insurance limits. For example, the recent closures of Silicon Valley Bank, where we maintained a portion of our cash, Signature Bank and First

Republic Bank and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, future adverse developments with respect to *specific* financial institutions or the broader financial services industry, including concerns or rumors about any events of these kinds or similar risks, may lead to market-wide liquidity shortages and the FDIC may elect not to make all account holders whole. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds and could have a material adverse effect on our business and financial condition.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

Finally, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us or others, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. Any supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a supplier, or the loss of any significant supplier relationships, could result in material losses to the Company and may have a material adverse impact on our business.

Our business could be negatively impacted by environmental, social and corporate governance matters or our reporting of such matters.

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning environmental, social and corporate governance ("ESG") matters. For instance, the SEC has recently proposed climate change and ESG reporting requirements, which, if approved, would significantly increase our costs, divert management resources and attention and require us to expend significant time and resources, which could have an adverse effect on our business, financial condition and results of operations. If our ESG practices fail to meet investor, customer, consumer, employee or other stakeholders' evolving expectations and standards in areas such as environmental stewardship, Board of Directors and employee diversity, human capital management, corporate governance and transparency, our reputation could be negatively impacted, which could have a material adverse effect on our business or financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

We have no unresolved written comments regarding our periodic or current reports from the staff of the United States Securities and Exchange Commission ("SEC").

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

In the normal course of business, we collect and store personal information and other sensitive information, including proprietary and confidential business information, intellectual property, information regarding patients, sensitive third-party information and employee information. To protect this information, we have implemented a framework that is designed to identify, assess, and mitigate cybersecurity threats.

We use managed detection and response services to monitor our network infrastructure and associated endpoints for possible cybersecurity threats. In addition, we engage third parties to perform penetration testing and to assess the effectiveness of our cybersecurity practices. We conduct a cybersecurity risk assessment by identifying critical assets, recognizing potential threats and vulnerabilities, and implementing strategies to mitigate these cybersecurity risks and their possible impacts. We also actively engage with key vendors and industry participants as part of our continuing efforts to evaluate and enhance the effectiveness of our information security policies and procedures.

We have established a cybersecurity incident response plan and provide cybersecurity training to our employees and monitor their activity for adherence to our security protocols.

No risks from cybersecurity threats have occurred that have affected our business strategy, results of operations, or financial condition. See "*Risk Factors - General Risk Factors*" for additional information.

Governance

Our information security program is overseen by our Executive Director of Information Technology ("IT"). The Executive Director of IT reports to the Chief Financial Officer and oversees the team responsible for leading enterprise-wide cybersecurity strategy, policy, standards, and processes. The Executive Director of IT possesses over twenty-five years of experience in information technology and approximately ten years in cybersecurity risk management.

Our Board of Directors ("Board") has responsibility for oversight of risk management and, pursuant to the Audit Committee Charter, has delegated to our Audit Committee oversight of our cybersecurity risk management program. The Executive Director of IT provides reports to the Audit Committee at least annually as well as the Chief Executive Officer and other members of our senior management as appropriate. These reports include updates on the Company's cyber risks and threats, the status of projects to strengthen our information security systems, assessments of the information security program, and the emerging threat landscape. Our program is regularly evaluated by internal and external security professionals with the results of those reviews reported to senior management and the Board.

ITEM 2. PROPERTIES

Our principal office and development laboratory site are both located at 1375 West Fulton Street, Chicago, Illinois and occupy approximately 87,032 square feet of leased space. The term will expire on March 31, 2036. We believe that our offices are suitable and adequate to meet our needs.

ITEM 3. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

The common stock of Xeris Biopharma Holdings, Inc. (the "Company") is listed on The Nasdaq Global Select Market ("Nasdaq") under the symbol "XERS". Prior to October 6, 2021, the common stock of Xeris Pharmaceuticals, Inc. ("Xeris Pharma") (the predecessor company) was listed on Nasdaq under the symbol "XERS" starting on June 21, 2018. Prior to that time, there was no public market for our common stock. On October 5, 2021, pursuant to the transaction agreement for the acquisition of Strongbridge Biopharma plc ("Strongbridge"), Xeris Pharma completed its acquisition of Strongbridge. Immediately following the transactions, both Xeris Pharma and Strongbridge became wholly-owned subsidiaries of the Company. The common stock of Xeris Pharma and the ordinary shares of Strongbridge were de-registered after completion of the Transactions.

Holders of Record

On March 4, 2024, there were approximately 225 stockholders of record of our common stock and the closing price of our common stock was $3.04 per share as reported by Nasdaq. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

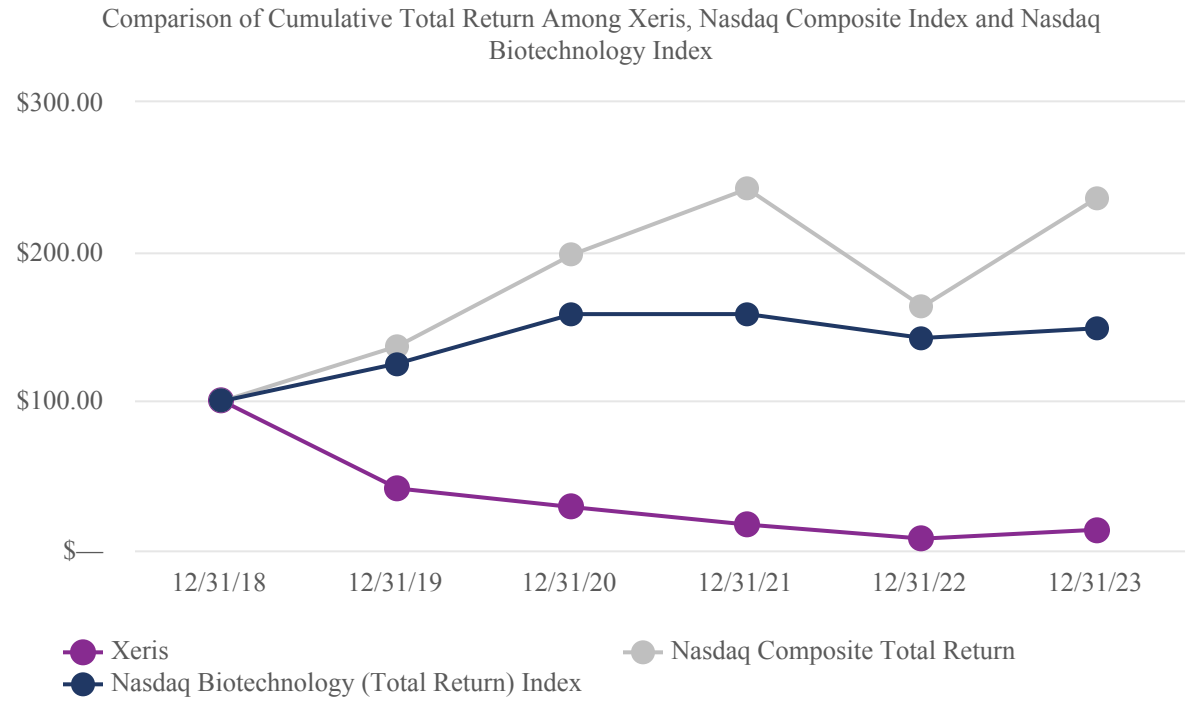
Stock Price Performance Graph

This graph is not "soliciting material" or subject to Regulation 14A, deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to liabilities under that section, and shall not be deemed incorporated by reference into any filing

of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the cumulative total return to stockholder return on our common stock relative to the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index. An investment of $100 is assumed to have been made in our common stock and each index on December 31, 2018 and its relative performance is tracked through December 31, 2023. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

		December 31,					
$100 investment in stock or index	**Ticker**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
Xeris	XERS	$ 100.00	$ 41.47	$ 28.94	$ 17.24	$ 7.82	$ 13.82
Nasdaq Composite Total Return	XCMP	$ 100.00	$ 136.69	$ 198.10	$ 242.03	$ 163.28	$ 236.17
Nasdaq Biotechnology (Total Return) Index	XNBI	$ 100.00	$ 125.11	$ 158.17	$ 158.20	$ 142.19	$ 148.72



ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those set forth in Part I, Item 1A. Risk Factors, of this Annual Report on Form 10-K. This discussion and analysis compares 2023 results to 2022. For discussion and analysis that compares 2022 results to 2021, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7. of this Annual Report on Form 10-K for the year ended December 31, 2022.

Overview

As used herein, the "Company", "Xeris", "we" or "our" refers to Xeris Biopharma Holdings, Inc. ("Xeris Biopharma"). Throughout this document, unless otherwise noted, references to Gvoke include Gvoke PFS, Gvoke HypoPen, Gvoke Kit and Ogluo.

We are focused on building an innovative, self-sustaining, growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing clinically meaningful products across a range of therapies. We are uniquely positioned to achieve this through our three commercial products and our proprietary formulation science (XeriSol and XeriJect), which generates partnerships and enhances our product candidates.

Patents

We currently own 170 patents issued globally, including composition of matter patents covering our ready-to-use glucagon formulation that expire in 2036. Included in the total patents, we have 60 granted patents globally related to our platform technologies and 8 patents granted in the United States and listed in the United States FDA Orange Book covering proprietary formulations of levoketoconazole (the active pharmaceutical ingredient in Recorlev) and the uses of such formulations in treating certain endocrine-related diseases and syndromes. The latter includes United States Patent Nos. 11,020,393, 11,278,547 and 11,903,940, which were granted on June 1, 2021, March 22, 2022, and February 22, 2024, respectively, and which provide patent protection through 2040 for the use of Recorlev in the treatment of certain patients with persistent or recurrent Cushing's syndrome.

Financing

We have funded our operations to date primarily with proceeds from the sale of our preferred and common stock and debt financing.

For the years ended December 31, 2023 and 2022, we reported net losses of $62.3 million and $94.7 million, respectively. We have not been profitable since inception, and, as of December 31, 2023, our accumulated deficit was $617.0 million. In the near term, we expect to continue to incur significant expenses, operating losses and net losses as we:

- continue our marketing and selling efforts related to commercialization of Gvoke, Recorlev and Keveyis;
- continue our research and development efforts;
- continue to operate as a public company; and
- continue to fund our operations with an increased cost of borrowing due to a higher interest rate environment and tighter lending requirements.

We may 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, if approved. In addition, we may not be profitable even if we commercialize any of our product candidates.

Components of our Results of Operations

The following discussion sets forth certain components of the statement of operations of Xeris for years ended December 31, 2023 and 2022 as well as factors that impact those items.

Product revenue, net

Product revenue, net, represents gross product sales less estimated allowances for patient copay assistance programs, prompt payment discounts, payor rebates, chargebacks, service fees, and product returns, all of which are recorded at the time of sale to the pharmaceutical wholesaler or other customer. We apply significant judgment and estimates in determining some of these allowances. If actual results differ from our estimates, we make adjustments to these allowances in the period in which the actual

results or updates to estimates become known. See "Critical Accounting Policies and Use of Estimates and Assumptions" for further information regarding the significant judgments and estimates involved in the determination of product revenue, net.

Royalty, contract and other revenue

Royalty and contract revenue is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

Cost of goods sold

Cost of goods sold primarily includes product costs, which include all costs directly related to the purchase of raw materials, charges from our contract manufacturing organizations, and manufacturing overhead costs, as well as shipping and distribution charges. Cost of goods sold also includes losses from excess, slow-moving or obsolete inventory and inventory purchase commitments, if any. Manufacturing costs for Gvoke and Recorlev incurred prior to approval and initial commercialization were expensed as research and development expenses.

Research and development expenses

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

- the cost of acquiring and manufacturing preclinical study and clinical trial materials and manufacturing costs related to commercial production and scale-up until a product is approved and initially available for commercial sale;
- expenses incurred under agreements with contract research organizations ("CROs") as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- personnel-related expenses, which include salaries, benefits and stock-based compensation;
- laboratory materials and supplies used to support our research activities;
- outsourced product development services;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility-related costs.

Research and development activities are central to our business model. We expect to continue to incur significant research and development expenses as we advance our pipeline candidates and in particular plan and conduct clinical trials, prepare regulatory filings for our product candidates, and utilize internal resources to support these efforts. Our research and development costs have declined as compared to previous levels as a result of directing significant funding to our commercial activities.

Our research and development expenses may vary significantly over time due to uncertainties relating to the timing and results of our clinical trials, feedback received from interactions with the FDA and the timing of regulatory approvals.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of compensation and related personnel costs, marketing and selling expenses, professional fees and facility costs not otherwise included in research and development expenses.

Amortization of intangible assets

Amortization of intangible assets relates to the amortization of our products: Keveyis and Recorlev. These two intangible assets are being amortized over a five-year and fourteen-year period, respectively, using the straight-line method.

Other income (expense)

Other income (expense) consists primarily of interest expense related to our convertible debt, Hayfin Loan Agreement, Oxford Loan Agreement, interest income earned on deposits and investments, gains and losses on extinguishment of debt and lease remeasurement, and the change in fair value of our warrants and CVRs.

Income tax

We have incurred operating losses since inception and therefore do not have any taxable income. As of December 31, 2023, we had federal net operating loss carryforwards of $494.3 million and various state net operating loss carryforwards of $352.2 million, $6.9 million in federal income tax credits will begin to expire in 2038, and the $3.7 million of state economic development and research and development credits will begin to expire in 2024.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Years Ended December 31,		Variance	
	2023	2022	$	%
Product revenue:				
Gvoke	$ 67,045	$ 52,527	$ 14,518	27.6
Keveyis	56,772	49,307	7,465	15.1
Recorlev	29,547	7,429	22,118	297.7
Product revenue, net	153,364	109,263	44,101	40.4
Royalty, contract and other revenue	10,550	985	9,565	nm
Total revenue	163,914	110,248	53,666	48.7
Cost and expenses:				
Cost of goods sold, excluding amortization of intangible assets	28,645	22,634	6,011	26.6
Research and development	22,341	20,966	1,375	6.6
Selling, general and administrative	146,095	137,745	8,350	6.1
Amortization of intangible assets	10,843	10,843	—	—
Total cost and expenses	207,924	192,188	15,736	8.2
Loss from operations	(44,010)	(81,940)	37,930	(46.3)
Other income (expense):				
Interest and other income	4,751	2,578	2,173	84.3
Loss on debt extinguishment	(2,837)	(1,223)	(1,614)	132.0
Interest expense	(26,609)	(14,102)	(12,507)	88.7
Change in fair value of warrants	1	1,760	(1,759)	nm
Change in fair value of contingent considerations	5,200	(3,157)	8,357	nm
Total other expense	(19,494)	(14,144)	(5,350)	37.8
Net loss before benefit from income taxes	(63,504)	(96,084)	32,580	(33.9)
Benefit from income taxes	1,249	1,424	(175)	(12.3)
Net loss	$ (62,255)	$ (94,660)	$ 32,405	(34.2)

nm: not meaningful

Product revenue, net

Gvoke net revenue increased by $14.5 million or 27.6% for the year ended December 31, 2023 compared to the year ended December 31, 2022. Gvoke prescriptions grew approximately 48.9% in 2023 compared to prior year. The growth in product demand was partially offset by a decrease in net pricing.

Keveyis net revenue increased by $7.5 million or 15.1% for the year ended December 31, 2023 compared to the year ended December 31, 2022. These increase was driven by higher patient demand coupled with an increase in net pricing.

Recorlev net revenue increased by $22.1 million or 297.7% for the year ended December 31, 2023 compared to the year ended December 31, 2022, driven primarily by increases in the number of patients on therapy.

Royalty, contract and other revenue

Royalty and contract revenue in 2023 was primarily generated from various collaboration agreements, including one with Horizon Therapeutics plc (subsequently acquired by Amgen Inc.) for which $6.0 million was recognized in connection with the target produce profile milestone achieved.

Cost of goods sold

Cost of goods sold increased by $6.0 million or 26.6% for the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase was mainly attributable to higher product sales, partially offset by the product mix and a one-time contract credit in the first quarter of 2023.

Research and development expenses

Research and development expenses increased by $1.4 million or 6.6% for the year ended December 31, 2023 compared to the year ended December 31, 2022, driven by the expenses related to the Phase 2 study for XP-8121.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $8.4 million or 6.1% for the year ended December 31, 2023 compared to the year ended December 31, 2022, due to higher personnel costs and rent expenses related to the new lease which commenced in April 2023.

Amortization of intangible assets

For the years ended December 31, 2023 and December 31, 2022, amortization of intangible assets were both $10.8 million.

Other income (expense)

For the year ended December 31, 2023, interest expense increased $12.5 million or 88.7% compared to the year ended December 31, 2022. The increase was primarily due to a higher principal amount and increased interest rates related to third party debt arrangements.

Other expense in the years ended December 31, 2023 and December 31, 2022 included losses of $2.8 million and $1.2 million, respectively, on extinguishment of debt related to the third party debt arrangements.

For the year ended December 31, 2023, change in fair value of contingent value rights was a gain of $5.2 million compared to a loss of $3.2 million for the year ended December 31, 2022. The gain in 2023 were primarily due to changes in revenue assumptions based on recent trends adjusted for management's estimates of future sales.

Liquidity and Capital Resources

Our primary uses of cash are to fund costs related to the manufacturing, marketing and selling of products, the research and development of our product candidates, general and administrative expenses and working capital requirements. Historically, we have funded our operations primarily through private placements of convertible preferred stock, public equity offerings of common stock, and issuance of debt.

On January 2, 2022, we entered into a securities purchase agreement in connection with the private placement of our common stock with Armistice for aggregate gross proceeds of approximately $30.0 million and completed the transaction on January 3, 2022. In January 2022, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on February 7, 2022, and which covers the offering, issuance and sale by us of up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units.

In March 2022, we, Xeris Pharma and certain subsidiary guarantors, entered into a Credit Agreement and Guaranty (the "Hayfin Loan Agreement") with the lenders from time to time parties thereto (the "Lenders") and Hayfin Services LLP, as administrative agent for the Lenders, pursuant to which we and our subsidiaries party thereto granted a first priority security interest on substantially all of our assets, including intellectual property, subject to certain exceptions. The Hayfin Loan Agreement provided for the Lenders to extend $100.0 million in term loans to us on the closing date and up to an additional $50.0 million in delayed draw term loan(s) during the one year period immediately following the closing date (collectively, the "Loans"). On December 28, 2022, we borrowed the full amount of such $50.0 million delayed draw term loan under the Hayfin Loan Agreement. In conjunction with the execution of the Hayfin Loan Agreement, the Oxford Loan Agreement balance of $43.5 million was repaid in full and fees of $2.1 million in connection with the loan repayment were paid. In addition to utilizing the proceeds to repay the obligations under the Oxford Loan Agreement in full, the proceeds were otherwise used for general corporate purposes. After repayment, the Loans may not be re-borrowed.

In September 2023, we completed the exchange of $32.0 million in aggregate principal amount of the 2025 Convertible Notes for $33.6 million in aggregate principal amount of the 2028 Convertible Notes. As of December 31, 2023, the outstanding balance of the 2025 Convertible Notes was $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million.

Capital Resources and Funding Requirements

We have incurred operating losses since inception, and we have an accumulated deficit of $617.0 million at December 31, 2023. Based on our current operating plans and existing working capital at December 31, 2023, we believe that our cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months. We expect to incur substantial additional expenditures in the near term to support the marketing and selling of Gvoke, Recorlev and Keveyis as well as our ongoing research and development activities. We expect to continue to incur net losses for at least the next 12 months. Our ability to fund marketing and selling of Gvoke, Recorlev and Keveyis, as well as our product development and clinical operations, including

completion of future clinical trials, will depend on the amount and timing of cash received from product revenue and potential future financings. Our future capital requirements will depend on many factors, including, but not limited to:

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

As we continue the marketing and selling of Gvoke, Recorlev and Keveyis, we may not generate a sufficient amount of product revenue to fund our cash requirements. Accordingly, we may need to obtain additional financing in the future which may include public or private debt and/or equity financings. As detailed in "Note 1 – Liquidity and capital resources" of Item 8 in this Form 10-K, 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 market and sell Gvoke, Recorlev and Keveyis.

Cash Flows

	Years Ended December 31,	
(**in thousands**)	**2023**	**2022**
Net cash used in operating activities	$ (47,023)	$ (102,891)
Net cash (used in)/provided by investing activities	(6,004)	34,461
Net cash (used in)/provided by financing activities	(1,613)	127,473

Operating activities

Net cash used in operating activities was $47.0 million for the year ended December 31, 2023, compared to $102.9 million for the year ended December 31, 2022. The decrease in net cash used in operating activities was primarily driven by reduced working capital usage, partially offset by changes to the fair value of contingent value rights. For a discussion regarding product revenue, net and increases in spending, refer to "Results of Operations" included in this "Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations" of Part II.

Investing activities

Net cash used in investing activities was $6.0 million for the year ended December 31, 2023, compared to net cash provided by investing activities of $34.5 million for the year ended December 31, 2022. Cash used in investing activities in 2023 was primarily due to the purchase of short-term investments. In 2022, we used the majority of investments that matured to fund operations instead of re-investing.

Financing activities

Net cash used in financing activities was $1.6 million for the year ended December 31, 2023, compared to net cash provided by financing activities of $127.5 million for the year ended December 31, 2022. The cash provided by financing activities in 2022 was primarily due to the net proceeds of $30.0 million from the January 2022 private placement of our common stock with an affiliate of Armistice, proceeds net of debt issuance costs of $141.3 million from the Hayfin Loan Agreement, partially offset by the payoff of the outstanding principal under the Oxford Loan Agreement of $43.5 million in March 2022.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES AND ASSUMPTIONS

Our management's discussion and analysis of our financial condition and results of operations on our financial statements have been prepared in accordance with generally accepted accounting principles ("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, among others, those related to revenue recognition and contingent considerations. 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.

We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. Our significant accounting policies are more fully described in "Note 2 - Summary of Significant Accounting Policies" of Item 8 in this Form 10-K.

Revenue recognition

We apply the guidance in ASC 606, *Revenue Recognition*, to all contracts with customers within the scope of the standard.

We sell product primarily to wholesalers or a specialty pharmacy that subsequently resell to retail pharmacies or patients. We enter into arrangements with payors, group purchasing organizations, and healthcare providers that provide for government-mandated or privately-negotiated rebates, chargebacks and discounts related to our products. We currently sell Gvoke, Recorlev and Keveyis in the United States only and Ogulo (the brand name in the European Union and United Kingdom for the Company's ready-to-use liquid glucagon product) in the United Kingdom.

Revenue is recognized when our customer (e.g., a wholesaler or specialty pharmacy) obtains control of promised goods or services, which is when our obligations under the terms of the contract with the customer are satisfied, based on the consideration we expect to receive in exchange for those goods or services.

Revenues are recorded at the net product sales price, which includes estimated allowances for patient copay assistance programs, prompt payment discounts, payor rebates, chargebacks, service fees, and product returns, all of which are recorded at the time of sale to the pharmaceutical wholesaler or other customer. The Company applies significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, adjustments are made to these allowances in the period in which the actual results or updates to estimates become known.

Patient Copay Assistance Program

We offer savings programs to commercially insured patients under which the cost of a prescription to a patient is discounted. We reimburse pharmacies for this discount through a third-party vendor. We record an accrual to reduce gross sales for the estimated copay on units sold to wholesalers and other customers. The estimate is based on estimated percentages of products that will be prescribed to qualified patients, expected patient utilization of the discount program, average assistance paid based on reporting from the third-party vendor as well as industry data and estimated levels of inventory in the distribution channel. Accrued copay fees are recorded as a reduction of product revenue and included in accrued trade discounts and rebates on the consolidated balance sheets.

Commercial Rebates

We contract with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, to provide rebates with respect to utilization of the products and contracted formulary status. We accrue estimated rebates based on actual average rebate amounts and estimated percent of product that will be prescribed to qualified patients and record the rebate as a reduction of product revenue. Accrued commercial rebates are included in accrued trade discounts and rebates on the consolidated balance sheets.

Government Rebates

We participate in certain federal and state government rebate programs such as the Medicaid Drug Rebate Program, TRICARE Retail Refunds Program, and Medicare Part D Program. We accrue estimated rebates and discounts based on actual average rebate amounts and estimated percent of product that will be prescribed to qualified patients and record the rebates as a reduction of product revenue. Accrued government rebates are included in accrued trade discounts and rebates on the consolidated balance sheets.

Chargebacks

We arrange with certain commercial and government entities allowing them to buy products directly from wholesalers at specific prices. These entities purchase products through wholesalers at the discounted price and the wholesalers charge the difference between their list price and the discounted price back to us. We accrue estimated chargebacks based on estimated percentages of products sold to these entities, contract prices, and estimated levels of inventory in the distribution channel and records the chargebacks as a reduction of product revenue. Accrued chargebacks are recorded as an allowance against trade receivables on the consolidated balance sheets.

Product Returns

For some products, our customers generally have the right to return product during the period beginning six months prior to the product expiration date and up to one year after the product expiration date. We use actual return data to estimate the provision for returns. In a reporting period, we may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels, inventory dating, prescription data, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products. While we believe that our returns reserve is sufficient to avoid a significant reversal of revenue in future periods, if it were to increase or decrease the rate by 1%, it would have a $1.5 million impact on revenue in the year ended December 31, 2023. We record estimated product returns in accrued returns reserve on the consolidated balance sheets and as a reduction of product revenue.

Contingent considerations

The fair value of the CVRs was calculated by using a discounted cash flow method for the Keveyis patent milestone and an option pricing method for the Recorlev and Keveyis sales milestones. In the case of Keveyis milestones, we applied a scenario-based method

and weighted them based on the possible achievement of the milestone. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820, *Fair Value Measurement*. The key assumptions used include the discount rate and sales growth. A 1% change of the discount rate will change the CVR value by approximately $0.02 million or 0.1%. A 10% change of estimated net revenue will change the CVR value by approximately $1.7 million or 8%. The estimated value of the CVR consideration is based upon available information and certain assumptions which our management believes are reasonable under the circumstances. The ultimate payout under the CVRs may differ materially from the assumptions used in determining the fair value of the CVR consideration. This value is then remeasured for future expected payout as well as the increase in fair value due to the time value of money. These gains or losses, if any, are recognized in the consolidated statements of operations and comprehensive loss.

NEW ACCOUNTING STANDARDS

Refer to "Note 2 - Basis of presentation and summary of significant accounting policies and estimates," in Item 8 of this Form 10-K for a description of recent accounting pronouncements applicable to our financial statements.

JOBS ACT ACCOUNTING ELECTION

We were an “emerging growth company”, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). However, we became an accelerated filer and thus ceased to be an emerging growth company on December 31, 2023. As a result, we were required to adopt new or revised accounting standards as required by public companies, including those standards which we had previously deferred pursuant to the JOBS Act. Additionally, we are no longer able to take advantage of the reduced regulatory and reporting requirements of emerging growth companies.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to certain market risks arising from transactions in the normal course of business, principally risk associated with interest rate and foreign currency exchange rate fluctuations.

Interest Rate Risk

Cash, Cash Equivalents restricted cash and Investments—We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash, cash equivalents, restricted cash and investments. A hypothetical one-percentage point increase or decrease in interest rates applicable to our cash, cash equivalents, restricted cash and investments outstanding at December 31, 2023 would increase or decrease interest income by approximately $0.7 million on an annual basis.

Long-term Debt—Our interest rate risk relates primarily to the United States dollar SOFR-indexed borrowings. Based on our outstanding borrowings pursuant to the Hayfin Loan Agreement, interest is incurred at a floating per annum rate in an amount equal to the sum of (i) 9.0% (or 8.0% per annum if the replacement rate in effect is the Wall Street Journal Prime Rate) plus (ii) the greater of (x) (1) CME Group Benchmark Administration Limited (CBA) Term SOFR (or the replacement rate, if applicable) if CBA Term SOFR is greater than 1.00% plus 0.26161% or (2) 1.00% if CME Term SOFR is less than 1.00% and (y) one percent (1.00%) per annum (or 2.0% per annum if the replacement rate in effect is the Wall Street Journal Prime Rate). Interest on the 2025 Convertible Notes is assessed at a fixed rate of 5.0% annually and interest on the 2028 Convertible Notes is assessed at a fixed rate of 8.0% annually and therefore do not subject us to interest rate risk.

Foreign Exchange Risk

We contract with research organizations outside the United States at times. We may be subject to fluctuations in foreign currency exchange rates in connection with certain of these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. Net foreign currency gains and losses did not have a material effect on our results of operations for the year ended December 31, 2023.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Financial Statements

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Xeris is responsible for establishing and maintaining adequate internal control over financial reporting. Management has designed our internal control over financial reporting to provide reasonable assurance that our published financial statements are fairly presented, in all material respects, in conformity with generally accepted accounting principles.

Management is required by paragraph (c) of Rule 13a-15 of the Securities Exchange Act of 1934, as amended, to assess the effectiveness of our internal control over financial reporting as of each year end. In making this assessment, management used the Internal Control - Integrated Framework (2013) by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Management conducted the required assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023. Based upon this assessment, management believes that our internal control over financial reporting is effective as of December 31, 2023.

Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included in this Form 10-K, has also audited our internal control over financial reporting. Their attestation report follows this report of management.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Xeris Biopharma Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Xeris Biopharma Holdings, Inc. (the Company) as of December 31, 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 6, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosures to which it relates.

Valuation of Contingent Value Rights Liability

Description of the Matter	As described in Notes 2 and 13 to the consolidated financial statements, the Company recognized a liability for contingent value rights ("CVRs") in connection with its acquisition of Strongbridge in 2021. The CVR liability was recorded at fair value on the acquisition date and is revalued at the end of each subsequent reporting period, with changes in fair value recognized in the consolidated statement of operations and comprehensive loss in the period of change. At December 31, 2023, the fair value of the CVR liability was $20.5 million. Auditing the Company's accounting for the CVR liability was complex and required significant auditor judgment due to the complexity of the valuation methodology and the significant estimation uncertainty in determining the fair value of the CVR liability. The significant estimation uncertainty was primarily due to the sensitivity of the fair value to the underlying revenue growth rate assumption. This significant assumption is forward-looking and could be affected by future market conditions.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's accounting for the CVR liability. For example, we tested controls over the valuation of the CVR liability, including management's review of the significant assumption described above. To test the fair value of the CVR liability, we performed audit procedures that included, among others, inspecting the terms of the CVR agreement, evaluating the valuation methodologies used with assistance of our valuation specialist, and testing the key contractual inputs and significant assumption discussed above. We evaluated the revenue growth assumption by comparing it to observable historical product level sales trends, and third-party analyses of the products. We also performed sensitivity analyses over the revenue growth assumption to evaluate the changes in the fair value that would result from changes in that assumption.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2023.

Grand Rapids, Michigan

March 6, 2024

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Xeris Biopharma Holdings, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Xeris Biopharma Holdings, Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Xeris Biopharma Holdings, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheet of the Company as of December 31, 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the year then ended, and the related notes and our report dated March 6, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Grand Rapids, Michigan

March 6, 2024

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Xeris Biopharma Holdings, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Xeris Biopharma Holdings, Inc. and subsidiaries (the Company) as of December 31, 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We served as the Company's auditor from 2017 to 2023.

Chicago, Illinois

March 8, 2023

XERIS BIOPHARMA HOLDINGS, INC.
Consolidated Balance Sheets
(in thousands, except share and par value)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 67,449	$ 121,966
Short-term investments	5,002	—
Trade accounts receivable, net	39,197	30,830
Inventory	38,838	24,735
Prepaid expenses and other current assets	5,778	9,287
Total current assets	156,264	186,818
Property and equipment, net	5,971	5,516
Operating lease right-of-use assets	23,204	3,992
Goodwill	22,859	22,859
Intangible assets, net	109,764	120,607
Other assets	4,540	4,730
Total assets	$ 322,602	$ 344,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,565	$ 4,606
Current operating lease liabilities	3,495	1,580
Other accrued liabilities	23,510	36,786
Accrued trade discounts and rebates	22,149	16,818
Accrued returns reserve	14,198	11,173
Current portion of contingent value rights	19,109	—
Other current liabilities	1,167	2,658
Total current liabilities	95,193	73,621
Long-term debt, net of unamortized debt issuance costs	190,932	187,075
Non-current operating lease liabilities	34,764	9,402
Non-current contingent value rights	1,379	25,688
Deferred tax liabilities	2,268	3,518
Other liabilities	4,848	31
Total liabilities	329,384	299,335
Commitments and contingencies (Note 18)		
Stockholders' equity (deficit):		
Preferred stock—par value $0.0001, 25,000,000 shares and 25,000,000 shares authorized and no shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	—	—
Common stock—par value $0.0001, 350,000,000 shares and 350,000,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively; 138,130,715 and 136,273,090 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	14	14
Additional paid in capital	610,254	599,966
Accumulated deficit	(617,025)	(554,770)
Accumulated other comprehensive loss	(25)	(23)
Total stockholders' equity (deficit)	(6,782)	45,187
Total liabilities and stockholders' equity (deficit)	$ 322,602	$ 344,522

See accompanying notes to consolidated financial statements.

XERIS BIOPHARMA HOLDINGS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Years Ended December 31,		
	2023	**2022**	**2021**
Product revenue, net	$ 153,364	$ 109,263	$ 49,280
Royalty, contract and other revenue	10,550	985	310
Total revenue	163,914	110,248	49,590
Costs and expenses:			
Cost of goods sold	28,645	22,634	13,318
Research and development	22,341	20,966	25,160
Selling, general and administrative	146,095	137,745	125,718
Amortization of intangible assets	10,843	10,843	550
Total costs and expenses	207,924	192,188	164,746
Loss from operations	(44,010)	(81,940)	(115,156)
Other income (expense):			
Interest and other income	4,751	2,578	313
Loss on debt extinguishment, net	(2,837)	(1,223)	—
Interest expense	(26,609)	(14,102)	(7,180)
Change in fair value of warrants	1	1,760	(702)
Change in fair value of contingent value rights	5,200	(3,157)	—
Total other expense	(19,494)	(14,144)	(7,569)
Net loss before benefit from income taxes	(63,504)	(96,084)	(122,725)
Benefit from income taxes	1,249	1,424	—
Net loss	$ (62,255)	$ (94,660)	$ (122,725)
Other comprehensive loss, net of tax:			
Unrealized gains (losses) on investments	(2)	7	(38)
Foreign currency translation adjustments	—	1	1
Comprehensive loss	$ (62,257)	$ (94,652)	$ (122,762)
Net loss per common share - basic and diluted	$ (0.45)	$ (0.70)	$ (1.55)
Weighted average common shares outstanding - basic and diluted	137,674,857	135,628,721	79,027,062

See accompanying notes to consolidated financial statements.

XERIS BIOPHARMA HOLDINGS, INC.
Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share data)

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2020	59,611,202	$ 6	$ 371,134	$ 6	$ (337,385)	$ 33,761
Net loss	—	—	—	—	(122,725)	(122,725)
Issuance of common stock upon equity offering	6,553,398	1	26,924	—	—	26,925
Issuance of common stock in connection with the Transactions	58,082,606	6	137,649	—	—	137,655
Issuance of equity awards to Strongbridge equity award holders in connection with the Transactions	—	—	7,964	—	—	7,964
Exercise of stock options	93,399	—	199	—	—	199
Vesting of restricted stock units (net of 141,644 shares withheld for tax)	316,772	—	(534)	—	—	(534)
Stock-based compensation	—	—	11,381	—	—	11,381
Issuance of common stock through employee stock purchase plan	215,939	—	642	—	—	642
Other comprehensive loss	—	—	—	(37)	—	(37)
Balance, December 31, 2021	124,873,316	$ 13	$ 555,359	$ (31)	$ (460,110)	$ 95,231
Net loss	—	—	—	—	(94,660)	(94,660)
Issuance of common stock and warrants upon equity offering	10,238,908	1	29,999	—	—	30,000
Issuance of warrants related to loan agreement			2,080	—	—	2,080
Exercise of stock options	11,228	—	8	—	—	8
Vesting of restricted stock units (net of 231,324 shares withheld for tax)	477,771	—	(468)	—	—	(468)
Stock-based compensation	—	—	12,160	—	—	12,160
Issuance of common stock through employee stock purchase plan	671,867	—	828	—	—	828
Other comprehensive loss	—	—	—	8	—	8
Balance, December 31, 2022	136,273,090	$ 14	$ 599,966	$ (23)	$ (554,770)	$ 45,187
Net loss	—	—	—	—	(62,255)	(62,255)
Exercise of stock options	14,036	—	32	—	—	32
Vesting of restricted stock units (net of 815,177 shares withheld for tax)	1,265,805	—	(1,009)	—	—	(1,009)
Stock-based compensation	—	—	10,716	—	—	10,716
Issuance of common stock through employee stock purchase plan	577,784	—	549	—	—	549
Other comprehensive loss	—	—	—	(2)	—	(2)
Balance, December 31, 2023	138,130,715	$ 14	$ 610,254	$ (25)	$ (617,025)	$ (6,782)

See accompanying notes to consolidated financial statements.

XERIS BIOPHARMA HOLDINGS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net loss	$ (62,255)	$ (94,660)	$ (122,725)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,487	1,399	1,329
Amortization of intangible assets	10,843	10,843	550
Amortization of premium/discount on investments	(1,263)	184	413
Amortization of debt discount and debt issuance costs	2,205	1,559	961
Amortization of operating right-of-use assets	830	426	—
Deferred income tax benefit	(1,249)	(1,424)	—
Stock-based compensation	10,716	12,160	11,381
Loss on extinguishment of debt	2,837	1,223	—
Loss on disposal of property and equipment	321	236	—
Gain on the remeasurement of lease liabilities	—	(1,084)	—
Change in fair value of warrants	(1)	(1,760)	702
Change in fair value of contingent value rights	(5,200)	3,157	—
Changes in operating assets and liabilities:			
Trade accounts receivable	(8,367)	(13,374)	(6,237)
Prepaid expenses and other current assets	3,206	(3,887)	3,290
Inventory	(14,804)	(7,465)	(7,418)
Accounts payable	6,959	(4,318)	5,527
Other accrued liabilities	(5,855)	(11,384)	12,556
Accrued trade discounts and rebates	5,331	1,777	4,213
Accrued returns reserve	3,025	7,173	1,110
Supply agreement liabilities	(6,720)	(5,280)	—
Operating lease liabilities	7,538	(899)	—
Other	3,393	2,507	(1,187)
Net cash used in operating activities	(47,023)	(102,891)	(95,535)
Cash flows from investing activities:			
Capital expenditures	(2,263)	(524)	(1,085)
Purchases of investments	(43,741)	—	(43,020)
Sales and maturities of investments	40,000	34,985	103,600
Cash acquired through acquisition of business	—	—	38,469
Net cash (used in) provided by investing activities	(6,004)	34,461	97,964
Cash flows from financing activities:			
Proceeds from equity offerings	—	30,000	27,000
Payments of equity offering costs	—	—	(54)
Proceeds from issuance of debt	—	146,214	—
Repayment of debt	—	(43,496)	—
Payments of debt issuance costs	(1,185)	(4,876)	—
Payments for loss on extinguishment of debt	—	(737)	—
Proceeds from issuance of employee stock purchase plan shares	549	828	642
Proceeds from exercise of stock awards	32	8	193
Repurchase of common stock withheld for taxes	(1,009)	(468)	(534)
Net cash (used in) provided by financing activities	(1,613)	127,473	27,247
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	—	(3)
Increase (decrease) in cash, cash equivalents and restricted cash	(54,640)	59,043	29,673
Cash, cash equivalents and restricted cash, beginning of year	126,314	67,271	37,598
Cash, cash equivalents and restricted cash, end of year	$ 71,674	$ 126,314	$ 67,271

XERIS BIOPHARMA HOLDINGS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2023	**2022**	**2021**
Supplemental schedule of cash flow information:			
Cash paid for interest	$ 27,686	$ 10,859	$ 7,294
Supplemental schedule of non-cash activities:			
Issuance of warrants related to loan agreement	$ —	$ 2,080	$ —
Initial operating lease right-of-use assets for adoption of ASU 2016-02	$ —	$ (6,277)	$ —
Initial current and non-current operating lease liabilities for adoption of ASU 2016-02	$ —	$ 14,013	$ —
Settlement agreement with debt and warrant holders accounted for as extinguishment and re issuance of debt:			
Extinguishment of convertible note	$ (31,975)	$ —	$ —
Issuance of convertible note	$ 33,574	$ —	$ —
Stock issued in connection with the acquisition of Strongbridge	$ —	$ —	$ 137,655
Initial fair value of equity awards and PIPE warrants consideration at acquisition date	$ —	$ —	$ 8,871
Initial fair value of contingent consideration at acquisition date	$ —	$ —	$ 22,531

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that agrees to the same amounts shown in the consolidated statements of cash flows (in thousands):

	As of December 31,	
	2023	**2022**
Cash flows from operating activities:		
Cash and cash equivalents	$ 67,449	$ 121,966
Restricted cash included in Other assets [(1)]	4,225	4,348
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 71,674	$ 126,314

[(1)] These restricted cash items are primarily security deposit in the form of letters of credit for the Company to secure lease.

See accompanying notes to consolidated financial statements.

Note 1. Organization and nature of the business

Nature of business

Xeris Biopharma Holdings, Inc. ("Xeris Biopharma" or the "Company") is a growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing clinically meaningful products across a range of therapies. The Company currently has three commercially available products: Gvoke, a ready-to-use, liquid-stable glucagon for the treatment of severe hypoglycemia; Keveyis, the first therapy approved in the United States to treat hyperkalemic, hypokalemic, and related variants of Primary Periodic Paralysis ("PPP"); and Recorlev, a cortisol synthesis inhibitor for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome approved by the Food and Drug Administration ("FDA") in December 2021. The Company also has a pipeline of development programs to bring new products forward using its proprietary formulation science, XeriSol and XeriJect.

As used herein, the "Company" or "Xeris" refers to Xeris Pharmaceuticals, Inc. ("Xeris Pharma") when referring to periods prior to the acquisition of Strongbridge Biopharma plc ("Strongbridge") on October 5, 2021 and to Xeris Biopharma when referring to periods on or subsequent to October 5, 2021.

Throughout this document, unless otherwise noted, references to Gvoke include Gvoke PFS, Gvoke HypoPen, Gvoke Kit and Ogluo (glucagon).

The Company is subject to a number of risks similar to other specialty pharmaceutical companies, including, but not limited to, successful commercialization and market acceptance of available products and any future products, if and when approved, successful development of the product candidates, the development of new technological innovations by competitors, and protection of intellectual property.

Liquidity and capital resources

The Company has incurred operating losses since inception and has an accumulated deficit of $617.0 million as of December 31, 2023. The Company expects to continue to incur net losses for at least the next 12 months beyond the issuance date of these consolidated financial statements. Based on the Company's current operating plans, existing working capital at December 31, 2023, the Company believes that its cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months from the issuance date of these consolidated financial statements.

If needed, the Company may elect to finance its operations through equity or debt financing along with revenues. There can be no assurance that such funding may be available to the Company on acceptable terms, or at all, or that the Company will be able to successfully market and sell Gvoke, Recorlev and Keveyis. Market volatility resulting from geopolitical instability resulting from the ongoing military conflicts between Russia and Ukraine and Israel and Hamas, rising interest rates, inflationary pressures, the tightening of lending standards, a potential shutdown of the U.S. government, any further deterioration in the macroeconomic economy or financial services industry resulting from actual or potential bank failures, or other factors could also adversely impact the Company's ability to access capital as and when needed. The issuance of equity securities may result in dilution to stockholders. If the Company raises additional funds through the issuance of additional debt, which may have rights, preferences and privileges senior to those of the Company's common stockholders, the terms of the debt could impose significant restrictions on the Company's operations. 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. If additional funding is not secured when required, the Company may need to delay or curtail its operations until such funding is received, which would have a material adverse impact on the business prospects and results of operations.

Note 2. Basis of presentation and summary of significant accounting policies and estimates

Basis of presentation

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair presentation of the Company's financial position, results of operations and cash flows for the periods presented. The results of operations for such periods are not necessarily indicative of the results that may be expected for any future period.

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 Update ("ASU") issued by the Financial Accounting Standards Board ("FASB").

Basis of consolidation

These consolidated financial statements include the financial statements of Xeris Biopharma Holdings, Inc. and subsidiaries. All intercompany transactions have been eliminated.

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, revenues and expenses included in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue recognition

The Company applies the guidance in ASC 606, *Revenue Recognition*, to all contracts with customers within the scope of the standard.

The Company sells product primarily to wholesalers or a specialty pharmacy that subsequently resell to retail pharmacies or patients. The Company enters into arrangements with payors, group purchasing organizations, and healthcare providers that provide for government-mandated or privately-negotiated rebates, chargebacks and discounts related to the Company's products. The Company currently sells Gvoke, Recorlev and Keveyis in the United States only.

Revenue is recognized when the Company's customer (e.g., a wholesaler or specialty pharmacy) obtains control of promised goods or services, which is when the Company's obligations under the terms of the contract with the customer are satisfied, based on the consideration the Company expects to receive in exchange for those goods or services.

Revenues are recorded at the net product sales price, which includes estimated allowances for patient copay assistance programs, prompt payment discounts, payor rebates, chargebacks, service fees, and product returns, all of which are recorded at the time of sale to the pharmaceutical wholesaler or other customer. The Company applies significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, adjustments are made to these allowances in the period in which the actual results or updates to estimates become known.

Patient Copay Assistance Program

The Company offers savings programs to commercially insured patients under which the cost of a prescription to a patient is discounted. The Company reimburses pharmacies for this discount through a third-party vendor. The Company records an accrual to reduce gross sales for the estimated copay on units sold to wholesalers and other customers. The estimate is based on estimated percentages of products that will be prescribed to qualified patients, expected patient utilization of the discount program, average assistance paid based on reporting from the third-party vendor as well as industry data and estimated levels of inventory in the distribution channel. Accrued copay fees are recorded as a reduction of product revenue and included in accrued trade discounts and rebates on the consolidated balance sheets.

Commercial Rebates

The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, to provide rebates with respect to utilization of the products and contracted formulary status. The Company accrues estimated rebates based on actual average rebate amounts and estimated percent of product that will be prescribed to qualified patients and records the rebate as a reduction of product revenue. Accrued commercial rebates are included in accrued trade discounts and rebates on the consolidated balance sheets.

Government Rebates

The Company participates in certain federal and state government rebate programs such as the Medicaid Drug Rebate Program, TRICARE Retail Refunds Program, and Medicare Part D Program. The Company accrues estimated rebates and discounts based on actual average rebate amounts and estimated percent of product that will be prescribed to qualified patients and records the rebates as a reduction of product revenue. Accrued government rebates are included in accrued trade discounts and rebates on the consolidated balance sheets.

Chargebacks

The Company arranges with certain commercial and government entities allowing them to buy products directly from wholesalers at specific prices. These entities purchase products through wholesalers at the discounted price and the wholesalers charge the difference between their list price and the discounted price back to the Company. The Company accrues estimated chargebacks based on estimated percentages of products sold to these entities, contract prices, and estimated levels of inventory in the distribution channel and records the chargebacks as a reduction of product revenue. Accrued chargebacks are recorded as an allowance against trade receivables on the consolidated balance sheets.

Product Returns

For some products, the Company's customers may have the right to return product during the period beginning six months prior to the product expiration date and up to one year after the product expiration date. The Company uses actual return data to estimate the provision for returns. In a reporting period, the Company may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels, inventory dating, prescription data, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic

products. While the Company believes that the returns reserve is sufficient to avoid a significant reversal of revenue in future periods, if it were to increase or decrease the rate by 1%, it would have a $1.5 million impact on revenue in the year ended December 31, 2023. The Company records estimated product returns in accrued returns reserve on the consolidated balance sheets and as a reduction of product revenue.

Prompt Payment Discounts

As an incentive for prompt payment, the Company offers a discount to most customers. The Company expects that all eligible customers will comply with the contractual terms to earn the discount, and, therefore, the Company accrues the discount on all eligible sales. The Company records the discount as an allowance against trade accounts receivable on the consolidated balance sheets and as a reduction of product revenue.

Service Fees

The Company records service fees paid to the wholesaler and specialty pharmacy customers for distribution and inventory management services as a reduction to product revenue. The Company accrues estimated service fees based on contractually determined amounts. Accrued service fees are included in accrued trade discounts and rebates on the consolidated balance sheets.

Concentration of credit risk

For the years ended December 31, 2023, 2022 and 2021, four customers accounted for 97%, 96%, and 95% of the Company's gross product revenue, respectively. At each of December 31, 2023 and December 31, 2022, the same four customers accounted for 99% of the trade accounts receivable, net.

Cost of goods sold

Cost of goods sold includes primarily product costs, which include all costs directly related to the purchase of raw materials, charges from contract manufacturing organizations, and manufacturing overhead costs, including shipping and distribution charges. Cost of goods sold also includes losses on excess, slow-moving or obsolete inventory and inventory purchase commitments, if any. Manufacturing costs for Gvoke and Recorlev incurred prior to approval and initial commercialization were expensed as research and development expenses.

The Company does not incur material cost of goods sold related to royalty, contract and other revenue.

Research and development expenses

Research and development expenses are expensed as incurred. Research and development expenses include salaries, stock compensation and other personnel-related costs, consulting fees, fees paid for contract research and development services including those for preclinical and clinical trials, laboratory equipment and facilities costs, and other external costs. In addition, manufacturing costs of products prior to approval and initial commercialization are expensed as research and development 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, the services are performed, or the arrangement is terminated.

Stock-based compensation expense

The Company accounts for stock-based compensation awards in accordance with ASC 718, *Compensation-Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments, including stock options, restricted stock units and employee stock purchases, 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, the risk-free interest rate and the expected dividend yield of the common stock. Restricted stock units are valued based on the fair market value of the Company's common stock on the date they were granted. The Company recognizes stock-based compensation expense equal to the grant date fair value of stock options, restricted stock units and employee stock purchases on a straight-line basis over the requisite service period. The Company accounts for forfeitures as they are incurred.

Income taxes

Income taxes are recorded in accordance with ASC 740, *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 the 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. The Company's policy is to include interest and penalties related to uncertain tax positions, if any, within the provision for taxes in the statements of operations and comprehensive loss. For the years ended December 31, 2023, 2022 and 2021, the Company did not accrue any interest or penalties on uncertain tax positions.

Cash and cash equivalents

The Company considers all demand deposits with financial institutions and highly liquid investments with an original maturity of three months or less when purchased as cash equivalents.

Restricted Cash

Restricted cash includes amounts required to be held as a security deposit in the form of letters of credit for the Company to secure leases and state licenses.

Investments

The Company classifies investments in debt securities as available-for-sale investments. Investments classified as short-term on the balance sheets have original maturities of greater than 90 days but less than one year.

Inventory

Inventory is stated at the lower of cost or net realizable value, using the first-in, first-out convention. Inventory consists of raw materials, work in process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture or purchase of raw materials and production supplies. The Company’s inventory includes the direct purchase cost of materials and supplies, charges from contract manufacturing organizations and manufacturing overhead costs. The Company reviews inventory to assess if there is obsolete or excess inventory and records a charge to cost of goods sold if and when applicable.

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	3 years
Leasehold improvements	Lesser of useful life or lease term
Software	3-5 years
Furniture and fixtures	5 years
Office equipment	5 years

Impairment of long-lived assets

The Company periodically evaluates long-lived assets such as property and equipment, intangible assets subject to amortization, and right-of-use assets on operating leases for potential impairment in accordance with ASC 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 no impairment charges for the years ended December 31, 2023, 2022 and 2021.

Goodwill

The Company tests goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. Goodwill is recorded as the difference, if any, between the aggregate consideration paid for an acquisition and the fair value of the net

tangible and identified intangible assets acquired under a business combination. Goodwill is reviewed for impairment at a reporting unit level annually in the fourth quarter, or more frequently if events or circumstances indicate that the goodwill might be impaired. The Company first assesses qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. If, after assessing the totality of events or circumstances, the Company determines that it is not more likely than not that the fair value of the net assets is less than their carrying amount, then the quantitative goodwill impairment test is unnecessary.

If, based on the qualitative assessment, it is determined that it is more likely than not that the fair value of the net assets is less than their carrying amount, then the Company proceeds to perform the quantitative goodwill impairment test. In connection with the annual impairment test conducted in the fourth quarter of 2023, 2022 and 2021, the Company performed a qualitative assessment in connection with the annual goodwill impairment evaluation and determined that it was more likely than not that the fair value of the net assets exceeded their carrying value.

Intangible assets

Acquired definite life intangible assets are amortized using the straight-line method over their respective estimated useful lives. The Company evaluates the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate.

The identified intangible assets are reviewed for impairment whenever events or changes in business circumstances arise that may indicate that the carrying amount of its intangible assets may not be recoverable. These events and changes can include significant current period operating losses or negative cash flows associated with the use of an intangible asset, or group of assets, combined with a history of such factors, significant changes in the manner of use of the assets, and current expectations that it is more likely than not that an intangible asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. When impairment indicators are present, the Company compares undiscounted future cash flows to the asset group’s carrying value to determine if the asset group is recoverable. If the carrying values are in excess of undiscounted expected future cash flows, the Company measures any impairment by comparing the fair value of the asset or asset group to its carrying value.

No impairment expense was recorded for identified intangible assets during the year ended December 31, 2023, 2022 and 2021.

For further discussion of identified intangible assets, see "Note 8 – Intangible assets".

Debt issuance costs

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, reduce the carrying value of the related debt.

Contingent considerations

The fair value of the Contingent Value Rights ("CVRs") is calculated by using a discounted cash flow method for the Keveyis patent milestone and an option pricing method for the Recorlev and Keveyis sales milestones. In the case of Keveyis milestones, the Company applies a scenario-based method and weights them based on the possible achievement of the milestone. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820, *Fair Value Measurement*. The key assumptions used include the discount rate and sales growth. The estimated value of the CVR consideration is based upon available information and certain assumptions which the Company's management believes are reasonable under the circumstances. The ultimate payout under the CVRs may differ materially from the assumptions used in determining the fair value of the CVR consideration. This value is then remeasured for future expected payout as well as the increase in fair value due to the time value of money. These gains or losses, if any, are recognized in the consolidated statements of operations and comprehensive loss.

Lease Accounting

Right-of-use (“ROU”) assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the present value of the Company’s obligation to make lease payments arising from the lease over the lease term at the commencement date of the lease. As most of the Company’s leases do not provide an implicit rate, the Company estimated the incremental borrowing rate based on the information available at the date of adoption in determining the present value of lease payments and used the implicit rate when readily determinable. The Company determined incremental borrowing rates through market sources for secured borrowings including relevant industry rates. The Company excludes variable payments from lease ROU assets and lease liabilities to the extent not considered in-substance fixed, and instead, expenses variable payments as incurred. The Company’s operating leases expire at various times in 2031 and 2037, some of which include options to extend leases. The exercise of lease renewal options is at the Company’s sole discretion and the Company’s lease ROU assets and liabilities reflect only the options the Company is reasonably certain that it will exercise. We do not have leases with residual value guarantees or similar covenants.

Warrant liability

Warrants required to be settled in cash are accounted for as liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity.* The fair value of these warrants are remeasured each reporting period using the Black-Scholes option-pricing model which considers the expected term of the warrants as well as the risk-free interest rate and expected volatility of the Company's common stock. The liability is recorded in other current liabilities on the consolidated balance sheets. Generally, changes in the fair value of the warrant liabilities are recorded in the consolidated statements of operations and comprehensive loss.

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, cash equivalents, restricted cash, 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 Amended and Restated 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 investments, warrants and CVRs. The fair value of the convertible senior notes is determined from using current interest rates based on credit ratings and the remaining term of maturity.

Segment reporting

Operating segments are identified as components of an enterprise for which separate discrete financial information is available and utilized by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The Company operates in one segment.

New accounting pronouncements

Adopted accounting standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard requires entities to estimate an expected lifetime credit loss on financial assets ranging from short-term trade accounts receivable to long-term financings and report credit losses using an expected losses model rather than the incurred losses model that was previously used and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if the fair value increases. The Company adopted this standard beginning on January 1, 2023, and it did not have a material impact on the financial statements.

Pending accounting standards

In December 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Segment Reporting Disclosures.* This standard requires an entity to provide more detailed information about its reportable segment expenses that are included within management’s measurement of profit and loss and will require certain annual disclosures to be provided on an interim basis. The amendments in this ASU are effective for the Company in 2025 for annual reporting and in 2026 for interim reporting, with early adoption permitted beginning in 2024, and is required to be applied using the full retrospective method of transition. The Company is evaluating the timing and effects of adoption of this ASU on the Company’s segment disclosures.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*. This standard eliminates certain accounting models to simplify the accounting for convertible instruments, expands the disclosure requirements related to the terms and features of convertible instruments, and amends the guidance for the derivatives scope exception for contracts settled in an entity’s own equity. This standard enhances the consistency of earnings-per-share ("EPS") calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted EPS calculations and disclosures. This standard is effective for the Company for fiscal years beginning after December 15, 2023. The Company is currently evaluating the impact the adoption of this new standard will have on the financial statements and disclosures.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. This standard provides optional expedients for application of GAAP, if certain criteria are met, to contracts and other transactions that reference London Inter-bank Offered Rate ("LIBOR") or other reference rates that are expected to

be discontinued because of reference rate reform. This standard is effective for all entities as of March 12, 2020 through December 31, 2022. On December 21, 2022, the FASB issued ASU 2022-06, Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848, which extends the period of time entities can utilize the reference rate reform relief guidance under ASU 2020-04 from December 31, 2022 to December 31, 2024. The Company does not currently expect the adoption of this new standard to have a material impact on the financial statements.

Note 3. Disaggregated revenue

Disaggregated revenue by product (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Product revenue:			
Gvoke	$ 67,045	$ 52,527	$ 38,917
Keveyis	56,772	49,307	10,363
Recorlev	29,547	7,429	—
Product revenue, net	153,364	109,263	49,280
Royalty, contract and other revenue	10,550	985	310
Total revenue	$ 163,914	$ 110,248	$ 49,590

Note 4. Short-term investments

The Company classifies investments in debt securities as available-for-sale. Debt securities are comprised of liquid investments that are highly rated securities and, as of December 31, 2023, consist of U.S. government securities, all with remaining maturities of less than one year. Debt securities as of December 31, 2023 had an average remaining maturity of 0.1 years. The debt securities are reported at fair value with unrealized gains or losses recorded in accumulated other comprehensive income (loss) in the consolidated balance sheets. The cost of short-term investments is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion, as well as interest income, are included in interest and other income in the consolidated statements of operations and comprehensive loss. Refer to "Note 13 - Fair Value Measurements," for information related to the fair value measurements and valuation methods utilized.

The following table represents the Company’s short-term investments by major security type as of December 31, 2023 (in thousands):

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:				
U.S. government securities	$ 5,004	$ —	$ (2)	$ 5,002
Total available-for-sale investments	$ 5,004	$ —	$ (2)	$ 5,002

There were no short-term investments as of December 31, 2022.

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, the Company first assesses whether they are intended to be sold, or if it is more likely than not that the Company will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security’s amortized cost basis is written down to fair value through earnings. For available-for-sale securities that do not meet the above criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive loss on the statements of operations and comprehensive loss. No credit loss allowance was recorded in the years ended December 31, 2023, 2022 and 2021.

Note 5. Inventory

The components of inventory consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$ 17,404	$ 7,410
Work in process	10,959	11,367
Finished goods	10,475	5,958
Inventory	$ 38,838	$ 24,735

Inventory reserves were $2.4 million and $1.3 million at December 31, 2023 and December 31, 2022, respectively.

Note 6. Property and equipment

Property and equipment consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Lab equipment	$ 4,153	$ 3,841
Furniture and fixtures	539	1,355
Computer equipment	860	474
Office equipment	97	8
Software	374	307
Leasehold improvements	5,984	5,065
Total property and equipment	12,007	11,050
Less: accumulated depreciation and amortization	(6,036)	(5,534)
Property and equipment, net	$ 5,971	$ 5,516

Depreciation and amortization expense relating to property and equipment was $1.5 million, $1.4 million and $1.3 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Note 7. Goodwill

Goodwill is evaluated for potential impairment annually, as of the beginning of the fourth quarter and whenever events or changes in circumstances indicate the carrying amount of goodwill may not be recoverable. The process of evaluating goodwill for potential impairment is subjective and requires significant estimates, assumptions and judgments.

As of December 31, 2023, the Company assessed qualitative and quantitative factors and determined that it was not more-likely-than-not that the fair value of the one reporting unit was less than the carrying value as of the testing date. As a result of the assessment, no goodwill impairment charge was recorded during the fiscal year ended December 31, 2023, 2022 and 2021.

Note 8. Intangible assets

Identified intangible assets consist of the following (in thousands):

		December 31, 2023			December 31, 2022		
	Life (Years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Definite-lived intangible asset - Keveyis	5	$ 11,000	$ (4,950)	$ 6,050	$ 11,000	$ (2,750)	$ 8,250
Definite-lived intangible asset - Recorlev	14	121,000	(17,286)	103,714	121,000	(8,643)	112,357
Total intangible assets		$ 132,000	$ (22,236)	$ 109,764	$ 132,000	$ (11,393)	$ 120,607

As of December 31, 2023, expected amortization expense for intangible assets subject to amortization for the next five years and thereafter is as follows (in thousands):

2024	$	10,843
2025		10,843
2026		10,293
2027		8,643
2028		8,643
Thereafter		60,499
Total	$	109,764

Note 9. Other accrued liabilities

Other accrued liabilities consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Accrued employee costs	$ 16,956	$ 13,400
Supply agreement - current portion	—	6,720
Accrued supply chain costs	523	562
Accrued marketing costs	598	2,593
Accrued research and development costs	960	1,411
Accrued restructuring charges	—	2,799
Accrued interest expense	1,374	4,656
Accrued other costs	3,099	4,645
Other accrued liabilities	$ 23,510	$ 36,786

Note 10. Restructuring costs

After the completion of the acquisition of Strongbridge on October 5, 2021, the Company undertook a restructuring plan to streamline the organization and realize operating expense synergies. The Company incurred total restructuring costs of approximately $11.1 million, which primarily related to employee termination costs. These costs were fully recognized and recorded by 2022 in selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss. The plan was fully paid out in the fourth quarter of 2023.

The following table summarizes the restructuring reserve in connection with the Strongbridge acquisition and the payments made during the years ended December 31, 2023, 2022 and 2021 (in thousands):

	Restructuring Costs
Restructuring costs	$ 9,657
Payments	(2,944)
Balance accrued at December 31, 2021	$ 6,713
Restructuring costs	1,488
Payments	(5,402)
Balance accrued at December 31, 2022	$ 2,799
Payments	(2,799)
Balance accrued at December 31, 2023	$ —

Note 11. Long-term debt

Convertible Senior Notes

In June 2020, Xeris Pharma completed a public offering of $86.3 million aggregate principal amount of Xeris Pharma's 5.00% Convertible Senior Notes due 2025 (the "2025 Convertible Notes"), including $11.3 million pursuant to the underwriters' option to purchase additional notes, which was exercised in full in July 2020. Since January 15, 2021, the 2025 Convertible Notes bear cash interest at the rate of 5.00% per annum, payable semi-annually in arrears on January 15 and July 15 of each year.

Xeris Pharma incurred debt issuance costs of $5.1 million in connection with the issuance of the 2025 Convertible Notes. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders of 2025 Convertible Notes may convert their 2025 Convertible Notes at their option into shares of the Company's common stock, together, if applicable, with cash in lieu of any fractional share, at a conversion rate of 326.7974 shares of the Company's common stock per $1,000 principal amount of 2025 Convertible Notes. In the second half of 2020, $39.1 million in principal amount of 2025 Convertible Notes were converted into 13,171,791 shares of Xeris Pharma's common stock.

On September 29, 2023, the Company completed the exchange of $32.0 million in aggregate principal amount of the 2025 Convertible Notes for $33.6 million in aggregate principal amount of new 8.00% Convertible Notes due 2028 (the "2028 Convertible Notes" and together with the 2025 Convertible Notes, the "Convertible Notes"). As of December 31, 2023, the outstanding balance of the 2025 Convertible Notes was $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million.

The Company evaluated the exchange agreement for debt modification and concluded that the debt qualified for debt extinguishment. Upon extinguishment, the Company recognized the new 2028 Convertible Notes at their fair value of $34.1 million, and derecognized the carrying value of $32.0 million for the 2025 Convertible Notes and $0.7 million of unamortized initial debt issuance costs resulting in a net loss on debt extinguishment of $2.8 million.

The 2025 Convertible Notes are governed by the terms of a base indenture for senior debt securities dated June 30, 2020 (the "2025 Base Indenture"), as supplemented by the first supplemental indenture dated June 30, 2020 (the "First Supplemental Indenture"), and the second supplemental indenture dated October 5, 2021 (the "Second Supplemental Indenture" and together with the 2025 Base Indenture and First Supplemental Indenture, the "2025 Indenture"), among the Company, Xeris Pharma and U.S. Bank Trust Company, National Association (f/k/a U.S. Bank National Association), as trustee (the "Trustee"). The 2028 Convertible Notes are governed by the terms of an indenture for senior debt securities dated September 29, 2023 (the "2028 Indenture" and together with the 2025 Indenture, the "Indentures") among the Company, Xeris Pharma and the Trustee. The 2025 Convertible Notes and the 2028 Convertible Notes will mature on July 15, 2025 and July 15, 2028, respectively, unless earlier converted or redeemed or repurchased.

The Convertible Notes are senior, unsecured obligations and are equal in right of payment with Xeris Pharma's existing and future senior, unsecured indebtedness, senior in right of payment to its future indebtedness, if any, that is expressly subordinated to the Convertible Notes, and effectively subordinated to its existing and future secured indebtedness to the extent of the value of the collateral securing that indebtedness. The Convertible Notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent Xeris Pharma is not a holder thereof) preferred equity, if any, of the Company's other direct and indirect subsidiaries.

As a result of the transactions associated with the acquisition of Strongbridge, and pursuant to the Second Supplemental Indenture, the 2025 Convertible Notes are no longer convertible into shares of common stock of Xeris Pharma. Instead, subject to the terms and conditions of the 2025 Indenture, the 2025 Convertible Notes will be exchangeable into cash and shares of common stock of the Company in proportion to the transaction consideration payable pursuant to the transaction agreement for the acquisition of Strongbridge, and the "Reference Property" provisions in the 2025 Indenture.

The fair value of the Convertible Notes is determined from using current interest rates based on credit ratings and the remaining term of maturity. As of December 31, 2023, the fair value of the Convertible Notes was approximately $55.1 million. The fair value of the convertible debt was estimated using inputs for volatility, the Company's stock price, time to maturity, the risk-free rate and the Company's credit spread, some of which are considered Level 3 inputs in the fair value hierarchy disclosed in "Note 13 - Fair value measurement."

Loan Agreement

In September 2019, Xeris Pharma entered into an Amended and Restated Loan and Security Agreement (the "Oxford Loan Agreement") with Oxford Finance LLC ("Oxford"), as the collateral agent and a lender, and Silicon Valley Bank, as a lender ("SVB," and together with Oxford, the "Prior Lenders"). The Oxford Loan Agreement provided for the Prior Lenders to extend up to $85.0 million in term loans to Xeris Pharma in three tranches, of which $60.0 million was drawn down in September 2019.

In June 2020, Xeris Pharma paid a portion of the term loan equal to the sum of $20.0 million, plus all accrued and unpaid interest. In November 2020, an additional $3.5 million was drawn from the term loan.

In March 2022, the Company, Xeris Pharma and certain subsidiary guarantors of the Company entered into a Credit Agreement and Guaranty (as amended, modified or amended and restated from time to time, the "Hayfin Loan Agreement") with the lenders from time to time parties thereto (the "Lenders") and Hayfin Services LLP, as administrative agent for the Lenders (in such capacity, together with its successors and assigns, the "Agent"), pursuant to which the Company and its subsidiaries party thereto granted a first priority security interest on substantially all of their assets, including intellectual property, subject to certain exceptions. The Hayfin Loan Agreement provided for the Lenders to extend $100.0 million in term loans to the Company on the closing date and up to an additional $50.0 million in delayed draw term loans during the one year period immediately following the closing date (collectively, the "Loans"). On December 28, 2022, the Company borrowed the full amount of such $50.0 million delayed draw term loan under the Hayfin Loan Agreement. In conjunction with the execution of the Hayfin Loan Agreement, the Oxford Loan Agreement remaining balance of $43.5 million and fees of $2.1 million in connection with the loan repayment were paid. In addition to utilizing the proceeds to repay the obligations under the Oxford Loan Agreement in full, the proceeds were otherwise used for general corporate purposes.

The Loans incur interest at a floating per annum rate in an amount equal to the sum of (i) 9.0% (or 8.0% per annum if the replacement rate in effect is the Wall Street Journal Prime Rate) plus (ii) the greater of (x) (1) CME Group Benchmark Administration Limited (CBA) Term SOFR (or the replacement rate, if applicable) if CBA Term SOFR is greater than 1.00% plus 0.26161% or (2) 1.00% if CME Term SOFR is less than 1.00% and (y) one percent (1.00%) per annum (or 2.0% per annum if the replacement rate in effect is the Wall Street Journal Prime Rate). The Company has incurred total debt issuance costs of approximately $3.6 million related to the Hayfin Loan Agreement, which are being amortized to interest expense over the life of the loan using the effective interest method. The remaining balance of unamortized debt issuance costs have been reflected as a direct reduction to the loan balance. The effective interest rate, including the amortization of debt discount and debt issuance costs, amounts to approximately 11.8%. The debt outstanding under the Hayfin Loan Agreement approximates fair value due to the variable interest rate on the debt.

The Loans will mature on March 8, 2027; provided, however, the Loans will mature on January 15, 2025 if the 2025 Convertible Notes are outstanding as of such date and either (i) the maturity date thereof has not been extended to a date on or after September 4, 2027 or (ii) the Company has not received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.6 million of cash on hand, is sufficient to redeem and discharge the 2025 Convertible Notes in full.

The components of debt are as follows (in thousands):

	December 31, 2023	December 31, 2022
Convertible Notes	$ 49,306	$ 47,175
Loan facility	145,569	144,487
Less: unamortized debt issuance costs	(3,943)	(4,587)
Long-term debt, net of unamortized debt issuance costs	$ 190,932	$ 187,075

The following table sets forth the Company's future minimum principal payments on the Convertible Note and the loan facility (in thousands):

2024	$	—
2025		15,200
2026		—
2027		150,000
2028		33,574
Thereafter		—
	$	198,774

For the years ended December 31, 2023, 2022 and 2021, the Company recognized interest expense of $26.6 million, $14.1 million and $7.2 million, respectively, of which $2.2 million, $1.6 million and $1.0 million, respectively, related to the amortization of debt discount and issuance costs, respectively. Losses of $2.8 million and $1.2 million on extinguishment of debts related to the third party debt arrangements were recorded in other expense in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022, respectively.

Note 12. Warrants

On January 3, 2022, the Company entered into a securities purchase agreement in connection with a private placement with an affiliate of Armistice Capital, LLC ("Armistice") for aggregate gross proceeds of approximately $30.0 million. In accordance with the purchase agreement, the Company issued to Armistice an aggregate of (i) 10,238,908 shares of the Company's common stock, par value $0.0001 per share at a purchase price of $2.93 per share, and (ii) warrants to purchase an aggregate of 5,119,454 shares of the Company's common stock at an exercise price of $3.223 per share. The warrants became exercisable immediately upon the closing of the transaction and have a term of five years from the earliest of the date (a) of effectiveness of the resale registration statement, which was February 7, 2022, (b) all of the shares of the Company's common stock issued or issuable to Armistice under the securities purchase agreement and all shares of the Company's common stock issuable upon exercise of the warrants (the "Warrant Shares") have been sold pursuant to Rule 144 or may be sold pursuant to Rule 144 without the requirement for the Company to be in compliance with the current public information required under Rule 144 and without volume or manner-of-sale restrictions, (c) following the one-year anniversary of the date of closing provided that the holder of Shares or Warrant Shares is not an affiliate of the Company, or (d) all of the shares and Warrant Shares may be sold pursuant to an exemption from registration under Section 4(a)(1) of the Securities Act without volume or manner-of-sale restrictions.

Associated with the Hayfin Loan Agreement disclosed in "Note 11 - Long-term debt," the Lenders also received warrants to purchase 1,315,789 shares of the common stock of the Company at a price of $2.28 per share. The warrants are (i) exercisable until March 8, 2029; (ii) freely transferable and detachable from the Loans; and (iii) subject to customary warrant holder rights and protections, including structural-based anti-dilution protection and adjustments for stock dividends, splits, combinations, reclassifications and the like.

As of December 31, 2023, the following warrants were outstanding:

Warrants classified as liabilities:	**Outstanding Warrants**	**Exercise Price per Warrant**	**Expiration Date**
2018 Term A Warrants	53,720	$11.169	February 2025
2018 Term B Warrants	40,292	$11.169	September 2025
	94,012		
Warrants classified as equities:			
Warrants in connection with CRG loan agreement	309,122	$9.410	July 2024
Warrants in connection with CRG loan amendment in January 2018	978,628	$12.760	January 2025
Warrants in connection with Avenue Capital loan agreement	209,633	$2.390	May 2025
Warrants in connection with Avenue Capital loan agreement	209,633	$2.390	December 2025
Warrants in connection with Horizon and Oxford loan agreement	125,999	$3.130	December 2026
Warrants in connection with Armistice securities purchase agreement	5,119,454	$3.223	February 2027
Warrants in connection with Hayfin Loan Agreement	1,315,789	$2.280	March 2029
	8,268,258		

Note 13. 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.

Level 3: Measured based on prices or valuation models that require 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 considers the market for the 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, 2023 and December 31, 2022 (in thousands):

	Total as of December 31, 2023	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 67,449	$ 67,449	$ —	$ —
Investments:				
U.S. government securities	$ 5,002	$ 5,002	$ —	$ —
Other assets:				
Restricted cash	$ 4,225	$ 4,225	$ —	$ —
Liabilities				
Current portion of contingent value rights	$ 19,109	$ —	$ —	$ 19,109
Non-current contingent value rights	$ 1,379	$ —	$ —	$ 1,379
Warrant liabilities	$ 8	$ —	$ —	$ 8

	Total as of December 31, 2022	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 121,966	$ 121,966	$ —	$ —
Other assets:				
Restricted cash	$ 4,348	$ 4,348	$ —	$ —
Liabilities				
Non-current contingent value rights	$ 25,688	$ —	$ —	$ 25,688
Warrant liabilities	$ 9	$ —	$ —	$ 9

Contingent Value Rights

As part of the 2021 acquisition of Strongbridge, the Company issued contingent value rights ("CVRs") representing additional contingent consideration of up to $1.00 for each CVR upon the achievement of the following:

- Keveyis Milestone: $0.25 per CVR, upon the earlier of the first listing of any patent in the FDA's Orange Book for Keveyis by the end of 2023 or the first achievement of at least $40 million in net revenue of Keveyis in 2023;
- 2023 Recorlev Milestone: $0.25 per CVR, upon the first achievement of at least $40 million in net revenue of Recorlev in 2023; and
- 2024 Recorlev Milestone: $0.50 per CVR, upon the first achievement of at least $80 million in net revenue of Recorlev in 2024.

There are approximately 74.1 million CVRs. Up to 8.3 million CVRs may be issued to holders of Strongbridge rollover options and assumed warrants upon the exercise thereof. CVRs are settleable in cash, common stock, or a combination of cash and common stock, at the Company's sole election.

Contingent consideration obligations are recorded at their estimated fair values and these obligations are revalued at each reporting period until the related contingencies are resolved. The CVRs are adjusted to fair value using the methods described above at the end of each reporting period. Significant changes which increase or decrease the probabilities of achieving the related milestones or shorten or lengthen the time required to achieve such events would result in corresponding increases or decreases in the fair values of these obligations.

The Company has determined that the CVR liabilities' fair values are Level 3 items within the fair value hierarchy. The following table presents the change in the CVR liabilities (in thousands):

Balance at the acquisition of Strongbridge	$	22,531
Change in fair value of CVRs		—
Balance at December 31, 2021	$	22,531
Change in fair value of CVRs		3,157
Balance at December 31, 2022	$	25,688
Change in fair value of CVRs		(5,200)
Balance at December 31, 2023	$	20,488
Balance at Current portion of contingent value rights	$	19,109
Balance at Non-current contingent value rights		1,379
Balance at December 31, 2023	$	20,488

Note 14. Stockholders' equity

The Company’s 375.0 million authorized shares of stock are divided into 350.0 million shares of common stock, par value $0.0001 per share, and 25.0 million shares of undesignated preferred stock, par value $0.0001 per share. At December 31, 2023, none of the 25.0 million shares of preferred stock were outstanding, and the Company has no present plans to issue any shares of preferred stock. The Company’s board of directors has the authority, without action by the Company’s stockholders, to designate and issue the preferred stock in one or more series and to designate the rights, preferences, limitations and privileges of each series of preferred stock, which may be greater than the rights of the Company’s common stock.

The Company has not paid any cash dividends on the common stock during the periods presented.

On January 3, 2022, the Company entered into a securities purchase agreement in connection with a private placement with an affiliate of Armistice Capital, LLC ("Armistice") for aggregate gross proceeds of approximately $30.0 million. In accordance with the purchase agreement, the Company issued to Armistice an aggregate of (i) 10,238,908 shares of the Company’s common stock, par value $0.0001 per share at a purchase price of $2.93 per share, and (ii) warrants to purchase an aggregate of 5,119,454 shares of the Company's common stock at an exercise price of $3.223 per share. The warrants became exercisable immediately upon the closing of the transaction and have a term of five years from the earliest of the date (a) of effectiveness of the resale registration statement, which was February 7, 2022, (b) all of the shares and the Company's common stock issuable upon exercise of the warrants (the "Warrant Shares") have been sold pursuant to Rule 144 or may be sold pursuant to Rule 144 without the requirement for the Company to be in compliance with the current public information required under Rule 144 and without volume or manner-of-sale restrictions, (c) following the one-year anniversary of the date of closing provided that the holder of Shares or Warrant Shares is not an affiliate of the Company, or (d) all of the shares and Warrant Shares may be sold pursuant to an exemption from registration under Section 4(a)(1) of the Securities Act without volume or manner-of-sale restrictions.

Note 15. Stock compensation plan

In 2011, the Company adopted the 2011 Stock Option Issuance Plan (the "2011 Plan") and subsequently amended it to authorize the Board of Directors to issue up to 4,714,982 incentive stock option and non-qualified stock option awards.

The 2018 Stock Option and Incentive Plan (the "2018 Plan") was adopted by the Board of Directors in April 2018 and approved by the Company's stockholders in June 2018 to award up to 1,822,000 shares of common stock. The 2018 Plan replaced the 2011 Plan as the Board of Directors decided not to make additional awards under the 2011 Plan following the closing of the IPO, which occurred in June 2018. The 2018 Plan allows the compensation committee to make equity-based and cash-based incentive awards to the Company's officers, employees, directors and other key persons (including consultants). No grants of stock options or other awards may be made under the 2018 Plan after the tenth anniversary of the effective date.

As of December 31, 2023, there were 3,240,766 shares of common stock available for future issuance under the 2018 Plan.

The 2018 Employee Stock Purchase Plan (the "ESPP") was adopted by the Board of Directors in April 2018 and approved by the Company's stockholders in June 2018 to issue up to 193,000 shares of common stock to participating employees. Through the ESPP, eligible employees may authorize payroll deductions of up to 15% of their compensation to purchase up to the number of shares of common stock determined by dividing $25,000 by the closing market price of Xeris common stock on the offering date. The purchase price per share at each purchase date is equal to 85% of the lower of (i) the closing market price per share of Xeris common stock on the employee’s offering date or (ii) the closing market price per share of Xeris common stock on the purchase date. Each offering period has a six-month duration and purchase interval. As of December 31, 2023, there were 76 shares available for issuance under the ESPP.

The Equity Inducement Plan (the "Inducement Plan") was adopted by the Board of Directors in February 2019. The Inducement Plan allows the Company 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 the Company. The Company uses this Inducement Plan to help it attract and retain prospective employees who are necessary to support the commercialization of products and the expansion of the Company generally. As of December 31, 2023, there were 365,949 shares of common stock available for future issuance under the Inducement Plan.

Assumed Plans

On the acquisition date of Strongbridge, the Company assumed all then-outstanding stock options and shares available and reserved for issuance under some legacy equity incentive plans of Strongbridge, including the Strongbridge 2015 equity compensation plan and Strongbridge 2017 inducement plan (collectively, the "Assumed Plans"). Shares reserved under the Assumed Plans will be available for future grants. The Company also assumed all then-outstanding stock options from the rest of the legacy equity incentive plans of Strongbridge without assuming the shares available and reserved for issuance under these plans. The number of shares subject to stock options outstanding under all Strongbridge legacy equity incentive plans are included in the tables below. As of December 31, 2023, there were 1,908,897 shares reserved for future grants under the Assumed Plans.

Stock options

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, three or four years after the grant date and expire seven to 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 term 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 United States Treasury yield curve in effect at the time of grant. The expected stock price volatility assumption is based on the historical volatilities of a peer group of publicly traded companies as well as the historical volatility of the Company's common stock, since the Company began trading subsequent to the IPO in June 2018, over the 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.

Stock option activity under the 2011 Plan, 2018 Plan, Inducement Plan and Assumed Plans for the years ended December 31, 2023 and December 31, 2022 was as follows:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)
Outstanding - December 31, 2021	11,362,336	$ 5.86	5.62
Granted	175,000	$ 2.10	
Exercised	(11,228)	$ 0.69	
Forfeited	(87,680)	$ 5.25	
Expired	(1,738,267)	$ 8.31	
Outstanding - December 31, 2022	9,700,161	$ 5.37	4.76
Granted	—	—	
Exercised	(14,036)	2.33	
Forfeited	(13,334)	5.54	
Expired	(473,047)	8.38	
Outstanding - December 31, 2023	9,199,744	$ 5.22	3.84
Vested and expected to vest at December 31, 2023	9,199,744	$ 5.22	3.84
Exercisable - December 31, 2023	9,002,580	$ 5.23	3.77

At December 31, 2023, there was a total of $0.6 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 0.9 years.

Restricted Stock Units

The Company grants Restricted Stock Units ("RSUs") to employees. RSUs that are granted vest over either three or four years in equal annual installments beginning on the one-year anniversary of the date of grant, provided that the employee is employed by the Company on such vesting date. If and when the RSUs vest, the Company will issue one share of common stock for each whole RSU that has vested, subject to satisfaction of the employee's tax withholding obligations. Upon vesting and settlement of RSUs or exercise of stock options, at the election of the grantee, the Company does not collect withholding taxes in cash from employees. Instead, the Company withholds upon settlement as RSUs vest, or as stock options are exercised, the portion of those shares with a fair market value equal to the amount of the minimum statutory withholding taxes due. The withheld shares are accounted for as repurchases of common stock. Stock-based compensation expense related to RSUs is recognized on a straight-line basis over the employee's requisite service period.

A summary of outstanding RSU awards and the activity for the years ended December 31, 2023 and December 31, 2022 was as follows:

	Number of Units	Weighted Average Grant Date Fair Value Per Share
Unvested balance - December 31, 2021	2,005,041	$ 5.15
Granted	4,477,850	$ 2.71
Vested	(708,970)	$ 5.46
Forfeited	(518,261)	$ 2.90
Unvested balance - December 31, 2022	5,255,560	$ 3.25
Granted	8,955,400	1.39
Vested	(2,080,982)	3.59
Forfeited	(550,430)	1.64
Unvested balance - December 31, 2023	11,579,548	$ 1.83

As of December 31, 2023, there was $12.4 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over the weighted-average remaining vesting period of 1.7 years.

The following table summarizes the reporting of total stock-based compensation expense resulting from stock options, RSUs and the ESPP (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Cost of goods sold	$ —	$ —	$ 106
Research and development	1,413	1,593	1,696
Selling, general and administrative	9,303	10,567	9,579
Total stock-based compensation expense	$ 10,716	$ 12,160	$ 11,381

Note 16. Other employee benefit plans

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. Commencing in 2019, the Company began discretionary matching employee contributions up to certain limits. For the years ended December 31, 2023, 2022 and 2021, the Company made $2.4 million, $1.7 million and $0.7 million of matching contributions to the plan, respectively.

Deferred Compensation Plan

The Compensation Committee of the Board of Directors adopted a deferred compensation plan ("Deferred Compensation Plan") in April 2020. The Deferred Compensation Plan allows a select group of executive management and non-employee directors to defer payment of certain of their cash compensation. Participants in the Deferred Compensation Plan who are employees may defer all or a portion of their annual base salaries and all or a portion of their annual cash performance-based compensation. Participants who are non-employee directors may defer all or a portion of their annual cash retainers. The participants' elective deferrals are 100% vested immediately and accrue interest at a rate of two percent per annum. The Deferred Compensation Plan is unfunded and unsecured. As of December 31, 2021, the total deferred compensation liability under the Deferred Compensation Plan was approximately $1.6 million recorded in other current liabilities in the consolidated balance sheets and was fully paid off in January 2022.

Note 17. Leases

The Company has non-cancellable operating leases for office and laboratory space, which expire at various times in 2031 and 2037. The non-cancellable lease agreements provide for monthly lease payments, which increase during the term of each lease agreement.

On September 29, 2022, Xeris Pharma amended and restated its existing lease with Fulton Ogden Venture, LLC to expand the leased premises to accommodate the Company's relocation of its headquarters to such premises. The term of the space existing prior to the amendment and restatement commenced on January 1, 2021 and the lease for the combined expanded space commenced on April 1, 2023. The term of the amended and restated lease will expire on March 31, 2036, unless extended or earlier terminated pursuant to the terms of the lease.

All of the Company's leases are classified as operating leases, which are included as operating lease right-of-use assets and current and non-current operating lease liabilities in the consolidated balance sheets. The Company's operating lease costs are included in operating expenses in the accompanying consolidated statements of operations and comprehensive loss. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

A majority of the Company's lease agreements include fixed rental payments. Certain lease agreements include fixed rental payments that are adjusted periodically by a fixed rate. The fixed payments, including the effects of changes in the fixed rate or amount, and renewal options reasonably certain to be exercised, are included in the measurement of the related lease liability. The exercise of lease renewal options is at the Company's sole discretion. The depreciable life of assets and leasehold improvements are limited by the expected lease term, which includes renewal options reasonably certain to be exercised. The majority of the Company's real estate leases require that the Company pay maintenance, real estate taxes and insurance in addition to rent. These payments are generally variable and based on actual costs incurred by the lessor. Therefore, these amounts are not included in the consideration of the contract when determining the right-of-use asset and lease liability but are reflected as variable lease expenses.

As the interest rate implicit in the lease is not readily determinable, the Company uses the incremental borrowing rate as the discount rate. The Company considers observable inputs as of the effective date of the ASC 842 adoption including the credit rating, existing borrowings and other relevant borrowing rates, such as risk-free rates like the United States Treasury rate, and then adjusting as necessary for the appropriate lease term. The incremental borrowing rate is reassessed if there is a change to the lease term or if a modification occurs and it is not accounted for as a separate contract. As of December 31, 2023, the Company's operating leases had a weighted-average remaining lease term of 11.6 years and a weighted-average discount rate of 11.9%.

Supplemental cash flow information related to the Company's operating leases was as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 1,648	$ 2,159
Right of use assets obtained in exchange for new lease obligations:		
Operating leases	$ 20,043	$ —

The Company reports the amortization of operating lease right-of-use assets and the change in operating lease liabilities on a net basis in other in the operating activities of the accompanying consolidated statements of cash flows.

The components of lease expense were as follows (in thousand):

	Years Ended December 31,	
Lease cost	2023	2022
Operating lease expense	$ 4,474	$ 1,799
Variable lease cost	1,208	1,091
Sublease income	(216)	(212)
Total lease cost	$ 5,466	$ 2,678

Rental expense for operating leases was approximately $2.4 million for the year ended December 31, 2021.

As of December 31, 2023, maturities of lease liabilities are summarized as follows (in thousands):

2024	3,495
2025	6,080
2026	6,232
2027	6,389
2028	6,549
Thereafter	45,441
Total lease payments	74,186
Less: Effect of discounting to net present value	(35,927)
Present value of lease liabilities	$ 38,259
Operating lease liabilities, current	3,495
Operating lease liabilities, non-current	34,764
Total operating lease liabilities	$ 38,259

Note 18. Commitments and contingencies

Commitments

Commitments to Taro

The Company has a supply agreement with Taro Pharmaceuticals North America, Inc. ("Taro") to produce Keveyis. In 2023, the Company amended the agreement to extend the initial term until March 2027. As part of the agreement, as amended, the Company has agreed to certain annual minimum marketing spend requirements and minimum purchase order quantities for each year, which in the case of the minimum purchase order quantities, is based on the previous year's purchases.

Leases

As of December 31, 2023, the Company had unused letters of credit of $4.2 million, which were issued primarily to secure leases. These letters of credit are collateralized by $4.2 million of restricted cash, which is recorded in other assets in the consolidated balance sheets.

Contingencies

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, 2023, 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.

Long Term Debt

In the event the 2025 Convertible Notes are still outstanding as of January 15, 2025 and the maturity date thereof has not been extended to a date on or after September 4, 2027, then unless the Company has received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.6 million of cash on hand, is sufficient to

redeem and discharge the 2025 Convertible Notes in full, the loans outstanding under the Hayfin Loan Agreement will mature on January 15, 2025.

Note 19. Net loss per common share

Basic and diluted net loss per common share are determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. For all periods presented, the shares issuable upon conversion, exercise or vesting of Convertible Notes, warrants, stock option awards and RSUs 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 net loss per common share are the same.

The following potentially dilutive securities were excluded from the computation of diluted weighted average common shares outstanding due to their anti-dilutive effect:

	As of December 31,	
	2023	2022
Shares to be issued upon conversion of Convertible Notes	15,939,216	15,416,667
Vested and unvested stock options	9,199,744	9,700,161
Restricted stock units	11,579,548	5,255,560
Warrants	8,362,270	8,362,270
Total anti-dilutive securities excluded from EPS computation [1]	45,080,778	38,734,658

[1] Total anti-dilutive securities exclude CVRs which are settleable in cash, additional Xeris Biopharma shares, or a combination, at the election of the Company.

Note 20. Income taxes

Total income (loss) before income taxes by source of income was as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Foreign	$ 3,757	$ (18,999)	$ (7,985)
United States	(67,261)	(77,085)	(114,740)
Total loss before income taxes	$ (63,504)	$ (96,084)	$ (122,725)

Total income tax benefit by source was as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Foreign	$ 387	$ (1,595)	$ (9,716)
United States	(15,855)	(20,991)	(19,926)
Change in Valuation Allowance	14,219	21,162	29,642
Total income tax benefit	$ (1,249)	$ (1,424)	$ —

A reconciliation of the expected income tax benefit computed using the federal statutory income tax rate of 21% to the Company's effective income tax rate is as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Federal tax benefit at statutory rate	$ (13,336)	$ (20,178)	$ (25,772)
State tax benefit, net of federal benefit	(4,201)	(4,325)	(4,422)
Research and development and orphan drug credits	—	(320)	(350)
Uncertain tax positions	(28)	94	(302)
Subpart F Income	3,092	—	—
Permanent adjustments to expenses	142	726	1,779
Stock-based compensation	142	414	901
Return to provision adjustment	(1,080)	(1,103)	(2,450)
Statutory tax rate differential	(330)	1,600	663
Changes in valuation allowance	14,219	21,162	29,642
Other	131	506	311
Total income tax benefit	$ (1,249)	$ (1,424)	$ —

The benefit for income taxes for 2023 was attributable to the amortization of the deferred tax liability set up with the Acquisition.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A valuation allowance is required to be established or maintained when, based on currently available information, it is more likely than not that all or a portion of a deferred tax asset will not be realized. The guidance on accounting for income taxes provides important factors in determining whether a deferred tax asset will be realized, including whether there has been sufficient taxable income in recent years and whether sufficient income can reasonably be expected in future years in order to utilize the deferred tax asset. For the years ended December 31, 2023, 2022 and 2021, the Company evaluated the need to maintain a valuation allowance for deferred tax assets based on the assessment of whether it is more likely than not that deferred tax benefits will be realized through the generation of future taxable income. Appropriate consideration is given to all available evidence, both positive and negative, in assessing the need for a valuation allowance.

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2023	December 31, 2022 [2]
Deferred tax assets:		
Net operating losses	$ 119,346	$ 111,631
Federal research and orphan drug credits	9,116	8,836
Stock-based compensation	7,752	5,714
Section 163(j) interest	19,800	14,903
Capitalized R&D	6,293	1,493
Operating lease liabilities	10,472	—
Other temporary differences	18,679	16,581
Valuation allowance	(173,262)	(159,043)
Total assets	18,196	115
Deferred tax liabilities:		
Fixed and intangible assets	(13,740)	(11)
Operating lease right-of-use assets	(6,352)	—
Other deferred tax liabilities	(373)	(3,622)
Total liabilities	(20,465)	(3,633)
Net deferred tax liabilities	$ (2,269)	$ (3,518)

[2] Certain reclasses have been made to the 2022 balances in this table to conform to the 2023 presentations.

As of December 31, 2023, the Company had federal net operating loss carryforwards of $494.3 million and various state net operating loss carryforwards of $352.2 million. As of December 31, 2022, the Company had federal net operating loss carryforwards of $501.4 million and various state net operating loss carryforwards of $345.3 million. Net operating loss carryforwards for the United States federal income tax purposes that were generated prior to January 1, 2018 have a twenty-year carryforward life and will expire in 2037. Under the Tax Cuts and Jobs Act of 2017, federal net operating losses incurred in 2018 and later years may be carried forward indefinitely, but the deductibility of such net operating losses is limited to 80% of the current year's taxable income. The United States state net operating loss carryforwards will start to expire in 2029 for the earliest net operating loss layers to the extent there is not sufficient state taxable income to utilize those net operating loss carryforwards.

At December 31, 2023, the Company had $6.9 million and $3.7 million of federal and state income tax credits, respectively, to reduce future tax liabilities. At December 31, 2022, the Company had $6.7 million and $3.1 million of federal and state income tax credits, respectively, to reduce future tax liabilities. The federal income tax credits consist primarily of orphan drug credits and research and development credits. The United States state income tax credits consist primarily of California and Illinois research and development credits, as well as Illinois Economic Development for a Growing Economy Tax Credit. Both the United States federal orphan drug credits and research and development credits have a twenty-year carryforward life. The United States federal orphan drug credits and research and development credits will both begin to expire in 2038.

A reconciliation of the beginning and ending amounts of valuation allowances for the years ended December 31, 2023, 2022 and 2021 is as follows (in thousands):

Valuation allowance at December 31, 2020	$	(92,493)
Increase for 2021 activity		(45,388)
Valuation allowance at December 31, 2021		(137,881)
Increase for 2022 activity		(21,162)
Valuation allowance at December 31, 2022		(159,043)
Increase for 2023 activity		(14,219)
Valuation allowance at December 31, 2023	$	(173,262)

The Company is required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. The Company accounts for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken, or are expected to be taken, on an income tax return. The changes in the Company's uncertain income tax positions for the years ended December 31, 2023, 2022 and 2021, excluding interest and penalties, consisted of the following (in thousands):

	December 31,		
	2023	2022	2021
Beginning balance - uncertain tax positions	$ 722	$ 627	$ 929
Increases related to tax positions taken during the current year	—	92	17
Increases/(decreases) related to tax positions taken during the prior year	(28)	3	(319)
Ending balance - uncertain tax positions	$ 694	$ 722	$ 627

For the year ended December 31, 2023, the decrease in current year uncertain tax positions was attributable primarily to the United States federal orphan drug credits and research and development credits and the decrease related to tax positions taken during the prior year was a result of return to provision adjustments. In the Company’s balance sheet, uncertain tax positions of $0.7 million were offset against deferred tax assets. Tax years prior to 2019 generally are not subject to examination by the Internal Revenue Service or state or local taxing authorities.

The Company policy is to include interest and penalties related to uncertain tax penalties, if any, within the provision for taxes in the statements of operations. During the years ended December 31, 2023, 2022 and 2021, the Company incurred no interest and penalties related to income taxes.

21. Subsequent events

Loan facility

On March 5, 2024, the Company, Xeris Pharma and certain subsidiary guarantors of the Company entered into an Amended and Restated Credit Agreement and Guaranty (the "Amended and Restated Credit Agreement") with the lenders from time to time parties thereto (the "New Lenders") and Hayfin Services LLP, as administrative agent for the New Lenders, pursuant to which the Company and its subsidiaries party thereto granted a first priority security interest on substantially all of their assets, including intellectual property, subject to certain exceptions. The Amended and Restated Credit Agreement provided for the New Lenders to extend $200.0 million in term loans to the Company on the closing date and up to an additional $15.2 million in additional term loans, which additional term loans are available only to redeem the Company's existing 2025 Convertible Notes (collectively, the "2029 Loans"). The proceeds from the initial term loans will be used for general corporate purposes. In conjunction with the execution of the Amended and Restated Credit Agreement, the aggregate principal balance of $150.0 million plus all accrued and unpaid interest outstanding under the Hayfin Loan Agreement was continued under the Amended and Restated Credit Agreement.

The 2029 Loans incur interest at a floating per annum rate in an amount equal to 6.95% (the “Margin”) plus the greater of the forward-looking term rate based on SOFR for a three-month tenor and 2.00%. Upon the occurrence and during the continuance of certain events of default, the Margin will be increased by three percent (3.00%) per annum, and all interest shall be payable monthly.

The 2029 Loans will mature on March 5, 2029; provided, however, that the 2029 Loans will mature on (A) January 15, 2025 if the 2025 Convertible Notes are outstanding as of such date or (B) January 15, 2028 if the 2028 Convertible Notes are outstanding as of such date and, in both cases, either (i) the maturity date of the applicable notes has not been extended to a date not earlier than September 5, 2029 and (ii) the Company has not received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.6 million of cash on hand, is sufficient to redeem and discharge the 2025 Convertible Notes or the 2028 Convertible, as applicable, in full.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based on such evaluation, our chief executive officer and chief financial officer have concluded that the disclosure controls and procedures were effective as of December 31, 2023 to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the United States Securities and Exchange Commission's ("SEC") rules and forms, and to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its chief executive and chief financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Internal Control Over Financial Reporting

Management's report on internal control over financial reporting and the report of our independent registered public accounting firm are included in Part II, Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Plan

During the three months ended December 31, 2023, none of the Company's directors or officers adopted, materially modified, or terminated any contract, instruction, or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2023 and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2023 and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be contained in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2023 and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2023 and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Our independent public accounting firm is Ernst & Young LLP, Grant Rapids, Michigan, PCAOB Auditor ID: 42. KPMG LLP, Chicago, Illinois, PCAOB Auditor ID: 185, served as our independent public accounting firm through May 13, 2023.

The information required by this item will be contained in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2023 and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Form 10-K:

1. Financial Statements

   See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

   All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

ITEM 16. FORM 10-K SUMMARY

Not applicable.

XERIS BIOPHARMA HOLDINGS, INC.

FORM 10-K

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Transaction Agreement, dated as of May 24, 2021, by and among the Registrant, Strongbridge Biopharma plc, Xeris Pharmaceuticals, Inc. and Wells Merger Sub, Inc. (incorporated by reference to Annex A of the Registrant's Registration Statement on Form S-4 (File No. 333-257642) filed with the Securities and Exchange Commission on July 2, 2021)
2.2	Expenses Reimbursement Agreement, dated May 24, 2021, by and between the Xeris Pharmaceuticals, Inc. and Strongbridge Biopharma plc (incorporated by reference to Exhibit 2.3 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38536) filed with the Securities and Exchange Commission on May 24, 2021)
2.3	Contingent Value Rights Agreement, dated as of October 5, 2021, by and between the Registrant, Computershare, Inc. and Computershare Trust Company, N.A. (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
3.2	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
4.1	Specimen Stock Certificate Evidencing Shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-3 (File No. 333-262404) filed with the Securities and Exchange Commission on January 28, 2022)
4.2	Second Amended and Restated Investors' Rights Agreement by and among Xeris Pharmaceuticals, Inc. and certain of its stockholders, dated December 31, 2015 (incorporated by reference to Exhibit 4.1 to the Xeris Pharmaceuticals, Inc. Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)
4.3	Description of Registrant's Securities (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-40880) filed with the Securities and Exchange Commission on March 11, 2022)
4.4	Base Indenture, dated as of June 30, 2020, by and between Xeris Pharmaceuticals, Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
4.5	First Supplemental Indenture, dated as of June 30, 2020, by and between Xeris Pharmaceuticals, Inc. and U.S. Bank National Association (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
4.6	Form of 5.00% Convertible Senior Note due 2025 (included in Exhibit 4.5)
4.7	Second Supplemental Indenture, by and among the Registrant, Xeris Pharmaceuticals, Inc. and U.S. Bank National Association, dated October 5, 2021 (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
4.8	Form of Exchange Agreement between the Company, the Guarantor and certain holders of the Existing Notes (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on September 27, 2023)
4.9	Indenture, dated as of September 29, 2023, between the Company, the Guarantor and the Trustee (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on September 29, 2023)
4.10	Form of 8.00% Convertible Senior Notes due 2028 (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on September 29, 2023)

4.11	Form of Warrant by and between the Registrant and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on January 3, 2022)
4.12	Form of Registration Rights Agreement between the Registrant and Armistice Capital Master Fund Ltd. dated as of January 2, 2022 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on January 3, 2022)
4.13	Form of Warrant to purchase common stock by and between the Registrant and Hayfin Services LLP (incorporated by reference to Exhibit 4.1 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 11, 2022)
4.14^	Form of Lender Warrant issued December 28, 2016 in connection with Horizon and Oxford Loan Agreement (incorporated by reference to Exhibit 4.11 of Xeris BioPharma Inc.'s Annual Report on Form 10-K (File 001-40880) filed with the Securities and Exchange Commission on March 8, 2023)
4.15^	Form of Warrant to CR Group Lenders, dated July 14, 2017(incorporated by reference to Exhibit 4.12 of Xeris BioPharma Inc.'s Annual Report on Form 10-K (File 001-40880) filed with the Securities and Exchange Commission on March 8, 2023)
4.16^	Form of Warrant to CR Group Lenders, dated January 16, 2018 (incorporated by reference to Exhibit 4.13 of Xeris BioPharma Inc.'s Annual Report on Form 10-K (File 001-40880) filed with the Securities and Exchange Commission on March 8, 2023)
4.17^	Form of Warrant to Avenue Venture Opportunities Fund (incorporated by reference to Exhibit 4.14 of Xeris BioPharma Inc.'s Annual Report on Form 10-K (File 001-40880) filed with the Securities and Exchange Commission on March 8, 2023)
10.1#	2011 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)
10.2#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1/A (File No. 333-225191) filed with the Securities and Exchange Commission on June 11, 2018)
10.3#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.3 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)
10.4#	Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
10.5#	Form of Officer Indemnification Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
10.6#	Amended and Restated Employment Agreement by and among the Registrant, Xeris Pharmaceuticals, Inc. and Paul Edick, dated as of October 5, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
10.7#	Amended and Restated Employment Agreement by and among the Registrant, Xeris Pharmaceuticals, Inc. and John Shannon, dated as of October 5, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
10.8#	Amended and Restated Employment Agreement by and among the Registrant, Xeris Pharmaceuticals, Inc. and Steven Pieper, dated as of October 5, 2021 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
10.9#	Amended and Restated Employment Agreement by and among the Registrant, Xeris Pharmaceuticals, Inc. and Beth Hecht dated as of October 5, 2021 (incorporated by reference to Exhibit 10.1 of Xeris BioPharma Inc.'s Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 11, 2022)
10.10†	API Supply Agreement, dated as of January 1, 2018, by and between Xeris Pharmaceuticals, Inc. and Bachem Americas, Inc. (incorporated by reference to Exhibit 10.12 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)

10.11†	First Amendment to API Supply Agreement, dated as of February 26, 2021, by and between Xeris Pharmaceuticals, Inc. and Bachem Americas, Inc. (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on May 13, 2021)
10.12†	Second Amendment to API Supply Agreement, dated as of May 2, 2022, by and between Xeris Pharmaceuticals, Inc. and Bachem Americas, Inc. (incorporated by reference to Exhibit 10.1 of Xeris BioPharma Inc.'s Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on August 10, 2022)
10.13†	Quality Assurance Agreement, dated as of November 20, 2015, by and between Bachem AG and Xeris Pharmaceuticals, Inc., as amended by (i) Amendment 1 to the Quality Assurance Agreement, dated as of October 31, 2016, by and between Bachem AG and Xeris Pharmaceuticals, Inc. and (ii) Amendment 2 to the Quality Assurance Agreement, dated as of January 26, 2017, by and between Bachem AG and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.13 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)
10.14†	Commercial Supply Agreement, dated as of May 14, 2018, by and between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.14 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1/A (File No. 333-225191) filed with the Securities and Exchange Commission on June 14, 2018)
10.15†	Amendment No. 2 to the Commercial Supply Agreement, dated as of May 13, 2021, by and between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on August 5, 2021)
10.16†	Amendment No. 3 to Commercial Supply Agreement dated August 31, 2022 between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on November 9, 2022)
10.17†	Amendment No. 4 to Commercial Supply Agreement, dated as of January 26, 2023 between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 9, 2023)
10.18†	Joint Development Agreement, dated as of January 29, 2016, by and between Xeris Pharmaceuticals, Inc. and Scandinavian Health Limited (incorporated by reference to Exhibit 10.15 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)
10.19	Loan and Security Agreement, dated as of February 28, 2018, by and between Oxford Finance LLC, Silicon Valley Bank and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.16 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)
10.20†	Quality Agreement, dated as of November 16, 2016, by and between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.17 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-225191) filed with the Securities and Exchange Commission on May 24, 2018)
10.21†	Amendment No. 1 to the Quality Agreement, dated as of May 11, 2021, by and between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on August 5, 2021)
10.22#	2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.18 to Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1/A (File No. 333-225191) filed with the Securities and Exchange Commission on June 11, 2018)
10.23†	Product Supply Agreement by and between SHL Pharma, LLC and Xeris Pharmaceuticals, Inc., dated August 1, 2018 (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on November 8, 2018)
10.24#	Inducement Equity Plan (incorporated by reference to Exhibit 99.1 of Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-8 (File No. 333-229587) filed with the Securities and Exchange Commission on February 8, 2019)

10.25	First Amendment to Office Lease Agreement, dated as of November 20, 2018, by and between 180 N. LaSalle Property Owner LLC and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.22 of Xeris Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (File No. 333-229600) filed with the Securities and Exchange Commission on February 11, 2019)
10.26	Amended and Restated Loan and Security Agreement, dated as of September 10, 2019, by and between Oxford Finance LLC, Silicon Valley Bank and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38536) filed with the Securities and Exchange Commission on September 10, 2019)
10.27	Second Amendment to Loan and Security Agreement, dated as of May 15, 2019, by and among Oxford Finance LLC, Silicon Valley Bank and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on August 6, 2019)
10.28#	Deferred Compensation Plan (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38536) filed with the Securities and Exchange Commission on April 10, 2020)
10.29†	Amendment No. 3 to the Quality Assurance Agreement, dated as of February 26, 2020, by and between Xeris Pharmaceuticals, Inc. and Bachem AG (incorporated by reference to Exhibit 10.3 of Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on May 7, 2020)
10.30†	Amendment No. 4 to the Quality Assurance Agreement, dated as of May 5, 2021, by and between Bachem AG and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on August 5, 2021)
10.31†	Amendment 5 to the Quality Assurance Agreement, dated as of May 22, 2023, between Bachem AG and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-40880) filed with the Securities and Exchange Commission on August 8, 2023)
10.32	Amendment No 3., Waiver and Consent to Credit and Guaranty Agreement, dated as of April 21, 2023, among Xeris Pharmaceuticals, Inc., the Registrant, the lenders party thereto and Hayfin Services LLP, as administrative agent (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on August 8, 2023)
10.33	First Amendment to Amended and Restated Loan and Security Agreement, dated as of April 21, 2020, by and among Oxford Finance LLC, Silicon Valley Bank and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 of Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on May 7, 2020)
10.34†	Second Amendment to Amended and Restated Loan and Security Agreement, dated as of June 30, 2020, by and among Oxford Finance LLC, Silicon Valley Bank and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on August 10, 2020)
10.35†	First Amendment to the Product Supply Agreement, dated as of June 24, 2020, by and between Xeris Pharmaceuticals, Inc. and SHL Pharma LLC (incorporated by reference to Exhibit 10.2 of Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on August 10, 2020)
10.36†	Amended and Restated Product Supply Agreement, effective as of January 30, 2023, by and between Xeris Pharmaceuticals, Inc. and SHL Pharma LLC (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 9, 2023)
10.37†	Statement of Work #1 – Device, effective as of January 30, 2023, between Xeris Pharmaceuticals, Inc. and SHL Pharma, LLC (incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 9, 2023)
10.38†	Statement of Work #2 – Product, effective as of January 30, 2023, between Xeris Pharmaceuticals, Inc. and SHL Pharma, LLC (incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 9, 2023)
10.39*†	First Amendment to the Statement of Work No. 2 - Product, dated as of October 17, 2023, between Xeris Pharmaceuticals, Inc. and SHL Pharma LLC

10.40	Omnibus Assignment and Assumption Agreement and Amendment No. 1 to Asset Purchase Agreement and Supply Agreement, effective as of March 13, 2023, among Xeris Pharmaceuticals, Inc., Strongbridge Dublin Limited and Taro Pharmaceuticals North America, Inc ((incorporated by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 9, 2023)
10.41	Omnibus Amendment No. 2 to Asset Purchase Agreement and Supply Agreement, effective as of March 13, 2023, between Xeris Pharmaceuticals, Inc. and Taro Pharmaceuticals North America, Inc (incorporated by reference to Exhibit 10.7 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 9, 2023)
10.42†	Third Amendment to Amended and Restated Loan and Security Agreement, dated as of August 5, 2020, by and among Oxford Finance LLC, Silicon Valley Bank and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of Xeris Pharmaceuticals, Inc.' s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on November 9, 2020)
10.43†	Fourth Amendment to Amended and Restated Loan and Security Agreement, dated as of October 23, 2020, by and among Oxford Finance LLC, Silicon Valley Bank and the Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.34 to Xeris Pharmaceuticals, Inc.' s Annual Report on Form 10-K (File No. 001-38536) filed with the Securities and Exchange Commission on March 9, 2021)
10.44	Consent Under Amended and Restated Loan and Security Agreement, dated as of May 24, 2021, by and among Xeris Pharmaceuticals, Inc., Oxford Finance LLC, and Silicon Valley Bank (incorporated by reference to Exhibit 10.4 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38536) filed with the Securities and Exchange Commission on May 24, 2021)
10.45	Fifth Amendment to Amended and Restated Loan and Security Agreement, dated May 3,2021, by and among Xeris Pharmaceuticals, Inc., Oxford Finance LLC, and Silicon Valley Bank (incorporated by reference to Exhibit 10.5 to Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-38536) filed with the Securities and Exchange Commission on August 5, 2021)
10.46	Joinder and Sixth Amendment to Amended and Restated Loan and Security Agreement, dated October 5, 2021, by and among the Registrant, Xeris Pharmaceuticals, Inc., Oxford Finance LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
10.47	Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38536) filed with the Securities and Exchange Commission on November 16, 2020)
10.48	Amended and Restated Quality Agreement, dated as of November 16, 2020, by and between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.36 to Xeris Pharmaceuticals, Inc.' s Annual Report on Form 10-K (File No. 001-38536) filed with the Securities and Exchange Commission on March 9, 2021)
10.49#	Separation Agreement, dated as of July 28, 2021, by and between Xeris Pharmaceuticals, Inc. and Barry Deutsch (incorporated by reference to Exhibit 10.1 to Xeris Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-38536) filed with the Securities and Exchange Commission on July 29, 2021)
10.50†	Asset Purchase Agreement, dated December 12, 2016, between Taro Pharmaceutical North America, Inc. and Strongbridge plc (incorporated by reference to Exhibit 10.3 to Strongbridge Biopharma plc's Form F-3 (File No. 333-215531) filed with the Securities and Exchange Commission on January 12, 2017)
10.51†	Supply Agreement, dated December 12, 2016, between Taro Pharmaceutical North America, Inc. and Strongbridge plc (incorporated by reference to Exhibit 10.4 to Strongbridge Biopharma plc's Form F-3 (File No. 333-215531) filed with the Securities and Exchange Commission on January 12, 2017)
10.52	Investors' Rights Agreement, dated as of February 10, 2015, by and among Cortendo AB and the Investors listed therein (incorporated by reference to Exhibit 10.11 to Strongbridge Biopharma plc's Form F-1 (File No. 333-206654) filed with the Securities and Exchange Commission on August 28, 2015)
10.53#	Strongbridge Biopharma plc 2015 Equity Compensation Plan (incorporated by reference to Exhibit 10.13 of Strongbridge Biopharma plc's Annual Report on Form 10-K (File No. 001-37569) filed with the Securities and Exchange Commission on February 27, 2019)
10.54#	Strongbridge Biopharma plc Non-Employee Director Equity Compensation Plan (incorporated by reference to Exhibit 10.14 of Strongbridge Biopharma plc's Annual Report on Form 10-K (File No. 001-37569) filed with the Securities and Exchange Commission on February 27, 2019)
10.55#	Strongbridge Biopharma plc 2017 Inducement Plan (incorporated by reference to Exhibit 10.15 of Strongbridge Biopharma plc's Annual Report on Form 10-K (File No. 001-37569) filed with the Securities and Exchange Commission on February 27, 2019)

10.56	Credit Agreement and Guaranty dated as of March 8, 2022, by and among the Registrant, Xeris Pharmaceuticals, Inc., Strongbridge Biopharma Limited, Strongbridge Dublin Limited, Cortendo AB, the lenders from time to time parties thereto and Hayfin Services LLP, as administrative agent (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 11, 2022)
10.57	Form of Securities Purchase Agreement between the Registrant and Armistice Capital Master Fund Ltd. dated as of January 2, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-04880) filed with Securities and Exchange Commission on January 3, 2022)
10.58	Amended and Restated Lease dated September 29, 2022 between Xeris Pharmaceuticals, Inc. and Fulton Ogden Venture, LLC (incorporated by reference to Exhibit 10.1 of Xeris BioPharma Inc.'s Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on November 9, 2022)
10.59	Amendment No. 1 to Credit Agreement and Guaranty dated September 29, 2022 among Xeris Pharmaceuticals, Inc., the Registrant, the lenders party thereto and Hayfin Services LLP, as administrative agent (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on November 9, 2022)
10.60	Amendment No 2. to Credit Agreement and Guaranty, dated as of January 19, 2023, among Xeris Pharmaceuticals, Inc., the Registrant, the lenders party thereto and Hayfin Services LLP, as administrative agent (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on May 9, 2023)
10.61	Amendment No 3., Waiver and Consent to Credit and Guaranty Agreement, dated as of April 21, 2023, among Xeris Pharmaceuticals, Inc., the Registrant, the lenders party thereto and Hayfin Services LLP, as administrative agent (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on August 8, 2023)
10.62	Consent to Credit and Guaranty Agreement, dated as of September 26, 2023, among Xeris Pharmaceuticals, Inc., the Registrant, the lenders party thereto and Hayfin Services LLP, as administrative agent (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File 001-40880) filed with the Securities and Exchange Commission on November 9, 2023)
10.63#	Xeris Biopharma Holdings, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-04880) filed with Securities and Exchange Commission on March 29, 2023)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Independent Registered Public Accounting Firm, Ernst & Young LLP
23.2*	Consent of Independent Registered Public Accounting Firm, KPMG LLP
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1#*	Xeris Biopharma Holdings, Inc. Compensation Recovery Policy
101.INS*	XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

# Indicates a management contract or any compensatory plan, contract or arrangement

+ The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this report and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit have been omitted because they are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

^ Pertains to certain Strongbridge warrants assumed by the Company in connection with the Acquisition.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Xeris Biopharma Holdings, Inc.

By /s/ Paul R. Edick

Paul R. Edick

Chief Executive Officer and Chairman

Date March 6, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below as of March 6, 2024, by the following persons on behalf of the registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ Paul R. Edick Paul R. Edick	Chief Executive Officer and Chairman (Principal Executive Officer)
/s/ Steven M. Pieper Steven M. Pieper	Chief Financial Officer (Principal Financial Officer and Principal Accounting officer)
/s/ B.J. Bormann B.J. Bormann	Director
/s/ Ricki Fairley Ricki Fairley	Director
/s/ Dawn Halkuff Dawn Halkuff	Director
/s/ John H. Johnson John H. Johnson	Director
/s/ Garheng Kong Garheng Kong	Director
/s/ Marla Persky Marla Persky	Director
/s/ John Schmid John Schmid	Director
/s/ Jeffrey Sherman Jeffrey Sherman	Director

EXECUTIVE OFFICERS

Paul R. Edick
Chief Executive Officer &
Chairman of the Board

John Shannon
President & Chief
Operating Officer

Steven M. Pieper
Chief Financial Officer

Beth P. Hecht
Chief Legal Officer & Corporate
Secretary

Ken Johnson
Senior Vice President,
Global Development
and Medical Affairs

BOARD OF DIRECTORS

Paul R. Edick
Chief Executive Officer & Chairman of the Board

BJ Bormann, Ph.D.
Vice President for Translational Science and Network Alliances for The Jackson Laboratory

Ricki L. Fairley
Co-founder and Chief Executive Officer of TOUCH, The Black Breast Cancer Alliance

Dawn Halkuff
Former Chief Executive Officer of Ideal Protein of America, Inc.

John H. Johnson
Chief Executive Officer of Reaction Biology Corp.

Garheng Kong, M.D., Ph.D., M.B.A.
Founder and Managing Partner of HealthQuest Capital

Marla S. Persky
Chief Executive Officer and President of WOMN LLC

John P. Schmid
Former Chief Financial Officer of Auspex Pharmaceuticals, Inc

Jeffrey W. Sherman, M.D., FACP
Former Chief Medical Officer of Horizon Therapeutics plc

CORPORATE INFORMATION

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Canton, MA, 02021
UNITED STATES
Phone: (800) 736-3001

Investor Relations
Information about Xeris Biopharma Holdings, Inc., press releases, and other investor information is available on our website at:
https://www.xerispharma.com/investor-relations

Investor inquiries can be sent via email to:
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