

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

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.)

**180 N. LaSalle Street, Suite 1600
Chicago, Illinois**

60601

(Address of principal executive offices)

(Zip Code)

(844) 445-5704

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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

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

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of July 31, 2022, 135,957,280 shares, par value \$0.0001 per share, of common stock were outstanding.

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:

- < Our business may be adversely affected by the ongoing COVID-19 pandemic.
- < As a company, we have a limited operating history and limited experience commercializing pharmaceutical products and have incurred significant losses since inception. We expect to incur losses over the next few years and may not be able to achieve or sustain revenues or profitability in the future.
- < Although we generate revenue from Gvoke, Keveyis, and Recorlev, we have not yet generated revenue from any of our current or future product candidates, and may never be profitable.
- < We may require additional capital to sustain our business, and this capital may cause dilution to our stockholders and might not be available on terms favorable to us, or at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.
- < 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.
- < 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, and a limited number of options for alternate sources for Gvoke, Keveyis, and Recorlev or our product candidates could harm our ability to develop our product candidates or to commercialize Gvoke, Keveyis, Recorlev or any product candidates that are approved.
- < Reimbursement decisions by third-party payors and consolidation within the healthcare industry and among competitors more generally 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 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, Keveyis, Recorlev 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.
- < We operate in a competitive business environment and, if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our products or product candidates, even if approved.
- < Our success depends on our ability to protect our intellectual property and proprietary technology, as well as the ability of our collaborators to protect their intellectual property and proprietary technology.
- < Our stock price has been and will likely continue to be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

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 Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes, as well as in other documents that we file with the U.S. 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 Quarterly Report on Form 10-Q

	Page
Part I. Financial Information	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets as of June 30, 2022 (unaudited) and December 31, 2021</u>	4
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and six months ended June 30, 2022 and 2021</u>	5
<u>Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and six months ended June 30, 2022 and 2021</u>	6
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2022 and 2021</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	30
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	38
<u>Item 4. Controls and Procedures</u>	38
Part II. Other Information	
<u>Item 1. Legal Proceedings</u>	39
<u>Item 1A. Risk Factors</u>	40
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	75
<u>Item 3. Defaults Upon Senior Securities</u>	75
<u>Item 4. Mine Safety Disclosures</u>	75
<u>Item 5. Other Information</u>	75
<u>Item 6. Exhibits</u>	76
Signatures	77

Solely for convenience, the trademarks and trade names in this Quarterly Report on Form 10-Q (this "Quarterly 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 Quarterly Report are the property of their respective owners.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 95,340	\$ 67,271
Short-term investments	16,213	35,162
Trade accounts receivable, net	25,756	17,456
Inventory	17,887	18,118
Prepaid expenses and other current assets	6,010	4,589
Total current assets	<u>161,206</u>	<u>142,596</u>
Property and equipment, net	6,170	6,627
Goodwill	22,859	22,859
Intangible assets, net	126,029	131,450
Other assets	2,352	829
Total assets	<u>\$ 318,616</u>	<u>\$ 304,361</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 6,631	\$ 8,924
Other accrued liabilities	36,945	49,088
Accrued trade discounts and rebates	14,843	15,041
Accrued returns reserve	5,210	4,000
Other current liabilities	916	1,987
Total current liabilities	<u>64,545</u>	<u>79,040</u>
Long-term debt, net of unamortized debt issuance costs	138,068	88,067
Contingent value rights	30,218	22,531
Supply agreement liability, less current portion	—	5,991
Deferred rent	6,799	6,883
Deferred tax liabilities	4,195	4,942
Other liabilities	848	1,676
Total liabilities	<u>244,673</u>	<u>209,130</u>
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock—par value \$0.0001, 25,000,000 shares and 25,000,000 shares authorized and no shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	—	—
Common stock—par value \$0.0001, 350,000,000 shares and 350,000,000 shares authorized as of June 30, 2022 and December 31, 2021, respectively; 135,920,743 and 124,873,316 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	14	13
Additional paid in capital	593,990	555,359
Accumulated deficit	(520,009)	(460,110)
Accumulated other comprehensive loss	(52)	(31)
Total stockholders' equity	<u>73,943</u>	<u>95,231</u>
Total liabilities and stockholders' equity	<u>\$ 318,616</u>	<u>\$ 304,361</u>

See accompanying notes to condensed consolidated financial statements.

XERIS BIOPHARMA HOLDINGS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data; unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue, net	\$ 25,260	\$ 8,835	\$ 47,170	\$ 16,886
Royalty, contract and other revenue	46	71	209	215
Total revenue	<u>25,306</u>	<u>8,906</u>	<u>47,379</u>	<u>17,101</u>
Costs and expenses:				
Cost of goods sold, excluding amortization of intangible assets	4,810	3,383	11,083	5,209
Research and development	3,718	5,383	9,968	9,415
Selling, general and administrative	32,984	25,927	68,897	45,004
Amortization of intangible assets	2,710	—	5,421	—
Total costs and expenses	<u>44,222</u>	<u>34,693</u>	<u>95,369</u>	<u>59,628</u>
Loss from operations	<u>(18,916)</u>	<u>(25,787)</u>	<u>(47,990)</u>	<u>(42,527)</u>
Other income (expense):				
Interest and other income	195	77	263	177
Interest expense	(3,448)	(1,795)	(6,969)	(3,586)
Change in fair value of warrants	516	(10)	1,737	10
Change in fair value of contingent value rights	(4,871)	—	(7,687)	—
Total other expense	<u>(7,608)</u>	<u>(1,728)</u>	<u>(12,656)</u>	<u>(3,399)</u>
Net loss before benefit from income taxes	<u>(26,524)</u>	<u>(27,515)</u>	<u>(60,646)</u>	<u>(45,926)</u>
Benefit from income taxes	339	—	747	—
Net loss	<u>\$ (26,185)</u>	<u>\$ (27,515)</u>	<u>\$ (59,899)</u>	<u>\$ (45,926)</u>
Other comprehensive loss, net of tax:				
Unrealized gains (losses) on investments	14	(12)	(21)	(29)
Foreign currency translation adjustments	—	2	—	3
Comprehensive loss	<u>\$ (26,171)</u>	<u>\$ (27,525)</u>	<u>\$ (59,920)</u>	<u>\$ (45,952)</u>
Net loss per common share - basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.41)</u>	<u>\$ (0.44)</u>	<u>\$ (0.72)</u>
Weighted average common shares outstanding - basic and diluted	<u>135,529,968</u>	<u>66,367,125</u>	<u>135,282,749</u>	<u>63,820,321</u>

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2020	59,611,202	\$ 6	\$ 371,134	\$ 6	\$ (337,385)	\$ 33,761
Net loss	—	—	—	—	(18,411)	(18,411)
Issuance of common stock upon equity offering	6,553,398	1	26,924	—	—	26,925
Exercise of stock options	20,213	—	32	—	—	32
Vesting of restricted stock units (net of 71,782 shares withheld for tax)	148,643	—	(365)	—	—	(365)
Stock-based compensation	—	—	2,461	—	—	2,461
Other comprehensive loss	—	—	—	(16)	—	(16)
Balance, March 31, 2021	66,333,456	\$ 7	\$ 400,186	\$ (10)	\$ (355,796)	\$ 44,387
Net loss	—	—	—	—	(27,515)	(27,515)
Exercise of stock options	55,818	—	140	—	—	140
Stock-based compensation	—	—	2,512	—	—	2,512
Issuance of common stock through employee stock purchase plan	108,096	—	374	—	—	374
Other comprehensive loss	—	—	—	(10)	—	(10)
Balance, June 30, 2021	66,497,370	\$ 7	\$ 403,212	\$ (20)	\$ (383,311)	\$ 19,888

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2021	124,873,316	\$ 13	\$ 555,359	\$ (31)	\$ (460,110)	\$ 95,231
Net loss	—	—	—	—	(33,714)	(33,714)
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 197,257 shares withheld for tax)	404,743	—	(416)	—	—	(416)
Stock-based compensation	—	—	3,301	—	—	3,301
Other comprehensive loss	—	—	—	(35)	—	(35)
Balance, March 31, 2022	135,528,195	\$ 14	\$ 590,331	\$ (66)	\$ (493,824)	\$ 96,455
Net loss	—	—	—	—	(26,185)	(26,185)
Vesting of restricted stock units (net of 1,317 shares withheld for tax)	2,561	—	(3)	—	—	(3)
Stock-based compensation	—	—	3,152	—	—	3,152
Issuance of common stock through employee stock purchase plan	389,987	—	510	—	—	510
Other comprehensive loss	—	—	—	14	—	14
Balance, June 30, 2022	135,920,743	\$ 14	\$ 593,990	\$ (52)	\$ (520,009)	\$ 73,943

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (59,899)	\$ (45,926)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	673	657
Amortization of intangible assets	5,421	—
Amortization of investments	129	280
Amortization of debt issuance costs	673	492
Stock-based compensation	6,453	4,973
Loss on extinguishment of debt	1,223	—
Change in fair value of warrants	(1,737)	(10)
Change in fair value of contingent value rights	7,687	—
Changes in operating assets and liabilities:		
Trade accounts receivable	(8,300)	(5,420)
Prepaid expenses and other current assets	(921)	942
Inventory	(305)	(3,886)
Accounts payable	(2,293)	2,068
Other accrued liabilities	(12,478)	582
Accrued trade discounts and rebates	(198)	815
Accrued returns reserve	1,210	412
Deferred rent	(84)	—
Supply agreement liabilities	(5,280)	—
Other	(992)	43
Net cash used in operating activities	<u>(69,018)</u>	<u>(43,978)</u>
Cash flows from investing activities:		
Capital expenditures	(216)	(647)
Purchases of investments	—	(20,146)
Sales and maturities of investments	18,800	63,650
Net cash provided by investing activities	<u>18,584</u>	<u>42,857</u>
Cash flows from financing activities:		
Proceeds from equity offerings	30,000	27,000
Payments of equity offering costs	—	(54)
Proceeds from issuance of debt	97,295	—
Repayment of debt	(43,496)	—
Payments of debt issuance costs	(4,657)	—
Payments for loss on extinguishment of debt	(737)	—
Proceeds from issuance of employee stock purchase plan shares	510	374
Proceeds from exercise of stock awards	8	166
Repurchase of common stock withheld for taxes	(419)	(365)
Net cash provided by financing activities	<u>78,504</u>	<u>27,121</u>
Effect of exchange rate changes on cash and cash equivalents	(1)	1
Increase in cash and cash equivalents	28,069	26,001
Cash and cash equivalents, beginning of period	67,271	37,598
Cash and cash equivalents, end of period	<u>\$ 95,340</u>	<u>\$ 63,599</u>
Supplemental schedule of cash flow information:		
Cash paid for interest	<u>\$ 4,767</u>	<u>\$ 3,205</u>
Supplemental schedule of non-cash investing and financing activities:		
Issuance of warrants related to loan agreement	<u>\$ 2,080</u>	<u>\$ —</u>
Accrued debt issuance costs	<u>\$ 160</u>	<u>\$ —</u>

See accompanying notes to condensed consolidated financial statements.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

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 patient lives by developing and commercializing innovative products across a range of therapies. The Company currently has three commercially available products: Gvoke, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia; Keveyis, the first and only U.S. Food and Drug Administration ("FDA") approved therapy for primary periodic paralysis ("PPP"); and Recorlev, approved by the FDA in December 2021 for the treatment of endogenous hypercortisolemia in adult patients with Cushing's Syndrome. The Company also has a pipeline of development programs to bring new products forward using its proprietary formulation technology platforms, XeriSol™ and XeriJect™.

On October 5, 2021, Xeris Pharmaceuticals, Inc. ("Xeris Pharma") acquired Strongbridge Biopharma plc ("Strongbridge"), a biopharmaceutical company commercializing therapies for rare diseases with significant unmet needs. Immediately following the acquisition and related transactions, both Xeris Pharma and Strongbridge became wholly owned subsidiaries of Xeris Biopharma. The common stock of Xeris Pharma and the ordinary shares of Strongbridge were de-registered after completion of the Transactions (as defined below in Note 4). On October 6, 2021, Xeris Biopharma's common stock, par value \$0.0001 per share, commenced trading on the Nasdaq Global Select Market ("Nasdaq") under the ticker symbol "XERS". See "Note 4 – Business combination" for a more detailed description of the Transactions.

As used herein, the "Company" or "Xeris" refers to Xeris Pharma when referring to periods prior to the acquisition of 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).

Liquidity and capital resources

The Company has incurred operating losses since inception and has an accumulated deficit of \$520.0 million as of June 30, 2022. The Company expects to continue to incur net losses for at least the next 12 months beyond the issuance date of these consolidated financials. Based on the Company's current operating plans, existing working capital at June 30, 2022, capital raised in the first quarter and access to the additional \$50.0 million remaining from the Credit Agreement and Guaranty with Hayfin Services LLP, the Company believes the 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 the 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, Keveyis and Recorlev. Market volatility resulting from the COVID-19 pandemic, and geopolitical instability resulting from the ongoing military conflict between Russia and Ukraine, rising interest rates, the tightening of lending standards 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 our common stockholders, the terms of the debt could impose significant restrictions on the 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 the business strategies. If additional funding is not secured when required, the Company may need to delay or curtail the 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 condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), including those for interim financial information, and with the instructions for Quarterly Reports on Form 10-Q and Article 10 of Regulation S-X issued by the U.S. Securities and Exchange Commission (the "SEC").

In the opinion of management, the accompanying condensed 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. The accompanying financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on March 11, 2022.

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").

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Basis of consolidation

These condensed 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 who 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, Keveyis and Recorlev in the United States only and Ogluo (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 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.

Refer to the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 for further discussion of the Company's accounting policies.

Concentration of credit risk

For the three months June 30, 2022 and June 30, 2021, four customers accounted for 98% and 94% of the Company's gross product revenues, respectively. For the six months ended June 30, 2022 and June 30, 2021, the same four customers accounted for 96% and 94% of the Company's gross product revenues, respectively. The same four customers accounted for 99% of the trade accounts receivable, net at both June 30, 2022 and December 31, 2021.

New accounting pronouncements

Adopted accounting standards

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)*. This standard addresses issuers' accounting for certain modifications or exchanges of freestanding equity-classified written call options. This standard is effective for all entities, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company adopted this standard in first quarter 2022 and it did not have a material impact on the financial statements.

Pending accounting standards

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, to make incremental improvements to GAAP and address stakeholder suggestions, including, among other things, clarifying that the requirement to provide comparative information in the financial statements extends to the corresponding disclosures section. This standard will be effective for the Company for annual periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption of this standard is permitted. The Company does not currently expect the adoption of this new standard to have a material impact on the financial statements.

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-

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

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. Early adoption is permitted but not earlier than periods beginning after December 15, 2020. 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. The Company does not currently expect the adoption of this new standard to have a material impact on the financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard eliminates certain exceptions in the current guidance related to the approach for intra-period tax allocation and the methodology for calculating income taxes in an interim period and amends other aspects of the guidance to help clarify and simplify U.S. GAAP. This standard is effective for the Company for annual periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption of this standard is permitted. The Company does not currently expect the adoption of this new standard to have a material impact on the financial statements.

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 fair value increases. This standard would have been effective for the Company for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. However, on November 15, 2019, the FASB delayed the effective date of FASB ASC Topic 326 for certain small public companies and other private companies. As amended, the effective date of ASC Topic 326 was delayed until fiscal years beginning after December 15, 2022 for SEC filers that are eligible to be smaller reporting companies under the SEC's definition, as well as private companies and not-for-profit entities. The Company is currently evaluating the impact the adoption of this new standard will have on the financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The new standard requires lessees to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of their classification. Leases will be classified as either operating or finance leases under the new guidance. Operating leases will result in straight-line expense in the income statement, similar to current operating leases, and finance leases will result in more expense being recognized in the earlier years of the lease term, similar to current capital leases. This standard is effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The FASB has extended the effective date of this standard for certain companies. As amended in ASU 2020-05, this standard will be effective for the Company for fiscal years beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact the adoption of this new standard will have on the financial statements and related disclosures; however, since the Company is a lessee to certain leases for property whose terms exceed twelve months, it expects, once adopted, to report assets and liabilities related to these leases on the balance sheet.

Note 3. Disaggregated revenue

The Company's revenue is comprised primarily of sales of products and royalty revenue. Depending on the type of contract, the method of accounting and timing of revenue recognition may differ. Below, descriptions have been provided that summarize the Company's different types of contracts and how revenue is recognized for each.

- **Product revenue** - The Company sells product primarily to wholesalers or a specialty pharmacy who 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. Revenue is recognized at the point in time 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. There is no deferred revenue or remaining performance obligation recorded on the Company's balance sheet.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

- Royalty revenue - the Company recognizes the royalty revenue on net revenue of products with respect to which the Company has contractual royalty rights in the period in which the royalties are earned.

The disaggregated revenue by primary products is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue (in thousands):				
Gvoke	\$ 11,479	\$ 8,835	\$ 23,932	\$ 16,886
Keveyis	12,812	—	22,136	—
Recorlev	969	—	1,102	—
Product revenue, net	<u>25,260</u>	<u>8,835</u>	<u>47,170</u>	<u>16,886</u>
Royalty, contract and other revenue	46	71	209	215
Total revenue	<u>\$ 25,306</u>	<u>\$ 8,906</u>	<u>\$ 47,379</u>	<u>\$ 17,101</u>

Note 4. Business combination

On October 5, 2021 (the "acquisition closing date"), pursuant to the Transaction Agreement, dated as of May 24, 2021 (the "Transaction Agreement"), among Xeris Pharma, Strongbridge, Xeris Biopharma and Wells MergerSub, Inc., Xeris Pharma completed the acquisition of Strongbridge (the "Acquisition"). Upon completion of the Acquisition, (a) the Company acquired Strongbridge by means of a scheme of arrangement (the "Scheme") under Irish law pursuant to which the Company acquired all of the outstanding ordinary shares of Strongbridge ("Strongbridge Shares") in exchange for (i) 0.7840 of a share of the Company's common stock ("Company Shares") and cash in lieu of fractions of Company Shares in exchange for each Strongbridge Share held by such Strongbridge Shareholders and (ii) one (1) non-tradeable Contingent Value Right ("CVR"), worth up to a maximum of \$1.00 per Strongbridge Share settleable in cash, additional Company Shares, or a combination of cash and additional Company Shares, at the Company's sole election and (b) MergerSub merged with and into Xeris Pharma, with Xeris Pharma, as the surviving corporation in the merger (the "Merger," and the Merger together with the Acquisition, the "Transactions").

Upon completion of the Merger, (a) each share of Xeris Pharma common stock was assumed by the Company and converted into the right to receive one Company Share and any cash in lieu of fractional entitlements due to a Xeris Pharma shareholder and (b) each Xeris Pharma option, stock appreciation right, restricted share award and other Xeris Pharma share based award that was outstanding was assumed by the Company and converted into an equivalent equity award of the Company, which award was subject to the same number of shares and the same terms and conditions as were applicable to the Xeris Pharma award in respect of which it was issued. On October 6, 2021, the Company's common stock, par value \$0.0001 per share, commenced trading on the Nasdaq Global Select Market ("Nasdaq") under the ticker symbol "XERS".

See "Note 15 – Stock compensation plans" for a more detailed description of the equity award plans assumed in the Transactions. See "Note 12 – Warrants" for a more detailed description of the warrants assumed in the Transactions.

Acquisition was accounted for as a business combination using the acquisition method of accounting under the provisions of ASC 805, *Business Combinations*.

The Acquisition has and will continue to diversify and increase the Company's revenue base into the specialized commercial platforms and expand the development pipeline. Additionally, the Company expects to achieve significant synergies by eliminating redundant processes and reducing headcount, most notably within the commercial, executive and general and administrative functions.

Acquisition consideration

The acquisition-date fair value of the consideration transferred totaled \$169.1 million, which consisted of the following:

Fair value of consideration transferred (in thousands, except share number)	
Xeris Biopharma Holdings, Inc. common shares (58,082,606 shares)	\$ 137,655
Unexercised Strongbridge options assumed by Xeris Pharma and converted into options to purchase Company Shares	6,404
Strongbridge warrants	2,467
Contingent consideration (Contingent value rights)	<u>22,531</u>
Total consideration	<u>\$ 169,057</u>

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The fair value of the common stock issued was determined based on the closing market price of shares of the Company's common stock on the acquisition date. During the three and six months ended June 30, 2022, there were no changes to the purchase price allocation and the measurement period has closed.

The fair value of the equity accounting warrants which were assumed by the Company in connection with the Transactions, was determined using the Black-Scholes valuation model, which considers the expected terms of the warrants from the acquisition closing date as well as the risk-free interest rate, new exercise price after the 0.7840 conversion rate multiplied by and a volatility of 89.63% (a weighting of 60% of Xeris volatility and 40% of Strongbridge volatility is used).

The fair value of the private placement warrants which were assumed by the Company in connection with the Transactions, was determined using the Black-Scholes valuation model which considers the expected terms of the private placement warrants from the acquisition closing date as well as the risk-free interest rate, current exercise price of \$2.50 multiplied by (the average of Xeris Pharma closing prices for the 20-day period ending three trading days prior to acquisition closing date/the average of Strongbridge closing prices for the 20-day period ending three trading days prior to acquisition closing date) and a volatility of 50%.

The CVRs represent contingent additional consideration of up to \$1.00 for each CVR, payable to CVR holders, to satisfy future performance milestones, settleable in cash, common stock, or a combination of cash and common stock, at the Company's sole election. The CVRs are conditioned 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.

Refer to "Note 13 - Fair Value Measurements", for information related to the fair value measurements on CVRs and valuation methods utilized.

As of the acquisition closing date, there were approximately 74.1 million CVRs. There will be additional issuance of up to 10.5 million CVRs to holders of Strongbridge rollover options and assumed warrants upon exercise.

Purchase price allocation

In accordance with ASC 805, Xeris Pharma was determined to be the accounting acquirer in the Acquisition. The Company has applied the acquisition method of accounting that requires, among other things, that identifiable assets acquired and liabilities assumed generally be recognized on the balance sheet at fair value as of the acquisition date. In determining the fair value, the Company utilized various forms of the income, cost and market approaches depending on the asset or liability being fair valued. The estimation of fair value required significant judgment related to future net cash flows (including revenue, operating expenses, and working capital), discount rates reflecting the risk inherent in each cash flow stream, competitive trends, market comparables and other factors. Inputs were generally determined by taking into account historical data (supplemented by current and anticipated market conditions), trends and growth rates.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The table below presents the estimated fair value that was allocated to Strongbridge's assets and liabilities based upon fair values as determined by the Company (in thousands):

		Fair Value
Cash and cash equivalents	\$	38,469
Trade accounts receivable		4,344
Inventory		1,862
Prepaid expenses and other current assets		4,683
Property and equipment		161
IPR&D		121,000
Other intangible asset		11,000
Other assets		860
Total identifiable assets acquired		182,379
Accounts payable		(279)
Other accrued liabilities		(13,703)
Accrued trade discounts and rebates		(4,844)
Supply agreement liability		(12,000)
Deferred tax liabilities		(4,942)
Other liabilities		(413)
Total liabilities assumed		(36,181)
Net identifiable assets acquired		146,198
Goodwill		22,859
Net assets acquired	\$	169,057

During the three and six months ended June 30, 2022, there were no changes to the purchase price allocation and the measurement period has closed.

The following is a description of the methods used to determine the fair values of significant assets and liabilities.

In-process research and development ("IPR&D") and other intangible asset

The IPR&D intangible asset represents the recording of the acquired IPR&D indefinite-lived intangible asset related to Recorlev. The other intangible asset represents the commercial product in the form of Keveyis. The fair value for the IPR&D and other intangible assets were based on assumptions developed by management and other information compiled by management including, but not limited to, discounted future expected cash flows. The fair value of intangibles relies heavily on projected future net cash flows including, but not limited to, key assumptions for revenue and operating expenses. The discount rates used for intangible assets are based on current market rates and reflect the risk inherent in each cash flow stream. The estimated useful life of the intangible asset of Keveyis is five years which reflects the time period in which the Company expects to receive the benefits of the related cash flows.

Goodwill

The excess of the consideration transferred over the fair value of assets acquired and liabilities assumed was recognized as goodwill. The goodwill is generated from operational synergies and cost savings the Company expects to achieve from the combined operations and Strongbridge's knowledgeable and experienced workforce. The majority of the goodwill is not expected to be deductible for tax purposes.

Transaction costs

In connection with the Transactions, the Company incurred significant expenses in 2021, including transaction costs (e.g., bankers' fees, legal fees, consultant fees, etc.). Such transaction costs totaled \$8.6 million and were recorded in the selling, general and administrative expenses in third quarter 2021 through second quarter 2022.

Supplemental pro forma information

The following unaudited supplemental pro forma financial information assumes the companies were combined as of January 1, 2021. The pro forma financial information as presented below is for informational purposes only and is based on estimates and assumptions that have been made solely for purposes of developing such pro forma information. This is not necessarily indicative of the results of

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

operations that would have been achieved if the Acquisition had taken place on January 1, 2021, nor is it necessarily indicative of future results. Consequently, actual results could differ materially from the unaudited pro forma financial information presented below. The following table presents the pro forma operating results as if Strongbridge had been included in the Company's Condensed Consolidated Statements of Operations as of January 1, 2021 (unaudited, in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	\$ 25,306	\$ 18,948	\$ 47,379	\$ 35,525
Net loss	\$ (26,185)	\$ (39,241)	\$ (59,899)	\$ (67,978)

These amounts have been calculated after applying the Company's accounting policies and adjusting the results of Xeris to reflect the additional depreciation and amortization that would have been charged assuming the fair value adjustments to intangible assets had been applied on January 1, 2021.

The unaudited supplemental pro forma information above does not include any cost saving synergies from operating efficiencies. There is a tax impact on the pro forma adjustments due to deferred tax liabilities being greater than the deferred tax assets in Ireland. For the other non-Irish entities, there is no tax impact of the pro forma adjustments reflected as both companies are, and have been for some time, in net operating loss positions and have full valuation allowances against their net deferred tax assets on both a historical and pro forma basis.

Note 5. Short-term investments

The Company classifies investments in debt securities as available-for-sale. Debt securities are comprised of highly liquid investments with minimum "A" rated securities and, as of June 30, 2022, consist of U.S. Treasury and agency bonds and corporate entity commercial paper and securities, all with maturities of more than three months but less than one year at the date of purchase. Debt securities as of June 30, 2022 had an average remaining maturity of 0.5 years. The debt securities are reported at fair value with unrealized gains or losses recorded in accumulated other comprehensive income (loss) in the condensed consolidated balance sheet. 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 available-for-sale investments by major security type as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:				
Commercial paper	\$ 9,493	\$ —	\$ —	\$ 9,493
Corporate securities	5,435	—	(17)	5,418
Foreign government securities	1,312	—	(10)	1,302
Total available-for-sale investments	<u>\$ 16,240</u>	<u>\$ —</u>	<u>\$ (27)</u>	<u>\$ 16,213</u>
	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:				
Commercial paper	\$ 21,773	\$ —	\$ —	\$ 21,773
Corporate securities	12,072	2	(7)	12,067
Foreign government securities	1,324	—	(2)	1,322
Total available-for-sale investments	<u>\$ 35,169</u>	<u>\$ 2</u>	<u>\$ (9)</u>	<u>\$ 35,162</u>

The Company reviews available-for-sale investments for other-than-temporary impairment loss periodically. The Company considers factors such as the duration, severity of and reason for the decline in value, the potential recovery period and our intent to sell. For

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

debt securities, the Company also consider whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the six months ended June 30, 2022 and 2021, the Company did not recognize any other-than-temporary impairment losses. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

Note 6. Inventory

The components of inventories consisted of the following (in thousands):

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Raw materials	\$ 5,743	\$ 5,181
Work in process	5,938	7,442
Finished goods	6,206	5,495
Inventory	<u>\$ 17,887</u>	<u>\$ 18,118</u>

Inventory reserves were \$1.1 million and \$1.0 million at June 30, 2022 and December 31, 2021, respectively.

Note 7. Property and equipment

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Lab equipment	\$ 3,946	\$ 3,739
Furniture and fixtures	1,355	1,355
Computer equipment	358	307
Office equipment	8	28
Software	307	307
Leasehold improvements	5,004	5,026
Total property and equipment	<u>10,978</u>	<u>10,762</u>
Less: accumulated depreciation and amortization	<u>(4,808)</u>	<u>(4,135)</u>
Property and equipment, net	<u>\$ 6,170</u>	<u>\$ 6,627</u>

Depreciation and amortization expense relating to property and equipment was \$0.4 million and \$0.4 million for the three months ended June 30, 2022 and June 30, 2021, respectively. Depreciation and amortization expense relating to property and equipment was \$0.7 million and \$0.7 million for the six months ended June 30, 2022 and June 30, 2021, respectively.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 8. Intangible assets

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

	Life (Years)	June 30, 2022		
		Gross assets	Accumulated amortization	Net
Definite-lived intangible asset - Keveyis	5	\$ 11,000	\$ (1,650)	\$ 9,350
Definite-lived intangible asset - Recorlev	14	121,000	(4,321)	116,679
Total intangible assets		\$ 132,000	\$ (5,971)	\$ 126,029

Keveyis is the developed product rights obtained from Strongbridge's acquisition of U.S. marketing rights to Keveyis (dichlorphenamide) from Taro Pharmaceuticals U.S.A., Inc. ("Taro").

Recorlev was acquired as a result of the Acquisition and was approved by the FDA on December 30, 2021. The IPR&D asset was reclassified as a definite-lived intangible asset in 2021 and began being amortized on a straight-line basis over an estimated useful life of 14 years assigned based on the economic life and remaining patent life.

As of June 30, 2022, expected amortization expense for intangible assets subject to amortization for the next five years is as follows (in thousands):

2022 remaining	\$	5,422
2023		10,843
2024		10,843
2025		10,843
2026		10,293
Thereafter		77,785
Total	\$	126,029

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 9. Other accrued liabilities

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Accrued employee costs	\$ 10,624	\$ 19,638
Supply agreement - current portion	6,720	6,009
Accrued supply chain costs	831	595
Accrued marketing and selling costs	2,786	3,237
Accrued research and development costs	1,562	1,998
Accrued restructuring charges	4,780	6,715
Accrued interest expense	3,615	1,413
Accrued Strongbridge transaction costs	—	1,839
Accrued other costs	6,027	7,644
Other accrued liabilities	<u>\$ 36,945</u>	<u>\$ 49,088</u>

Note 10. Restructuring costs

After the completion of the Acquisition on October 5, 2021, the Company undertook a strategic restructuring to streamline the organization and realize operating expense synergies. The costs associated with the restructuring include employee termination costs. The Company expects to incur total restructuring cost of approximately \$11.1 million related to this plan, which has been fully recorded as of June 30, 2022. Costs of \$1.4 million were incurred in the six months ended June 30, 2022, with the majority incurred in first quarter 2022. The majority of the restructuring costs are included in selling, general and administrative expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The Company anticipates the restructuring related to the Strongbridge acquisition to be substantially complete by the fourth quarter of 2023. The restructuring reserve is included in other accrued liabilities and other liabilities in the condensed consolidated balance sheet.

The following table summarizes the initial restructuring reserve in connection with the Strongbridge acquisition and the payments made during the six months ended June 30, 2022 (in thousands):

	<u>Restructuring Costs</u>
Balance accrued at December 31, 2021	\$ 6,713
Restructuring costs	1,412
Payments	(2,529)
Balance accrued at June 30, 2022	<u>\$ 5,596</u>

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 "Convertible Notes"), including \$11.3 million pursuant to the underwriters' option to purchase additional notes, which was exercised in full in July 2020. Xeris Pharma incurred debt issuance costs of \$5.1 million in connection with the issuance of the Convertible Notes. Xeris Pharma used \$20.0 million and \$4.2 million of the net proceeds from the sale to prepay a portion of the principal amount on the Term A Loan (as defined below) and the remaining amount of borrowings outstanding under the PPP Loan (as defined below), respectively.

The Convertible Notes are governed by the terms of a base indenture for senior debt securities dated June 30, 2020 (the "Base Indenture"), between Xeris Pharma and U.S. Bank National Association, as trustee, as supplemented by the first supplemental indenture thereto dated June 30, 2020, between U.S. Bank National Association, as trustee, and the second supplemental indenture thereto dated October 5, 2021 ("the Supplemental Indentures" and together with the Base Indenture, the "Indenture"), among the Company, Xeris Pharma and U.S. Bank National Association, as trustee. The 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, beginning on January 15, 2021, to holders of record at the close of business on the preceding January 1 and July 1, respectively. The Convertible Notes will mature on July 15, 2025, unless earlier converted or redeemed or repurchased by the Company.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

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 the Company's 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 will initially be 326.7974 shares of the Company's 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, the Company will increase the conversion rate, provided that the conversion rate will not exceed 367.6470 shares of the Company's common stock per \$1,000 principal amount of Convertible Notes.

In the second half of 2020, \$8.4 million in principal amount of Convertible Notes were converted into 2,736,591 shares of Xeris Pharma's common stock at the conversion rate of 326.7974 shares per \$1,000 principal amount of Convertible Notes. Additionally, in the fourth quarter of 2020, Xeris Pharma entered into separate, privately negotiated exchange agreements with certain holders of Convertible Notes to exchange \$30.7 million in principal amount of Convertible Notes for 10,435,200 shares of Xeris Pharma's common stock. Xeris Pharma recognized a \$2.6 million loss related to the convertible note exchange transactions.

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, and pursuant to the Second Supplemental Indenture, the Convertible Notes are no longer convertible into shares of common stock of Xeris Pharma common stock. Instead, subject to the terms and conditions of the Indenture, the 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, and the "Reference Property" provisions in the Indenture.

Pursuant to the Second Supplemental Indenture, the Company agreed to guarantee (a) the full and punctual payment when due of all monetary obligations of Xeris Pharma under the Indenture and (b) the full and punctual performance within applicable grace periods of all other obligations of Xeris Pharma under the Indenture.

Loan Agreement

In September 2019, Xeris Pharma entered into an Amended and Restated Loan and Security Agreement (the "Amended Loan Agreement") with Oxford Finance LLC ("Oxford"), as the collateral agent (in such capacity, the "Collateral Agent") and a lender, and Silicon Valley Bank, as a lender ("SVB", and together with Oxford, the "Prior Lenders"), which amended and restated that certain Loan and Security Agreement dated February 28, 2018 with the Prior Lenders, in its entirety. The Amended Loan Agreement provided for the 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 March 2022, the Company, Xeris Pharma and certain subsidiary guarantors of the Company 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 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 (the "Initial Loan") 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 (the "Delayed Draw Term Loan" and, together with the Initial Loan, the "Loans") in no more than three drawings of no less than \$10.0 million per drawing, subject to the Company being in pro forma compliance with the financial covenants and other conditions set forth therein. In conjunction with the execution of the Hayfin Loan Agreement, the Amended 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 Amended Loan Agreement in full, the proceeds will otherwise be used for general corporate purposes. After repayment, the Loans may not be re-borrowed.

All of 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 \$3.5 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 12.1%, maturing March 2027. The debt outstanding under the Hayfin Loan Agreement approximates fair value due to the variable interest rate on the debt.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The Loans will mature on March 8, 2027; provided, however, that the Loans will mature on January 15, 2025 if the Convertible Notes are still 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 \$15.0 million of cash on hand, is sufficient to redeem and discharge the Convertible Notes in full.

The Hayfin Loan Agreement allows the Company to voluntarily prepay the outstanding amounts thereunder. The Company is subject to an early prepayment fee equal to (i) for any prepayment that occurs prior to the second anniversary of the closing date, the applicable make-whole amount, (ii) for any prepayment that occurs after the second anniversary of the closing date but on or prior to the fourth anniversary of the closing date: (x) the amount of any principal so prepaid, multiplied by (y) for any prepayment that occurs (A) after the second anniversary of the closing date and on or prior to the third anniversary of the closing date, five percent (5.0%), (B) after the third anniversary of the closing date and on or prior to the fourth anniversary of the closing date, three percent (3.0%), and (C) after the fourth anniversary of the closing date, zero percent (0.0%).

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 the Company's 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. Associated with the Hayfin Loan Agreement, 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. Refer to "Note 12 - Warrants" for further information on the warrants.

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

	June 30, 2022	December 31, 2021
Convertible Notes	\$ 47,175	\$ 47,175
Loan facility	95,977	43,500
Less: unamortized debt issuance costs	(5,084)	(2,608)
Long-term debt, net of unamortized debt issuance costs	\$ 138,068	\$ 88,067

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

2022 remaining	\$	—
2023		—
2024		—
2025		47,175
2026		—
Thereafter		100,000
	\$	147,175

For the three and six months ended June 30, 2022, the Company recognized interest expense of \$3.4 million and \$7.0 million, respectively, of which \$0.5 million and \$0.7 million, respectively, related to the amortization of debt discount and issuance costs and a \$1.2 million loss on extinguishment of debt in both periods related to the Amended Loan Agreement with the Prior Lenders which ceased in March 2022. For the three and six months ended June 30, 2021, the Company recognized interest expense of \$1.8 million and \$3.6 million, respectively, of which \$0.2 million and \$0.5 million, respectively, related to the amortization of debt issuance costs.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 12. Warrants

On completion of the Strongbridge Acquisition, (a) 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) and (b) each outstanding and unexercised Strongbridge private placement warrant was assumed by the Company such that the applicable holders will have the right to subscribe for Company Shares, in accordance with certain terms of the Strongbridge private placement warrants. The assumed Strongbridge private placement warrants expired in June 2022.

Associated with the Armistice securities purchase agreement disclosed in "Note 14 - Stockholders' equity", the Company also issued warrants (the "Armistice 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 the seventh (7th) anniversary of the closing date; (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.

The assumed Strongbridge private placement warrants described in "Note 4 - Business combination" expired in June 2022.

As of June 30, 2022, 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
	<u>94,012</u>		
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
	<u>8,268,258</u>		

The Company recognized gains of \$23,000 and \$18,000 upon the change in fair value of the warrants during the three months ended June 30, 2022 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively. The Company recognized gains of \$0.5 million related to the expiration of the assumed Strongbridge private placement warrants in June 2022. The Company recognized losses of \$5,000 and \$5,000 upon the change in fair value of the warrants during the three months ended June 30, 2021 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively.

The Company recognized gains of \$35,000 and \$26,000 upon the change in fair value of the warrants during the six months ended June 30, 2022 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively. The Company recognized gains of \$1.7 million related to the change in fair value and the expiration of the assumed Strongbridge private placement warrants in June 2022. The Company recognized gains of \$6,000 and \$4,000 upon the change in fair value of the warrants during the six months ended June 30, 2021 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

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; and

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 takes into account 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.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The following tables present the Company's fair value hierarchy for those assets and liabilities measured at fair value as of June 30, 2022 and December 31, 2021 (in thousands):

	Total as of June 30, 2022	Level 1	Level 2	Level 3
<i>Assets</i>				
Cash and cash equivalents:				
Cash and money market funds	\$ 95,340	\$ 95,340	\$ —	\$ —
Investments:				
Corporate securities	5,418	—	5,418	—
Commercial paper	9,493	—	9,493	—
Foreign government	1,302	—	1,302	—
Total investments	<u>\$ 16,213</u>	<u>\$ —</u>	<u>\$ 16,213</u>	<u>\$ —</u>
<i>Liabilities</i>				
Contingent value rights	\$ 30,218	\$ —	\$ —	\$ 30,218
Warrant liabilities	\$ 32	\$ —	\$ —	\$ 32
	Total as of December 31, 2021	Level 1	Level 2	Level 3
<i>Assets</i>				
Cash and cash equivalents:				
Cash and money market funds	\$ 67,271	\$ 67,271	\$ —	\$ —
Investments:				
U.S. government securities	—	—	—	—
Corporate securities	12,067	—	12,067	—
Commercial paper	21,773	—	21,773	—
Foreign government	1,322	\$ —	1,322	—
Total investments	<u>\$ 35,162</u>	<u>\$ —</u>	<u>\$ 35,162</u>	<u>\$ —</u>
<i>Liabilities</i>				
Contingent value rights	\$ 22,531	\$ —	\$ —	\$ 22,531
Warrant liabilities	\$ 1,769	\$ —	\$ —	\$ 1,769

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Contingent Value Rights

Upon completion of the Merger described in "Note 4 – Business combination", the Company acquired all of the outstanding Strongbridge Shares in exchange for (i) 0.7840 of a share of the Company Shares and cash in lieu of fractions of Company Shares in exchange for each Strongbridge Share held by such Strongbridge Shareholders and (ii) one CVR. Strongbridge's outstanding equity awards were treated as set forth in the Transaction Agreement, such that (i) each Strongbridge Share Award was vested and settled for Strongbridge Shares immediately prior to the effective time of the Scheme, (ii) each Strongbridge Option became fully vested and exercisable immediately prior to the effective time of the Scheme, (iii) each unexercised Strongbridge Option was assumed by the Company and converted into an option to purchase Company Shares.

The fair value of the 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 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. The estimated value of the CVR consideration is preliminary only and 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.

Contingent consideration obligations are recorded at their estimated fair values and these obligations are revalued each reporting period until the related contingencies are resolved. The contingent value rights 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 December 31, 2021	\$	22,531
Change in fair value of warrants		7,687
Balance at June 30, 2022	\$	30,218

As of June 30, 2022, the CVRs were revalued at \$30.2 million using the same methods described above. During the six months ended June 30, 2022, a loss of \$7.7 million was recognized in the condensed consolidated statements of operations from changes in the fair values of the CVRs. Refer to "Note 16 – Commitments and contingencies" for additional information on the CVRs.

Warrant liability

The fair value of the Company's warrant liabilities is based on a Black-Scholes valuation, 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 uncertainty of the fair value measurement due to the use of unobservable inputs and interrelationships between these unobservable inputs could result in higher or lower fair value measurement.

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

Balance at December 31, 2021	\$	1,769
Change in fair value of warrants		(1,737)
Balance at June 30, 2022	\$	32

There were no transfers between any of the levels of the fair value hierarchy during the six months ended June 30, 2022.

Note 14. Stockholders' equity

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

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

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. This plan became effective on the date immediately prior to the effectiveness of the Company's IPO registration statement. The 2018 Plan replaced the 2011 Plan as 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.

The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, and each January 1 thereafter, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by the compensation committee. This number is subject to adjustment in the event of a stock split, stock dividend or other change affecting the Company's common stock. On January 1, 2022 and 2021, the number of shares of common stock available for issuance under the 2018 Plan was automatically increased by 4,994,933 shares and 2,384,448 shares, respectively. As of June 30, 2022, there were 3,115,603 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 with a purchase date of the last business day of June and December each year. This plan became effective on the date immediately prior to the effectiveness of the Company's IPO registration statement. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and each January 1 thereafter through January 1, 2028, by the least of (i) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31; (ii) 386,000 shares or (iii) such lesser number of shares as determined by the ESPP administrator. On January 1, 2022 and 2021, the number of shares of common stock available for issuance under the ESPP increased by 386,000 shares and 386,000 shares, respectively. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change affecting the Company's common stock. The Company issued 389,987 shares at a price of \$1.54 per share for the ESPP offering period which ended June 30, 2022. As of June 30, 2022, there were 473,740 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 was adopted without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. 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. The Company initially reserved 750,000 shares of common stock for the issuance of awards under the Inducement Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change affecting the Company's common stock. As of June 30, 2022, there were 241,885 shares of common stock available for future issuance under the Inducement Plan.

On October 8, 2020, the Company's stockholders, upon recommendation of the Board of Directors, approved an amendment to the Company's 2011 Plan and 2018 Plan to allow the Company to permit certain employee option holders, subject to specified conditions, to exchange some or all of their outstanding options to purchase shares of the Company's common stock for a lesser number of new options to purchase shares of the Company's common stock (the "Option Exchange").

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

On November 10, 2020, the Company filed with the SEC a Tender Offer Statement on Schedule TO defining the terms and conditions of the Option Exchange. The total number of shares of common stock underlying a new option with respect to an exchanged eligible option was determined by dividing the number of shares of common stock underlying the exchanged eligible option by the applicable exchange ratio and rounding to the nearest whole number, subject to the terms and conditions described in the Exchange Offer. On December 10, 2020, the completion date of the Option Exchange, the Company canceled the options accepted for exchange and granted 832,907 new options to purchase shares of common stock in exchange for 1,127,906 options issued under the 2011 Plan and 2018 Plan. The exercise price per share of the options granted pursuant to the Exchange Offer was \$4.09 per share, which was the closing price per share of common stock on The Nasdaq Global Select Market on the grant date of such new options. The new options will vest and become exercisable in two equal installments following the grant date, subject to an option holder's continuous service, and expire seven years from the grant date. On the grant date, the fair values of the options exchanged were similar to the fair values of the new options granted and, as such, the incremental compensation cost related to the Option Exchange was not material.

Assumed Plans

At the effective time of the Scheme, Strongbridge's outstanding equity awards were treated as set forth in the Transaction Agreement, such that (i) each award (other than options to buy shares, each a "Strongbridge Share Award") denominated in Strongbridge Shares was vested and settled for Strongbridge Shares immediately prior to the effective time of the Scheme, (ii) each Strongbridge Option became fully vested and exercisable immediately prior to the effective time of the Scheme, (iii) each unexercised Strongbridge Option was assumed by the Company and converted into an option to purchase Company shares (each, a "Strongbridge Rollover Option"), with the exercise price per Company share and the number of Company shares underlying the Strongbridge Rollover Option adjusted to reflect the conversion from Strongbridge Shares into Company shares, provided that each Strongbridge Rollover Option will continue to have, and be subject to, the same terms and conditions that applied to the corresponding Strongbridge Rollover Option (except for terms rendered inoperative by reason of the Acquisition or for immaterial administrative or ministerial changes that are not adverse to any holder other than in any de minimis respect), provided that the terms of each Strongbridge Rollover Option with an exercise price of \$4.50 or less (prior to the adjustment described above) were amended to provide that it shall remain exercisable for a period of time following the effective time of the Scheme equal to the lesser of (A) the maximum remaining term of such corresponding Strongbridge Option and (B) the fourth anniversary of the effective date of the Merger, in each case regardless of whether the holder of such Strongbridge Rollover Option experiences a termination of employment or service on or following the effective time of the Scheme.

On the acquisition closing date, 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 June 30, 2022, there were 3.6 million shares reserved for future grants under the Assumed Plans.

CVRs were also issued to the holders of Strongbridge vested and unexercised options that were outstanding and assumed by the Company at the acquisition date, provided that in no event shall such holder be entitled to any payments with respect to such CVR unless the corresponding option has been exercised on or prior to any such payment.

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 U.S. 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.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

The fair value of stock options granted during the period was estimated with the following weighted average assumptions:

	Six Months Ended June 30,	
	2022	2021
Expected term (years)	5.5	6.0
Risk-free interest rate	3.01%	1.14%
Expected volatility	80.18%	76.30%
Expected dividends	—	—

Stock option activity under the 2011 Plan, 2018 Plan, Inducement Plan and Assumed Plans for the six months ended June 30, 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	(52,301)	5.27	
Expired	(1,464,314)	8.64	
Outstanding - June 30, 2022	10,009,493	\$ 5.40	5.17
Exercisable - June 30, 2022	8,687,474	\$ 5.49	4.77
Vested and expected to vest at June 30, 2022	10,009,493	\$ 5.40	5.17

The weighted average fair value of awards granted during the six months ended June 30, 2022 was \$1.43 per share.

At June 30, 2022, there was a total of \$3.7 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 1.4 years.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Restricted Share Units

The Company grants 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 six months ended June 30, 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	4,190,850	2.79
Vested	(605,878)	5.84
Forfeited	(208,859)	2.84
Unvested balance - June 30, 2022	<u>5,381,154</u>	<u>\$ 3.32</u>

As of June 30, 2022, there was \$14.4 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over the weighted-average remaining vesting period of 2.3 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of goods sold	\$ —	\$ 31	\$ —	\$ 47
Research and development	416	407	963	754
Selling, general and administrative	2,736	2,074	5,490	4,172
Total stock-based compensation expense	<u>\$ 3,152</u>	<u>\$ 2,512</u>	<u>\$ 6,453</u>	<u>\$ 4,973</u>

Note 16. Commitments and contingencies

Commitments

Commitments to Taro Pharmaceuticals U.S.A., Inc. ("Taro")

Upon the completion of Strongbridge acquisition, the Company also acquired the supply agreement Strongbridge had with Taro to produce Keveysis. Strongbridge was obligated to purchase annual minimum amounts of product totaling approximately \$29.1 million over a six-year period from Taro. As of June 30, 2022, the remaining obligation under the Supply Agreement was \$8.0 million. The agreement with Taro will extend beyond the orphan exclusivity period. If Taro declines to renew the agreement, the Company has the right to manufacture the product on its own or have the product manufactured by a third party on its behalf. The Company is also required to reimburse Taro for royalty obligation resulting from its sale of Keveysis to the Company.

Leases

The Company has non-cancellable operating leases for office and laboratory space, which expire at various times in 2031 and 2033. The non-cancellable lease agreements provide for monthly lease payments which increase during the term of each lease agreement.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Future minimum lease payments under operating leases at June 30, 2022 are as follows (in thousands):

2022 remaining	\$	998
2023		2,031
2024		1,982
2025		1,930
2026		1,982
Thereafter		11,741
Total minimum lease payments	\$	<u>20,664</u>

Total rent expense under these operating leases was \$0.7 million and \$0.6 million for the three months ended June 30, 2022 and June 30, 2021, respectively, and \$1.4 million and \$1.2 million for the six months ended June 30, 2022 and June 30, 2021, respectively.

As of June 30, 2022, the Company had unused letters of credit of \$1.7 million which were issued primarily to secure leases.

Contingencies

CVR liability

Upon closing the Transactions, the Company entered into a CVR Agreement. Each CVR entitles its holder to receive additional consideration of up to \$1.00, to satisfy future performance milestones, settleable in cash, common stock, or a combination of cash and common stock, at the Company's sole election. As of the acquisition closing date, there were approximately 74.1 million CVRs. There will be additional issuance of up to 10.5 million CVRs to holders of Strongbridge rollover options and assumed warrants upon exercise.

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of June 30, 2022, 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 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 \$15.0 million of cash on hand, is sufficient to redeem and discharge the Convertible Notes in full, then the loans outstanding under the Hayfin Loan Agreement will mature on January 15, 2025.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 17. 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 June 30,	
	2022	2021
Shares to be issued upon conversion of Convertible Notes	15,416,667	15,416,667
Vested and unvested stock options	10,009,493	5,100,426
Restricted stock units	5,381,154	1,879,512
Warrants	8,362,270	94,012
Total anti-dilutive securities excluded from EPS computation ¹	<u>39,169,584</u>	<u>22,490,617</u>

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.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary statements for forward-looking information

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and with the audited financial statements and the notes to those financial statements included in the Annual Report on Form 10-K filed on March 11, 2022 with the U.S. Securities and Exchange Commission. In addition to financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. All statements in this document other than statements of historical fact are, or could be, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "will," "would," "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," and terms of similar meaning are also generally intended to identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including without limitation, the regulatory approval of our product candidates, our ability to market and sell our products and product candidates if approved, the effect of uncertainties related to the current coronavirus pandemic, or any other health epidemic, on U.S. and global markets, our business, financial condition, operations, third-party suppliers or the global economy as a whole, and other factors discussed in Item 1A of Part II of this Quarterly Report on Form 10-Q. Any forward-looking statements contained herein speak only as of the date hereof, and Xeris expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

Unless otherwise indicated, references to "Xeris," the "Company," "we," "our" and "us" in this Quarterly Report on Form 10-Q refer to Xeris Pharmaceuticals, Inc. ("Xeris Pharma") when referring to periods prior to the acquisition of Strongbridge Biopharma plc, an Irish public limited company ("Strongbridge") (discussed below) on October 5, 2021 and to Xeris Biopharma Holdings, Inc. 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).

We are a growth-oriented biopharmaceutical company committed to improving patients lives by developing and commercializing innovative products across a range of therapies. We currently have three commercially available products, Gvoke, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, Keveyis, the first and only U.S. Food and Drug Administration ("FDA") approved therapy for primary periodic paralysis ("PPP") and Recorlev, approved by the FDA in December 2021 for the treatment of endogenous hypercortisolemia in adult patients with Cushing's Syndrome. We also have a pipeline of development programs to bring new products forward using our proprietary formulation technology platforms, XeriSol™ and XeriJect™.

Acquisition of Strongbridge

On May 24, 2021, Xeris Pharma and Strongbridge entered into the Transaction Agreement together with Xeris Biopharma Holdings, Inc., a Delaware corporation ("the Company"), and Wells MergerSub, Inc., a Delaware corporation ("MergerSub") (the "Transaction Agreement") whereby we would acquire Strongbridge (the "Acquisition") pursuant to a scheme of arrangement (the "Scheme") under Irish law. Under the terms of the Transaction Agreement, (i) the Company acquired Strongbridge by means of the Acquisition pursuant to the Scheme and (ii) MergerSub merged with and into Xeris Pharma, with Xeris Pharma as the surviving corporation in the merger (the "Merger," and the Merger together with the Acquisition, the "Transactions"). As a result of the Transactions, both Xeris Pharma and Strongbridge became wholly owned subsidiaries of the Company. The Company acquired all of the outstanding Strongbridge ordinary shares ("Strongbridge Shares") in exchange for (i) 0.7840 of a share of the Company's common stock ("Company Shares") and cash in lieu of fractions of Company Shares due to a holder of Strongbridge Shares per Strongbridge Share and (ii) one (1) non-tradeable contingent value right, worth up to a maximum of \$1.00 per Strongbridge Share settleable in cash, additional Company Shares, or a combination of cash and additional Company Shares, at the Company's sole discretion. On October 5, 2021, pursuant to the Transaction Agreement, we completed the Transactions.

Through the Acquisition, we added Keveyis (dichlorphenamide) to our commercial product portfolio. Keveyis is the first and only treatment approved by FDA for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis ("PPP"), a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. In addition, we added a clinical-stage product candidate for rare endocrine diseases, Recorlev. Recorlev (levoketoconazole), the pure 2S,4R enantiomer of the enantiomeric pair comprising ketoconazole, is a next-generation steroidogenesis inhibitor which serves as a chronic therapy for adults with endogenous Cushing's syndrome. Levoketoconazole has received orphan designation from the FDA and the European Medicines Agency. Recorlev was acquired as an in-process research and development asset and subsequently approved by the FDA on December 30, 2021 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. Recorlev was commercially launched in January 2022.

Patents

We currently own 141 patents issued globally, including a composition of matter patent covering our ready-to-use glucagon formulation that expires in 2036. Upon completion of the Transactions, Xeris Biopharma Holdings, Inc. controls the patents of Xeris Pharma and Strongbridge Dublin Limited, the latter of which has 53 granted patents globally related to proprietary formulations of levoketoconazole (the active pharmaceutical ingredient in Recorlev) and the uses of such formulations in treating certain endocrine-related diseases and syndromes. This includes US Patent No. 11,020,393, which was granted on June 1, 2021, and which provides patent protection through 2040 for the use of Recorlev in the treatment of certain patients with persistent or recurrent Cushing's syndrome.

Outlook and strategies

Our goal is to build a leading and profitable biopharmaceutical company that innovates products that improve the lives of patients. To achieve our goal, we are pursuing the following strategies:

- < **Maximize the commercial potential of our three commercial products.** We have built out a robust endocrinology and rare disease-focused commercial infrastructure – including fully operational patient and provider support teams – primed to bring the benefits of our products to a wider range of patients with unmet needs. Our sales, marketing, market access and patient service capabilities in the United States are positioned to drive the growth of our products. We believe that our ability to execute on this strategy is enhanced by the significant commercial experience of key members of our management team.
- < **Create momentum through commercial execution leading to profitability.** We have three innovative commercial assets: Gvoke, Keveyis and Recorlev. Gvoke and Keveyis are growing in large untapped addressable markets. We are executing the launch of Recorlev, leveraging our experienced, endocrinology-focused commercial infrastructure, in a large and unsatisfied Cushing Syndrome marketplace. Through the momentum created by the execution of our three commercial products, we believe we will have a path to profitability.
- < **Continue to leverage our technology and expertise to develop a portfolio of product candidates.** We have a pipeline of development programs to bring new products forward using our formulation technology platforms, supporting long-term product development and commercial success. XeriSol and XeriJect have broad application and have the potential to be utilized across a range of potential product candidates in multiple therapeutic areas.
- < **Collaborate with pharmaceutical and biotechnology companies to apply our technology platforms to enhance the formulations of their proprietary products and candidates.** We are pursuing formulation and development partnerships to apply our XeriSol and XeriJect technology platforms to broaden our revenue stream and enhance the formulation, delivery and clinical profile of other companies' proprietary drugs and biologics. We currently are collaborating with several major pharmaceutical companies on the development of formulations of their proprietary therapeutics with XeriSol or XeriJect. Our strategic goal is to ultimately enter into commercial licensing agreements with these partners upon successful completion of formulation development.

We believe these four pillars of our strategy can bring new products to market and transform the lives of patients with life-threatening 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.

Financing

We have funded our operations to date primarily with proceeds from the sale of our preferred and common stock and debt financing. We have received gross proceeds of \$253.0 million from public equity offerings of our common stock (including our June 2018 initial public offering ("IPO") and our February 2019, February 2020, June 2020, March 2021 offerings), \$30.0 million from a private placement of our common stock in January 2022, \$104.9 million from sales of our preferred stock, \$86.3 million from our June 2020 Convertible Notes offering, \$63.5 million from the Amended and Restated Loan and Security Agreement (as amended, the "Amended Loan Agreement") with Oxford Finance LLC and Silicon Valley Bank, of which \$20.0 million was repaid in June 2020 and the remaining \$43.5 million was repaid in March 2022, and \$100.0 million (and access to the additional \$50 million remaining) from the Hayfin Loan Agreement in March 2022.

For the three months ended June 30, 2022 and June 30, 2021, we reported net losses of \$26.2 million and \$27.5 million, respectively. For the six months ended June 30, 2022 and June 30, 2021, we reported net losses of \$59.9 million and \$45.9 million, respectively. We have not been profitable since inception, and, as of June 30, 2022, our accumulated deficit was \$520.0 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, Keveyis and Recorlev;
- < continue our research and development efforts; and
- < continue to operate as a public company.

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.

Development of product candidates

Active programs:

- < *Ready-to-Use Product for Endocrinology (Levothyroxine; XP-8121):* We are currently in Phase 1 development with product candidate XP-8121, a potential once weekly sub-cutaneous injection designed to address maintenance therapy in patients with congenital or acquired hypothyroidism who require daily thyroid hormone replacement. The third dosage cohort has been conducted and we are compiling the data. We will assess the data in the second half of the year to determine if we have a viable candidate with which to approach the FDA with a proposed Phase 2 and Phase 3 program.

Programs undergoing pipeline prioritization review:

- < *Ready-to-Use Glucagon (XP-9164) for Gastroenterology:* We have completed Phase 1 development with product candidate XP-9164, an early-stage compound for gastroenterology. XP-9164 is intended to address unmet needs in the growing procedural gastroenterology market. Data from the Phase 1 study and commercial opportunity are being assessed to determine viability and value of continued clinical development.
- < *Ready-to-Use Glucagon for Exercise-Induced Hypoglycemia (EIH) in Diabetes:* We have completed Phase 2 for our ready-to-use glucagon for exercise-induced hypoglycemia in diabetes. Based on FDA interactions and expectations for a registrational program to support a mini-dose prevention indication for Glucagon RTU in EIH, we submitted an IND in February 2022. We received FDA clearance in March 2022 and were planning to initiate a new phase 2 clinical program by the end of 2022 to further address the management of EIH in people with diabetes who use insulin. Initiation of this development program is also being reviewed as part of our clinical prioritization and commercial opportunity assessment, taking FDA requirements and costs into consideration.

Inactive programs available for license:

- < *XeriSol Pramlintide-Insulin Co-formulation (XP-3924):* We have developed a novel, investigational fixed-ratio co-formulation of pramlintide and regular human insulin (XP-3924) to improve glycemic control in adult and pediatric patients with diabetes mellitus (T1D and T2D). Xeris' proprietary formulation technology (XeriSol™) enables the 2 peptides (pramlintide and insulin), which require different aqueous pH environments for optimal stability, to be co-formulated in a stable ready-to-use solution. The current formulation patent exists through at least Q4 2032, expected to extend through 2041-2042 with the ongoing formulation development work. This product is available for license of the development and commercialization rights in the US.
- < *Ready-to-Use Diazepam (XP-0863):* XP-0863 is a liquid formulation of diazepam for intramuscular injection being studied for the treatment of ARS. Xeris' patent protected technology XeriSol™ has been used to develop a room-temperature stable, ready-to-use, small-volume solution of diazepam for intramuscular injection delivered by an auto-injector, which will provide patients and caregivers an alternative to rectal and nasal administrations of benzodiazepines. XP-0863 is designed to address variable absorption, and suboptimal PK profiles of the currently marketed formulations of benzodiazepines, by offering a longer duration of action, consistent absorption of drug delivered through intramuscular administration, and a convenient and reliable form factor of the autoinjector. XP-0863 has been granted an orphan designation by the FDA for the treatment of ARS and Dravet syndrome in patients with epilepsy. This product is available for license of the development and commercialization rights in the US.

Impact of COVID-19

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and has impacted our business operations, employees, patients and communities as well as the global economy and financial markets. The COVID-19 pandemic continues to evolve and has led to the implementation of various responses, including government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures.

To date, we and our suppliers and third-party manufacturing partners have been able to continue to supply our products and product candidates to our patients and clinical trials, respectively, and currently do not anticipate any interruptions in supply. However, while our third-party contract manufacturing partners continue to operate at or near normal levels, we are seeing increasingly long lead times. While we currently do not anticipate any interruptions in our manufacturing process that would impact supply of our products and product candidates, it is possible that the COVID-19 pandemic, response efforts related to COVID-19, and its repercussions such as supply chain delays, may have an impact in the future on our third-party suppliers and contract manufacturing partners' ability to supply and/or manufacture our products and product candidates.

We believe that customer demand for our products has been adversely impacted by the COVID-19 pandemic due to the disruption the pandemic has caused in patients' normal access to healthcare as well as our sales and marketing personnel's access to customers. Remote interactions, when required, generally are not as effective as in-person interactions. In addition, several conferences and other programs at which we intended to market our products were postponed, canceled and/or transitioned to virtual meetings.

We have incurred operating losses since inception, and we have an accumulated deficit of \$520.0 million at June 30, 2022. Although we believe that our cash, cash equivalents, investments, and expected revenue from sales of Gvoke, Keveyis, and Recorlev will enable us to fund our operating and capital expenditure requirements for at least the next 12 months, we cannot predict the impact of the COVID-19 pandemic on our future results of operations and financial condition due to a variety of factors, including the health of our employees, the ability of suppliers to continue to operate and deliver, the ability of Xeris and our customers to maintain operations, continued access to transportation resources, the changing needs and priorities of customers, any further government and/or public actions taken in response to the pandemic, the emergence of variants and acceptance of vaccines, and ultimately the length of the pandemic. As further detailed in "Liquidity and Capital Resources" below, we have relied on equity and debt financing for our funding to date and completed concurrent convertible debt and equity offerings in June/July 2020 under which we raised gross proceeds of \$109.4 million and a registered direct offering in March 2021 under which we raised gross proceeds of \$27.0 million. On January 3, 2022, we entered into a securities purchase agreement in connection with a private placement for aggregate gross proceeds of approximately \$30.0 million. In March 2022, we entered into a Credit Agreement and Guaranty which 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 loans during the one year period immediately following the closing date.

We are closely monitoring the impact of the COVID-19 pandemic on all aspects of our business, including the impact on our operations and the operations of our customers, suppliers, vendors and business partners. We may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, we have taken and continue to take steps to try and minimize the current environment's impact on our business, including devising contingency plans and backup resources.

We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems, or the global economy, and we cannot presently predict the scope and severity of any potential business shutdowns or disruptions. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international markets. If we, or any of the third parties with whom we engage, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition.

Components of our Results of Operations

The following discussion sets forth certain components of our statement of operations of Xeris for three and six months ended June 30, 2022 and June 30, 2021 as well as factors that impact those items.

Product revenue, net

Product revenue, net, represent 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 judgments 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.

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, with the approval and launch of our products.

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 principally of compensation and related personnel costs, marketing and selling expenses, professional fees and facility costs not otherwise included in research and development expenses. We expect to continue to incur significant marketing and selling expenses in the near term related to the commercialization of Gvoke, Keveyis and Recorlev in the United States.

As a public reporting company, we have incurred greater expenses, including increased payroll, legal and compliance, accounting, insurance and investor relations costs. We expect some of these costs to continue to increase in conjunction with our anticipated growth and complexity as a public reporting company.

Other income (expense)

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

Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2022 and June 30, 2021 (in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Product revenue:								
Gvoke	\$ 11,479	\$ 8,835	\$ 2,644	29.9	\$ 23,932	\$ 16,886	\$ 7,046	41.7
Keveyis	12,812	—	12,812	nm	22,136	—	22,136	nm
Recorlev	969	—	969	nm	1,102	—	1,102	nm
Product revenue, net	\$ 25,260	\$ 8,835	\$ 16,425	185.9	\$ 47,170	\$ 16,886	\$ 30,284	179.3
Royalty, contract and other revenue	46	71	(25)	(35.2)	209	215	(6)	(2.8)
Total revenue	25,306	8,906	16,400	184.1	47,379	17,101	30,278	177.1
Cost and expenses:								
Cost of goods sold, excluding amortization of intangible assets	4,810	3,383	1,427	42.2	11,083	5,209	5,874	112.8
Research and development	3,718	5,383	(1,665)	(30.9)	9,968	9,415	553	5.9
Selling, general and administrative	32,984	25,927	7,057	27.2	68,897	45,004	23,893	53.1
Amortization of intangible assets	2,710	—	2,710	nm	5,421	—	5,421	nm
Total cost and expenses	44,222	34,693	9,529	27.5	95,369	59,628	35,741	59.9
Loss from operations	(18,916)	(25,787)	6,871	(26.6)	(47,990)	(42,527)	(5,463)	12.8
Other income (expense):								
Interest and other income	195	77	118	153.2	263	177	86	48.6
Interest expense	(3,448)	(1,795)	(1,653)	92.1	(6,969)	(3,586)	(3,383)	94.3
Change in fair value of warrants	516	(10)	526	nm	1,737	10	1,727	nm
Change in fair value of contingent considerations	(4,871)	—	(4,871)	nm	(7,687)	—	(7,687)	nm
Total other expense	(7,608)	(1,728)	(5,880)	340.3	(12,656)	(3,399)	(9,257)	272.3
Net loss before benefit from income taxes	(26,524)	(27,515)	991	(3.6)	(60,646)	(45,926)	(14,720)	32.1
Benefit from income taxes	339	—	339	nm	747	—	747	nm
Net loss	\$ (26,185)	\$ (27,515)	\$ 1,330	(4.8)	\$ (59,899)	\$ (45,926)	\$ (13,973)	30.4

¹ nm: not meaningful

Product revenue, net

Gvoke net revenue increased by \$2.6 million or 29.9% and \$7.0 million or 41.7% for the three and six months ended June 30, 2022 compared to the same periods ended June 30, 2021, respectively. Gvoke prescriptions grew 60.4% and 72.6% during the three and six months ended June 30, 2022 compared to the same period ended June 30, 2021. The growth in product demand was partially offset by a decrease in net pricing.

Keveyis net revenue were \$12.8 million and \$22.1 million for the three and six months ended June 30, 2022, respectively.

Recently launched Recorlev had net revenue of \$1.0 million and \$1.1 million for the three and six months ended June 30, 2022, respectively.

Cost of goods sold

Cost of goods sold were \$4.8 million and \$11.1 million for the three and six months ended June 30, 2022, respectively. The increases were attributable to an increase in sales as well as product mix and increased costs.

Research and development expenses

Research and development expenses decreased \$1.7 million or 30.9% for the three months ended June 30, 2022 when compared to the three months ended June 30, 2021. The decrease was primarily driven by reduced spend on clinical and product development.

Research and development expenses increased \$0.6 million or 5.9% for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. The increase was primarily driven by higher personnel related costs, offset by lower product development costs.

Selling, general and administrative expenses

Selling, general and administrative expenses increased \$7.1 million or 27.2% for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. We incurred \$9.7 million of increased personnel-related costs due to the build out of our sales force to support Gvoke, Keveyis and recently launched Recorlev. These were offset by \$3.8 million decreased expenses related to the acquisition of Strongbridge.

Selling, general and administrative expenses increased \$23.9 million or 53.1% for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. We incurred \$19.6 million of increased personnel-related costs due to the build out of our sales force to support Gvoke, Keveyis and recently launched Recorlev. We also had a \$2.5 million increase in marketing expenses to primarily support the launch of Recorlev.

Amortization of intangible assets

For the three and six months ended June 30, 2022, amortization of intangible assets was \$2.7 million and \$5.4 million, respectively, from Keveyis and Recorlev, each of which was acquired as part of the Strongbridge Acquisition in October 2021.

Other income (expense)

For the three and six months ended June 30, 2022, interest expense increased \$1.7 million or 92.1% and \$3.4 million or 94.3% in comparison to the three and six months ended June 30, 2021, respectively. The higher interest expenses in both periods were primarily due to a loss on extinguishment of debt of \$1.2 million and higher interest expense related to Hayfin loan.

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. In June 2018, we completed our IPO of 6,555,000 shares of our common stock at a price of \$15.00 per share for aggregate net proceeds of \$88.9 million after deducting underwriting discounts and commissions as well as other equity offering expenses. In February 2019, we completed an equity offering and sold an aggregate of 5,996,775 shares of common stock at a price of \$10.00 per share. Net proceeds from this equity offering were \$55.5 million after deducting underwriting discounts and commissions as well as other equity offering expenses. In September 2019, we entered into the Amended Loan Agreement that provided for term loans of up to an aggregate of \$85.0 million, of which \$60.0 million was drawn in September 2019 and of which \$20.0 million was repaid in June 2020. Additional tranches of \$15.0 million (the "Term B Loan") and \$10.0 million (the "Term C Loan") were contingent on achievement of certain revenue targets which were not achieved. In August 2019, we filed a shelf registration statement on Form S-3 with the SEC, which covered 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. We simultaneously entered into a Sales Agreement with Jefferies LLC, as sales agent, to provide for the offering, issuance and sale by us of up to \$50.0 million of our common stock from time to time in "at-the-market" offerings under the shelf. As of October 5, 2021, the acquisition closing date, we have sold an aggregate of 204,427 shares of common stock in at-the-market offerings under the shelf for gross proceeds of \$1.8 million. The shelf ceased to be available upon the consummation of the Transactions. 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 February 2020, we completed an equity offering and sold 10,299,769 shares of common stock. Net proceeds from this equity offering were \$39.8 million after deducting underwriting discounts and commissions as well as other equity offering expenses. In June 2020, we completed a public notes offering and sold \$86.3 million aggregate principal amount of 5.00% Convertible Senior Notes, including \$11.3 million pursuant to the underwriters' option to purchase additional notes which was fully exercised in July 2020. Concurrently with the public notes offering, in June 2020, we completed an equity offering and sold 8,510,000 shares of common stock, including 1,110,000 shares pursuant to the underwriters' option to purchase additional shares of common stock which was also fully exercised in July 2020. Net proceeds from both June 2020 offerings (including the net proceeds from the exercise of the underwriters' over-allotment options in July 2020) were \$102.8 million after deducting underwriting discounts and commissions as well as other offering expenses. 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. In March 2021, we completed a registered direct offering of 6,553,398 shares of our common stock, the net proceeds of which were \$26.9 million. As of June 30, 2022, the outstanding balance of Convertible Notes was \$47.2 million. In October 2020, we entered into a fourth amendment to the Amended Loan Agreement which provided for an additional \$3.5 million term loan which was drawn in November 2020. On January 2, 2022, we entered into a securities purchase agreement in connection with the Private Placement with Armistice for aggregate gross proceeds of approximately \$30.0 million and completed the transaction on January 3, 2022.

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 (the "Initial Loan") to us 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 (the "Delayed Draw Term Loans" and, together with the Initial Loan, the "Loans") in no more than three drawings of no less than \$10.0 million per drawing subject to us being in pro forma compliance with the financial covenants and other conditions set forth therein. In conjunction with the execution of the Hayfin Loan Agreement, the Amended 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 Amended Loan Agreement in full, the proceeds will otherwise be used for general corporate purposes. After repayment, the Loans may not be re-borrowed.

Capital Resources and Funding Requirements

We have incurred operating losses since inception, and we have an accumulated deficit of \$520.0 million at June 30, 2022. Based on our current operating plans and existing working capital at June 30, 2022 and access to the additional \$50.0 million remaining from the Hayfin Loan Agreement, 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, Keveyis and Recorlev 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, Keveyis and Recorlev, 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:

- < our degree of success in commercializing Gvoke, Keveyis and Recorlev;
- < the successful integration of the Acquisition and achievement of expected revenue and synergies;
- < 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.

We may not be able to successfully integrate and combine the businesses of Xeris and Strongbridge following the completion of the Transactions and we may not realize the anticipated benefits from the Transactions. Also, as we continue the marketing and selling of Gvoke, Keveyis and Recorlev, 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. 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, Keveyis and Recorlev. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. The issuance of equity securities may result in dilution to stockholders. If we raise additional funds through the issuance of additional debt, which may have rights, preferences and privileges senior to those of our common stockholders, the terms of the debt could impose significant restrictions on our operations. The failure to raise funds as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. If additional funding is not secured when required, we may need to delay or curtail our operations until such funding is received, which would have a material adverse impact on our business prospects and results of operations.

Cash Flows

(in thousands)	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	\$ (69,018)	\$ (43,978)
Net cash provided by investing activities	18,584	42,857
Net cash provided by financing activities	78,504	27,121

Operating activities

Net cash used in operating activities was \$69.0 million for the six months ended June 30, 2022, compared to \$44.0 million for the six months ended June 30, 2021. The increase in net cash used in operating activities was primarily driven by a change in working capital and an increase in net losses due to higher personnel related costs from increased headcount and restructuring costs related to the

Strongbridge acquisition. For a discussion regarding product revenue, net and increases in spending, refer to "Results of Operations" included in this "Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations."

Investing activities

Net cash provided by investing activities was \$18.6 million for the six months ended June 30, 2022, compared to \$42.9 million for the six months ended June 30, 2021. The decrease in cash provided by investing activities in 2022 was primarily due to a lower number of investments maturing or being sold, partially offset by lower purchases of investments in the current period.

Financing activities

Net cash provided by financing activities was \$78.5 million for the six months ended June 30, 2022, compared to \$27.1 million for the six months ended June 30, 2021. The increase 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 \$92.6 million from the March 2022 Hayfin Loan Agreement, partially offset by the payoff of the principles on the Amended Loan Agreement of \$43.5 million in March 2022, as compared to the proceeds of \$27.0 million from the March 2021 registered direct offering of our common stock.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES AND ASSUMPTIONS

Our Annual Report on Form 10-K for the year ended December 31, 2021 describes the critical accounting policies for which management uses significant judgments and estimates in the preparation of our consolidated financial statements. There have been no significant changes to our critical accounting policies since December 31, 2021.

NEW ACCOUNTING STANDARDS

Refer to "Note 2 - Summary of Significant Accounting Policies", for a description of recent accounting pronouncements applicable to our financial statements.

ITEM 3. 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 and Cash Equivalents and Investments—We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash and cash equivalents and investments. A hypothetical one-percentage point increase or decrease in interest rates applicable to our cash and cash equivalents and investments outstanding at June 30, 2022 would increase or decrease interest income by approximately one million on an annual basis.

Long-term Debt—Our interest rate risk relates primarily to U.S. dollar SOFR-indexed borrowings. Based on our outstanding borrowings pursuant to the Hayfin Loan Agreement at June 30, 2022, 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 Convertible Notes is assessed at a fixed rate of 5.0% annually and therefore does not subject us to interest rate risk.

Foreign Exchange Risk

We contract with contract 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. As of June 30, 2022, we had immaterial liabilities denominated in the Australian Dollar. Net foreign currency gains and losses did not have a material effect on our results of operations for the six months ended June 30, 2022.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and 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 principal executive officer and principal financial officer have concluded that the disclosure controls and procedures were effective as of June 30, 2022 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 U.S. 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 principal executive and principal financial officers, as appropriate, to allow timely decisions regarding disclosure.

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 June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**ITEM 1. 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 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.

Risk Related to the Impact of the COVID-19 Pandemic

Our business may be adversely affected by the ongoing COVID-19 pandemic.

The COVID-19 pandemic continues to affect many businesses, including ours. Among these impacts are ongoing personnel absences and the effectiveness of return-to-office transition plans. If we are unable to manage these absences and our return-to-office transition, we may experience short-term and/or long-term impacts on our business and business growth that could be material and adverse.

In addition, as a result of the ongoing and evolving COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- < If restrictive measures to reduce the spread of the virus are reintroduced, our sales and marketing personnel's access to customers may be adversely impacted. Remote interactions, if required, may be less effective as in-person interactions and could adversely impact demand for our products. In addition, several conferences and other programs at which we intended to market our products were postponed, canceled and/or transitioned to virtual meetings and if restrictions are reintroduced, we may be similarly impacted again.
- < We currently rely on third-party suppliers and contract manufacturing organizations ("CMOs") for the manufacturing of Gvoke, Kevevis, and Recorlev, as well as to perform third-party logistics functions, including warehousing and distribution of Gvoke, Kevevis, and Recorlev. In addition, we rely on third parties to perform quality testing and supply other goods and services to run our business. Certain of our third party suppliers in our supply chain for materials have been adversely impacted by restrictions resulting from the COVID-19 pandemic or supply chain issues, including staffing shortages, production slowdowns and disruptions in delivery systems, and may continue to be impacted such that our supply chain may be disrupted, limiting our ability to manufacture commercial quantities.
- < Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. Further, this could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. Additionally, if personnel absences persist and if our return-to-office plans are not well received, we may experience short-term and/or long-term impacts on our business and business growth that could be material and adverse.
- < Health regulatory agencies globally may experience disruptions in their operations as a result of the coronavirus pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. Any elongation or deprioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the COVID-19 pandemic and could result in delays to our clinical trials.
- < The trading prices for our common shares have been highly volatile as a result of the COVID-19 pandemic and its effects. As a result, we may face difficulties raising further capital through sales of our common shares or convertible debt or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common shares.

Since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials and/or commercial product, which could lead to delays in these trials and/or issues with our commercial supply.

The coronavirus pandemic continues to rapidly evolve. The ultimate impact of the coronavirus pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the emergence of new variants, the acceptance and availability of vaccines in various geographies, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions taken to contain coronavirus or address its impact in the short and long term, among others. We do not yet know the full

extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

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. We expect to incur losses over the next few years and may not be able to achieve or sustain revenues or profitability in the future.

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. 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 have incurred significant losses in every fiscal year since inception. For the six months ended June 30, 2022 and 2021, we reported a net loss of \$59.9 million and \$45.9 million, respectively. In addition, our accumulated deficit as of June 30, 2022 was \$520.0 million.

We expect to continue to incur significant operating expenses as we continue the commercialization of Gvoke, Keveyis and Recorlev, 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, Keveyis and Recorlev commercial strategies in the U.S.;
- < continue our research and development efforts;
- < seek regulatory approval for new product candidates and product enhancements;
- < analyze the results of integration of Strongbridge; and
- < continue to operate as a public company.

Our ability to generate revenue to transition to profitability and generate positive cash flows is uncertain and depends on the successful commercialization of Gvoke, Keveyis and Recorlev and any of our product candidates for which we obtain marketing approval. Many of our product candidates are still in development. Successful development and commercialization will require achievement of key milestones, including completing clinical trials and obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are sufficient enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

Although we generate revenue from Gvoke, Keveyis, and Recorlev, we have not yet generated revenue from any of our current or future product candidates, and may never be profitable.

Our ability to generate revenue from Gvoke, Keveyis and Recorlev, 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; 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, Keveyis and Recorlev. 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, Keveyis and Recorlev, if we are unable to generate sufficient product revenue, we will not become profitable and may be unable to continue operations without additional funding.

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 would 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, Keveyis and Recorlev 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 resulting from the ongoing COVID-19 pandemic and geopolitical instability resulting from the ongoing military conflict between Russia and Ukraine, rising interest rates, the tightening of lending standards or other factors could also adversely impact our ability to access capital as and when needed.

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 interest expense, 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, with the lenders from time to time parties thereto (the "Lenders"), Hayfin Services LLP, as administrative agent for the Lenders, Xeris Pharmaceuticals, Inc. and Xeris Biopharma Holdings, Inc. (the "Hayfin Loan Agreement"), 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 repurchase our Convertible Notes for cash following a fundamental change, 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 "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. As of June 30, 2022, the outstanding balance of Convertible Notes was \$47.2 million. The Convertible Notes are governed by the terms of a base indenture for senior debt securities dated June 30, 2020 (the "Base Indenture"), as supplemented by the first supplemental indenture thereto dated June 30, 2020 and the second supplemental indenture thereto dated October 5, 2021 ("the Supplemental Indentures" and together with the Base Indenture, the "Indenture"), each between us and U.S. Bank National Association, as trustee. Failure to satisfy our current and future debt obligations under the Indenture 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 Indenture 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 Indenture that governs the Convertible Notes. A default under the Indenture 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 \$100.0 million outstanding under our Hayfin Loan Agreement as of June 30, 2022 and up to an additional \$50 million in delayed draw term loans. 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 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 Indenture. 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 U.S. 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 Convertible Notes and equity offerings.

We may be subject to CARES Act-specific lookbacks and audits 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 do not have extensive history of product returns and use various factors to estimate the provision for returns, including the launch date of products, 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. While we believe that our returns reserve is sufficient to avoid a significant reversal of revenue in future periods, any significant increase in returns that exceeds our reserves could adversely affect our revenue and operating results.

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 launching, marketing and commercializing our approved products, Gvoke, Keveyis and Recorlev, 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, Keveyis, Recorlev 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. There is no guarantee that the infrastructure, systems, processes, policies, relationships and materials we have built for the commercialization of Gvoke, Keveyis and Recorlev will 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*" in our most recent Annual Report on Form 10-K.

Even if all regulatory approvals are obtained, the commercial success of our products and product candidates will depend on gaining 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:

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

Additionally, if, after 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, a contraindication or 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 products, and our business, financial condition and results of operations may be materially harmed. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new therapeutics are introduced that are more favorably received than our products or that render our products obsolete, or if significant adverse events occur. If our products do not achieve and maintain market acceptance, we will not be able to generate sufficient revenue from product sales to attain profitability.

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, Keveyis, and Recorlev. 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 and recently expanded our sales force to market our products in the United States. There are significant expenses and risks involved with maintaining 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, Keveyis and Recorlev and the launch and commercialization of our product candidates, if approved.

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

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. For example, as a result of the COVID-19 pandemic, from time to time we have had to limit in-person interactions and engage with many healthcare professionals remotely, which may be less effective. In addition, due to the prioritization of healthcare resources toward pandemic efforts, even remote interactions may not be possible.

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

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

Risks Related to Third-Parties Actions and Market Acceptance

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

We do not currently own or operate any manufacturing facilities for the production of Gvoke, Keveysis or Recorlev 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. ("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 Pharmaceuticals U.S.A., Inc. ("Taro") produces all of our requirements for Keveysis. The agreement with Taro may extend beyond the orphan exclusivity period unless terminated by either party pursuant to the terms of the agreement. If terminated by Taro prior to the next renewal, we will need to find a new third party to manufacture Keveysis 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 is 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 Keveysis, enabling Taro 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 for Keveysis 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 are experiencing significantly longer 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. For example, the COVID-19 pandemic and the resulting impacts to global supply chains could continue to impact our and our suppliers' ability to procure sufficient supplies for the manufacture of our commercial products or our product candidates. Any disruption to the facilities or operations of our third-party suppliers resulting from weather-related events, epidemics, including the global health concerns such as the COVID-19 pandemic, fire, acts of terrorism, political instability or any other cause could materially impair our ability to manufacture our products and to distribute our products to customers. For example, we have a global supply chain and manufacture some components of our products outside the United States, including without limitation, Taiwan. 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, and Cosmetic Act (the "FDCA") based on their primary mode of action as a drug. Third-party manufacturers may not be able 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 Regulations ("QSRs") 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 approved by the FDA pursuant to inspections conducted by the FDA. The FDA and other foreign regulatory authorities 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 QSRs. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable CGMP or QSR requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications, CGMP and/or QSRs 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 QSRs, 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.

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, geo-political events, or epidemics that may result in a sustained interruption in the manufacture and supply of our products;
- < fluctuations in demand for our products or a supplier's demand from other customers may affect their ability or willingness to deliver materials or products in a timely manner or may lead to long-term capacity constraints at the supplier;
- < we may not be able to find new or alternative sources or reconfigure our products and manufacturing processes in a timely manner if 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. 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 more generally 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 U.S. and foreign governmental, private third-party insurers and payors and other third-party payors, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products 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. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our potential purchasers. If competitive forces drive down the prices we are able to charge for our products, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business. For more information, see the sections entitled, "*Business — Coverage and Reimbursement*" and "*Business — Healthcare Reform*" in our most recent Annual Report on Form 10-K.

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 U.S. 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. Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

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; (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 (iii) 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, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our products and our product candidates.

Some patients may require health insurance coverage to afford our products 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 of our products will have a material adverse effect on our ability to achieve profitability.

The success of Gvoke, Kevevis, Recorlev and our other product candidates will be dependent on its proper use by patients, healthcare practitioners and caregivers.

While 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. Even though our products were used correctly by individuals in our human factors studies for Gvoke, there is no guarantee that these results will be replicated by users in the future. If we are not successful in promoting the proper use of our 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.

Risks Related to our Dependence on Third Parties

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

We depend on independent clinical investigators, CROs, academic institutions and other third-party service providers to conduct clinical trials with and for our product candidates. Although we rely heavily on these parties for successful execution of our clinical trials, we are ultimately responsible for the results of their activities and many aspects of their activities are beyond our control. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, but the independent clinical investigators may prioritize other projects over ours or may fail to timely communicate issues regarding our products to us. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. 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. However, we cannot assure you that our clinical trial vendors or personnel will 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 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, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

NDAs 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 in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- < may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- < may determine that 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;
- < may change its approval policies or adopt new regulations; or
- < may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

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

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

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

We cannot be certain that existing clinical trial results will be sufficient to support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Moreover, success in clinical trials in a particular indication does not ensure that a product candidate will be successful in other indications. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials or successful later-stage trials in other related indications. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any 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 Authorization 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 Federal Food, Drug, and Cosmetic Act, 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. Thus our XeriSol pramlintide-insulin co-formulation which would have previously been reviewed through a 505(b)(2) NDA was instead required to be approved under the PHS Act. 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, Kevevis, Recorlev 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.

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

To date, patients treated with our ready-to-use glucagon have experienced drug-related side effects typically observed with glucagon products, including nausea, vomiting and headaches. 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. It is possible that there may be side effects associated with our product candidates' use. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. 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 such products:

- < regulatory authorities may require the addition of labeling statements, including "black box" warnings, contraindications or dissemination of field alerts to physicians and pharmacies;
- < we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- < we may be subject to limitations on how we may promote the product;
- < sales of the product may decrease significantly;
- < regulatory authorities may require us to take our approved product off the market;
- < we may be subject to litigation or 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 four indications for our product candidates, which are our ready-to-use glucagon for PBH and Congenital Hyperinsulinism ("CHI") and our ready-to-use diazepam for acute repetitive seizures and Dravet syndrome. We have also received orphan drug designation from the EMA for our ready-to-use glucagon for CHI and Noninsulinoma Pancreatogenous Hypoglycaemia Syndrome ("NIPHS") which includes patients with PBH. We may pursue such designation for others in specific orphan indications in which there is an unmet medical need. We will continue to rely on orphan drug exclusivity in the marketing and sales of Keveyis until it expires on August 7, 2022 and intend to rely on orphan drug exclusivity and, if granted, new chemical entity ("NCE") exclusivity in the marketing and sale of Recorlev. 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 we can demonstrate that our 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 Europe, the period of orphan drug exclusivity is ten years, although it may be reduced to six years if, at the end of the fifth year, it is established that the criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. We have received orphan drug designation from the EMA for our ready-to-use glucagon for the treatment of CHI and NIPHS, which includes patients with PBH.

Even with the FDA approval of Gvoke, Keveyis and Recorlev 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, Keveyis and Recorlev 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*" in our most recent Annual Report on Form 10-K.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

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 U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, improve transparency in drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. 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, including Strongbridge, which is cooperating with these voluntary requests for information. 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.

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 U.S. 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 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 technology platforms, 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 technology platforms to obtain approval of additional product candidates.

In the future, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license product candidates, approved products or the underlying technology to us. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. 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 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 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 U.S. and non-U.S. 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 similar agencies 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 QSRs. 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 reactions and production problems, if any, to the FDA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products for indications or uses for which they are not approved.

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

Regulatory agencies may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice ("DOJ"), closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we, or any future collaborators, do not market any of our products for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing, 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 August 14, 2020, we received an untitled letter from FDA's Office of Prescription Drug Promotion regarding a promotional television advertisement for Gvoke PFS. The letter raised concerns that the advertisement did not include sufficient risk information, made misleading claims as to the product's ease of use, and omitted information about the seriousness of the condition for which Gvoke PFS is indicated and the circumstances when it is appropriate to administer Gvoke PFS. The television advertisement cited in the untitled letter was discontinued in March of 2020. We submitted a response to the FDA regarding our plan to revise the advertisement at issue. The FDA completed evaluation of our response and confirmed that we have addressed all the violations 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 inspection costs, required due dates for specific actions and penalties for noncompliance;
- < impose other administrative or judicial civil or criminal penalties including fines, imprisonment and disgorgement of profits;
- < suspend or withdraw regulatory approval;
- < refuse to approve pending applications or supplements to approved applications filed by us;
- < close the facilities of our third-party suppliers;
- < suspend ongoing clinical trials;
- < impose restrictions on operations, including costly new manufacturing requirements; or
- < seize or detain products or recommend or require a product recall.

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

Our relationships with customers and payors will be 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 will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with investigators, healthcare practitioners, consultants, third-party payors and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. For more information, see the section entitled, "*Business — Other Healthcare Laws and Compliance Requirements*" in our most recent Annual Report on Form 10-K.

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

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 U.S. 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 their 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. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict how the implementation of and any further changes to this rule will affect our business.

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 U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission ("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 U.S. 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-U.S. 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 outside the United States, which could limit our growth potential and increase our development costs.

The creation and implementation of international business practices compliance programs, particularly FCPA compliance, 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 U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor.

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

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

In some 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 U.S. 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

We operate in a competitive business environment and, if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our 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. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing products competitive to our product candidates.

For example, Gvoke has numerous competitors in the severe hypoglycemia market, which currently include Eli Lilly's Baqsimi®, an intranasal glucagon dry powder, Eli Lilly's GEK, Novo Nordisk's GlucaGen HypoKit and Fresenius Kabi's glucagon emergency kit for low blood sugar. 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. Zealand Pharma received approval by the FDA of its dasiglucagon auto-injector Zegalogue® in March 2021 and launched in June 2021. 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. 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.

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

In addition, Keveyis is an oral carbonic anhydrase inhibitor, that was approved in the United States to treat hyperkalemic, hypokalemic and related variants of PPP. 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, mexilitine and other sodium channel blockers, and others. We are not aware of drugs currently in development for prophylactic chronic treatment of PPP.

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

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an abbreviated new drug application ("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 entities developing generic drugs and biosimilar biological products. 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. If we are required to provide product samples or allocate additional resources to responding to such requests or any legal challenges under this law, our business could be adversely impacted. 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. We will continue to rely on orphan drug exclusivity in the marketing and sales of Keveyis through expiration of orphan drug exclusivity in August 2022 and intend to rely on orphan drug exclusivity and NCE, if available, 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 Our Intellectual Property

Risks Related to Protecting Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries with respect to 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 U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- < countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates in such countries.

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

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 licensors and cannot guarantee that we would receive it and on what terms. We cannot be certain that those licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we 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 U.S. or foreign laws; or
- < if issued, the patents under which we hold rights may not be valid or enforceable.

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

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. 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 U.S. 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, Keveyis, Recorlev, 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 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 U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that 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 U.S. patents in lawsuits in U.S. federal courts and uses a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier and less costly for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which 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 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. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold due to the COVID-19 pandemic, the FDA has been working to resume routine surveillance, biosearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be appropriate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. During the COVID-19 public health emergency, the FDA has worked to ensure timely reviews of applications for medical products in line with its user fee performance goals and conduct mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to 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, Steven Prestrelski, our Chief Scientific Officer and Co-Founder, 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 not be able to resell shares of our common stock at or above the price you paid.

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, Keveyis and Recorlev;
- < 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, Keveyis, Recorlev 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 us, our insiders or other stockholders;
- < variations in our financial results or those of companies that are perceived to be similar to us;
- < changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- < changes in the structure of healthcare payment systems;
- < market conditions in the pharmaceutical and biotechnology sectors;
- < general economic, industry and market conditions, including impacts from inflation;
- < global health concerns, such as the COVID-19 pandemic; and
- < the other factors described in this "Risk Factors" section.

In recent years, the stock markets, and particularly the stock of smaller pharmaceutical and biotechnology companies, at times have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. Broad market and industry factors may significantly affect the market price of our common stock unrelated to our actual operating performance. Since shares of our common stock were sold in our IPO in June 2018 at a price of \$15.00 per share, our stock price has fluctuated significantly.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business. On August 9, 2022, the closing price of a share of our common stock was \$1.7 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 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 June 30, 2022, the outstanding balance of Convertible Notes was \$47.2 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 will initially be 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. Because the conversion rates of the Convertible Notes adjust 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.

Upon completion of the Acquisition, 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 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 June 30, 2022, we had federal net operating loss carryforwards of \$475.7 million and various state net operating loss carryforwards of \$309.7 million. If not utilized, the federal net operating losses generated in taxable years beginning on or before December 31, 2017 will expire at various dates between 2025 and 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 June 30, 2022. As of June 30, 2022, we had \$5.4 million and \$2.5 million of federal and state income tax credits, respectively, to reduce future tax liabilities. If not utilized, the \$5.4 million in federal income tax credits will begin to expire in 2025, and the \$2.5 million of state research and development credits will begin to expire in 2022, and these tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. 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 U.S. 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 U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. 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 Indenture for our Convertible Notes, Charter and Bylaws

Provisions in the Indenture 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
- < provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any state law derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty by one or more of our directors, officers or employees, any action asserting a claim against us pursuant to the Delaware General Corporation Law or our charter documents (including the interpretation, validity or enforceability thereof), or any action asserting a claim against us that is governed by the internal affairs doctrine, and that the federal district courts of the United States of America will be the sole and exclusive forum for claims arising under the Securities Act of 1933, as amended (the "Securities Act").

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 Indenture 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 indenture 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, like those of other companies, are vulnerable to damages from computer viruses, natural disasters, unauthorized access, cyber attack, including ransomware, and other similar disruptions. Any system failure, accident or security breach could result in disruptions to our operations. For example, third parties may attempt to hack into systems and may obtain our proprietary information or other sensitive information, which could cause significant damage to our reputation, lead to claims against the Company and ultimately harm our business.

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 the 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 of the safety or efficacy of our products, our manufacturing processes and facilities, our marketing programs, our internal safety reporting systems or our staff conduct. A

regulatory authority investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval. 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. However, for as long as we are an “emerging growth company” under the Jumpstart Our Business Startups Act (“JOBS Act”) enacted in April 2012, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an “emerging growth company” for up to five years from the date of our IPO. 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. For example, we have devoted and expect to continue to devote significant resources to complete the assessment and documentation of our internal controls over financial reporting under Section 404 of the Sarbanes-Oxley Act, including assessment of the design and effectiveness of our internal controls related to our information systems.

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

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

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

executive compensation in our periodic reports and proxy statements and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

As a result, our public filings may not be comparable to companies that are not “emerging growth companies”. We may remain an “emerging growth company” until the fiscal year-end following the fifth anniversary of the completion of our IPO, though we may cease to be an “emerging growth company” earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30, in which case we would cease to be an “emerging growth company” as of the following January 1, (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the previous three years, or (iii) if our gross revenue exceeds \$1.07 billion in any fiscal year.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. In addition, we qualify as a “smaller reporting company,” which allows us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Even after we no longer qualify as an “emerging growth company,” we may still qualify as a “smaller reporting company” if the market value of our common stock that is held by non-affiliates is below \$250 million (or \$700 million if our annual revenue is less than \$100 million) as of June 30 in any given year, which would allow us to continue to take advantage of these exemptions.

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

Our 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 US 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 EU and/or the UK subjecting us to additional privacy restrictions and data protection requirements. The collection and use of personal health data in the EU are governed by the provisions of the General Data Protection Regulation (“GDPR”), as well as other national data protection legislation in force in relevant Member States (including the UK GDPR and the Data Protection Act 2018 in 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 European Economic Area, or EEA (or in the case of the UK GDPR, outside of 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 new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Although the UK is regarded as a third country under the EU’s GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the European Commission’s new standard contractual clauses but has published a draft version of a UK-specific transfer mechanism, which, once finalized, will enable transfers from the UK. Following a ruling from the Court of Justice of the EU, in *Data Protection Commissioner v Facebook Ireland Limited and Maximilian Schrems*, Case C-311/18 (“*Schrems II*”), companies relying on standard contractual clauses to govern transfers of personal data to third countries (in particular the United States) will need to assess whether 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. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost.

If we are investigated by a European data protection authority, we may face fines and other penalties, including bans on processing and transferring personal data. EU data protection authorities have the power to impose administrative fines for violations of the GDPR of up to a maximum of €20 million or 4% of the data controller’s or data processor’s 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.

Similarly, non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. This 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 EU personal information and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EU.

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.

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

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

Economic uncertainty in various global markets caused by political instability and conflict and economic challenges caused by the COVID-19 pandemic has 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 U.S. government shutdowns and the transition in administrations, and the United States' ongoing trade disputes with China and other countries. In addition, the current military conflict between Russia and Ukraine could disrupt or otherwise adversely impact our operations and related sanctions, export controls or other actions that may be initiated by nations including the U.S., the EU or Russia (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 impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, prolonged periods of higher inflation, 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 levels of inflation. If the inflation rate continues to increase, for example due to increases in the costs of labor and supplies, it will affect our expenses, such as employee compensation, supply costs and research and development expenses. Additionally, the United States is experiencing an acute workforce shortage, which in turn, has created a very competitive wage environment that may increase our operating costs. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our financial condition and results of operations.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds from Initial Public Offering

Not applicable.

(c) Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Index to Exhibits, which is incorporated herein by reference.

XERIS BIOPHARMA HOLDINGS, INC.

FORM 10-Q

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
10.1*†	Second Amendment to API Supply Agreement, dated as of May 2, 2022, by and between Xeris Pharmaceuticals, Inc. and Bachem Americas, Inc.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1*+	Certification of Periodic Financial Report by the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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.

+ 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 10, 2022

Xeris Biopharma Holdings, Inc.

By /s/ Paul R. Edick

Paul R. Edick

Chief Executive Officer and Chairman

(Principal Executive Officer)

Date: August 10, 2022

By /s/ Steven M. Pieper

Steven M. Pieper

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED
BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM
TO THE REGISTRANT IF PUBLICLY DISCLOSED

**SECOND AMENDMENT TO
API SUPPLY AGREEMENT**

This Second Amendment (“Second Amendment”) is entered into as of May 2, 2022 (the “Second Amendment Effective Date”), by and between Xeris Pharmaceuticals, Inc. (“Xeris”) and Bachem Americas, Inc. (“Bachem”). Xeris and Bachem may be referred to individually as a “Party” or collectively as the “Parties.” Capitalized terms used in this Second Amendment without definition shall have the same meaning as set forth in the Agreement (defined below).

WHEREAS Xeris and Bachem entered into that certain API Supply Agreement for Glucagon, dated and effective January 1, 2018, and that certain First Amendment to API Supply Agreement dated February 26, 2021 (collectively “the Agreement”); and

WHEREAS the Parties have agreed to amend the Agreement to update Glucagon tiered pricing for Calendar Year [***], and to set forth a mechanism to review and confirm recently negotiated [***] pricing for the years [***];

NOW THEREFORE in consideration of the mutual promises contained herein, effective as of the Second Amendment Effective Date, the Parties affirm and agree as follows:

1. Exhibit 1, API Pricing, of the Agreement is hereby deleted and replaced with Exhibit 1 attached hereto, which contains [***] tiered pricing for Glucagon beginning Calendar Year [***], and [***] tiered pricing for Glucagon for the years [***];
2. Section 3.4 is hereby added to the Agreement as follows:

3.4 Annual Price Adjustment. The Parties acknowledge that annual price adjustments may be necessary to account for changes in the Specifications or a change in BACHEM's cost of (i) raw materials; or (ii) labor costs; or (iii) costs for energy and other utilities; or (iv) any other costs to manufacture the Product that results in a material increase in the cost of manufacturing of the API. BACHEM and XERIS agree to meet once annually, acting reasonably and in good faith, to review and confirm in writing by September 30th of each prior year the [***] tiered pricing set forth in *Exhibit 1*.

This Second Amendment shall be governed by, and construed in accordance with, the laws of the State of New York, as if entered into by New York residents and executed and wholly performed within the State of New York. This Second Amendment may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument. All other terms, conditions and obligations of the Agreement shall remain in force. To the extent any provision of the Agreement conflicts with any provision of this Second Amendment, this Second Amendment shall control.

[Signature page follows]

IN WITNESS THEREOF, each of Xeris and Bachem have caused this Second Amendment to be executed by their respective duly authorized representatives as of the Second Amendment Effective Date.

Xeris Pharmaceuticals, Inc.

By: /s/ Peter Valentinsson

Name: Peter Valentinsson

Title: SVP, Global Technical Operations

Bachem Americas, Inc.

By: /s/ Anne-Kathrin Stoller

Name: Anne-Kathrin Stoller

Title: Chief Operating Officer

ACKNOWLEDGED BY:

Bachem AG

By: /s/ Andre Casagrande

Name: Andre Casagrande

Title: Head of Global Sales Generics

EXHIBIT 1
API PRICING

[***] Pricing (Effective [***])

Glucagon	[***]
[***]g	USD [***]/g
[***]g	USD [***]/g
[***]g	USD [***]/g
> [***]g	USD [***]/g

[***] Pricing*

Glucagon	[***]	[***]	[***]
[***]g	USD [***]	USD [***]	USD [***]/g
[***]g	USD [***]	USD [***]	USD [***]/g
[***]g	USD [***]	USD [***]	USD [***]/g
> [***]g	USD [***]	USD [***]	USD [***]/g

*[***] API pricing to be converted to [***] API Pricing through good faith discussion and written mutual agreement by September 30th of the previous year.

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Paul R. Edick, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Xeris Biopharma Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2022

By: /s/ Paul R. Edick

Paul R. Edick
Chairman and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Steven M. Pieper, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Xeris Biopharma Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2022

By: /s/ Steven M. Pieper

Steven M. Pieper
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

We, Paul R. Edick and Steven M. Pieper, of Xeris Biopharma Holdings, Inc., certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of our knowledge, that:

1. The quarterly report on Form 10-Q for the quarter ended June 30, 2022 (Periodic Report) to which this statement is an exhibit fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and
2. Information contained in the Periodic Report fairly presents, in all material aspects, the financial condition and results of operations of Xeris Biopharma Holdings, Inc.

Date: August 10, 2022

/s/ Paul R. Edick

Paul R. Edick
Chairman and Chief Executive Officer
(Principal Executive Officer)

/s/ Steven M.
Pieper

Steven M. Pieper
Chief Financial Officer
(Principal Financial
Officer)