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 September 30, 2021

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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of October 31, 2021, the registrant had 124,708,935 shares of common stock, par value $0.0001 per share, 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:

- We may not be able to successfully integrate and combine the businesses of Xeris Pharma and Strongbridge following the completion of the Transactions and we may not realize the anticipated benefits from the Transactions.
- Our business may be adversely affected by the ongoing coronavirus 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 several years and may not be able to achieve or sustain revenues or profitability in the future.
- Although we generate revenue from Gvoke and Keveyis, we have not yet generated revenue from any of our current or future product candidates, including Recorlev, 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 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.
- The market opportunity for Gvoke, Keveyis, Recorlev (if approved), and our product candidates may be smaller than we estimate.
- Our reliance on third-party suppliers, including single-source suppliers, and a limited number of options for alternate sources for Gvoke, Keveyis, and Recorlev (if approved) or our product candidates could harm our ability to develop our product candidates or to commercialize Gvoke, Keveyis, Recorlev (if approved) or any product candidates that are approved.
- Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.
- If our third-party manufacturers of Gvoke, Keveyis, Recorlev (if approved) or our product candidates are unable to increase the scale of their production of our products or our product candidates, or increase the product yield of manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed or interrupted.
- We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.
- 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.
- Delays in conducting clinical trials could result in increased costs to us and delay our ability to obtain regulatory approval for our product candidates.
- Gvoke, Keveyis, Recorlev (if approved) 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.
- 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.
- It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.
- Our 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.
FORM 10-Q

INDEX

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

	September 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 59,492	$ 37,598
Short-term investments	33,491	96,190
Trade accounts receivable, net	13,561	6,875
Inventory	14,241	8,353
Prepaid expenses and other current assets	3,582	3,196
Total current assets	124,367	152,212
Property and equipment, net	6,682	6,707
Other assets	211	232
Total assets	$ 131,260	$ 159,151
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 4,290	$ 3,117
Other accrued liabilities	22,957	15,895
Accrued trade discounts and rebates	6,782	5,984
Accrued returns reserve	3,161	2,889
Other current liabilities	95	322
Total current liabilities	37,285	28,207
Long-term debt, net of unamortized debt issuance costs	87,713	87,021
Deferred rent	6,826	6,629
Other liabilities	1,897	3,533
Total liabilities	133,721	125,390
Commitments and Contingencies (Note 9)		
Stockholders' (Deficit) Equity:		
Preferred stock—par value $0.0001, 10,000,000 shares authorized and no shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	—
Common stock—par value $0.0001, 150,000,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; 66,497,895 and 59,611,202 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	7	6
Additional paid in capital	406,878	371,134
Accumulated deficit	(409,320)	(337,385)
Accumulated other comprehensive income (loss)	(26)	6
Total stockholders' (deficit) equity	(2,461)	33,761
Total liabilities and stockholders' (deficit) equity	$ 131,260	$ 159,151

The accompanying notes are an integral part of the condensed consolidated financial statements.

XERIS PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Net sales	$ 11,035	$ 9,404	$ 27,921	$ 13,066
Grant and other income	25	44	240	197
Cost of goods sold	3,220	2,832	8,429	5,921
Gross profit	7,840	6,616	19,732	7,342
Operating expenses:				
Research and development	5,663	3,876	15,078	15,811
Selling, general and administrative	26,535	16,484	71,539	55,734
Total operating expenses	32,198	20,360	86,617	71,545
Loss from operations	(24,358)	(13,744)	(66,885)	(64,203)
Other income (expense):				
Interest and other income	66	232	243	943
Interest expense	(1,798)	(2,328)	(5,384)	(6,069)
Change in fair value of warrants	81	(160)	91	(64)
Total other income (expense)	(1,651)	(2,256)	(5,050)	(5,190)
Net loss before benefit from income taxes	(26,009)	(16,000)	(71,935)	(69,393)
Benefit from income taxes	—	—	—	110
Net loss	$ (26,009)	$ (16,000)	$ (71,935)	$ (69,283)
Other comprehensive loss, net of tax:				
Unrealized gains (losses) on investments	(5)	(125)	(34)	1
Foreign currency translation adjustments	(1)	17	2	12
Comprehensive loss	$ (26,015)	$ (16,108)	$ (71,967)	$ (69,270)
Net loss per common share - basic and diluted	$ (0.39)	$ (0.35)	$ (1.11)	$ (1.78)
Weighted average common shares outstanding - basic and diluted	66,497,593	46,145,116	64,722,552	38,995,707

The accompanying notes are an integral part of the condensed consolidated financial statements.

XERIS PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Stockholders' (Deficit) Equity

(in thousands, except share data; unaudited)

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance, December 31, 2019	27,214,523	$ 3	$ 260,635	$ 43	$ (246,245)	$ 14,436
Net loss	—	—	—	—	(29,184)	(29,184)
Issuance of common stock upon equity offering	10,299,769	1	39,844	—	—	39,845
Exercise and vesting of stock options	5,296	—	10	—	—	10
Vesting of restricted stock units and related repurchases	21,449	—	(63)	—	—	(63)
Stock-based compensation	—	—	2,008	—	—	2,008
Other comprehensive income	—	—	—	17	—	17
Balance, March 31, 2020	37,541,037	$ 4	$ 302,434	$ 60	$ (275,429)	$ 27,069
Net loss	—	—	—	—	(24,099)	(24,099)
Issuance of common stock upon equity offering	7,400,000	1	18,778	—	—	18,779
Exercise and vesting of stock options	40,094	—	72	—	—	72
Stock-based compensation	—	—	2,071	—	—	2,071
Issuance of common stock through employee stock purchase plan	170,201	—	385	—	—	385
Other comprehensive income	—	—	—	104	—	104
Balance, June 30, 2020	45,151,332	$ 5	$ 323,740	$ 164	$ (299,528)	$ 24,381
Net loss	—	—	—	—	(16,000)	(16,000)
Issuance of common stock upon equity offering	1,110,000	—	2,890	—	—	2,890
Issuance of common stock upon conversion of convertible notes	367,317	—	1,060	—	—	1,060
Exercise and vesting of stock options	35,854	—	59	—	—	59
Stock-based compensation	—	—	2,054	—	—	2,054
Other comprehensive loss	—	—	—	(108)	—	(108)
Balance, September 30, 2020	46,664,503	$ 5	$ 329,803	$ 56	$ (315,528)	$ 14,336

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) 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 and vesting of stock options	20,213	—	32	—	—	32
Vesting of restricted stock units and related repurchases	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 and vesting 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
Net loss	—	—	—	—	(26,009)	(26,009)
Exercise and vesting of stock options	525	—	1	—	—	1
Stock-based compensation	—	—	3,665	—	—	3,665
Other comprehensive loss	—	—	—	(6)	—	(6)
Balance, September 30, 2021	66,497,895	$ 7	$ 406,878	$ (26)	$ (409,320)	$ (2,461)

The accompanying notes are an integral part of the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (71,935)	$ (69,283)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	980	1,021
Amortization of investments	353	(53)
Amortization of debt issuance costs	727	707
Stock-based compensation	8,638	6,133
Loss on extinguishment of debt	—	443
Change in fair value of warrants	(91)	64
Changes in operating assets and liabilities:		
Trade accounts receivable	(6,686)	(7,235)
Prepaid expenses and other current assets	(386)	1,179
Inventory	(5,144)	(3,457)
Accounts payable	1,173	(909)
Other accrued liabilities	4,650	(6,485)
Accrued trade discounts and rebates	798	4,383
Accrued returns reserve	272	1,214
Other	62	2,589
Net cash used in operating activities	(66,589)	(69,689)
Cash flows from investing activities:		
Capital expenditures	(954)	(152)
Purchases of investments	(30,784)	(91,408)
Sales and maturities of investments	93,100	56,906
Net cash provided by (used in) investing activities	61,362	(34,654)
Cash flows from financing activities:		
Proceeds from equity offerings	27,000	65,891
Payments of equity offering costs	(54)	(4,292)
Proceeds from issuance of debt	—	91,339
Payments of debt	—	(25,089)
Payments of debt issuance costs	—	(5,546)
Proceeds from employee stock purchase plan	374	385
Proceeds from exercise of stock awards	167	113
Repurchase of common stock withheld for taxes	(365)	(63)
Net cash provided by financing activities	27,122	122,738
Effect of exchange rate changes on cash and cash equivalents	(1)	(28)
Increase in cash and cash equivalents	21,894	18,367
Cash and cash equivalents, beginning of period	37,598	19,519
Cash and cash equivalents, end of period	$ 59,492	$ 37,886
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 5,350	$ 3,677
Supplemental schedule of non-cash investing and financing activities:		
Issuance of stock for conversion of debt	$ —	$ 1,060
Accrued debt issuance costs	$ —	$ 299
Accrued equity offering costs	$ 3	$ 38

The accompanying notes are an integral part of the condensed consolidated financial statements.

Note 1. Organization

Nature of business

As used herein, the “Company” or "Xeris" refers to Xeris Pharmaceuticals, Inc. ("Xeris Pharma") when referring to periods prior to the acquisition of Strongbridge Biopharma plc, 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. As a result, Xeris Pharma became the predecessor to Xeris Biopharma Holdings, Inc. upon completion of the Merger (as described below) on October 5, 2021. The financial statements of Xeris Pharma for periods ended September 30, 2021 are considered to be the financial statements of Xeris Biopharma Holdings, Inc. as this periodic report is being filed subsequent to October 5, 2021.

Xeris Pharma was a specialty pharmaceutical company that was incorporated in Delaware in 2005. Xeris was dedicated to the development of ready-to-use, room-temperature stable injectable and infusible drug formulations that offer distinct advantages over conventional product formulations, are intended to be easier to use by patients, caregivers and health practitioners, and help reduce costs for payors and the healthcare system. Through the acquisition of Strongbridge in October 2021 (discussed below), Xeris expanded its business to the development and commercialization of therapies for rare diseases with significant unmet needs and became a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology, neurology and gastroenterology.

Since the inception of Xeris, the Company has devoted the majority of its resources to conducting research and development, including preclinical studies of its product candidates and clinical trials of its most advanced product candidates, organizing and staffing the Company, raising capital and commercializing its first product, Gvoke®, which was approved by the FDA in September 2019. Gvoke delivers ready-to-use glucagon via a commercially available pre-filled syringe or auto-injector for the treatment of severe hypoglycemia, a potentially life-threatening condition. The Company commercially launched Gvoke pre-filled syringe ("Gvoke PFS") in November 2019 and auto-injector ("Gvoke HypoPen®") in July 2020.

On May 24, 2021, the Company issued an announcement pursuant to Rule 2.5 of the Irish Takeover Panel Act 1997 (as amended), Takeover Rules, 2013, disclosing that the boards of directors of the Company and Strongbridge (with the exception of Jeffrey W. Sherman, M.D., a director in common to both companies, who abstained from the voting), had reached agreement on the terms of a recommended acquisition of Strongbridge by the Company (the "Acquisition"). The Company, Strongbridge, Xeris Biopharma Holdings, Inc. ("HoldCo") and Wells MergerSub, Inc., a Delaware corporation ("MergerSub"), entered into a Transaction Agreement, dated as of May 24, 2021 (the "Transaction Agreement").

On October 5, 2021 (the "acquisition closing date"), pursuant to the Transaction Agreement, the Company completed its acquisition of Strongbridge. 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 HoldCo acquired all of the outstanding ordinary shares of Strongbridge ("Strongbridge Shares") in exchange for (i) 0.7840 of a share of HoldCo's common stock ("HoldCo Shares") and cash in lieu of fractions of HoldCo 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 HoldCo Shares, or a combination of cash and additional HoldCo Shares, at HoldCo'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 HoldCo and converted into the right to receive one HoldCo 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 HoldCo and converted into an equivalent equity award of HoldCo, 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.

At the effective time of the Scheme, Strongbridge's outstanding equity awards will be treated as set forth in the Transaction Agreement, such that (i) each Strongbridge Share Award will be vested and settled for Strongbridge Shares immediately prior to the effective time of the Scheme (or such earlier time as Strongbridge considers administratively practical), (ii) each Strongbridge Option shall become fully vested and exercisable immediately prior to the effective time of the Scheme, (iii) each unexercised Strongbridge Option will be assumed by HoldCo and converted into an option to purchase HoldCo Shares (each, a "Strongbridge Rollover Option"), with the exercise price per HoldCo Share and the number of HoldCo Shares underlying the Strongbridge Rollover Option adjusted to reflect the conversion from Strongbridge Shares into HoldCo 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) shall be 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 and (iv) HoldCo shall issue to each holder of a Strongbridge Rollover Option one CVR with respect to each Strongbridge Share subject to the applicable Strongbridge Option, provided that in no event shall such holder be entitled to any payments with respect to such CVR unless the corresponding Strongbridge Option has been exercised on or prior to any such payment.

Additionally, on completion of the Acquisition, (a) each outstanding and unexercised Strongbridge warrant (except private placement warrants) was assumed by HoldCo 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 HoldCo such that the applicable holders will have the right to subscribe for HoldCo Shares, in accordance with certain terms of the Strongbridge private placement warrants.

Immediately following the Transactions, both Xeris Pharma and Strongbridge became wholly owned subsidiaries of HoldCo. The common stock of Xeris Pharma and the ordinary shares of Strongbridge were de-registered after completion of the Transactions. On October 6, 2021, HoldCo'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 3 – Acquisition" for a more detailed description of the Acquisition.

Strongbridge was a global, commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs. The Acquisition has added Keveyis® (dichlorphenamide) to the Company's commercial product portfolio. Keveyis is the first and only treatment approved by the U.S. Food and Drug Administration (the "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, the Company has 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 being investigated as a chronic therapy for adults with endogenous Cushing's syndrome. Veldoreotide is a next-generation somatostatin analog which was acquired as part of the Acquisition that has potential application in conditions amenable to somatostatin receptor activation. Levoketoconazole has received orphan designation from the FDA and the European Medicines Agency. On May 12, 2021, Strongbridge received the official Day 74 letter from the FDA for Recorlev. Within the Day 74 letter, the FDA set a Prescription Drug User Fee Act (PDUFA) target action date of January 1, 2022, which reflects a projected 10-month standard review period.

Liquidity and capital resources

The Company has incurred operating losses since inception and has an accumulated deficit of $409.3 million as of September 30, 2021. The Company expects to continue to incur net losses for at least the next 12 months. Based on the Company's current operating plans and existing working capital at September 30, 2021, the Company believes its cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months. If needed, the Company may elect to finance its operations through equity or debt financing along with revenues.

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"). Accordingly, such financial statements do not include all of the information and note disclosures required by GAAP for complete financial statements.

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 and its 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, 2020 included in the Company's Annual Report on Form 10-K filed with the SEC on March 9, 2021.

Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") issued by the Financial Accounting Standards Board ("FASB").

Basis of consolidation

These condensed consolidated financial statements include the financial statements of Xeris Pharmaceuticals, Inc. and its subsidiary, Xeris Pharmaceuticals Australia Pty Ltd. All intercompany transactions have been eliminated.

Note 2. Summary of significant accounting policies

Net sales

The Company commercially launched Gvoke PFS and Gvoke HypoPen for the treatment of severe hypoglycemia in people with diabetes in November 2019 and July 2020, respectively. Total net sales of Gvoke were $11.0 million and $9.4 million for the three months ended September 30, 2021 and 2020, respectively, and $27.9 million and $13.1 million for the nine months ended September 30, 2021 and 2020, respectively. Net sales 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. The Company applies significant judgments and estimates in

determining some of these allowances. If actual results differ from its estimates, the Company makes adjustments 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, 2020 for further discussion of the Company's accounting policies.

New accounting pronouncements

Recently issued accounting pronouncements

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 issuer's accounting for certain modifications or exchanges of freestanding equity-classified written call options. This amendment is effective for all entities, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted. The Company is evaluating the effects, if any, of the adoption of ASU 2021-04 guidance on its financial statements and disclosures.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This standard eliminates certain accounting models to simplify the accounting for convertible instruments, expands the disclosure requirements related to the terms and features of convertible instruments, and amends the guidance for the derivatives scope exception for contracts settled in an entity's own equity. This standard enhances the consistency of earnings-per-share ("EPS") calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted EPS calculations and disclosures. This standard will be effective for the Company for annual and interim periods 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 its 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. ASU 2020-04 was further amended in January 2021 by ASU 2021-01 to expand and clarify the scope of Topic 848 to include derivative instruments on discounting transactions. Both ASU 2020-04 and ASU 2021-01 are currently effective prospectively for all entities through December 31, 2022 when the reference rate replacement activity is expected to have been completed. The guidance in ASU 2020-04 and ASU 2021-01 is optional and may be elected over time as reference rate reform activities occur. The Company does not currently expect the adoption of this new standard to have a material impact on its 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 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, with early adoption permitted. The Company does not currently expect the adoption of this new standard to have a material impact on its financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, as further updated by ASU 2018-19, 2019-04, 2019-05, 2019-10 and 2020-03. 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 will require 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 will be effective for the Company for annual and interim periods beginning after December 15, 2022, with early adoption permitted. The Company is currently evaluating the impact the adoption of this new standard will have on its 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. The FASB has recently extended the effective date of this standard for certain companies. 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 its balance sheet.

Note 3. Acquisition

As disclosed in Note 1, on October 5, 2021, pursuant to the Transaction Agreement, the Company completed its acquisition of Strongbridge. The Acquisition will be accounted for as a business combination using the acquisition method of accounting under the provisions of ASC 805, "Business Combinations." As the Acquisition was not consummated until October 5, 2021, the Acquisition is not reflected in the Company's balance sheet as of September 30, 2021 and the operating results of Strongbridge are not reflected in the Company's statement of operations for the three and nine months ended September 30, 2021.

The Acquisition will diversify and increase the Company's revenue base into the specialized commercial platforms and expand its development pipeline. Additionally, the Company expects to achieve significant synergies by eliminating redundant processes and 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 HoldCo shares		6,404
Strongbridge warrants		2,467
Contingent consideration (Contingent value rights)		22,531
Total consideration	$	169,057

The Company's acquisition accounting is primarily pending final valuation and potential CVR fair value adjustments to the consideration. 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.

Upon completion of the Acquisition, each outstanding and unexercised Strongbridge warrant (except private placement warrants) was assumed by HoldCo 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). The fair value of the assumed warrants was determined using the Black-Scholes valuation model which considers the expected terms of the assumed warrants from the acquisition closing date as well as the risk-free interest rate and expected volatility of both Xeris Pharma and Strongbridge's common stock.

Each outstanding and unexercised Strongbridge private placement warrant was assumed by HoldCo such that the applicable holders will have the right to subscribe for HoldCo Shares, in accordance with certain terms of the Strongbridge private placement warrants. The fair value of the private placement warrants 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 sales of Keveyis in 2023;
- 2023 Recorlev Milestone: $0.25 per CVR, upon the first achievement of at least $40 million in net sales of Recorlev in 2023; and
- 2024 Recorlev Milestone: $0.50 per CVR, upon the first achievement of at least $80 million in net sales of Recorlev in 2024.

The fair value of the CVRs was calculated by using a discounted cash flow method for the Keveyis patent milestone and an option pricing method for the Recorlev and Keveyis sales milestones. In the case of Keveyis milestones, the Company applied a scenario-based method and weighted them based on the possible achievement of each 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. The key assumptions used include the discount rate. The estimated value of the CVR consideration is preliminary only and is based upon available information and certain assumptions which Xeris 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.

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.

Preliminary 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.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the acquisition date. The Company is in the process of finalizing the valuations of certain intangible assets; thus, the provisional measurements of intangible assets and goodwill may be subject to change.

(in thousands)

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 assets		11,000
Other assets		860
Total identifiable assets acquired		182,379
Accounts payable		(279)
Other accrued liabilities		(13,521)
Accrued trade discounts and rebates		(4,844)
Supply agreement liability		(12,000)
Other liabilities		(413)
Total liabilities assumed		(31,057)
Net identifiable assets acquired		151,322
Goodwill		17,735
Net assets acquired	$	169,057

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 assets

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 marketed 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 the second and third quarter of 2021 such as transaction costs (e.g. bankers fees, legal fees, consultant fees, etc.). Total transaction costs recorded in the selling, general and administrative expenses totaled $2.3 million and $6.2 million for the three and nine months ended September 30, 2021, respectively .

Supplemental pro forma information

The following unaudited supplemental pro forma financial information assumes the companies were combined as of January 1, 2020. 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 operations that would have been achieved if the Acquisition had taken place on January 1, 2020, 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, 2020 (unaudited, in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenue	$ 22,556	$ 17,519	$ 58,081	$ 35,768
Net loss attributable to Xeris Biopharma Holdings Inc.	$ (23,965)	$ (17,931)	$ (82,183)	$ (99,630)

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, 2020.

The unaudited supplemental pro forma information above does not include any cost saving synergies from operating efficiencies. 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 a pro forma basis.

Note 4. Inventory

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

	September 30, 2021	December 31, 2020
Raw materials	$ 5,184	$ 2,874
Work in process	5,943	4,247
Finished goods	3,114	1,232
Inventory	$ 14,241	$ 8,353

Inventory reserves were $2.4 million and $2.2 million at September 30, 2021 and December 31, 2020, respectively.

Note 5. Other accrued liabilities

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

	September 30, 2021	December 31, 2020
Accrued employee costs	$ 11,467	$ 7,989
Accrued supply chain costs	615	1,702
Accrued marketing and selling costs	1,077	1,114
Accrued research and development costs	2,042	678
Accrued restructuring charges	10	811
Accrued interest expense	813	1,527
Accrued Strongbridge transaction costs	2,668	—
Accrued other costs	4,265	2,074
Other accrued liabilities	$ 22,957	$ 15,895

Note 6. Long-term debt

Convertible Senior Notes

In June 2020, the Company completed a public offering of $86.3 million aggregate principal amount of the Company'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. The Company incurred debt issuance costs of $5.1 million in connection with the issuance of the Convertible Notes. The Company 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”), 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 the Company 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.

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 the Company’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, the Company 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 the Company’s common stock. The Company 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 the Company'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 the Company is not a holder thereof) preferred equity, if any, of its 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 HoldCo 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, HoldCo 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.

Senior Secured Loan Facility

In February 2018, the Company entered into the Loan and Security Agreement, dated as of February 28, 2018 (as amended, the “Original 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 “Lenders”), which provided for a senior secured loan facility of up to an aggregate principal amount of $45.0 million. The first tranche of $20.0 million was drawn down in February 2018 (the "2018 Term A Loan"). The second tranche of $15.0 million was drawn down in September 2018 (the "2018 Term B Loan"). The Company also issued warrants to the Lenders to purchase common stock, which is further discussed in Note 8, "Warrants."

In September 2019, the Company entered into an Amended and Restated Loan and Security Agreement (the "Loan Agreement") with the Lenders which amended and restated the Original Loan Agreement in its entirety. The Loan Agreement provided for the Lenders to extend up to $85.0 million in term loans to the Company in three tranches. The initial tranche of $60.0 million (the “Term A Loan”) was drawn down in September 2019. 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 conjunction with the execution of the Loan Agreement, the 2018 Term A Loan and 2018 Term B Loan were repaid and the final payment fee of $2.3 million was paid.

Effective April 21, 2020, the Company entered into that certain First Amendment to Amended and Restated Loan and Security Agreement with the Lenders (the “First Amendment”) to amend the Loan Agreement to allow the Company to incur indebtedness under the U.S. Small Business Administration (the “SBA”) the Paycheck Protection Program enabled by the Coronavirus Aid, Relief and Economic Security Act of 2020 (the “CARES Act”) in the amount of $5.1 million (the “PPP Loan”).

On June 30, 2020, the Company entered into that certain Second Amendment to Amended and Restated Loan and Security Agreement with the Lenders (the "Second Amendment") to amend the Loan Agreement to provide for the Lenders’ consent to and allow for the Company's underwritten public offering of the Company's 5.00% Convertible Senior Notes due 2025 and permit the Company to prepay its PPP Loan in full. The Second Amendment also provided for the extension of the interest-only payment period through December 31, 2021, after which the term loans would be payable in 30 equal monthly installments. However, if the Company achieved a certain revenue milestone prior to January 1, 2022, then the period for interest-only payments would be extended through September 30, 2022, after which the term loans would be payable in 21 equal monthly installments. In addition the Second Amendment further provided for an extension of the maturity date from June 1, 2023 to June 1, 2024. After repayment, no loans may be re-borrowed.

Pursuant to the Second Amendment, the Company prepaid a portion of the Term A Loan equal to the sum of (i) $20.0 million, plus all accrued and unpaid interest as of the date of the Second Amendment, (ii) the applicable final payment fee of $0.6 million, (iii) the applicable prepayment fee of $0.3 million and (iv) all outstanding Lenders’ expenses as of the date of the Second Amendment.

Additionally, the Company is required to maintain a minimum balance of $5.0 million in unrestricted cash at SVB at all times and to pay an amendment fee of up to $0.1 million at the earliest to occur of the maturity date, acceleration of any term loan, or prepayment of any term loan amount.

On August 5, 2020, the Company entered into that certain Third Amendment to Amended and Restated Loan and Security Agreement with the Lenders (the "Third Amendment) to amend the Loan Agreement to (i) amend the definition of "Permitted Indebtedness" to include a new standby letter of credit in an amount not to exceed $0.4 million issued to the landlord for the Company's new leased laboratory space and (ii) permit the sale of certain equipment related to the relocation of the Company's research and development laboratory from San Diego to Chicago.

On October 23, 2020, the Company entered into that certain Fourth Amendment to Amended and Restated Loan and Security Agreement with the Lenders (the "Fourth Amendment") to amend the Loan Agreement to provide an additional tranche of $3.5 million (the "Term D Loan", and, together with the Term A Loan, Term B Loan, and Term C Loan, the "Term Loan"), available upon execution. The Term D Loan of $3.5 million was drawn in November 2020 and will be payable under the same payment terms as the term loans. After repayment, the loan may not be re-borrowed.

On May 3, 2021, the Company entered into that certain Fifth Amendment to Amended and Restated Loan and Security Agreement with the Lenders (the "Fifth Amendment") to amend the Loan Agreement. The Fifth Amendment provides that if the Company achieves a certain revenue milestone prior to November 30, 2021, then the period for interest-only payments is extended six months to July 2022 and the Term Loan will be payable in 24 equal monthly installments. If the Company achieves another revenue milestone prior to May 31, 2022, the period for interest-only payments is further extended three months, to October 2022 and the Term Loan will be payable in 21 equal monthly installments. If the Company achieves a third revenue milestone by August 31, 2022, the period for interest-only payments is further extended three months, to January 2023 and the Term Loan will be payable in 18 equal monthly installments.

On May 24, 2021, the Company entered into that certain Consent Under Amended and Restated Loan and Security Agreement (the "Consent") with the Lenders to permit the Company to execute, deliver and perform (a) the Transaction Agreement with Strongbridge and (b) that certain Expenses Reimbursement Agreement dated as of May 24, 2021 by and between the Company and Strongbridge pursuant to which the Company and Strongbridge have agreed to certain reimbursement obligations related to the transactions contemplated by the Transaction Agreement.

In connection with the completion of the Transactions, on October 5, 2021, HoldCo entered into that certain Joinder and Sixth Amendment to Amended and Restated Loan and Security Agreement (the "Sixth Amendment") with Xeris Pharma, the Lenders and Strongbridge US, Inc. ("Strongbridge US") (each of Strongbridge US and HoldCo, a "New Borrower") to amend the Loan Agreement. The Sixth Amendment adds the New Borrowers as borrowers under the Loan Agreement and provides for the grant by the New Borrowers to the Collateral Agent, for the ratable benefits of the Lenders, a first priority security interest on substantially all of their assets, including intellectual property, subject to certain exceptions. The Sixth Amendment also updates certain negative covenants and definitions to among, other things, permit certain intercompany arrangements and restructuring activities, as well as modifies the revenue milestones to address both Gvoke and non-Gvoke revenues. The Company currently expects to achieve each revenue milestone and has therefore classified the amounts due under the Loan Agreement (as amended by that certain First Amendment, Second Amendment, Third Amendment, Fourth Amendment, Fifth Amendment, Consent and Sixth Amendment, the "Amended Loan Agreement") as non-current on its balance sheet as of September 30, 2021.

All of the loans incur interest at a floating per annum rate in an amount equal to the sum of 6.25% plus the greater of (a) 2.43% and (b) the thirty-day U.S. Dollar LIBOR rate (or, the LIBOR replacement rate as applicable). For the period from the funding date of the Term A Loan through and including September 30, 2021, the interest rate was 8.68%. The Company has incurred total debt issuance costs of $2.0 million related to the Original Loan Agreement and the Amended 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 Amended Loan Agreement allows the Company to voluntarily prepay the outstanding amounts thereunder, but not less than $2.0 million of the outstanding principal at any time. The Company is subject to a prepayment fee equal to 1.50% of the principal amount being prepaid. Also, a final payment fee of 3.0% multiplied by the amount to be repaid is due upon the earliest to occur of the maturity date of the Amended Loan Agreement, the acceleration of the amounts outstanding under the Amended Loan Agreement or prepayment of such borrowings and is recorded in other liabilities on the condensed consolidated balance sheets.

The Amended Loan Agreement contains customary representations and warranties, events of default (including an event of default upon a material adverse change of the Company) 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.

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

	September 30, 2021	December 31, 2020
Convertible Notes	$ 47,175	$ 47,175
Senior secured loan facility	43,500	43,500
Less: unamortized debt issuance costs	(2,962)	(3,654)
Long-term debt, net of unamortized debt issuance costs	$ 87,713	$ 87,021

The following table sets forth the Company's future minimum principal payments on the senior secured loan facility (which reflect the Fifth Amendment) and the Convertible Notes (in thousands):

2021	$ —
2022	—
2023	29,000
2024	14,500
2025	47,175
	$ 90,675

For the three and nine months ended September 30, 2021, the Company recognized interest expense of $1.8 million and $5.4 million, respectively, of which $0.2 million and $0.7 million, respectively, was related to the amortization of debt issuance costs. For the three and nine months ended September 30, 2020, the Company recognized interest expense of $2.3 million and $6.1 million, respectively, of which $0.3 million and $0.7 million, respectively, related to the amortization of debt issuance costs. In the nine months ended September 30, 2020, $0.7 million related to a loss on extinguishment of debt.

Note 7. Stockholders' equity

The Company's authorized shares of stock of 160.0 million are divided into 150.0 million shares of common stock, par value $0.0001 per share, and 10.0 million shares of preferred stock, par value $0.0001 per share. At September 30, 2021 none of the 10.0 million shares of preferred stock were outstanding, and the Company has no present plans to issue any shares of preferred stock. The Company's board of directors has the authority, without action by the Company's stockholders, to designate and issue the preferred stock in one or more series and to designate the rights, preferences, limitations and privileges of each series of preferred stock, which may be greater than the rights of the Company's common stock.

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

In February 2020, the Company completed an equity offering of its common stock pursuant to a shelf registration statement on Form S-3, which was filed on August 6, 2019 and declared effective by the SEC on August 21, 2019. The Company sold an aggregate of 10,299,769 shares of common stock at a price of $4.15 per share, including 1,299,769 shares pursuant to the underwriters' option to purchase additional shares of common stock. Net proceeds from the equity offering were approximately $39.9 million after deducting underwriting discounts and commissions as well as other public offering expenses.

In June 2020, the Company completed an equity offering of its common stock pursuant to the Shelf. The Company sold an aggregate of 8,510,000 shares of common stock at a price of $2.72 per share, including 1,110,000 shares pursuant to the underwriters' option to purchase additional shares which was fully exercised in July 2020. Net proceeds from the equity offering were approximately $21.6 million after deducting underwriting discounts and commissions as well as other public offering expenses.

In the second half of 2020, $8.4 million in principal amount of Convertible Notes were converted into 2,736,591 shares of the Company'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, the Company 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 the Company's common stock. The Company recognized a $2.6 million loss related to the convertible note exchange transactions.
In March 2021, the Company completed a registered direct offering of 6,553,398 shares of its common stock at a price of $4.12 per share. Net proceeds from the equity offering were approximately $26.9 million after deducting offering expenses.

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. The Company then pays the minimum statutory withholding taxes in cash. During the nine months ended September 30, 2021, 220,425 RSUs vested for which 71,782 shares were withheld to cover the minimum statutory withholding taxes of $0.4 million. During the nine months ended September 30, 2020, 31,250 RSUs vested for which 9,801 shares were withheld to cover the minimum statutory withholding taxes of $0.1 million.

Note 8. Warrants

In 2014, the Company issued 19,931 warrants (the "2014 Warrants") to certain investors. The 2014 Warrants allow each holder to purchase one share of common stock for $5.912. Of the 2014 Warrants, 18,512 warrants were exercised and 1,419 warrants expired. There are no 2014 Warrants outstanding as of September 30, 2021.

As part of the Original Loan Agreement discussed in Note 6, "Long-term Debt," the Lenders received warrants concurrent with the borrowing. The warrants represent a right for the lender to purchase shares of the Company's common stock at an exercise price of $11.169 per share. The Company issued 53,720 warrants (the "2018 Term A Warrants") upon the drawdown of the 2018 Term A Loan in February 2018, and the Company issued 40,292 warrants (the "2018 Term B Warrants") upon the drawdown of the 2018 Term B Loan in September 2018. There have been no exercises of 2018 Term A Warrants or 2018 Term B Warrants. In connection with the Transactions and the Sixth Amendment, HoldCo assumed each outstanding warrant (the "Existing Warrants") issued to a Lender by Xeris Pharma. On October 20, 2021, the Company entered into Amended and Restated Warrant to Purchase Stock agreements with each Lender amending, restating and replacing each Existing Warrant to reflect the assumption of the warrants by the Company and make certain other administrative updates.

Because the warrants are a freestanding instrument, indexed to the Company's stock, they do not meet the criteria for equity classification. Therefore, the warrants are classified as liabilities and subject to remeasurement at each reporting period until they are exercised, expired, or otherwise settled.

The Company recognized gains of $46,000 and $35,000 upon the change in fair value of the 2018 Term A Warrants and the 2018 Term B Warrants, respectively, during the three months ended September 30, 2021. The Company recognized gains (losses) of $1,000, $(92,000) and $(69,000) upon the change in fair value of the 2014 Warrants, the 2018 Term A Warrants and the 2018 Term B Warrants, respectively, during the three months ended September 30, 2020. The Company recognized gains of $53,000 and $38,000 upon the change in fair value of the 2018 Term A Warrants and the 2018 Term B Warrants, respectively, during the nine months ended September 30, 2021. The Company recognized gains (losses) of $4,000, $(39,000) and $(29,000) upon the change in fair value of the 2014 Warrants, the 2018 Term A Warrants and the 2018 Term B Warrants, respectively, during the nine months ended September 30, 2020.

As of September 30, 2021, the following warrants were outstanding:

	Outstanding Warrants	Exercise Price per Warrant	Expiration Date
2018 Term A Warrants	53,720	$11.169	February 2025
2018 Term B Warrants	40,292	$11.169	September 2025
	94,012		

Note 9. Commitments and contingencies

Commitments

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

Future minimum lease payments under operating leases at September 30, 2021 are as follows (in thousands):

2021	$	323
2022		1,813
2023		2,031
2024		1,981
2025		1,931
Thereafter		13,723
Total minimum lease payments	$	21,802

Total rent expense under these operating leases was approximately $0.6 million and $0.6 million for the three months ended September 30, 2021 and 2020, respectively, and approximately $1.8 million and $1.7 million for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, the Company had unused letters of credit of $1.4 million which were issued primarily to secure leases.

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of September 30, 2021, management was not aware of any existing, pending or threatened legal actions that would have a material impact on the financial position or results of operations of the Company.

Note 10. Restructuring costs

In the third quarter of 2020, the Company commenced a plan to relocate its research and development laboratory from San Diego to Chicago. The costs associated with the plan include employee termination and relocation costs and other facility exit costs. The cumulative amount of restructuring costs incurred to date as of September 30, 2021 was $2.0 million related to the plan. Costs of $0.3 million were incurred in the nine months ended September 30, 2021, all of which is included in research and development expenses in the condensed consolidated statements of operations and comprehensive loss. The Company anticipates restructuring related to the relocation of the research and development laboratory to be substantially complete by the end of the fourth quarter of 2021. The restructuring reserve is included in other accrued liabilities in the condensed consolidated balance sheet.

The following table summarizes the initial restructuring reserve and the payments made during the nine months ended September 30, 2021 (in thousands):

	Employee Termination and Relocation Costs	Other	Total
Balance accrued at December 31, 2020	$ 646	$ 165	$ 811
Restructuring costs, net of reversals	206	69	275
Payments	(842)	(234)	(1,076)
Balance accrued at September 30, 2021	$ 10	$ —	$ 10

This is not inclusive of restructuring costs related to the Transactions that were completed on October 5, 2021.

Note 11. 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, 2021 and 2020, the number of shares of common stock available for issuance under the 2018 Plan was automatically increased by 2,384,448 shares and 1,088,580 shares, respectively. As of September 30, 2021, there were 1,475,486 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, 2021 and 2020, the number of shares of common stock available for issuance under the ESPP increased by 386,000 shares and 272,145 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 108,096 shares at a price of $3.46 per share for the ESPP offering period which ended June 30, 2021. As of September 30, 2021, there were 585,570 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 commercial launch of Gvoke 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 September 30, 2021, there were 185,773 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”).

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.

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 its 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.

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

	Nine Months Ended September 30,	
	2021	**2020**
Expected term (years)	6.0	5.9
Risk-free interest rate	1.14%	0.42%
Expected volatility	76.30%	69.85%
Expected dividends	—	—

Stock option activity under the 2011 Plan, 2018 Plan and Inducement Plan for the nine months ended September 30, 2021 was as follows:

	Options	**Weighted Average Exercise Price**	**Weighted Average Contractual Life (Years)**
Outstanding - January 1, 2021	4,953,906	$ 5.84	7.46
Granted	702,313	5.00	
Exercised and vested	(76,556)	2.26	
Forfeited	(363,277)	6.26	
Expired	(202,861)	12.15	
Outstanding - September 30, 2021	5,013,525	$ 5.48	6.80
Exercisable - September 30, 2021	2,729,400	$ 5.52	6.11
Vested and expected to vest as of September 30, 2021	4,847,191	$ 5.49	6.76

The weighted average fair value of awards granted during the nine months ended September 30, 2021 was $3.31 per share. The total intrinsic value of options exercised during the nine months ended September 30, 2021 was $0.1 million. As of September 30, 2021, the aggregate intrinsic value of awards vested and expected to vest was $1.0 million.

At September 30, 2021, there was a total of $7.9 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 1.9 years.

Restricted share units (the "RSU")

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. 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 nine months ended September 30, 2021 was as follows:

	Units	Weighted Average Grant Date Fair Value
Unvested balance - January 1, 2021	766,550	$ 7.07
Granted	1,613,344	4.9
Vested	(220,425)	7.43
Forfeited	(96,562)	5.38
Unvested balance - September 30, 2021	2,062,907	$ 5.41

As of September 30, 2021, there was $7.7 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of goods sold	$ 31	$ 37	$ 78	$ 113
Research and development	398	303	1,152	913
Selling, general and administrative	3,236	1,714	7,408	5,107
Total stock-based compensation expense	$ 3,665	$ 2,054	$ 8,638	$ 6,133

Note 12. 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 its financial assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The following tables present the Company's fair value hierarchy for those assets and liabilities measured at fair value as of September 30, 2021 and December 31, 2020 (in thousands):

	Total as of September 30, 2021	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 59,492	$ 59,492	$ —	$ —
Short-term investments				
U.S. government securities	1	1	—	—
Corporate securities	9,279	—	9,279	—
Commercial paper	20,382	—	20,382	—
Foreign government securities	2,612	—	2,612	—
Foreign corporate securities	1,217	—	1,217	—
Total investments	$ 33,491	$ 1	$ 33,490	$ —
Liabilities				
Warrant liabilities	$ 68	$ —	$ —	$ 68

	Total as of December 31, 2020	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 37,598	$ 37,598	$ —	$ —
Investments:				
U.S. government securities	64,386	64,386	—	—
Corporate securities	13,625	—	13,625	—
Commercial paper	18,179	—	18,179	—
Total investments	$ 96,190	$ 64,386	$ 31,804	$ —
Liabilities				
Warrant liabilities	$ 159	$ —	$ —	$ 159

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 have resulted 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, 2020	$	159
Change in fair value of warrants		(91)
Balance at September 30, 2021	$	68

There were no transfers between any of the levels of the fair value hierarchy during the three and nine months ended September 30, 2021.

Note 13. Available-for-sale investments

The Company classifies its investments in debt securities as available-for-sale. Debt securities are comprised of highly liquid investments with minimum “A” rated securities and, as of September 30, 2021, 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 September 30, 2021 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 sheets. Refer to Note 12, "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 September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:				
Commercial paper	$ 20,382	$ —	$ —	$ 20,382
Corporate securities	9,282	—	(3)	9,279
U.S. government securities	1	—	—	1
Foreign government securities	2,612	—	—	2,612
Foreign corporate securities	1,217	—	—	1,217
Total available-for-sale investments	$ 33,494	$ —	$ (3)	$ 33,491

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:				
Commercial paper	$ 18,179	$ —	$ —	$ 18,179
Corporate securities	13,597	29	(1)	13,625
U.S. government securities	64,383	7	(4)	64,386
Total available-for-sale investments	$ 96,159	$ 36	$ (5)	$ 96,190

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 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 three and nine months ended September 30, 2021 and 2020, 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 14. 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 September 30,	
	2021	**2020**
Shares to be issued upon conversion of Convertible Notes	15,416,667	27,818,955
Vested and unvested stock options	5,013,525	5,332,623
Restricted stock units	2,062,907	661,250
Warrants	94,012	94,012
Total anti-dilutive securities excluded from EPS computation	22,587,111	33,906,840

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 9, 2021 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 refers 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. Also, throughout this document, unless otherwise noted, references to Gvoke® include Gvoke PFS, Gvoke HypoPen® and Ogluo® (glucagon).

Xeris Pharma was a specialty pharmaceutical company that was incorporated in Delaware in 2005. Xeris was dedicated to the development of ready-to-use, room-temperature stable injectable and infusible drug formulations that offer distinct advantages over conventional product formulations, are intended to be easier to use by patients, caregivers and health practitioners, and help reduce costs for payors and the healthcare system. Through the acquisition of Strongbridge in October 2021 (discussed below), Xeris expanded its business to the development and commercialization of therapies for rare diseases with significant unmet needs and became a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology, neurology and gastroenterology.

With novel technology platforms, XeriSol™ and XeriJect™, that enable ready-to-use, room-temperature stable formulations of injectable and infusible therapies, we are advancing a portfolio of solutions in various therapeutic categories. Xeris Pharma's first product, Gvoke, delivers ready-to-use glucagon via a pre-filled syringe ("Gvoke PFS") or auto-injector ("Gvoke HypoPen") for the treatment of severe hypoglycemia, a potentially life-threatening condition, in people with diabetes. Gvoke was approved in September 2019 by the U.S. Food & Drug Administration ("FDA") for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages two years and older. We began the field launches of Gvoke PFS and Gvoke HypoPen in January 2020 and July 2020, respectively, and each is available in two doses: a 0.5 mg/0.1 mL dose for pediatric patients and a 1 mg/0.2 mL dose for adolescent and adult patients. In February 2021, the European Commission ("EC") granted a marketing authorization for and in April 2021 the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") approved Ogluo for the treatment of severe hypoglycemia in adults, adolescents, and children aged two years and over with diabetes mellitus. On July 19, 2021, we announced that we had entered into an exclusive agreement with Tetris Pharma Limited ("Tetris") for the commercialization of Ogluo in the European Economic Area, United Kingdom, and Switzerland (the "Territory"). Under the terms of the applicable agreements, Xeris will be responsible for product supply and Tetris will be responsible for commercialization of Ogluo in the Territory. Subject to the terms and conditions set forth in the agreements, Xeris will receive up to $71 million in payments over the contract tied to the first commercial sale and other time-, launch- and sales-related milestones and collect a royalty on sales. Tetris expects to launch Ogluo in the United Kingdom by the end of 2021. We are also continuing to evaluate additional applications of our ready-to-use glucagon formulation to address needs in hypoglycemia and related conditions. In addition, we have applied our technology platforms to other commercially available drugs to enable more convenient and patient-friendly subcutaneous ("SC") and intramuscular ("IM") routes of administration and continue to seek partners to further develop and commercialize products to address unmet needs in both diabetes and epilepsy. We own the rights to our proprietary formulation technology platforms, Gvoke, Ogluo, and our product candidates domestically and internationally.

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 ("HoldCo"), 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) HoldCo 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 HoldCo. HoldCo acquired all of the outstanding Strongbridge ordinary shares ("Strongbridge Shares") in exchange for (i) 0.7840 of a share of HoldCo's common stock ("HoldCo Shares") and cash in lieu of fractions of HoldCo 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 HoldCo Shares, or a combination of cash and additional HoldCo Shares, at HoldCo'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 being investigated as a chronic therapy for adults with endogenous Cushing's syndrome. Veldoreotide is a next-generation somatostatin analog which was acquired as part of the Acquisition that has potential application in conditions amenable to somatostatin receptor activation. Levoketoconazole has received orphan designation from the FDA and the European Medicines Agency. On May 12, 2021, Strongbridge received the official Day 74 letter from the FDA for Recorlev. Within the Day 74 letter, the FDA set a Prescription Drug User Fee Act (PDUFA) target action date of January 1, 2022, which reflects a projected 10-month standard review period.

Patents

Xeris Pharma currently owns 121 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 wich 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 formulation technologies have broad applicability across most therapeutic areas. There is increasing interest in our technology platforms by other pharmaceutical companies that seek higher drug concentrations and drug combinations in subcutaneous forms, including drugs with limited aqueous stability and solubility. In addition to use of these technologies for development of our own product candidates, we are currently conducting four evaluations projects with top tier pharmaceutical companies. Additional projects are under discussion with both large pharmaceutical and specialized biotech companies.

Our key priority is continuing the successful commercialization of Gvoke and Keveyis for the treatment of severe hypoglycemia and hyperkalemic, hypokalemic, and related variants of PPP, respectively, as well as the pre-commercialization preparations for the anticipated launch of Recorlev in the first quarter of 2022, subject to FDA approval for the treatment of endogenous Cushing's syndrome.

We have built a commercial organization to support the commercialization of our products in the United States. As noted above, we have entered into an agreement with Tetris for commercialization of Ogluo in the Territory. We currently contract with third parties for the manufacture, assembly, testing, packaging, storage and distribution of our products.

Since our inception in 2005, we have devoted substantially all of our resources to conducting research and development including preclinical studies of our product candidates and clinical trials of our most advanced product candidates, organizing and staffing our company, raising capital and commercializing our approved products.

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 and March 2021 offerings), $104.9 million from sales of our preferred stock, $86.3 million from our June 2020 Convertible Notes offering and $63.5 million from the Amended and Restated Loan and Security Agreement (as amended, the "Amended Loan Agreement"), of which $20.0 million was repaid in June 2020.

In February 2020, we completed an equity offering and sold 10,299,769 shares of common stock, including 1,299,769 shares pursuant to the underwriters' option to purchase additional shares of common stock. Net proceeds from the offering were $39.9 million. 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 exercised in full in July 2020. Concurrent 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 also was exercised in full in July 2020. Gross proceeds from the equity offering were $23.1 million. Net proceeds from both June 2020 offerings were $102.8 million. In March 2021, the Company completed a registered direct offering of 6,553,398 shares of its common stock at a price of $4.12 per share. Net proceeds from the equity offering were approximately $26.9 million after deducting public offering expenses. There currently remains $69.1 million available for future offerings under a shelf registration statement on Form S-3 filed with the U.S. Securities and Exchange Commission in August 2019 (the "Shelf"). During the second half of 2020, $39.1 million in principal amount of Convertible Notes were converted into 13,171,791 shares of the Company's common stock. As of September 30, 2021, 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. As of September 30, 2021, the outstanding balance under the Amended Loan Agreement was $43.5 million. Finally, as part of the Acquisition, we acquired $38.5 million cash on October 5, 2021.

For the three months ended September 30, 2021 and 2020, we reported net losses of $26.0 million and $16.0 million, respectively. For the nine months ended September 30, 2021 and 2020, we reported net losses of $71.9 million and $69.3 million, respectively. We have not been profitable since inception, and, as of September 30, 2021, our accumulated deficit was $409.3 million. In the near term, we expect to continue to incur significant expenses, operating losses and net losses as we:

- incur transaction and integration costs related to the acquisition of Strongbridge;
- continue our marketing and selling efforts related to commercialization of Gvoke and Keveyis;
- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements;
- prepare for the potential launch of Recorlev; 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.

Product developments

- Entered into a collaboration agreement with Merck Sharp & Dohme Corp., with an option to license Xeris' suspension-based formulation technology, XeriJect, for use with undisclosed monoclonal antibodies for the purpose of engineering ultra-high concentration, ready-to-use formulations.
- FDA accepted Investigational New Drug Application ("IND") for XeriSol Levothyroxine (XP-8121) for the treatment of hypothyroidism and completed enrollment of our Phase 1 Study.
- Received FDA approval of our Supplemental New Drug Application for our Gvoke Kit for the Treatment of Severe Hypoglycemia.

Impact of COVID-19

The current coronavirus ("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. Our third-party contract manufacturing partners continue to operate at or near normal levels, with enhanced safety measures intended to prevent the spread of the virus. While we currently do not anticipate any interruptions in our manufacturing process, it is possible that the COVID-19 pandemic and response efforts 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. Initially, we suspended in-person interactions by our sales and marketing personnel in healthcare settings. We were engaging with these customers remotely, via webinar programs and virtual meetings, as we sought to continue to support healthcare professionals and patient care. As parts of the country reopened, some of our sales and marketing personnel began to reengage with a limited number of in-person interactions. However, with the emergence of variants and, in some areas, lack of acceptance of vaccines, some areas implement or reintroduce restrictions, which may impact our sales and marketing personnel’s access to customers. Remote interactions generally are not as effective as in-person interactions. In addition, several conferences and other programs at which we intended to market our products have been postponed, canceled and/or transitioned to virtual meetings. We also have revised our Gvoke patient copay assistance program to offer a copay card with a buy-down to $0 for commercially eligible patients in response to the COVID-19 pandemic.

In addition to our sales and marketing personnel, we moved quickly to transition other employees to a remote work-from-home environment excluding essential services, such as personnel in our laboratory. We have since reopened our offices on a voluntary basis and have implemented safety measures designed to comply with applicable federal, state and local guidelines in response to the COVID-19 pandemic. We may be required to take additional actions that may impact our operations as required by applicable laws or regulations or which we determine to be in the best interests of our employees.

Xeris Pharma have incurred operating losses since inception, and we have an accumulated deficit of $409.3 million at September 30, 2021. Although we believe that our cash, cash equivalents, investments, and expected revenue from sales of Gvoke, Keveyis, and potentially Recorlev (if approved) 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. Given the impact of COVID-19 on the U.S. and global financial markets, we may be unable to access further equity or debt financing if and when needed.

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 Pharma for periods ended September 30, 2021 as well as factors that impact those items.

Net Sales

Net sales 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 includes primarily 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 incurred for Gvoke PFS and Gvoke HypoPen 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 Gvoke and as we have concluded ongoing clinical programs and not yet initiated any new studies. Following feedback from the FDA, we have decided not to advance our development program in Post-Bariatric Hypoglycemia ("PBH") due to the complexity and cost of a Phase 3 study design as proposed by the FDA. Also based on feedback from the FDA, we have decided not to move forward with a Phase 3 study for Exercise-Induced Hypoglycemia ("EIH"). We do anticipate filing an IND and potentially initiating a Phase 2 study in EIH in 2022 to examine the efficacy and safety of ready-to-use glucagon in a broader range of Type 1 and Type 2 patients that exercise at least twice a week.

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 cost of goods sold or research and development expenses. Our selling and marketing costs have increased significantly as we continue our marketing and selling efforts for Gvoke in the United States. We expect to continue to incur significant marketing and selling expenses in the near term related to the commercialization of Gvoke, Keveyis and Recorlev (if approved) 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 and Amended Loan Agreement, interest income earned on deposits and investments, and the change in fair value of our warrants.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	$ Change	2021	2020	$ Change
Net sales	$ 11,035	$ 9,404	$ 1,631	$ 27,921	$ 13,066	$ 14,855
Grant and other income	25	44	(19)	240	197	43
Cost of goods sold	3,220	2,832	388	8,429	5,921	2,508
Gross profit	7,840	6,616	1,224	19,732	7,342	12,390
Operating expenses:						
Research and development	5,663	3,876	1,787	15,078	15,811	(733)
Selling, general and administrative	26,535	16,484	10,051	71,539	55,734	15,805
Total operating expenses	32,198	20,360	11,838	86,617	71,545	15,072
Loss from operations	(24,358)	(13,744)	(10,614)	(66,885)	(64,203)	(2,682)
Other income (expense):						
Interest and other income	66	232	(166)	243	943	(700)
Interest expense	(1,798)	(2,328)	530	(5,384)	(6,069)	685
Change in fair value of warrants	81	(160)	241	91	(64)	155
Total other income (expense)	(1,651)	(2,256)	605	(5,050)	(5,190)	140
Net loss before benefit from income taxes	(26,009)	(16,000)	(10,009)	(71,935)	(69,393)	(2,542)
Benefit from income taxes	—	—	—	—	110	(110)
Net loss	$ (26,009)	$ (16,000)	$ (10,009)	$ (71,935)	$ (69,283)	$ (2,652)

Net Sales

We commercially launched Gvoke PFS and Gvoke HypoPen for the treatment of severe hypoglycemia in people with diabetes in November 2019 and July 2020, respectively. Total net sales were $11.0 million and $27.9 million for the three and nine months ended September 30, 2021, respectively, an increase of $1.6 million and $14.9 million compared to the same periods ended September 30, 2020, respectively. The increases in net sales for both periods were primarily due to increased demand for Gvoke.

Cost of Goods Sold

Cost of goods sold was $3.2 million for the three months ended September 30, 2021, an increase of $0.4 million compared to the three months ended September 30, 2020. Cost of goods sold was $8.4 million for the nine months ended September 30, 2021, an increase of $2.5 million compared to the nine months ended September 30, 2020, which is primarily made up of product cost on increased unit sales of $4.3 million, partially offset by lower excess and obsolete expense of $1.1 million as well as under-absorbed overhead costs of $0.8 million.

Research and Development Expenses

Research and development expenses increased by $1.8 million for the three months ended September 30, 2021 in comparison to the three months ended September 30, 2020. The increase was primarily driven by higher expenses associated with our clinical trials of $1.4 million and pharmaceutical process development costs of $0.8 million. Research and development expenses decreased by $0.7 million for the nine months ended September 30, 2021 in comparison to the nine months ended September 30, 2020. The decrease was primarily driven by a reduction in personnel-related costs of $1.2 million due to lower headcount and declines in expenses associated with our clinical trials of $0.7 million, partially offset by higher pharmaceutical process development costs of $1.3 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $10.1 million for the three months ended September 30, 2021 in comparison to the three months ended September 30, 2020. The increase was primarily driven by an increase of $6.5 million in personnel-related

costs due mainly to an increase in sales force headcount, transaction-related expenses of $2.3 million related to the Transactions and an increase in marketing and selling expenses of $2.0 million.

Selling, general and administrative expenses increased by $15.8 million for the nine months ended September 30, 2021 in comparison to the nine months ended September 30, 2020. The increase was primarily driven by an increase of $10.3 million in personnel-related costs due primarily to an increase in sales force headcount, transaction-related expenses of $6.2 million related to the Transactions and higher consulting expense of $0.6 million, partially offset by lower marketing and selling expenses of $2.0 million due to a decrease in advertising.

Other Income (Expense)

For the three and nine months ended September 30, 2021, interest and other income decreased by $0.2 million and $0.7 million in comparison to the same periods ended September 30, 2020, as a result of lower interest rates. In addition, for the three and nine months ended September 30, 2021, interest expense decreased by $0.5 million and $0.7 million in comparison to the same periods ended September 30, 2020, primarily due to lower interest expense on our bank debt due to lower amounts outstanding under the Amended Loan Agreement and $0.7 million expense related to the extinguishment of debt in June 2020, partially offset by interest on the convertible notes issued in the June 2020 offering.

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 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, which we refer to as the "Shelf". 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 September 30, 2021, 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 accessible upon the consummation of the Transactions, however, as of September 30, 2021, $69.1 million was still available for future offerings under the Shelf.

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 the Company’s 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 September 30, 2021, 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. As of September 30, 2021, the outstanding balance under the Amended Loan Agreement was $43.5 million. On May 3, 2021, we entered into a fifth amendment to the Amended Loan Agreement which provides that if we achieves a certain revenue milestone prior to November 30, 2021, then the period for interest-only payments is extended six months to July 2022 and the term loan will be payable in 24 equal monthly installments. If we achieve another revenue milestone prior to May 31, 2022, the period for interest-only payments is further extended three months to October 2022 and the term loan will be payable in 21 equal monthly installments. If the Company achieves a third revenue milestone by August 31, 2022, the period for interest-only payments is further extended three months, to January 2023 and the term loan will be payable in 18 equal monthly installments. We currently expects to achieve each revenue milestone and has therefore classified the amounts due under the Amended Loan Agreement as non-current on its balance sheet as of September 30, 2021.

We have incurred operating losses since inception, and we have an accumulated deficit of $409.3 million at September 30, 2021. Based on our current operating plans and existing working capital at September 30, 2021, 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 the potential launch of Recorlev (if approved) as well as and 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 and Keveyis and commercialization of our product candidates, if approved, 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:

- the successful integration of the Acquisition and achievement of expected revenue and synergies
- the costs of commercialization activities, including product marketing, sales and distribution;
- our degree of success in commercializing Gvoke, Keveyis and potentially Recorlev (if approved);
- 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 successfully integrate Strongbridge or achieve the expected level of revenue and synergies. Also, as we continue the marketing and selling of Gvoke and Keveyis, we may not generate a sufficient amount of product revenues 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 our product candidates, if approved. 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

	Nine Months Ended September 30,	
(**in thousands**)	**2021**	**2020**
Net cash used in operating activities	$ (66,589)	$ (69,689)
Net cash provided by (used in) investing activities	61,362	(34,654)
Net cash provided by financing activities	27,122	122,738

Operating activities

Net cash used in operating activities was $66.6 million for the nine-month period ended September 30, 2021, compared to $69.7 million for the nine-month period ended September 30, 2020. The decrease in net cash used in operating activities was primarily driven by a change in working capital. For a discussion regarding the change, 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 $61.4 million for the nine-month period ended September 30, 2021, compared to net cash used in investing activities of $34.7 million for the nine-month period ended September 30, 2020. The increase in cash provided by investing activities was primarily due to a greater number of investments maturing or being sold and invested in cash equivalents to fund operations.

Financing activities

Net cash provided by financing activities was $27.1 million for the nine-month ended September 30, 2021, compare to $122.7 million for the nine-month ended September 30, 2020. The decrease was primarily due to the net proceeds of $26.9 million from the March 2021 registered direct offering of our common stock, as compared to the net proceeds of $81.2 million from the June 2020 convertible debt offering, and the net proceeds of $39.9 million and $21.6 million from the February 2020 and June 2020 equity offerings of our common stock, respectively, partially offset by the $20.0 million pay down of principal on the Loan Agreement in June 2020.

Off-Balance Sheet Arrangements

As of September 30, 2021, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC, that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures, or capital resources.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES AND ASSUMPTIONS

Our Annual Report on Form 10-K for the year ended December 31, 2020 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, 2020.

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, principal 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 September 30, 2021 would increase or decrease interest income by approximately $0.9 million on an annual basis.

Long-term Debt—Our interest rate risk relates primarily to U.S. dollar LIBOR-indexed borrowings. Based on our outstanding borrowings under the Amended Loan Agreement at September 30, 2021, interest is incurred at a floating per annum rate in an amount equal to the sum of 6.25% plus the greater of (a) 2.43% and (b) the thirty-day U.S. Dollar LIBOR rate (or, the LIBOR replacement rate as applicable). A one-percentage point increase in interest rates would have no impact on interest expense on an annual basis as the thirty-day U.S. Dollar LIBOR rate at September 30, 2021 was 0.075%, which including a one-percent point increase would remain below 2.43%. 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 September 30, 2021, 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 nine months ended September 30, 2021.

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 September 30, 2021 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 September 30, 2021 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. We are providing the following information regarding updates to the previously disclosed risk factors in the SEC filings of Xeris Pharmaceuticals, Inc. and Strongbridge Biopharma plc prior to the consummation of the Acquisition and Merger. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized and described below are not intended to be exhaustive and are not the only risks facing us. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks Relating to the Integration of the Combined Company

We may not be able to successfully integrate and combine the businesses of Xeris Pharma and Strongbridge following the completion of the Transactions and we may not realize the anticipated benefits from the Transactions.

On October 5, 2021, we completed the previously announced Acquisition and Merger between Xeris Pharmaceuticals, Inc. ("Xeris Pharma") and Strongbridge Biopharma plc ("Strongbridge") as contemplated by the Transaction Agreement, dated as of May 24, 2021, by and among us, Xeris Pharma, Strongbridge and Wells MergerSub, Inc. (the "Transaction Agreement"). We entered into the Transaction Agreement with the expectation that the Transactions will result in various benefits, including certain cost savings and operational efficiencies or synergies. To realize these anticipated benefits, the businesses of Xeris Pharma and Strongbridge must be successfully integrated. Historically, Xeris Pharma and Strongbridge have been independent companies. The integration may be complex and time consuming and may require substantial resources and effort. If the companies are not successfully integrated, the anticipated benefits of the Transactions may not be realized fully (or at all) or may take longer to realize than expected. A variety of factors may adversely affect the combined company's ability to realize the currently expected operating synergies, savings and other benefits of the Transactions, including, without limitation:

- latent impacts resulting from the diversion of management team's attention from ongoing business concerns as a result of the devotion of management's attention to the Transactions;
- ongoing diversion of the attention of management from the operation of the combined company's business;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects;
- the possibility of faulty assumptions underlying expectations regarding the integration process, including with respect to the intended tax efficient transactions;
- unanticipated issues, costs and strained resources in integrating information technology, communications programs, financial procedures and operations, and other systems, procedures and policies;
- difficulties in managing a larger combined company, addressing differences in business culture and retaining key personnel and employees;
- unanticipated changes in applicable laws and regulations;
- uncertainty that employees may experience about their roles within the combined company, which may have an additional adverse effect on our ability to attract or retain key management personnel and other key employees;
- coordinating geographically separate organizations; and
- failure to otherwise integrate Xeris Pharma' and Strongbridge's respective businesses.

Some of these factors will be outside of our control and any one of them could result in increased costs and diversion of management's time and energy, as well as decreases in the amount of expected revenue which could materially impact our business, financial conditions and results of operations. The integration process and other disruptions resulting from the Transactions may also adversely affect our relationships with employees, suppliers, customers, licensors and others, and difficulties in integrating the separate businesses or regulatory functions could harm the reputation of the combined company. If we are not able to adequately address integration challenges, we may be unable to successfully integrate our operations or realize the anticipated benefits of the Transactions.

We will incur significant costs in connection with the integration of the combined company.

We are required to integrate a large number of processes, policies, procedures, operations, technologies and systems in connection with the consummation of the Transactions. While we have assumed that a certain level of expenses would be incurred in connection with the Transactions and post-merger activities, there are many factors beyond our control that could affect the total amount of, or the timing of, anticipated expenses with respect to the integration and implementation of the combined company.

There may also be additional unanticipated significant costs in connection with the Transactions that we may not recoup. These costs could reduce the benefits and additional revenue we expect to achieve from the Transactions. Although we expect that these benefits will offset the transaction expenses and implementation costs over time, this net benefit may not be achieved in the near term or at all.

Regulatory approvals of the Transactions may impose conditions that are not presently anticipated or that cannot be met.

At any time after the Transactions were consummated, the DOJ, the FTC or U.S. state attorneys general or foreign governmental authorities could take action under the antitrust laws in opposition to the Transactions, including imposing restrictions on our post-transaction operations. These actions could negatively affect our results of operations and financial condition as a combined company following completion of the Transactions. Any such requirements or restrictions may reduce the anticipated benefits of the Transactions, which could also have a material adverse effect on our and the combined company's business and cash flows, financial condition and results of operations.

The combined company may be exposed to increased litigation, which could have an adverse effect on the combined company's business and operations.

The combined company may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of our business and Strongbridge's business following the Transactions. Such litigation may have an adverse impact on the combined company's business and results of operations or may cause disruptions to the combined company's operations.

Risks Related to the Impact of the COVID-19 Coronavirus

Our business may be adversely affected by the ongoing coronavirus pandemic.

Our business could be adversely affected by health epidemics in regions where we have business activities and could cause significant disruption in the operations of third-party manufacturers and contract research organizations ("CROs") upon whom we rely, and for which we may not have adequate insurance coverage. For example, beginning in late 2019, the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, has evolved into a global pandemic. The coronavirus has spread to most regions of the world, and the global impact of the outbreak is continually evolving, particularly in light of new variants of COVID-19.

As a result of the coronavirus pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- We believe that the COVID-19 pandemic has had, and may continue to have, an adverse impact on demand for certain of our products due to government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures which may result in patients not visiting their healthcare providers or their pharmacies to get their prescriptions filled. Initially, we suspended in-person interactions by our sales and marketing personnel in healthcare settings. We were engaging with these customers remotely, via webinar programs and virtual meetings, as we sought to continue to support healthcare professionals and patient care. As parts of the country reopened, some of our sales and marketing personnel began to reengage with a limited number of in-person interactions. With the emergence of variants and, in some areas, lack of acceptance of vaccines, some areas implement or reintroduce restrictions, which may impact our sales and marketing personnel's access to customers. Remote interactions generally are not as effective as in-person interactions. In addition, several conferences and other programs at which we intended to market our products have been postponed, canceled and/or transitioned to virtual meetings. Remote interactions may be less effective than in-person interactions. In addition, due to the prioritization of healthcare resources toward pandemic efforts, even remote interactions may not be possible.
- We currently rely on third-party suppliers and contract manufacturing organizations ("CMOs") for the manufacturing of Gvoke, Keveyis, and Recorlev (if approved), as well as to perform third-party logistics functions, including warehousing and distribution of Gvoke, Keveyis, and Recorlev (if approved). In addition, we rely on third parties to perform quality testing and supply other goods and services to run our business. If any such third party in our supply chain for materials is adversely impacted by restrictions resulting from the COVID-19 pandemic or supply chain issues, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture commercial quantities of Gvoke.

- In March 2020, we closed our offices and requested that most of our personnel, including all of our administrative employees, work remotely, restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site and limited the number of staff in any given location. We have since reopened our offices on a voluntary basis and have implemented safety measures designed to comply with applicable federal, state and local guidelines in response to the COVID-19 pandemic. 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. We implemented certain measures to reduce spending and delayed or suspended projects. However, we may still not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from such measures due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected cost savings from such measures, our operating results and financial condition could be adversely affected.
- Although essential personnel in our laboratory currently remain on-site, they and other employees and contractors conducting research and development activities on our behalf may not be able to access our laboratory or conduct such activities for an extended period of time in the event of the closure of our offices or the offices of our contractors and/or the possibility that governmental authorities further modify current restrictions. As a result, this could delay timely completion of preclinical activities.
- We have previously and may in the future conduct clinical trials for product candidates in geographies which are affected by the coronavirus pandemic. Potential impacts of the coronavirus pandemic on our various clinical trials may include disruptions or delays in patient enrollment, standard study monitoring practices, sample shipments, data analysis and reporting of results due to changes in policies at various clinical sites or in federal, state, local or foreign laws, rules and regulations. Other impacts could include quarantines or other travel restrictions and prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials. Interruption or delays in the operations of the FDA could also impair our ability to discuss ongoing or future clinical programs. If the coronavirus pandemic continues, other aspects of our clinical trials could be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, and availability of clinical trial materials. It is unknown how long these pauses or disruptions could continue.
- 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 coronavirus pandemic and could result in delays to our clinical trials.
- The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of the coronavirus pandemic. 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, three vaccines for COVID-19 have received Emergency Use Authorization by the FDA and one 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 ultimate geographic spread of the disease, 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 several 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 commercially launched Gvoke PFS in November 2019 and Gvoke HypoPen in July 2020. Strongbridge commercially launched Keveyis in April 2017. We are in the early stages of commercializing our pharmaceutical products and have a limited operating history. Pharmaceutical 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 pharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to successfully complete the transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.
We have incurred significant losses in every fiscal year since inception. For the nine months ended September 30, 2021 and 2020, Xeris Pharma reported a net loss of $71.9 million and $69.3 million, respectively. In addition, our accumulated deficit as of September 30, 2021 was $409.3 million. Substantially all of our operating losses have resulted from costs incurred in connection with research and development, clinical and regulatory initiatives to obtain approvals for our product candidates and preparation for commercialization of Gvoke and more recently the commercial launch of Gvoke.

We expect to continue to incur significant operating expenses as we continue the commercialization of Gvoke and Keveyis, develop, enhance and commercialize new products (including Recorlev), 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:

- integrate the combined company;
- execute our Gvoke and Keveyis commercial strategies in the U.S.;
- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements;
- prepare for the potential launch of Recorlev; and
- continue to operate as a public company.

Gvoke was approved by the FDA for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages two years and above on September 10, 2019. In February 2021 the European Commission ("EC") granted marketing authorization and in April 2021 the United Kingdom's Medicines and Healthcare products Regulatory Agency approved Ogluo for the treatment of severe hypoglycemia in adults, adolescents, and children aged two years and over with diabetes mellitus. On July 19, 2021, we announced that we had entered into an exclusive agreement with Tetris Pharma Limited (“Tetris”) for the commercialization of Ogluo in the European Economic Area, United Kingdom, and Switzerland (the “Territory”). Under the terms of the applicable agreements, Xeris will be responsible for product supply and Tetris will be responsible for commercialization of Ogluo in the Territory. Subject to the terms and conditions set forth in the agreements, Xeris will receive up to $71 million in payments tied to the first commercial sale and other time-, launch- and sales-related milestones and collect a royalty on sales. Tetris expects to launch Ogluo in the United Kingdom by the end of 2021. Our ability to generate revenue from Gvoke and Keveyis and our product candidates and to transition to profitability and generate positive cash flows is uncertain and depends on the successful commercialization of Gvoke and Keveyis and our product candidates. 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 large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

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

Our ability to become profitable depends upon our ability to generate revenue. Our ability to generate revenue from Gvoke, Keveyis, and our product candidates (including Recorlev), 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;
- 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;
- launch and commercialize our products utilizing our own sales force or by entering into partnership or co-promotion arrangements with third parties; and
- successfully develop and obtain marketing approval for our product candidates.

We have incurred and expect to continue to incur significant sales and marketing costs as we commercialize Gvoke and Keveyis. Regardless of these expenditures, Gvoke and our product candidates, if approved, may not be commercially successful. Although we generate revenue from Gvoke and Keveyis, if we are unable to generate sufficient product revenue, we will not become profitable and may be unable to continue operations without continued 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.

Pharmaceutical 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 (if approved), and expect to continue to incur such expenses for Gvoke, Keveyis, as well as for any of our product candidates, if approved. We are currently advancing Recorlev through clinical development. While we expect that our costs associated with the clinical development of Recorlev will decrease as we complete the associated clinical trials, we expect that we will require additional capital to commercialize Recorlev if it is ultimately approved for marketing by the FDA, EMA or any comparable foreign regulatory agency. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. For example, due to the impacts of the COVID-19 pandemic on our business, including those discussed in the risk factor titled “Our business may be adversely affected by the ongoing coronavirus pandemic,” we applied for and received a Paycheck Protection Program Loan (the "PPP Loan") on April 22, 2020 for $5.1 million, of which $0.9 million was repaid on May 4, 2020 and the remaining $4.2 million on June 30, 2020. While we initiated a variety of cost reduction initiatives, we sought and obtained the PPP Loan due to our belief that such funds were necessary to support payroll costs, rent and utilities in order to avoid more drastic measures, such as deep workforce reductions, that would have likely significantly impaired our financial viability. 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.

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, the Amended and Restated Loan and Security Agreement dated September 10, 2019 (as amended, supplemented or otherwise modified from time to time, including by that certain First Amendment to the Amended and Restated Loan and Security Agreement dated April 21, 2020, that certain Second Amendment to Amended and Restated Loan and Security Agreement dated June 30, 2020, that certain Third Amendment to Amended and Restated Loan and Security Agreement dated August 5, 2020, that certain Fourth Amendment to the Amended and Restated Loan and Security Agreement dated October 23,

2020, that certain Fifth Amendment to Amended and Restated Loan and Security Agreement dated May 3, 2021, that certain Consent under Loan and Security Agreement dated May 24, 2021, and that certain Joinder and Sixth Amendment to Amended and Restated Loan and Security Agreement dated October 5, 2021, collectively, the "Amended Loan Agreement") with Oxford Finance LLC, as the collateral agent and a lender, and Silicon Valley Bank, as a lender, Xeris Biopharma Holdings, Inc., Xeris Pharmaceuticals, Inc. and Strongbridge U.S. Inc., we are restricted in our ability to incur additional indebtedness and to pay dividends but, in connection with our public notes offering, the Lenders consented to the Convertible Notes (defined below) offering as permitted convertible indebtedness. 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 Amended 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 Gvoke and Keveyis 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. Adequate additional financing may not be available to us on acceptable terms, or at all. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Any of these negative developments could have a material adverse effect on our business, operating results, financial condition and common stock price.

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

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 September 30, 2021, 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.

In addition, we have $43.5 million outstanding under our Amended Loan Agreement as of September 30, 2021. All obligations under our Amended 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 Amended 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 Amended Loan Agreement, including the Indenture. Affirmative covenants include the maintenance of a minimum cash balance of $5.0 million in an account with Silicon Valley Bank and, in the event that we also maintain one or more permitted accounts at other institutions, an additional amount equal to the outstanding obligations. Negative covenants include prohibition on the payment of dividends and distributions, certain mergers and change of control events, and restrictions on the incurrence of additional debt. In addition, the occurrence of material adverse changes in our business, including our prospect of repayment of our obligations, could result in an event of default. In the event of an acceleration of amounts due under our Amended 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.

We may be unable to raise the funds necessary to repurchase the Convertible Notes for cash following a fundamental change, and our existing and future indebtedness may limit our ability to repurchase the Convertible Notes.

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 Amended Loan Agreement. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Convertible Notes.

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.

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 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 products, Gvoke and Keveyis, in the United States. Our business and future success are substantially dependent on our ability to generate and increase product revenues in the near term. 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. We may not be able to successfully launch or commercialize our products or meet our expectations with respect to revenues. We commercially launched Keveyis in April 2017, Gvoke PFS, in November 2019, and Gvoke HypoPen in July 2020. There is no guarantee that the infrastructure, systems, processes, policies, relationships and materials we have built for the commercialization of Gvoke 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.

Even if all regulatory approvals are obtained, the commercial success of our products and product candidates, if approved, depends 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.

Our ability to successfully commercialize Recorlev (if approved) and any other product candidates for which we receive regulatory approval will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.

Our ability to successfully commercialize Recorlev (if approved) and any other product candidates for which we receive regulatory approval will depend, in part, on the extent to which coverage and reimbursement for these products will be available from government and health administration authorities, private health insurers and other third- party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new therapies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage and adequate reimbursement to such new technologies. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug

purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes of new technologies, we cannot be sure that coverage will be available for these products, and, if available, that the reimbursement rates will be adequate. If adequate levels of coverage and reimbursement for these products is unavailable, our ability to generate revenue from product sales and/or royalties will be compromised.

Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product, but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases on short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact such favorable coverage and reimbursement status. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

The unavailability or inadequacy of third-party coverage and reimbursement could negatively affect the market acceptance of Gvoke, Keveyis, Recorlev (if approved) and any product candidates for which we receive regulatory approval and the future revenues we may expect to receive from these products.

The market opportunity for Gvoke, Keveyis, Recorlev (if approved), and our product candidates may be smaller than we estimate.

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

Our company has limited experience marketing and selling drug products. 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 revenues 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 (if approved). In order to successfully commercialize Recorlev (if approved), and 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 Gvoke and Keveyis in the United States. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in our ability to maintain or expand, if needed, our internal sales, marketing and distribution capabilities would adversely impact the commercialization of Gvoke, Keveyis 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.

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

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

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 revenues. For example, as a result of the COVID-19 pandemic, 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 are establishing 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, Keveyis, and Recorlev (if approved) or our product candidates could harm our ability to develop our product candidates or to commercialize Gvoke, Keveyis, Recorlev (if approved) or any product candidates that are approved.

We do not currently own or operate manufacturing facilities for the production of Gvoke, Keveyis or our product candidates, including Recorlev. We rely on third-party suppliers to manufacture and supply our products. 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 Keveyis. 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 at the conclusion of the orphan exclusivity period, we will need to find a new third party to manufacture Keveyis or manufacture the product ourselves. We rely on other third parties to manufacture our product candidates for use in clinical trials and expect to rely on third-party manufacturers for commercial supply of Recorlev (if approved). 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.

Our third-party suppliers may not be able to produce sufficient inventory to meet commercial demand in a timely manner, or at all. Our third-party suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our products. As a result, there can be no assurances that we will be able to obtain sufficient quantities of products, including Gvoke, or other key materials in the future, which could have a material adverse effect on our business as a whole. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the manufacture of Gvoke, Keveyis, or development of our product candidates will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID-19 or treat its effects.

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

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 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 foreign regulatory authorities do not approve these facilities for the manufacture of Gvoke and if the FDA or such foreign regulatory authorities do not approve these facilities for the manufacture of our 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. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our research and development activities and our ability to develop our product candidates and market our products and any future products following approval.

There are a limited number of third-party suppliers that are compliant with cGMP and/or QSRs, as required by the FDA, the 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;
- 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; and
- our suppliers may encounter financial or other hardships unrelated to our demand for materials, products and services, which could inhibit their ability to fulfill our orders and meet our requirements.

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

If any CMOs with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or 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. We are also unable to predict how changing global economic conditions or global health concerns such as the COVID-19 pandemic will affect our third-party suppliers and manufacturers. 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. On March 27, 2020, former President Trump signed into law the CARES Act in response to the U.S. COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA's existing authority with respect to drug shortage measures. 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.

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

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

Our future revenues and profitability will be adversely affected if U.S. and foreign governmental, private third-party insurers and payors and other third-party payors, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities fail to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for some patients to afford them and physicians may not prescribe them. In addition, limitations on the amount of reimbursement for our products may also reduce our profitability. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. There have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our products or product candidates for which we obtain marketing approval. Government and other third-party payors are also challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain healthcare facilities. CMS altered the reimbursement formula for fiscal years 2018 and 2019, but the court ruled this change was not an "adjustment" that was within the Secretary's discretion to make. On May 6, 2019, the district court reiterated that the rate reduction exceeded the Secretary's authority and declared that the rate reduction for 2019 also exceeded the Secretary's authority and remanded the issue to the U.S. Department of Health and Human Services ("HHS") to devise an appropriate remedy. On July 10, 2019, the district court entered its final judgment and CMS filed an appeal. On July 31, 2020, the United States Court of Appeals for the District of Columbia Circuit ruled that CMS and HHS did not exceed their authority when it instituted the new reimbursement formula and reversed the judgment of the district court. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), and the court denied this Petition on October 16, 2020. Plaintiffs-appellees filed a petition for a writ of certiorari at the Supreme Court on February 10, 2021. On July 2, 2021, the Supreme Court granted the petition. It is unclear how this could affect covered hospitals who might purchase our products in the future and affect the rates we may charge such facilities for our approved products.

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 in some cases 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.

Market acceptance and sales of our products and product candidates that we develop, if approved, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. We cannot be certain that reimbursement will be available for any of our product candidates or that reimbursement rates will not change for our current products. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our products or product candidates.

In addition, 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 European Union 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. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. 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 European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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

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

At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, creating a process providing guidance for states to build and submit to the FDA importation plans for drugs from Canada, as further discussed below. Authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our products or product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and was intended to apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, on August 6, 2021 CMS announced a proposed rule to rescind the Most Favored Nations rule. On December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors have been delayed until January 1, 2023. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective and the Biden Administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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.

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

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

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.

The success of Gvoke, Keveyis, Recorlev (if approved) 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, 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, individual devices may fail. Increasing the scale of production inherently creates increased risk of manufacturing errors, and we may not be able to adequately inspect every device that is produced, and it is possible that individual devices may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of any of our products, result in negative press coverage, or increase the risk that we may be sued.

Guidelines and recommendations can reduce the use of our products.

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

Risks Related to our Dependence on Third Parties

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

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

We maintain compliance programs related to our clinical trials through our clinical operations and development personnel. 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.

If our third-party manufacturers of Gvoke, Keveyis, Recorlev (if approved) or our product candidates are unable to increase the scale of their production of our products or our product candidates, or increase the product yield of manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed or interrupted.

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

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

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

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

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

We may be adversely affected by any disruptions to third-party suppliers that manufacture and supply our products.

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, or any other cause could materially impair our ability to manufacture our products and to distribute our products to customers. We could incur significantly higher costs and longer lead times associated with distributing our products to our customers. If we are unable to arrange for third-party suppliers of our materials and products, or to do so on commercially reasonable terms, we may not be able to market our products or product candidates that may be approved in the future. Additionally, our business could be temporarily adversely affected by higher costs for materials, increased shipping and storage costs, increased labor costs, and scheduling issues. Any interruption in the production or delivery of our supplies could reduce sales of our products and increase our costs.

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.

We have submitted a NDA for Recorlev in the United States and will evaluate filing potentially elsewhere. We have determined, following FDA consultation, that the 505(b)(2) approval pathway, which permits an NDA applicant to rely on data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a Recorlev NDA. We are relying on published literature and safety information for ketoconazole in our NDA for Recorlev. There can be no assurances, however, that the 505(b)(2) approval pathway in the United States, or similar approval pathways outside of the United States, will be available for Recorlev or that the FDA or other regulatory authorities will approve Recorlev through an application based on such pathways.

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

We intend to utilize the 505(b)(2) pathway for the regulatory approval of certain of our product candidates. 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 will enable 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 might be required to be approved under the PHS Act rather than in a 505(b)(2) NDA. If our product candidates do not meet the requirements of Section 505(b)(2) or are otherwise ineligible for approval via the Section 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Some pharmaceutical companies and other actors have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA 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.

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.

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.

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

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

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates, competitive or comparator products or supportive care products or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in a trial;
- delays or failures in reaching agreement on acceptable terms with CROs and prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board ("IRB") to conduct a clinical trial at a prospective study site;
- receipt by a competitor of marketing approval for a product targeting an indication that our product candidate targets, such that we are not "first to market" with our product candidate;
- delays in recruiting or enrolling subjects to participate in a clinical trial, particularly with respect to our product candidates for certain rare indications, including those for which we have obtained, or plan to seek, orphan drug designation;
- failure of a clinical trial or clinical investigators to be in compliance with current Good Clinical Practices ("cGCPs");
- unforeseen safety issues;
- inability to monitor subjects adequately during or after treatment;
- difficulty monitoring multiple study sites;
- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;
- failure of our third-party clinical trial managers to satisfy their contractual duties, comply with regulations, or meet expected deadlines;
- determination by regulators that the clinical design of a trial is not adequate; and
- disruptions caused by global health concerns, such as the COVID-19 pandemic.

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

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

Further, conducting clinical trials in foreign countries, as we have done and 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.

Gvoke, Keveyis, Recorlev (if approved) 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. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. It is possible that there may be side effects associated with our product candidates' use. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential products liability claims. Any of these occurrences may harm our business, financial condition and prospects.

In our clinical trials of Recorlev to date, adverse events have included headache, nausea, back pain, dizziness, diarrhea and liver enzyme elevations among others. For veldoreotide, which is given by subcutaneous injections, adverse events have included injection site reaction such as swelling, itching and pain. Headache and gastrointestinal effects such as nausea and diarrhea have also been observed for veldoreotide. These adverse events can be dose-dependent and may increase in frequency and severity if we increase the dose to increase efficacy. Occurrence of serious treatment-related side effects could impede clinical trial enrollment, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA, EMA or any comparable foreign regulatory agency. They could also adversely affect physician or patient acceptance of our product candidates.

Even if our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products or Gvoke:

- 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 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 new chemical entity ("NCE") exclusivity in the marketing and sale of Recorlev, if approved. 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. 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. 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 and Keveyis in the United States and the EMA and MHRA approval of Ogluo in the European Union and the United Kingdom, 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 and Keveyis approved for sale in the United States, nor any products or product candidates other than Ogluo approved for sale in any international markets, and we do not have experience in obtaining regulatory approval in international markets outside of the European Union and the United Kingdom. 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.

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

In March 2010, former President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal AKS which include, among other things, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% effective January 1, 2019 pursuant to the Bipartisan Budget Act of 2018) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the requirements under the federal open payments program and its implementing regulations;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly known as the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate." However, as a result of tax reform legislation passed in December 2017, the individual mandate's penalty was decreased to $0, effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was decreased to $0 as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held the individual mandate is unconstitutional but remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. In March 2020, the U.S. Supreme Court agreed to hear this case, and oral arguments were held on November 10, 2020. Following an appeal made by certain defendants, on June 17, 2021, the U.S. Supreme Court dismissed the plaintiffs' challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

On October 13, 2017, former President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The Trump administration concluded that cost-sharing reduction ("CSR") payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what impact these rulings may have on our business.

In addition, CMS finalized regulations that gives states greater flexibility, as of 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Additionally, CMS finalized a rule, effective January 1, 2020, that allows Medicare Advantage Plans the option of using step therapy for Part B drugs. This final rule codified CMS's policy change that was effective January 1, 2019. It is unclear what effect such changes will have on our business. On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted including aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2030. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, and subsequent legislation, these reductions will be suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Since 2016, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing or delaying penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions.

Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in

payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The 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.

At the federal level, the former Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, in 2018, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition and increase the negotiating power of certain federal healthcare programs. The U.S. Department of Health and Human Services, or HHS, already started the process of soliciting feedback on some of these measures and is immediately implementing others under its existing authority. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for approved products. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our 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 could impair our ability to grow.

As part of our growth strategy, we intend to identify, develop and market additional product candidates leveraging our formulation technology platforms. We are exploring various therapeutic opportunities for our pipeline programs. We may spend several years completing our development of any particular current or future internal product candidates, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. Gvoke, which delivers ready-to-use glucagon via a pre-filled syringe or auto-injector, was approved by the FDA on September 10, 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 advance additional product candidates.

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

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

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

We may not be successful in executing our research programs or business development efforts.

Research programs and business development efforts to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs, business development efforts or licensing attempts may fail to yield additional complementary or successful product candidates for clinical development and commercialization, in which case we may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

Clinical trials are very expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and earlier clinical trials 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 studies and initial clinical trials. Furthermore, different countries have different standards of care and different levels of access to care for patients, which in part drives the heterogeneity of the patient populations that enroll in our studies.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of subjects or patients on time or be completed on schedule, if at all. There may be a limited patient pool for some of our product candidates, given our focus on addressing rare diseases.

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, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

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

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

- *False Claims Laws.* The federal civil and criminal false claims and civil monetary penalties laws, including the federal FCA, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using or causing to be made or used a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Companies that submit claims directly to payors also may be liable under the FCA for the direct submission of such claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.
- *Anti-Inducement Law.* The anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.
- *HIPAA.* The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In addition, HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- *Transparency Requirements.* The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to HHS information regarding any payment or other "transfer of value" made or distributed to healthcare professionals (currently defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the healthcare professionals and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners.
- *Analogous State and Foreign Laws*. Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, and are generally broad and are enforced by many different federal and state agencies as well as through private actions. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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, and imprisonment, 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.

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

We have personnel located in Ireland and have conducted and may in the future conduct clinical trials in the European Union ("EU") subjecting us to additional privacy restrictions. 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 Data Protection Act 2018 in the UK). This regulation imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data.

The GDPR also regulates the transfers of EU and European Economic Area ("EEA") individuals' personal data to other countries that have been deemed by the European Commission not to provide adequate protection to personal data. The U.S. is not deemed to have adequate laws to protect personal data. We had relied upon the EU-U.S. Privacy Shield program to legitimize certain transfers of personal data from the EU and EEA to the U.S. However, on July 16, 2020, the European Court of Justice ("ECJ") invalidated the EU-U.S. Privacy Shield program that we (along with thousands of other companies) have utilized to transfer data from the EU and EEA to the U.S. in compliance with GDPR. As a result of this decision, companies like us that previously relied upon Privacy Shield will be required to use another GDPR-approved method to legitimize transfers of personal data to the U.S. and other third countries in compliance with the GDPR. Although in its ruling about the Privacy Shield, the ECJ deemed that the Standard Contractual Clauses ("SCCs") approved by the European Commission for transfers of personal data between EU controllers and non-EU processors are valid, the Court also noted that transfers made pursuant to the SCCs need to be analyzed on a case-by-case basis to ensure EU standards of data protection are met in the jurisdiction where the data importer is based, and there continue to be concerns about whether the SCCs (including SCCs for controller-to-controller transfers) will face additional challenges. Further, EU member state data protection authorities are empowered to evaluate the adequacy of the SCCs adopted by businesses in any specific case and they are required to suspend or ban data transfers to a third country if, in the light of all the circumstances of that transfer, the SCCs are not or cannot be complied with in that country. Subsequent guidance published by the European Data Protection Board or EDPB on June 18, 2021 described what such supplementary measures must be, and stated that businesses should avoid or cease transfers of personal data if, in the absence of supplementary measures, equivalent protections cannot be afforded. On June 4, 2021, the European Commission published new versions of the SCCs, which seek to address the issues identified by the Court of Justice of the European Union's Schrems II decision and provide further details regarding the transfer assessments that the parties are required to conduct when implementing the New SCCs. However, there continue to be concerns about whether the SCCs and other mechanisms will face additional challenges. Until the remaining legal uncertainties regarding how to legally continue these transfers are settled, we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. This and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our products and services in some markets and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity, which could have an adverse effect on our reputation and business.

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. E.U. 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.

In addition, further to the United Kingdom's (UK) exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to

as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. 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. The UK, however, is now regarded as a third country under the EU's GDPR which means that transfers of personal data from the EEA to the UK will be restricted unless an appropriate safeguard, as recognized by the EU's GDPR, has been put in place. Although, under the EU-UK Trade Cooperation Agreement it is lawful to transfer personal data between the UK and the EEA for a six-month period following the end of the transition period, with a view to achieving an adequacy decision from the European Commission during that period. 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 (this means that personal data transfers from the UK to the EEA remain free flowing).

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. It is possible that over time the UK Data Protection Act could become less aligned with the EU General Data Protection Regulation, or GDPR, which could require us to implement different compliance measures for the UK and the European Union and result in potentially enhanced compliance obligations for EU personal data.

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

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

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

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

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

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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

Risks Related to 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 and governmental agencies and public and private research institutions. Many of our current and potential competitors are major pharmaceutical companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products

obsolete or noncompetitive. Our ability to compete successfully will depend on our ability to develop future products that reach the market in a timely manner, are well adopted by patients and healthcare providers and receive adequate coverage and reimbursement from third-party payors. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing products competitive to our product candidates.

For example, 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.

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

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, mexelitine and other sodium channel blockers, and others. We are not aware of drugs currently in development for prophylactic chronic treatment of PPP.

We are 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), all marketed by Recordati in the United States and European Union; and ketoconazole, metyrapone and mitotane marketed by HRA in the European Union. Corcept is developing relacorilant, a second-generation glucorticoid 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 exclusivity in the marketing and sale of Recorlev, if approved. 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 our proprietary product candidates and their use. 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.

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.

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

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

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. We have not conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, so we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our 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. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

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

We rely in part on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the

regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants, and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

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

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our 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 rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Intellectual Property Litigation

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

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

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

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

in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.

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 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.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods of treatment related to the use or manufacture of Gvoke, Keveyis or our product candidates. 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 or our product candidates. Because patent applications can take 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.

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

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

following:

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

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

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

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize 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).

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

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

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

Risks Related to 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. Patent reform legislation in the United States, including the Leahy-Smith America Invents Act ("America Invents Act") signed into law in September 2011, could increase those uncertainties and costs. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefining prior art and providing more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the America Invents Act reformed the United States patent law in part by changing the U.S. patent system from a “first to invent” system to a “first inventor to file” system. The America Invents Act, regulations promulgated under it, and court holdings interpreting the ACT 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.

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

Risks Related to Enforcement of Intellectual Property Rights

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.

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.

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.

Risks Related to Employee Matters, Managing Growth and Ongoing Operations

Risks Related to Ongoing Operations

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. Our products which are commercialized face greater risks and therefore, our risk will increase upon any commercialization by us of our product candidates. Any of these events could result in a claim of liability. Any such claims against us, regardless of their merit, could result in significant costs to defend or awards against us that could materially harm our business, financial condition or results of operations. In addition, any such claims against us could result in a distraction to management, decreased demand for our products, an adverse effect on our public reputation, and/or difficulties in commercializing our products. To date, we have not received notice of any 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.

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.

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

We hold a number of insurance policies, including products liability insurance, directors’ and officers’ liability insurance, general liability insurance, property insurance and workers’ compensation insurance and such policies contain customary conditions and exclusions. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Additionally, even if we maintain insurance coverage for a type of liability, a particular claim may not be covered if it is subject to a

coverage exclusion or we do not otherwise meet the conditions for coverage. If we operate our business without insurance, or with inadequate insurance, we could be responsible for paying claims or judgments against us, which could adversely affect our results of operations or financial condition.

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

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

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

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

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

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, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. 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 a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. 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. Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during

the COVID-19 pandemic in line with its user fee performance goals and conducting 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. 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.

Risks 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.

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.

Risks Related to Managing Growth

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

As of September 30, 2021, we had 325 employees. As we commercialize Gvoke, Keyevis, and development of our product candidates continues to progress, we may need to hire additional employees as required to add depth and specialized expertise to our team. This growth could place a strain on our administrative and operational infrastructure. If the product candidates that we are developing continue to advance in clinical trials, we will need to expand our development, regulatory, manufacturing, quality, compliance, recordkeeping, information technology, training, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to develop additional relationships with various collaborators, CROs, suppliers, manufacturers and other organizations. We may not be able to establish such relationships or may incur significant costs to do so. Our ability to manage our growth will also require us to continue to improve our operational, financial and management controls, reporting systems and procedures, and other compliance programs and processes, which will further increase our operating costs. Failure to manage our growth effectively could cause us to over-invest or under-invest in infrastructure and result in losses or weaknesses in our infrastructure, which could adversely affect us. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to monitor our suppliers carefully for quality assurance, and our business could suffer.

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

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

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

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

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

We do not know if we will be able to identify other suitable acquisitions, complete any such acquisitions on favorable terms or at all, successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to grow through acquisitions successfully depends upon our ability to identify, negotiate, complete and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time consuming and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to integrate any acquired businesses, products or technologies effectively, our business, results of operations and financial condition could be materially adversely affected.

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 or any of our product candidates, if approved;
- 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 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;
- 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.

If we are classified as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes, U.S. Holders of our ordinary shares may be subject to adverse U.S. federal income tax consequences..

A non-U.S. corporation generally will be classified as a PFIC for U.S. federal income tax purposes for any taxable year if either (1) 75% or more of its gross income for such year consists of certain types of "passive" income or (2) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. For

this purpose, "passive income" generally includes, among other items of income, dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income, and a non-U.S. corporation is treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which such non-U.S. corporation owns, directly or indirectly, more than 25% of the value of such other corporation's stock.

A U.S. Holder that holds ordinary shares during any taxable year in which we are a PFIC would be subject to substantially increased U.S. federal income tax liability, including upon the receipt of any "excess distributions" from us and upon the sale or other disposition of our ordinary shares. Although certain elections may be available to mitigate the adverse impact of the PFIC rules, such elections may result in a current U.S. federal tax liability prior to any distribution on or disposition of our ordinary shares. Further, there can be no assurances that we will supply U.S. Holders with information that such U.S. Holders are required to report under the rules governing such elections. Accordingly, the acquisition of our ordinary shares may not be an appropriate investment for certain holders that are not tax-exempt organizations. U.S. Holders should consult their tax advisers regarding the application of the PFIC rules to an investment in our ordinary shares.

Risks Related to Future Financial Condition

The conversion of any of the Convertible Notes into shares of common stock could have a dilutive effect that could cause our share price to go down.

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. During the second half of 2020, $39.1 million in principal amount of Convertible Notes were converted into 13,171,791 shares of the Company’s common stock. As of September 30, 2021, 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.

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

Risks Related to Tax

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

As of December 31, 2020, we had federal net operating loss carryforwards of $284.8 million and various state net operating loss carryforwards of $220.6 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 December 31, 2020. As of December 31, 2020, we had $8.0 million and $1.7 million of federal and state income tax credits, respectively, to reduce future tax liabilities. If not utilized, these carryforwards will expire at various dates between 2025 and 2038, 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. For example, on March 27, 2020, former President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. 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 any action asserting a claim against us that is governed by the internal affairs doctrine, and that the United States District Court for the District of Illinois will be the 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 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. While we will attempt to mitigate interruptions, we may experience difficulties in implementing some upgrades which would impact our business operations or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions of our information technology systems, we may not be able to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

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

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

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

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

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we face this type of litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

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.

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

Exhibit No.	Description
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.SCH+	Inline XBRL Taxonomy Extension Schema Document
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document
104+	Cover Page Interactive Data File (formatted in iXBRL and contained in Exhibit 101)

\+ 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.

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 hereunto duly authorized.

Xeris Biopharma Holdings, Inc.

Date: November 10, 2021

/s/ Paul R. Edick

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

Date: November 10, 2021

/s/ Steven M. Pieper

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

Exhibit 31.1

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: November 10, 2021

By: /s/ Paul R. Edick
Paul R. Edick
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: November 10, 2021

/s/ Steven M. Pieper
By: Steven M. Pieper
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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 September 30, 2021 (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: November 10, 2021

/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)