REFINITIV

DELTA REPORT

10-Q

XERS - XERIS BIOPHARMA HOLDINGS,

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	885
CHANGES	216
DELETIONS	323
ADDITIONS	346

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

(Mark One)

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

For the quarterly period ended June 30, 2023 September 30, 2023

or

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

For the transition period from _____ to _____

Commission file number: 001-40880

XERIS BIOPHARMA HOLDINGS, INC.

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

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

(844) 445-5704

(Registrant's telephone number, including area code)

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, $0.0001 par value per share	**XERS**	**The Nasdaq Global Select Market**

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

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

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

Large accelerated filer	☐	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 July 31, 2023 October 31, 2023, 138,065,993 138,124,595 shares, par value $0.0001 per share, of common stock were outstanding.

Summary of the Material Risks Associated with Our Business

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

- As a company, we have a limited operating history and limited experience commercializing pharmaceutical products and have incurred significant losses since inception. We may continue to incur losses over the next few years and may not be able to achieve or sustain revenues or profitability in the future.
- We may never be profitable and we may not be able to continue operations without additional fundings.
- We may require additional capital to sustain our business, and this capital may cause dilution to our stockholders and might not be available on terms favorable to us, or at all, which could force us to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our business depends entirely on the commercial success of our products and product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed.
- We operate in a competitive business environment, which may have an adverse impact on our revenue. If we are unable to compete successfully against our existing or 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.
- If we are unable to establish or do not maintain sufficient marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our products on terms acceptable to us, we may not be able to generate product revenue and our business, results of operations, and financial condition will be materially adversely affected.
- Our reliance on third-party suppliers, including single-source suppliers, together with a limited number of possible suppliers and long development lead-times for alternate sources for Gvoke, Keveyis, and Recorlev or our product candidates could harm our ability to develop our product candidates or to continue to commercialize Gvoke, Keveyis, Recorlev or any product candidates that are approved.
- Reimbursement decisions by third-party payors and consolidation within the healthcare industry and among competitors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used and pricing pressure may impact our ability to sell our products at prices necessary to support our current business strategies.
- Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates. If our clinical trials fail to demonstrate efficacy and safety to the satisfaction of the Food and Drug Administration ("FDA") or other regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.
- Gvoke, Keveyis, Recorlev and our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to include safety warnings, require them to be taken off the market or otherwise limit their sales.
- Our failure to successfully identify, develop and market additional product candidates, or acquire additional product candidates or enter into collaborations or other commercial agreements could impair our ability to grow.
- Our success depends on our ability to protect our intellectual property and proprietary formulation science, as well as the ability of our collaborators to protect their intellectual property and proprietary formulation science.
- Our stock price has been and will likely continue to be volatile, and you may lose part or all of your investment.
- Our data collection and processing activities are governed by restrictive regulations governing the use, processing and, in certain jurisdictions, cross-border transfer of personal information.

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

XERIS BIOPHARMA HOLDINGS, INC.

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

		June 30, 2023	December 31, 2022		September 30, 2023	December 31, 2022
Assets	**Assets**	(unaudited)		**Assets**	(unaudited)	
Current assets:	Current assets:			Current assets:		
Cash and cash equivalents	Cash and cash equivalents	$ 46,170	$ 121,966	Cash and cash equivalents	$ 46,143	$ 121,966
Short-term investments	Short-term investments	34,498	—	Short-term investments	19,832	—
Trade accounts receivable, net	Trade accounts receivable, net	30,225	30,830	Trade accounts receivable, net	45,966	30,830
Inventory	Inventory	36,538	24,735	Inventory	38,143	24,735
Prepaid expenses and other current assets	Prepaid expenses and other current assets	8,310	9,287	Prepaid expenses and other current assets	7,967	9,287
Total current assets	Total current assets	155,741	186,818	Total current assets	158,051	186,818
Property and equipment, net	Property and equipment, net	6,552	5,516	Property and equipment, net	6,185	5,516
Operating lease right-of-use assets	Operating lease right-of-use assets	23,632	3,992	Operating lease right-of-use assets	23,407	3,992
Goodwill	Goodwill	22,859	22,859	Goodwill	22,859	22,859
Intangible assets, net	Intangible assets, net	115,186	120,607	Intangible assets, net	112,475	120,607
Other assets	Other assets	4,808	4,730	Other assets	4,807	4,730

Total assets	Total assets	$ 328,778	$ 344,522	Total assets	$ 327,784	$ 344,522
Liabilities and Stockholders' Equity	**Liabilities and Stockholders' Equity**			**Liabilities and Stockholders' Equity**		
Current liabilities:	Current liabilities:			Current liabilities:		
Accounts payable	Accounts payable	$ 11,621	$ 4,606	Accounts payable	$ 12,078	$ 4,606
Current operating lease liabilities	Current operating lease liabilities	1,935	1,580	Current operating lease liabilities	2,366	1,580
Other accrued liabilities	Other accrued liabilities	19,413	36,786	Other accrued liabilities	19,073	36,786
Accrued trade discounts and rebates	Accrued trade discounts and rebates	17,034	16,818	Accrued trade discounts and rebates	21,554	16,818
Accrued returns reserve	Accrued returns reserve	11,320	11,173	Accrued returns reserve	13,328	11,173
Current portion of contingent value rights	Current portion of contingent value rights	16,637	—	Current portion of contingent value rights	17,517	—
Other current liabilities	Other current liabilities	1,718	2,658	Other current liabilities	1,123	2,658
Total current liabilities	Total current liabilities	79,678	73,621	Total current liabilities	87,039	73,621
Long-term debt, net of unamortized debt issuance costs	Long-term debt, net of unamortized debt issuance costs	188,182	187,075	Long-term debt, net of unamortized debt issuance costs	190,423	187,075
Non-current operating lease liabilities	Non-current operating lease liabilities	34,871	9,402	Non-current operating lease liabilities	35,154	9,402
Non-current contingent value rights	Non-current contingent value rights	6,911	25,688	Non-current contingent value rights	5,099	25,688
Deferred tax liabilities	Deferred tax liabilities	2,843	3,518	Deferred tax liabilities	2,504	3,518
Other liabilities	Other liabilities	2,652	31	Other liabilities	3,700	31
Total liabilities	Total liabilities	315,137	299,335	Total liabilities	323,919	299,335
Commitments and contingencies (Note 15)	Commitments and contingencies (Note 15)			Commitments and contingencies (Note 15)		
Stockholders' equity:	Stockholders' equity:			Stockholders' equity:		
Preferred stock—par value $0.0001, 25,000,000 shares and 25,000,000 shares authorized and no shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively		—	—			
Common stock—par value $0.0001, 350,000,000 shares and 350,000,000 shares authorized as of June 30, 2023 and December 31, 2022, respectively; 138,012,130 and 136,273,090 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively		14	14			

Preferred stock—par value $0.0001, 25,000,000 shares and 25,000,000 shares authorized and no shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively					Preferred stock—par value $0.0001, 25,000,000 shares and 25,000,000 shares authorized and no shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Common stock—par value $0.0001, 350,000,000 shares and 350,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 138,067,806 and 136,273,090 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively					Common stock—par value $0.0001, 350,000,000 shares and 350,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 138,067,806 and 136,273,090 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	14	14
Additional paid in capital	Additional paid in capital	605,151		599,966	Additional paid in capital	607,536	599,966
Accumulated deficit	Accumulated deficit	(591,446)		(554,770)	Accumulated deficit	(603,635)	(554,770)
Accumulated other comprehensive loss	Accumulated other comprehensive loss	(78)		(23)	Accumulated other comprehensive loss	(50)	(23)
Total stockholders' equity	Total stockholders' equity	13,641		45,187	Total stockholders' equity	3,865	45,187
Total liabilities and stockholders' equity	Total liabilities and stockholders' equity	$ 328,778		$ 344,522	Total liabilities and stockholders' equity	$ 327,784	$ 344,522

See accompanying notes to condensed consolidated financial statements.

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

		Three Months Ended June 30,		Six Months Ended June 30,			Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022		2023	2022	2023	2022
Product revenue, net	Product revenue, net	$ 36,893	$ 25,260	$ 69,158	$ 47,170	Product revenue, net	$ 41,697	$ 29,554	$ 110,855	$ 76,724
Royalty, contract and other revenue	Royalty, contract and other revenue	1,115	46	2,046	209	Royalty, contract and other revenue	6,623	171	8,669	380
Total revenue	Total revenue	38,008	25,306	71,204	47,379	Total revenue	48,320	29,725	119,524	77,104
Costs and expenses:	Costs and expenses:					Costs and expenses:				
Cost of goods sold	Cost of goods sold	7,555	4,810	12,874	11,083	Cost of goods sold	8,201	5,260	21,075	16,343

Research and development	6,087	3,718	10,925	9,968	Research and development	5,034	6,043	15,959	16,011
Selling, general and administrative	37,635	32,984	71,240	68,897	Selling, general and administrative	37,287	34,491	108,527	103,388
Amortization of intangible assets	2,710	2,710	5,421	5,421	Amortization of intangible assets	2,711	2,711	8,132	8,132
Total costs and expenses	53,987	44,222	100,460	95,369	Total costs and expenses	53,233	48,505	153,693	143,874
Loss from operations	(15,979)	(18,916)	(29,256)	(47,990)	Loss from operations	(4,913)	(18,780)	(34,169)	(66,770)
Other income (expense):					Other income (expense):				
Interest and other income	1,223	195	2,523	263	Interest and other income	1,121	472	3,644	735
Loss on debt extinguishment, net					Loss on debt extinguishment, net	(2,837)	—	(2,837)	(1,223)
Interest expense	(6,528)	(3,448)	(12,744)	(6,969)	Interest expense	(6,847)	(3,989)	(19,591)	(9,735)
Change in fair value of warrants	(14)	516	(14)	1,737	Change in fair value of warrants	17	9	3	1,746
Change in fair value of contingent value rights	781	(4,871)	2,140	(7,687)	Change in fair value of contingent value rights	932	118	3,072	(7,569)
Total other expense	(4,538)	(7,608)	(8,095)	(12,656)	Total other expense	(7,614)	(3,390)	(15,709)	(16,046)
Net loss before benefit from income taxes	(20,517)	(26,524)	(37,351)	(60,646)	Net loss before benefit from income taxes	(12,527)	(22,170)	(49,878)	(82,816)
Benefit from income taxes	675	339	675	747	Benefit from income taxes	338	339	1,013	1,086
Net loss	$ (19,842)	$ (26,185)	$ (36,676)	$ (59,899)	Net loss	$ (12,189)	$ (21,831)	$ (48,865)	$ (81,730)
Other comprehensive loss, net of tax:					Other comprehensive loss, net of tax:				
Unrealized gains (losses) on investments	(49)	14	(55)	(21)	Unrealized gains (losses) on investments	28	16	(27)	(5)
Foreign currency translation adjustments					Foreign currency translation adjustments	—	(1)	—	(1)
Comprehensive loss	$ (19,891)	$ (26,171)	$ (36,731)	$ (59,920)	Comprehensive loss	$ (12,161)	$ (21,816)	$ (48,892)	$ (81,736)
Net loss per common share - basic and diluted	$ (0.14)	$ (0.19)	$ (0.27)	$ (0.44)	Net loss per common share - basic and diluted	$ (0.09)	$ (0.16)	$ (0.36)	$ (0.60)
Weighted average common shares outstanding - basic and diluted	137,338,071	135,529,968	137,250,465	135,282,749	Weighted average common shares outstanding - basic and diluted	138,059,781	135,951,761	137,523,202	135,508,203

See accompanying notes to condensed consolidated financial statements.

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

		Common Stock		Additional Paid In	Accumulated Other Comprehensive		Total Stockholders'			Common Stock		Additional Paid In	Accumulated Other Comprehensive		T Stock
		Shares	Amount	Capital	Loss	Accumulated Deficit	Equity		Shares	Amount	Capital	Loss	Accumulated Deficit	E
Balance, December 31, 2021	Balance, December 31, 2021	124,873,316	$ 13	$ 555,359	$ (31)	$ (460,110)	$ 95,231	Balance, December 31, 2021	124,873,316	$ 13	$ 555,359	$ (31)	$ (460,110)	$
Net loss	Net loss	—	—	—	—	(33,714)	(33,714)	Net loss	—	—	—	—	(33,714)	
Issuance of common stock related to Armistice equity offering	Issuance of common stock related to Armistice equity offering	10,238,908	1	29,999	—	—	30,000	Issuance of common stock related to Armistice equity offering	10,238,908	1	29,999	—	—	
Issuance of warrants related to loan agreement	Issuance of warrants related to loan agreement	—	—	2,080	—	—	2,080	Issuance of warrants related to loan agreement	—	—	2,080	—	—	
Exercise of stock options	Exercise of stock options	11,228	—	8	—	—	8	Exercise of stock options	11,228	—	8	—	—	
Vesting of restricted stock units (net of 197,257 shares withheld for tax)	Vesting of restricted stock units (net of 197,257 shares withheld for tax)	404,743	—	(416)	—	—	(416)	Vesting of restricted stock units (net of 197,257 shares withheld for tax)	404,743	—	(416)	—	—	
Stock-based compensation	Stock-based compensation	—	—	3,301	—	—	3,301	Stock-based compensation	—	—	3,301	—	—	
Other comprehensive loss	Other comprehensive loss	—	—	—	(35)	—	(35)	Other comprehensive loss	—	—	—	(35)	—	
Balance, March 31, 2022	Balance, March 31, 2022	135,528,195	$ 14	$ 590,331	$ (66)	$ (493,824)	$ 96,455	Balance, March 31, 2022	135,528,195	$ 14	$ 590,331	$ (66)	$ (493,824)	$
Net loss	Net loss	—	—	—	—	(26,185)	(26,185)	Net loss	—	—	—	—	(26,185)	
Exercise of stock options	Exercise of stock options	2,561	—	(3)	—		(3)	Exercise of stock options	2,561	—	(3)	—		
Vesting of restricted stock units (net of 1,317 shares withheld for tax)	Vesting of restricted stock units (net of 1,317 shares withheld for tax)	—	—	—	—	—	—	Vesting of restricted stock units (net of 1,317 shares withheld for tax)	—	—	—	—	—	
Stock-based compensation	Stock-based compensation	—	—	3,152	—	—	3,152	Stock-based compensation	—	—	3,152	—	—	
Issuance of common stock through employee stock purchase plan	Issuance of common stock through employee stock purchase plan	389,987	—	510	—	—	510	Issuance of common stock through employee stock purchase plan	389,987	—	510	—	—	
Other comprehensive loss	Other comprehensive loss	—	—	—	14	—	14	Other comprehensive loss	—	—	—	14	—	
Balance, June 30, 2022	Balance, June 30, 2022	135,920,743	$ 14	$ 593,990	$ (52)	$ (520,009)	$ 73,943	Balance, June 30, 2022	135,920,743	$ 14	$ 593,990	$ (52)	$ (520,009)	$
Net loss								Net loss	—	—	—	—	(21,831)	

Vesting of restricted stock units (net of 19,007 shares withheld for tax)								Vesting of restricted stock units (net of 19,007 shares withheld for tax)	40,809	—	(28)	—	—	
Stock-based compensation								Stock-based compensation	—	—	2,941	—	—	
Other comprehensive loss								Other comprehensive loss	—	—	—	15	—	
Balance, September 30, 2022								Balance, September 30, 2022	135,961,552	$ 14	$ 596,903	$ (37)	$ (541,840)	$

		Common Stock		Additional Paid In	Accumulated Other Comprehensive		Total Stockholders'		Common Stock		Additional Paid In	Accumulated Other Comprehensive		T
		Shares	Amount	Capital	Loss	Accumulated Deficit	Equity		Shares	Amount	Capital	Loss	Accumulated Deficit	Stock E
Balance, December 31, 2022	Balance, December 31, 2022	136,273,090	$ 14	$ 599,966	$ (23)	$ (554,770)	$ 45,187	Balance, December 31, 2022	136,273,090	$ 14	$ 599,966	$ (23)	$ (554,770)	$
Net loss	Net loss	—	—	—	—	(16,834)	(16,834)	Net loss	—	—	—	—	(16,834)	
Vesting of restricted stock units (net of 743,677 shares withheld for tax)	Vesting of restricted stock units (net of 743,677 shares withheld for tax)	1,018,187	—	(863)	—	—	(863)	Vesting of restricted stock units (net of 743,677 shares withheld for tax)	1,018,187	—	(863)	—	—	
Stock-based compensation	Stock-based compensation	—	—	2,564	—	—	2,564	Stock-based compensation	—	—	2,564	—	—	
Other comprehensive loss	Other comprehensive loss	—	—	—	(6)	—	(6)	Other comprehensive loss	—	—	—	(6)	—	
Balance, March 31, 2023	Balance, March 31, 2023	137,291,277	$ 14	$ 601,667	$ (29)	$ (571,604)	$ 30,048	Balance, March 31, 2023	137,291,277	$ 14	$ 601,667	$ (29)	$ (571,604)	$
Net loss	Net loss	—	—	—	—	(19,842)	(19,842)	Net loss	—	—	—	—	(19,842)	
Exercise of stock options	Exercise of stock options	14,036	—	32	—	—	32	Exercise of stock options	14,036	—	32	—	—	
Vesting of restricted stock units (net of 13,525 shares withheld for tax)	Vesting of restricted stock units (net of 13,525 shares withheld for tax)	129,033	—	(25)	—	—	(25)	Vesting of restricted stock units (net of 13,525 shares withheld for tax)	129,033	—	(25)	—	—	
Stock-based compensation	Stock-based compensation	—	—	2,928	—	—	2,928	Stock-based compensation	—	—	2,928	—	—	
Issuance of common stock through employee stock purchase plan	Issuance of common stock through employee stock purchase plan	577,784	—	549	—	—	549	Issuance of common stock through employee stock purchase plan	577,784	—	549	—	—	
Other comprehensive loss	Other comprehensive loss	—	—	—	(49)	—	(49)	Other comprehensive loss	—	—	—	(49)	—	
Balance, June 30, 2023	Balance, June 30, 2023	138,012,130	$ 14	$ 605,151	$ (78)	$ (591,446)	$ 13,641	Balance, June 30, 2023	138,012,130	$ 14	$ 605,151	$ (78)	$ (591,446)	$
Net loss								Net loss	—	—	—	—	(12,189)	
Vesting of restricted stock units (net of 28,000 shares withheld for tax)								Vesting of restricted stock units (net of 28,000 shares withheld for tax)	55,676	—	(72)	—	—	

Stock-based compensation	Stock-based compensation	—	—	2,457	—	—
Other comprehensive loss	Other comprehensive loss	—	—	—	28	—
Balance, September 30, 2023	Balance, September 30, 2023	138,067,806	$ 14	$ 607,536	$ (50)	$ (603,635) $

See accompanying notes to condensed consolidated financial statements.

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

		Six Months Ended June 30,			Nine Months Ended September 30,			
		2023	2022		2023		2022	
Cash flows from operating activities:	Cash flows from operating activities:			Cash flows from operating activities:				
Net loss	Net loss	$ (36,676)	$ (59,899)	Net loss	$ (48,865)		$ (81,730)	
Adjustments to reconcile net loss to net cash used in operating activities:	Adjustments to reconcile net loss to net cash used in operating activities:			Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	Depreciation	750	673	Depreciation	1,141		1,033	
Amortization of intangible assets	Amortization of intangible assets	5,421	5,421	Amortization of intangible assets	8,132		8,132	
Amortization of premium/discount on investments	Amortization of premium/discount on investments	(812)	129	Amortization of premium/discount on investments	(1,117)		148	
Amortization of debt discount and debt issuance costs	Amortization of debt discount and debt issuance costs	1,107	673	Amortization of debt discount and debt issuance costs	1,678		1,111	
Amortization of operating right-of-use assets	Amortization of operating right-of-use assets	373	—	Amortization of operating right-of-use assets	628		—	
Stock-based compensation	Stock-based compensation	5,492	6,453	Stock-based compensation	7,949		9,394	
Loss on extinguishment of debt	Loss on extinguishment of debt	—	1,223	Loss on extinguishment of debt	2,837		1,223	
Loss on disposal of property and equipment						Loss on disposal of property and equipment	321	236
Change in fair value of warrants	Change in fair value of warrants	14	(1,737)	Change in fair value of warrants	(3)		(1,746)	
Change in fair value of contingent value rights	Change in fair value of contingent value rights	(2,140)	7,687	Change in fair value of contingent value rights	(3,072)		7,569	
Changes in operating assets and liabilities:	Changes in operating assets and liabilities:			Changes in operating assets and liabilities:				
Trade accounts receivable	Trade accounts receivable	605	(8,300)	Trade accounts receivable	(15,136)		(10,062)	
Prepaid expenses and other current assets	Prepaid expenses and other current assets	827	(921)	Prepaid expenses and other current assets	1,170		(2,758)	
Inventory	Inventory	(11,250)	(305)	Inventory	(13,403)		(1,960)	
Accounts payable	Accounts payable	7,015	(2,293)	Accounts payable	7,312		(5,008)	

Other accrued liabilities	Other accrued liabilities	(11,206)	(12,478)	Other accrued liabilities	(12,005)	(12,135)
Accrued trade discounts and rebates	Accrued trade discounts and rebates	216	(198)	Accrued trade discounts and rebates	4,736	4,280
Accrued returns reserve	Accrued returns reserve	147	1,210	Accrued returns reserve	2,155	3,277
Supply agreement liabilities	Supply agreement liabilities	(6,720)	(5,280)	Supply agreement liabilities	(6,720)	(5,280)
Operating lease liabilities	Operating lease liabilities	5,961	—	Operating lease liabilities	6,645	—
Other	Other	992	(1,076)	Other	1,123	(2,496)
Net cash used in operating activities	Net cash used in operating activities	(39,884)	(69,018)	Net cash used in operating activities	(54,494)	(86,772)
Cash flows from investing activities:	Cash flows from investing activities:			Cash flows from investing activities:		
Capital expenditures	Capital expenditures	(1,786)	(216)	Capital expenditures	(2,131)	(392)
Purchases of investments	Purchases of investments	(43,741)	—	Purchases of investments	(43,741)	—
Sales and maturities of investments	Sales and maturities of investments	10,000	18,800	Sales and maturities of investments	25,000	25,685
Net cash (used in) provided by investing activities	Net cash (used in) provided by investing activities	(35,527)	18,584	Net cash (used in) provided by investing activities	(20,872)	25,293
Cash flows from financing activities:	Cash flows from financing activities:			Cash flows from financing activities:		
Proceeds from equity offerings	Proceeds from equity offerings	—	30,000	Proceeds from equity offerings	—	30,000
Proceeds from issuance of debt	Proceeds from issuance of debt	—	97,295	Proceeds from issuance of debt	—	97,295
Repayment of debt	Repayment of debt	—	(43,496)	Repayment of debt	—	(43,496)
Payments of debt issuance costs	Payments of debt issuance costs	—	(4,657)	Payments of debt issuance costs	—	(4,816)
Payments for loss on extinguishment of debt	Payments for loss on extinguishment of debt	—	(737)	Payments for loss on extinguishment of debt	—	(737)
Proceeds from issuance of employee stock purchase plan shares	Proceeds from issuance of employee stock purchase plan shares	549	510	Proceeds from issuance of employee stock purchase plan shares	549	510
Proceeds from exercise of stock awards	Proceeds from exercise of stock awards	32	8	Proceeds from exercise of stock awards	32	8
Repurchase of common stock withheld for taxes	Repurchase of common stock withheld for taxes	(888)	(419)	Repurchase of common stock withheld for taxes	(960)	(447)
Net cash (used in) provided by financing activities	Net cash (used in) provided by financing activities	(307)	78,504	Net cash (used in) provided by financing activities	(379)	78,317
Effect of exchange rate changes on cash, cash equivalents and restricted cash		—	(1)			
Increase in cash, cash equivalents and restricted cash	Increase in cash, cash equivalents and restricted cash	(75,718)	28,069	Increase in cash, cash equivalents and restricted cash	(75,745)	16,838
Cash, cash equivalents and restricted cash, beginning of year	Cash, cash equivalents and restricted cash, beginning of year	126,314	67,271	Cash, cash equivalents and restricted cash, beginning of year	126,314	67,271

Cash, cash equivalents and restricted cash, end of year	Cash, cash equivalents and restricted cash, end of year	$ 50,596	$ 95,340	Cash, cash equivalents and restricted cash, end of year	$ 50,569		$ 84,109

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

		Six Months Ended June 30,			Nine Months Ended September 30,		
		2023	2022		2023		2022
Supplemental schedule of cash flow information:	Supplemental schedule of cash flow information:			Supplemental schedule of cash flow information:			
Cash paid for interest	Cash paid for interest	$ 15,206	$ 4,767	Cash paid for interest	$ 22,065		$ 7,689
Supplemental schedule of non-cash activities:	Supplemental schedule of non-cash activities:			Supplemental schedule of non-cash activities:			
Issuance of warrants related to loan agreement	Issuance of warrants related to loan agreement	$ —	$ 2,080	Issuance of warrants related to loan agreement	$ —		$ 2,080
Initial operating lease right-of-use assets for adoption of ASU 2016-02	Initial operating lease right-of-use assets for adoption of ASU 2016-02	$ —	$ (6,277)	Initial operating lease right-of-use assets for adoption of ASU 2016-02	$ —		$ (6,277)
Initial current and non-current operating lease liabilities for adoption of ASU 2016-02	Initial current and non-current operating lease liabilities for adoption of ASU 2016-02	$ —	$ 14,013	Initial current and non-current operating lease liabilities for adoption of ASU 2016-02	$ —		$ 14,013
Accrued debt issuance costs					Accrued debt issuance costs	$ 1,007	$ —
Settlement agreement with debt and warrant holders accounted for as extinguishment and re issuance of debt:					Settlement agreement with debt and warrant holders accounted for as extinguishment and re issuance of debt:		
Extinguishment of convertible note					Extinguishment of convertible note	$ (31,975)	$ —
Issuance of convertible note					Issuance of convertible note	$ 33,574	$ —

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

		As of June 30,			As of September 30,	
		2023	2022		2023	2022
Cash flows from operating activities:	Cash flows from operating activities:			Cash flows from operating activities:		
Cash and cash equivalents	Cash and cash equivalents	$ 46,170	$ 95,340	Cash and cash equivalents	$ 46,143	$ 84,109

Restricted cash included in Other assets [1]	Restricted cash included in Other assets [1]	4,426	—	Restricted cash included in Other assets [1]	4,426	—
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 50,596	$ 95,340	Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 50,569	$ 84,109

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

See accompanying notes to condensed consolidated financial statements.

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
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Note 1. Organization and nature of the business

Nature of business

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

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

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

Liquidity and capital resources

The Company has incurred operating losses since inception and has an accumulated deficit of $591.4 million $603.6 million as of June 30, 2023 September 30, 2023. The Company expects to continue to incur net losses for at least the next 12 months beyond the issuance date of these condensed consolidated financial statements. Based on the Company's current operating plans, existing working capital at June 30, 2023 September 30, 2023, the Company believes that its cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months from the issuance date of these condensed consolidated financial statements.

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

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

Basis of presentation

The condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), including those for interim financial information, and with the instructions for Quarterly Reports on Form 10-Q and Article 10 of Regulation S-X issued by the U.S. Securities and Exchange Commission (the "SEC").

In the opinion of management, the accompanying condensed consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair presentation of the Company's financial position, results of operations and cash flows for the periods presented. The results of operations for such periods are not necessarily indicative of the results that may be expected for any future period. The accompanying financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2023.

Certain information and disclosures normally included in the annual financial statements prepared in accordance with GAAP, but that is not required for interim reporting purposes, have been condensed or omitted.

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

XERIS BIOPHARMA HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
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Basis of consolidation

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

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses included in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue recognition

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

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

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

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

Such revenue is reported as product revenue, net in the condensed consolidated statements of operations and comprehensive loss.

Additionally, the Company earns revenue from research collaborations for the use of Xeris' proprietary formulation technology platforms and royalties from branded products. Such revenue is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured. This revenue is reported as royalty, contract and other revenue in the condensed consolidated statements of operations and comprehensive loss.

Concentration of credit risk

For the three and six nine months ended June 30, 2023 September 30, 2023, four customers accounted for 98% and 97% of the Company's gross product revenue, respectively. For the three and nine months ended September 30, 2022, the same four customers accounted for 97% and 96% of the Company's gross product revenue, respectively. For the three and six months ended June 30, 2022, the same four customers accounted for 98% and 96% of the Company's gross product revenue, respectively. At June 30, 2023 September 30, 2023 and December 31, 2022, the same four customers accounted for 97% 86% and 99% of the trade accounts receivable, net, respectively.

New accounting pronouncements

Adopted accounting standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard requires entities to estimate an expected lifetime credit loss on financial assets ranging from short-term trade accounts receivable to long-term financings and report credit losses using an expected losses model rather than the incurred losses model that was previously used and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if the fair value increases. This standard would have been effective for the Company for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The effective date of ASC Topic 326 was then delayed until fiscal years beginning after December 15, 2022 for SEC filers that are eligible to be smaller reporting companies under the SEC's definition, as well as private companies and not-for-profit entities. The Company adopted this standard beginning on January 1, 2023, and it did not have a material impact on the financial statements.

Pending accounting standards

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,

XERIS BIOPHARMA HOLDINGS, INC.
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expands the disclosure requirements related to the terms and features of convertible instruments, and amends the guidance for the derivatives scope exception for contracts settled in an entity's own equity. This standard enhances the consistency of earnings-per-share ("EPS") calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted EPS calculations and disclosures. This standard is effective for the Company for fiscal years beginning after December 15, 2023. Early adoption is permitted but not earlier than periods beginning after December 15, 2020. The Company is currently evaluating the impact the adoption of this new standard will have on the financial statements and disclosures.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. This standard provides optional expedients for the application of GAAP, if certain criteria are met, to contracts and other transactions that reference London Inter-bank Offered Rate ("LIBOR") or other reference rates that are expected to be discontinued because of reference rate reform. This standard is effective for all entities as of March 12, 2020 through December 31, 2022. On December 21, 2022, the FASB issued ASU 2022-06, Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848, which extends the period of time entities can utilize the reference rate reform relief guidance under ASU 2020-04 from December 31, 2022 to December 31, 2024. The Company is currently evaluating the impact the adoption of this standard will have on the financial statements and disclosures.

Note 3. Disaggregated revenue

Disaggregated revenue by product is as follows:

		Three Months Ended June 30,		Six Months Ended June 30,			Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022		2023	2022	2023	2022
Product revenue (in thousands):	Product revenue (in thousands):					Product revenue (in thousands):				
Gvoke	Gvoke	$ 15,638	$ 11,479	$ 30,671	$ 23,932	Gvoke	$ 17,735	$ 13,663	$ 48,406	$ 37,595
Keveyis	Keveyis	14,088	12,812	26,843	22,136	Keveyis	15,865	13,371	42,708	35,506
Recorlev	Recorlev	7,167	969	11,644	1,102	Recorlev	8,097	2,520	19,741	3,623
Product revenue, net	Product revenue, net	36,893	25,260	69,158	47,170	Product revenue, net	41,697	29,554	110,855	76,724
Royalty, contract and other revenue	Royalty, contract and other revenue	1,115	46	2,046	209	Royalty, contract and other revenue	6,623	171	8,669	380
Total revenue	Total revenue	$ 38,008	$ 25,306	$ 71,204	$ 47,379	Total revenue	$ 48,320	$ 29,725	$ 119,524	$ 77,104

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Note 4. Short-term investments

The Company classifies investments in debt securities as available-for-sale. Debt securities are comprised of liquid investments that are highly rated securities and, as of June 30, 2023 September 30, 2023, consist of U.S. government securities, all with remaining maturities of less than one year. Debt securities as of June 30, 2023 September 30, 2023 had an average remaining maturity of 0.3 0.2 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. The cost of short-term investments is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion, as well as interest income, are included in interest and other income in the condensed consolidated statements of operations and comprehensive loss. Refer to "Note 12 - Fair Value Measurements", Measurements," for information related to the fair value measurements and valuation methods utilized.

There were no short-term investments as of December 31, 2022. The following table represents the Company's short-term investments by major security type as of June 30, 2023 September 30, 2023 (in thousands):

		June 30, 2023					September 30, 2023			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:	Investments:					Investments:				
U.S. government securities	U.S. government securities	$ 34,553	$ —	$ (55)	$ 34,498	U.S. government securities	$ 19,859	$ —	$ (27)	$ 19,832
Total available-for-sale investments	Total available-for-sale investments	$ 34,553	$ —	$ (55)	$ 34,498	Total available-for-sale investments	$ 19,859	$ —	$ (27)	$ 19,832

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, the Company first assesses whether they are intended to be sold, or if it is more likely than not that the Company will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale securities that do not meet the above criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive loss on the statements of operations and comprehensive loss. No credit loss allowance was recorded in the three and six nine months ended June 30, 2023 September 30, 2023.

Note 5. Inventory

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

		June 30, 2023	December 31, 2022		September 30, 2023	December 31, 2022
Raw materials	Raw materials	$ 13,439	$ 7,410	Raw materials	$ 17,187	$ 7,410
Work in process	Work in process	6,418	11,367	Work in process	7,792	11,367
Finished goods	Finished goods	16,681	5,958	Finished goods	13,164	5,958
Inventory	Inventory	$ 36,538	$ 24,735	Inventory	$ 38,143	$ 24,735

Inventory reserves were $0.7 million $2.0 million and $1.3 million at June 30, 2023 September 30, 2023 and December 31, 2022, respectively.

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Note 6. Property and equipment

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

		June 30, 2023	December 31, 2022		September 30, 2023	December 31, 2022
Lab equipment	Lab equipment	$ 3,968	$ 3,841	Lab equipment	$ 4,153	$ 3,841
Furniture and fixtures	Furniture and fixtures	1,626	1,355	Furniture and fixtures	539	1,355
Computer equipment	Computer equipment	781	474	Computer equipment	728	474
Office equipment	Office equipment	70	8	Office equipment	97	8
Software	Software	353	307	Software	374	307
Leasehold improvements	Leasehold improvements	6,038	5,065	Leasehold improvements	5,984	5,065
Total property and equipment	Total property and equipment	12,836	11,050	Total property and equipment	11,875	11,050
Less: accumulated depreciation and amortization	Less: accumulated depreciation and amortization	(6,284)	(5,534)	Less: accumulated depreciation and amortization	(5,690)	(5,534)
Property and equipment, net	Property and equipment, net	$ 6,552	$ 5,516	Property and equipment, net	$ 6,185	$ 5,516

Depreciation and amortization expense relating to property and equipment was $0.4 million and $0.4 million for the three months ended June 30, 2023 September 30, 2023 and 2022, respectively. Depreciation and amortization expense relating to property and equipment was $0.8 million $1.1 million and $0.7 million $1.0 million for the six nine months ended June 30, 2023 September 30, 2023 and 2022, respectively.

Note 7. Intangible assets

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

			June 30, 2023			December 31, 2022				September 30, 2023				
		Life (Years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net		Life (Years)	Gross assets	Accumulated amortization	Net	Gr as
Definite-lived intangible asset - Keveyis	Definite-lived intangible asset - Keveyis	5	$ 11,000	$ (3,850)	$ 7,150	$ 11,000	$ (2,750)	$ 8,250	Definite-lived intangible asset - Keveyis	5	$ 11,000	$ (4,400)	$ 6,600	$ 1
Definite-lived intangible asset - Recorlev	Definite-lived intangible asset - Recorlev	14	121,000	(12,964)	108,036	121,000	(8,643)	112,357	Definite-lived intangible asset - Recorlev	14	121,000	(15,125)	105,875	12

Total intangible assets	Total intangible assets	$132,000	$ (16,814)	$115,186	$132,000	$ (11,393)	$120,607	Total intangible assets	$132,000	$ (19,525)	$112,475	$13

As of June 30, 2023 September 30, 2023, expected amortization expense for intangible assets subject to amortization for the next five years and thereafter is as follows (in thousands):

2023 remaining	2023 remaining	5,422	2023 remaining	2,711	
2024	2024	10,843	2024	10,843	
2025	2025	10,843	2025	10,843	
2026	2026	10,293	2026	10,293	
2027	2027	8,643	2027	8,643	
Thereafter	Thereafter	69,142	Thereafter	69,142	
Total	Total	$ 115,186	Total	$ 112,475	

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Note 8. Other accrued liabilities

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

		June 30, 2023	December 31, 2022		September 30, 2023	December 31, 2022
Accrued employee costs	Accrued employee costs	$ 10,968	$ 13,400	Accrued employee costs	$ 11,726	$ 13,400
Supply agreement - current portion	Supply agreement - current portion	—	6,720	Supply agreement - current portion	—	6,720
Accrued supply chain costs	Accrued supply chain costs	190	562	Accrued supply chain costs	161	562
Accrued marketing costs	Accrued marketing costs	1,977	2,593	Accrued marketing costs	1,083	2,593
Accrued debt issuance costs				Accrued debt issuance costs	1,007	—
Accrued research and development costs	Accrued research and development costs	455	1,411	Accrued research and development costs	425	1,411
Accrued restructuring charges	Accrued restructuring charges	802	2,799	Accrued restructuring charges	268	2,799
Accrued interest expense	Accrued interest expense	1,088	4,656	Accrued interest expense	504	4,656
Accrued other costs	Accrued other costs	3,933	4,645	Accrued other costs	3,899	4,645
Other accrued liabilities	Other accrued liabilities	$ 19,413	$ 36,786	Other accrued liabilities	$ 19,073	$ 36,786

Note 9. Restructuring costs

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

The following table summarizes the restructuring reserve for the six nine months ended June 30, 2023 September 30, 2023 (in thousands):

	Restructuring Costs
Balance accrued at December 31, 2022	2,799
Payments	(1,997) (2,531)
Balance accrued at June 30, 2023 September 30, 2023	$ 802 268

Note 10. Long-term debt

Convertible Senior Notes

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

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

On September 29, 2023, the Company completed the exchange of $32.0 million in aggregate principal amount of the 2025 Convertible Notes for $33.6 million in aggregate principal amount of new 8.00% Convertible Notes due 2028 (the "2028 Convertible Notes" and together with the 2025 Convertible Notes, the "Convertible Notes"). As of September 30, 2023, the outstanding balance of the 2025 Convertible Notes was $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million.

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

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

The Convertible Notes are senior, unsecured obligations and are equal in right of payment with Xeris Pharma's existing and future senior, unsecured indebtedness, senior in right of payment to its future indebtedness, if any, that is expressly subordinated to the Convertible Notes, and effectively subordinated to its existing and future secured indebtedness to the extent of the value of the

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collateral securing that indebtedness. The Convertible Notes are structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent Xeris Pharma is not a holder thereof) preferred equity, if any, of the Company's other direct and indirect subsidiaries.

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

The fair value of the convertible senior notes Convertible Notes is determined from using current interest rates based on credit ratings and the remaining term of maturity. As of June 30, 2023 September 30, 2023, the fair value of the convertible senior notes Convertible Notes was approximately $41.7 $48.9 million. The fair value of the convertible debt was estimated using inputs for volatility, the Company's stock price, time to maturity, the risk-free rate and the Company's credit spread, some of which are considered Level 3 inputs in the fair value hierarchy disclosed in "Note 12 - Fair value measurement". measurement."

Loan Agreement

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

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

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

Agreement. In conjunction with the execution of the Hayfin Loan Agreement, the Oxford Loan Agreement remaining balance of $43.5 million and fees of $2.1 million in connection with the loan repayment were paid. In addition to utilizing the proceeds to repay the obligations under the Oxford Loan Agreement in full, the proceeds will were otherwise be used for general corporate purposes.

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

The Loans will mature on March 8, 2027; provided, however, the Loans will mature on January 15, 2025 if the 2025 Convertible Notes are outstanding as of such date and either (i) the maturity date thereof has not been extended to a date on or after September 4, 2027 September 4,

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2027 or (ii) the Company has not received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.0 $15.6 million of cash on hand, is sufficient to redeem and discharge the 2025 Convertible Notes in full.

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

	June 30, 2023	December 31, 2022
Convertible Notes	$ 47,175	$ 47,175
Loan facility	145,012	144,487
Less: unamortized debt issuance costs	(4,005)	(4,587)
Long-term debt, net of unamortized debt issuance costs	$ 188,182	$ 187,075

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	September 30, 2023	December 31, 2022
Convertible Notes	$ 49,331	$ 47,175
Loan facility	145,286	144,487
Less: unamortized debt issuance costs	(4,194)	(4,587)
Long-term debt, net of unamortized debt issuance costs	$ 190,423	$ 187,075

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

2023 remaining	2023 remaining	$ —	2023 remaining	$ —	
2024	2024	—	2024	—	
2025	2025	47,175	2025	15,200	
2026	2026	—	2026	—	
2027	2027	150,000	2027	150,000	
Thereafter			Thereafter	33,574	
		$ 198,774			
		$ 197,175			

For the three and six nine months ended June 30, 2023 September 30, 2023, the Company recognized interest expense of $6.5 million $6.8 million and $12.7 million $19.6 million, respectively, of which $0.6 million and $1.1 million $1.7 million, respectively, related to the amortization of debt discount and issuance costs. Other expense in the three and nine months ended September 30, 2023 included a $2.8 million loss on extinguishment of debt related to the exchange of 2025 Convertible Notes for 2028 Convertible Notes, which completed in September 2023. For the three and six nine months ended June 30, 2022 September 30, 2022, the Company recognized interest expense of $3.4 million $4.0 million and $7.0 million $9.7 million, respectively, of which $0.5 $0.4 million and $0.7 $1.1 million, respectively, related to the amortization of debt discount and issuance costs. Interest Other expense in the six nine months ended June 30, 2022 also September 30, 2022 included a $1.2 million loss on extinguishment of debt in both periods related to the Oxford Loan Agreement with the Prior Lenders, which ceased was fully repaid in March 2022.

Note 11. Warrants

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

Associated with the Hayfin Loan Agreement disclosed in "Note 10 - Long-term debt", debt," the Lenders also received warrants to purchase 1,315,789 shares of the common stock of the Company at a price of $2.28 per share. The warrants are (i) exercisable until March 8, 2029; (ii) freely transferable and detachable from the Loans; and (iii) subject to customary warrant holder rights and protections, including structural-based anti-dilution protection and adjustments for stock dividends, splits, combinations, reclassifications and the like.

As of June 30, 2023 September 30, 2023, the following warrants were outstanding:

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

The Company recognized losses gains of $7,000 $8,000 and $7,000 $9,000 upon the change in fair value of the warrants during the three months ended June 30, 2023 September 30, 2023 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively. The Company recognized losses gains of $8,000 $71 and $6,000 $2,000 upon the change in fair value of the warrants during the six nine months ended June 30, 2023 September 30, 2023 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively.

The Company recognized gains of $23,000 $8,000 and $18,000 $1,000 upon the change in fair value of the warrants during the three months ended June 30, 2022 September 30, 2022 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively. The Company recognized gains of $0.5 $42,000 and $27,000 upon the change in fair value of the warrants during the nine months ended September 30, 2022 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively. The Company recognized gains of $1.7 million related to the expiration of the assumed Strongbridge private placement warrants in June 2022. The Company recognized gains of $35,000 and $26,000 upon the change in fair value of the warrants during the six months ended June 30, 2022 related to the 2018 Term A Warrants and the 2018 Term B Warrants, respectively.

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.

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Level 2: Measured using quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs, other than quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Measured based on prices or valuation models that require inputs that are both significant to the fair value measurement and less observable from objective sources (i.e., supported by little or no market activity).

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values stated below considers the market for the financial assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The following tables present the Company's fair value hierarchy for those assets and liabilities measured at fair value as of June 30, 2023 September 30, 2023 and December 31, 2022 (in thousands):

	Total as of June 30, 2023	Level 1	Level 2	Level 3		Total as of September 30, 2023	Level 1	Level 2	Level 3
Assets	*Assets*				*Assets*				
Cash and cash equivalents:	Cash and cash equivalents:				Cash and cash equivalents:				
Cash and money market funds	Cash and money market funds	$ 46,170	$ 46,170	$ —	$ —	Cash and money market funds	$ 46,143	$ 46,143	$ —	$ —
Investments:	Investments:				Investments:				
U.S. government securities	U.S. government securities	$ 34,498	$ 34,498	$ —	$ —	U.S. government securities	$ 19,832	$ 19,832	$ —	$ —
Other assets:	Other assets:				Other assets:				
Restricted cash	Restricted cash	$ 4,426	$ 4,426	$ —	$ —	Restricted cash	$ 4,426	$ 4,426	$ —	$ —
Liabilities	*Liabilities*				*Liabilities*				
Current portion of contingent value rights	Current portion of contingent value rights	$ 16,637	$ —	$ —	$ 16,637	Current portion of contingent value rights	$ 17,517	$ —	$ —	$ 17,517
Non-current contingent value rights	Non-current contingent value rights	$ 6,911	$ —	$ —	$ 6,911	Non-current contingent value rights	$ 5,099	$ —	$ —	$ 5,099
Warrant liabilities	Warrant liabilities	$ 23	$ —	$ —	$ 23	Warrant liabilities	$ 6	$ —	$ —	$ 6

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

Contingent Value Rights

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

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

- 2023 Recorlev Milestone: $0.25 per CVR, upon the first achievement of at least $40 million in net revenue of Recorlev in 2023; and

- 2024 Recorlev Milestone: $0.50 per CVR, upon the first achievement of at least $80 million in net revenue of Recorlev in 2024.

There are approximately 74.1 million CVRs. Up to 10.5 million CVRs may be issued to holders of Strongbridge rollover options and assumed warrants upon the exercise thereof. CVRs are settleable in cash, common stock, or a combination of cash and common stock, at the Company's sole election.

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

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

Balance at December 31, 2022	$	25,688
Change in fair value of CVRs		(2,140) (3,072)
Balance at June 30, 2023 September 30, 2023	$	23,548 22,616
Balance at Current portion of contingent value rights	$	16,637 17,517
Balance at Non-current contingent value rights		6,911 5,099
Balance at June 30, 2023 September 30, 2023	$	23,548 22,616

Note 13. Stock compensation plan

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

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

As of June 30, 2023 September 30, 2023, there were 3,856,319 3,962,766 shares of common stock available for future issuance under the 2018 Plan.

The 2018 Employee Stock Purchase Plan (the "ESPP") was adopted by the Board of Directors in April 2018 and approved by the Company's stockholders in June 2018 to issue up to 193,000 shares of common stock to participating employees. Through the ESPP, eligible employees may authorize payroll deductions of up to 15% of their compensation to purchase up to the number of shares of common stock determined by dividing $25,000 by the closing market price of Xeris common stock on the offering date. The purchase price per share at each purchase date is equal to 85% of the lower of (i) the closing market price per share of Xeris common stock on the employee's offering date or (ii) the closing market price per share of Xeris common stock on the purchase date. Each offering period has a six-month duration and purchase interval. As of June 30, 2023 September 30, 2023, there were 76 shares available for issuance under the ESPP.

The Equity Inducement Plan (the "Inducement Plan") was adopted by the Board of Directors in February 2019. The Inducement Plan allows the Company to make stock option or restricted stock unit awards to prospective employees of the Company as an inducement to such individuals to commence employment with the Company. The Company uses this Inducement Plan to help it attract and retain prospective employees who are necessary to support the commercialization of products and the expansion of the Company generally. As of June 30, 2023 September 30, 2023, there were 351,404 365,949 shares of common stock available for future issuance under the Inducement Plan.

Assumed Plans

On the acquisition date of Strongbridge, the Company assumed all then-outstanding stock options and shares available and reserved for issuance under some legacy equity incentive plans of Strongbridge, including the Strongbridge 2015 equity compensation plan and Strongbridge 2017 inducement plan (collectively, the "Assumed Plans"). Shares reserved under the Assumed Plans will be available

for future grants. The Company also assumed all then-outstanding stock options from the rest of the legacy equity incentive plans of Strongbridge without assuming the shares available and reserved for issuance under these plans. The number of shares subject to stock options outstanding under all Strongbridge legacy equity incentive plans are included in the tables below. As of June 30, 2023 September 30, 2023, there were 2,442,730 2,531,897 shares reserved for future grants under the Assumed Plans.

Stock options

Stock options are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Stock option awards typically vest over either two, three or four years after the grant date and expire seven to ten years from the grant date.

The fair value of each option is estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions noted in the following table. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free interest rate for periods during the contractual life of the option is based on the United States Treasury yield curve in effect at the time of grant. The expected stock price volatility assumption is based on the historical volatilities of a peer group of publicly traded companies as well as the historical volatility of the Company's common stock, since the Company began trading subsequent to the IPO in June 2018, over the

period corresponding to the expected life as of the grant date. The expected dividend yield is based on the expected annual dividend as a percentage of the market value of the Company's ordinary shares as of the grant date.

Stock option activity under the 2011 Plan, 2018 Plan, Inducement Plan and Assumed Plans for the six nine months ended June 30, 2023 September 30, 2023 was as follows:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)
Outstanding - December 31, 2022	9,700,161	$ 5.37	4.76
Granted	—	—	
Exercised	(14,036)	2.33	
Forfeited	(11,846)	5.49	
Expired	(366,433)	9.08	
Outstanding - June 30, 2023	9,307,846	$ 5.23	4.40
Vested and expected to vest at June 30, 2023	9,307,846	$ 5.23	4.40
Exercisable - June 30, 2023	8,968,523	$ 5.24	4.28

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)
Outstanding - December 31, 2022	9,700,161	$ 5.37	4.76
Granted	—	—	
Exercised	(14,036)	2.33	
Forfeited	(12,541)	5.48	
Expired	(426,020)	8.50	
Outstanding - September 30, 2023	9,247,564	$ 5.23	4.10
Vested and expected to vest at September 30, 2023	9,247,564	$ 5.23	4.10
Exercisable - September 30, 2023	8,973,009	$ 5.24	4.01

At June 30, 2023 September 30, 2023, there was a total of $1.0 million $0.8 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 1.3 1.1 years.

Restricted Stock Units

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

A summary of outstanding RSU awards and the activity for the six nine months ended June 30, 2023 September 30, 2023 was as follows:

	Number of Units	Weighted Average Grant Date Fair Value Per Share
Unvested balance - December 31, 2022	5,255,560	$ 3.25
Granted	7,499,400	1.31
Vested	(1,904,422)	3.69
Forfeited	(247,767)	1.75

	Number of Units	Weighted Average Grant Date Fair Value Per Share
Unvested balance - December 31, 2022	5,255,560	$ 3.25
Granted	7,610,400	1.33
Vested	(1,988,098)	3.66
Forfeited	(448,887)	1.68

Unvested balance - June 30, 2023	10,602,771	$	1.83		
Unvested balance - September 30, 2023				Unvested balance - September 30, 2023	10,428,975	$	1.83

As of June 30, 2023 September 30, 2023, there was $15.4 million $12.7 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over the weighted-average remaining vesting period of 2.2 2.0 years.

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

		Three Months Ended June 30,		Six Months Ended June 30,			Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022		2023	2022	2023	2022
Research and development	Research and development	632	416	$ 954	$ 963	Research and development	202	332	$ 1,156	$ 1,295
Selling, general and administrative	Selling, general and administrative	2,296	2,736	4,538	5,490	Selling, general and administrative	2,255	2,609	6,793	8,099
Total stock-based compensation expense	Total stock-based compensation expense	$ 2,928	$ 3,152	$ 5,492	$ 6,453	Total stock-based compensation expense	$ 2,457	$ 2,941	$ 7,949	$ 9,394

Note 14. Leases

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

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

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

A majority of the Company's lease agreements include fixed rental payments. Certain lease agreements include fixed rental payments that are adjusted periodically by a fixed rate. The fixed payments, including the effects of changes in the fixed rate or amount, and renewal options reasonably certain to be exercised, are included in the measurement of the related lease liability. The exercise of lease renewal options is at the Company's sole discretion. The depreciable life of assets and leasehold improvements are limited by the expected lease term, which includes renewal options reasonably certain to be exercised. The majority of the Company's real estate leases require that the Company pay maintenance, real estate taxes and insurance in addition to rent. These payments are generally

variable and based on actual costs incurred by the lessor. Therefore, these amounts are not included in the consideration of the contract when determining the right-of-use asset and lease liability but are reflected as variable lease expenses.

As the interest rate implicit in the lease is not readily determinable, the Company uses the incremental borrowing rate as the discount rate. The Company considers observable inputs as of the effective date of the ASC 842 adoption including the credit rating, existing borrowings and other relevant borrowing rates, such as risk-free rates like the United States Treasury rate, and then adjusting as necessary for the appropriate lease term. The incremental borrowing rate is reassessed if there is a change to the lease term or if a modification occurs and it is not accounted for as a separate contract. As of June 30, 2023 September 30, 2023, the Company's operating leases had a weighted-average remaining lease term of 12.1 11.8 years and a weighted-average discount rate of 11.9%.

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

	Three Months Ended June 30,		Six Months Ended June 30,			Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022		2023	2022	2023	2022

Cash paid for amounts included in the measurement of lease liabilities:	Cash paid for amounts included in the measurement of lease liabilities:								Cash paid for amounts included in the measurement of lease liabilities:						
Operating cash flows for operating leases	Operating cash flows for operating leases	$	440	$	613	$	918	$ 1,058	Operating cash flows for operating leases	$	365	$	624	$ 1,283	$ 1,682
Right of use assets obtained in exchange for new lease obligations:	Right of use assets obtained in exchange for new lease obligations:								Right of use assets obtained in exchange for new lease obligations:						
Operating leases	Operating leases	$	20,043	$	—	$	20,043	$ —	Operating leases	$	—	$	—	$ 20,043	$ —

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

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

		Three Months Ended June 30,		Six Months Ended June 30,			Three Months Ended September 30,		Nine Months Ended September 30,	
Lease cost	Lease cost	2023	2022	2023	2022	Lease cost	2023	2022	2023	2022
Operating lease expense	Operating lease expense	$ 1,350	$ 533	$ 1,763	$ 1,000	Operating lease expense	$ 1,394	$ 532	$ 3,157	$ 1,532
Variable lease cost	Variable lease cost	302	215	652	440	Variable lease cost	286	212	938	652
Sublease income	Sublease income	(54)	(52)	(108)	(104)	Sublease income	(54)	(54)	(162)	(158)
Total lease cost	Total lease cost	$ 1,598	$ 696	$ 2,307	$ 1,336	Total lease cost	$ 1,626	$ 690	$ 3,933	$ 2,026

As of June 30, 2023 September 30, 2023, maturities of lease liabilities are summarized as follows (in thousands):

2023 remaining	2023 remaining	$ 730	2023 remaining	$ 365
2024	2024	3,495	2024	3,495
2025	2025	6,080	2025	6,080
2026	2026	6,232	2026	6,232
2027	2027	6,389	2027	6,389
Thereafter	Thereafter	51,990	Thereafter	51,990
Total lease payments	Total lease payments	74,916	Total lease payments	74,551
Less: Effect of discounting to net present value	Less: Effect of discounting to net present value	(38,110)	Less: Effect of discounting to net present value	(37,031)
Present value of lease liabilities	Present value of lease liabilities	$ 36,806	Present value of lease liabilities	$ 37,520
Operating lease liabilities, current	Operating lease liabilities, current	1,935	Operating lease liabilities, current	2,366
Operating lease liabilities, non-current	Operating lease liabilities, non-current	34,871	Operating lease liabilities, non-current	35,154
Total operating lease liabilities	Total operating lease liabilities	$ 36,806	Total operating lease liabilities	$ 37,520

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

Note 15. Commitments and contingencies

Commitments

Commitments to Taro

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

Leases

As of June 30, 2023 September 30, 2023, the Company had unused letters of credit of $4.4 million, which were issued primarily to secure leases. These letters of credit are collateralized by $4.4 million of restricted cash, which is recorded in other assets in the condensed consolidated balance sheets.

Contingencies

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of June 30, 2023 September 30, 2023, management was not aware of any existing, pending or threatened legal actions that would have a material impact on the financial position or results of operations of the Company.

Long Term Debt

In the event the 2025 Convertible Notes are still outstanding as of January 15, 2025 and the maturity date thereof has not been extended to a date on or after September 4, 2027, then unless the Company has received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.0 $15.6 million of cash on hand, is sufficient to redeem and discharge the 2025 Convertible Notes in full, the loans outstanding under the Hayfin Loan Agreement will mature on January 15, 2025.

Note 16. Net loss per common share

Basic and diluted net loss per common share are determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. For all periods presented, the shares issuable upon conversion, exercise or vesting of Convertible Notes, warrants, stock option awards and RSUs have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted average common shares outstanding used to calculate both basic and diluted net loss per common share are the same.

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

		As of June 30,			As of September 30,	
		2023	2022		2023	2022
Shares to be issued upon conversion of Convertible Notes	Shares to be issued upon conversion of Convertible Notes	15,416,667	15,416,667	Shares to be issued upon conversion of Convertible Notes	15,939,216	15,416,667
Vested and unvested stock options	Vested and unvested stock options	9,307,846	10,009,493	Vested and unvested stock options	9,247,564	9,818,748
Restricted stock units	Restricted stock units	10,602,771	5,381,154	Restricted stock units	10,428,975	5,228,961
Warrants	Warrants	8,362,270	8,362,270	Warrants	8,362,270	8,362,270
Total anti-dilutive securities excluded from EPS computation [1]	Total anti-dilutive securities excluded from EPS computation [1]	43,689,554	39,169,584	Total anti-dilutive securities excluded from EPS computation [1]	43,978,025	38,826,646

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

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

Cautionary statements for forward-looking information

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated 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 8, 2023 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," "focus," "goal," "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, and factors discussed in Item 1A of Part II of this Quarterly Report on Form 10-Q. Any forward-looking statements contained herein speak only as of the date hereof, and Xeris expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

Unless otherwise indicated, references to "Xeris," the "Company," "we," "our" and "us" in this Quarterly Report on Form 10-Q refer to Xeris Biopharma Holdings, Inc. Throughout this document, unless otherwise noted, references to Gvoke include Gvoke PFS, Gvoke HypoPen, Gvoke Kit and Ogluo (glucagon).

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

Commercial Products

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

- *Gvoke* is a ready-to-use, liquid-stable glucagon for the treatment of severe hypoglycemia. The product is indicated for use in pediatric and adult patients with diabetes age 2 years and above and can be administered in 2 simple steps. The estimated total addressable market for this drug is approximately $5.0 billion in the United States.
- *Keveyis* is the first therapy approved in the United States to treat hyperkalemic, hypokalemic, and related variants of Primary Periodic Paralysis ("PPP"). PPP is a rare genetic, neuromuscular disorder that can cause extreme muscle weakness and/or paralysis; some forms are also commonly associated with myotonia or muscle stiffness. The estimated total addressable market for this therapy is greater than $0.5 billion in the United States.
- *Recorlev* is a cortisol synthesis inhibitor approved for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative. Endogenous Cushing's syndrome is a rare but serious and potentially fatal endocrine disease caused by chronic elevated cortisol exposure. The estimated total addressable market for this therapy is approximately $3.0 billion in the United States.

Our proprietary formulation capabilities

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

Patents

We currently own 171 174 patents issued globally, including a composition of matter patent covering our ready-to-use glucagon formulation that expires in 2036. Included in the total patents, we have 60 granted patents globally related to our platform technologies and 7 patents granted in the United States and listed in the United States FDA Orange Book covering proprietary formulations of levoketoconazole (the active pharmaceutical ingredient in Recorlev) and the uses of such formulations in treating certain endocrine-related diseases and syndromes. The latter includes United States Patent Nos. 11,020,393 and 11,278,547, which were granted on June

1, 2021 and March 22, 2022, respectively, and which provide patent protection through 2040 for the use of Recorlev in the treatment of certain patients with persistent or recurrent Cushing's syndrome.

Financing

We have funded our operations to date primarily with proceeds from the sale of our preferred and common stock and debt financing. We have received gross proceeds of $253.0 million from public equity offerings of our common stock (including Xeris Pharma's June 2018 initial public offering ("IPO") and our February 2019, February 2020, June 2020 and March 2021 offerings), $30.0 million from a private placement of our common stock in January 2022, $104.9 million from sales of our preferred stock, $86.3 million from our June 2020 Convertible Notes offering, $63.5 million from the Amended and Restated Loan and Security Agreement (as amended, the "Oxford Loan Agreement") with Oxford Finance LLC and Silicon Valley Bank, which was fully repaid in March 2022, and $150.0 million from the Hayfin Loan Agreement in 2022. 2022, which was fully drawn down and was used in part to repay the remaining balance of $43.5 million of the Oxford Loan Agreement in March 2022, and an exchange of $32.0 million of the 2025 Convertible Notes for $33.6 million of 2028 Convertible Notes. In addition, we filed a shelf registration statement on Form S-3 with the SEC in August 2019, which covered the offering, issuance and sale by us of up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units. We simultaneously entered into a Sales Agreement with Jefferies LLC, as sales agent, to provide for the offering, issuance and sale by us of up to $50.0 million of our common stock from time to time in "at-the-market" offerings under the shelf. We 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.

For the six nine months ended June 30, 2023 September 30, 2023 and June 30, 2022 September 30, 2022, we reported net losses of $36.7 $48.9 million and $59.9 $81.7 million, respectively. We have not been profitable since inception, and, as of June 30, 2023 September 30, 2023, our accumulated deficit was $591.4 $603.6 million. In the near term, we expect to continue to incur significant expenses, operating losses and net losses as we:

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

We may continue to seek public equity and debt financing to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our product candidates, if approved. In addition, we may not be profitable even if we commercialize any of our product candidates.

Outlook and strategies

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

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

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

Development of product candidates

Once Weekly Subcutaneous Injection of Levothyroxine (XP-8121)

We conducted a Phase 1 clinical study with product candidate Levothyroxine XP-8121, an early-stage program designed to address maintenance therapy in patients with congenital or acquired hypothyroidism who require continuous thyroid hormone replacement. We commenced a Phase 2 dose-finding study of XP-8121 in April 2023. The study is designed to assess XP-8121 in patients receiving oral thyroid replacement therapy to establish the average once-weekly dose, accrue chronic safety data, and facilitate a future Phase 3 program in consultation with the FDA.

Levothyroxine and Hypothyroidism

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

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

XP-8121 Overview

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

conducted a Phase 1 study of XP-8121 to evaluate the pharmacokinetics, safety and tolerability, and potential for weekly dosing in the treatment of hypothyroidism.

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

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

Components of our Results of Operations

The following discussion sets forth certain components of the statement of operations of Xeris for the three and six nine months ended June 30, 2023 September 30, 2023 and 2022 as well as factors that impact those items.

Product revenue, net

Product revenue, net, represents gross product sales less estimated allowances for patient copay assistance programs, prompt payment discounts, payor rebates, chargebacks, service fees, and product returns, all of which are recorded at the time of sale to the pharmaceutical wholesaler or other customer. We apply significant judgment and estimates in

determining some of these allowances. If actual results differ from our estimates, we make adjustments to these allowances in the period in which the actual results or updates to estimates become known.

Royalty, contract and other revenue

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

Cost of goods sold

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

Research and development expenses

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

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

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

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

Selling, general and administrative expenses

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

Amortization of intangible assets

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

Other income (expense)

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

Results of Operations

The following table summarizes our results of operations for the three and six nine months ended June 30, 2023 September 30, 2023 and 2022 (in thousands):

		Three Months Ended June 30,		Change		Six Months Ended June 30,		Change			Three Months Ended September 30,		Change		Nine Months Ended September 30,		
		2023	2022	$	%	2023	2022	$	%		2023	2022	$	%	2023	2022	
Product revenue:	Product revenue:									Product revenue:							
Gvoke	Gvoke	$ 15,638	$ 11,479	$4,159	36.2	$ 30,671	$ 23,932	$ 6,739	28.2	Gvoke	$ 17,735	$ 13,663	$4,072	29.8	$ 48,406	$ 37,595	$
Keveyis	Keveyis	14,088	12,812	1,276	10.0	26,843	22,136	4,707	21.3	Keveyis	15,865	13,371	2,494	18.7	42,708	35,506	
Recorlev	Recorlev	7,167	969	6,198	nm	11,644	1,102	10,542	nm	Recorlev	8,097	2,520	5,577	nm	19,741	3,623	
Product revenue, net	Product revenue, net	36,893	25,260	11,633	46.1	69,158	47,170	21,988	46.6	Product revenue, net	41,697	29,554	12,143	41.1	110,855	76,724	
Royalty, contract and other revenue	Royalty, contract and other revenue	1,115	46	1,069	nm	2,046	209	1,837	nm	Royalty, contract and other revenue	6,623	171	6,452	nm	8,669	380	
Total revenue	Total revenue	38,008	25,306	12,702	50.2	71,204	47,379	23,825	50.3	Total revenue	48,320	29,725	18,595	62.6	119,524	77,104	

Cost and expenses:	Cost and expenses:									Cost and expenses:							
Cost of goods sold, excluding amortization of intangible assets	Cost of goods sold, excluding amortization of intangible assets	7,555	4,810	2,745	57.1	12,874	11,083	1,791	16.2	Cost of goods sold, excluding amortization of intangible assets	8,201	5,260	2,941	55.9	21,075	16,343	
Research and development	Research and development	6,087	3,718	2,369	63.7	10,925	9,968	957	9.6	Research and development	5,034	6,043	(1,009)	(16.7)	15,959	16,011	
Selling, general and administrative	Selling, general and administrative	37,635	32,984	4,651	14.1	71,240	68,897	2,343	3.4	Selling, general and administrative	37,287	34,491	2,796	8.1	108,527	103,388	
Amortization of intangible assets	Amortization of intangible assets	2,710	2,710	—	—	5,421	5,421	—	—	Amortization of intangible assets	2,711	2,711	—	—	8,132	8,132	
Total cost and expenses	Total cost and expenses	53,987	44,222	9,765	22.1	100,460	95,369	5,091	5.3	Total cost and expenses	53,233	48,505	4,728	9.7	153,693	143,874	
Loss from operations	Loss from operations	(15,979)	(18,916)	2,937	(15.5)	(29,256)	(47,990)	18,734	(39.0)	Loss from operations	(4,913)	(18,780)	13,867	(73.8)	(34,169)	(66,770)	
Other income (expense):	Other income (expense):									Other income (expense):							
Interest and other income	Interest and other income	1,223	195	1,028	nm	2,523	263	2,260	nm	Interest and other income	1,121	472	649	nm	3,644	735	
Loss on debt extinguishment										Loss on debt extinguishment	(2,837)	—	(2,837)	nm	(2,837)	(1,223)	
Interest expense	Interest expense	(6,528)	(3,448)	(3,080)	89.3	(12,744)	(6,969)	(5,775)	82.9	Interest expense	(6,847)	(3,989)	(2,858)	71.6	(19,591)	(9,735)	
Change in fair value of warrants	Change in fair value of warrants	(14)	516	(530)	(102.7)	(14)	1,737	(1,751)	nm	Change in fair value of warrants	17	9	8	88.9	3	1,746	
Change in fair value of contingent considerations	Change in fair value of contingent considerations	781	(4,871)	5,652	nm	2,140	(7,687)	9,827	nm	Change in fair value of contingent considerations	932	118	814	nm	3,072	(7,569)	
Total other expense	Total other expense	(4,538)	(7,608)	3,070	(40.4)	(8,095)	(12,656)	4,561	(36.0)	Total other expense	(7,614)	(3,390)	(4,224)	124.6	(15,709)	(16,046)	
Net loss before benefit from income taxes	Net loss before benefit from income taxes	(20,517)	(26,524)	6,007	(22.6)	(37,351)	(60,646)	23,295	(38.4)	Net loss before benefit from income taxes	(12,527)	(22,170)	9,643	(43.5)	(49,878)	(82,816)	
Benefit from income taxes	Benefit from income taxes	675	339	336	99.1	675	747	(72)	(9.6)	Benefit from income taxes	338	339	(1)	(0.3)	1,013	1,086	
Net loss	Net loss	$(19,842)	$(26,185)	$6,343	(24.2)	$(36,676)	$(59,899)	$23,223	(38.8)	Net loss	$(12,189)	$(21,831)	$9,642	(44.2)	$(48,865)	$(81,730)	$

nm: not meaningful

Product revenue, net

Gvoke net revenue increased by $4.2 million $4.1 million or 36.2% 29.8% and $6.7 million $10.8 million or 28.2% 28.8% for the three and six nine months ended June 30, 2023 September 30, 2023 compared to the same periods ended June 30, 2022 September 30, 2022, respectively. Gvoke prescriptions grew approximately 49.7% 52.3% and

50.7% during both the three and six nine months ended June 30, 2023 September 30, 2023, respectively, compared to the same periods of 2022. The growth in product demand was partially offset by a decrease in net pricing.

Keveyis net revenue increased by $1.3 million $2.5 million or 10.0% 18.7% and $4.7 million $7.2 million or 21.3% 20.3% for the three and six nine months ended June 30, 2023 September 30, 2023, respectively, compared to the same periods ended June 30, 2022, respectively. This September 30, 2022. These increases in both periods were mainly driven by higher patient demand coupled with an increase in net pricing.

Recorlev, commercially launched in the first quarter of 2022, had net revenue of $7.2 million $8.1 million and $11.6 million $19.7 million for the three and six nine months ended June 30, 2023 September 30, 2023, respectively, driven primarily by increases in the number of patients on therapy.

Cost of goods sold

Cost of goods sold increased by $2.7 million $2.9 million or 57.1% 55.9% for the three months ended June 30, 2023 September 30, 2023 compared to the same period ended June 30, 2022 September 30, 2022. The increase was mainly attributable to higher product sales and product mix. sales. Cost of goods sold increased by $1.8 million $4.7 million or

16.2% 29.0% for the six nine months ended June 30, 2023 September 30, 2023 compared to the same period ended June 30, 2022 September 30, 2022. The increase was mainly attributable to higher product sales, and partially offset by the product mix partially offset by and a one-time contract credit in the first quarter of 2023.

Research and development expenses

Research and development expenses increased decreased by $2.4 million or 63.7% and $1.0 million or 9.6% 16.7% for the three and six months ended June 30, 2023, respectively, September 30, 2023 compared to the same periods period ended June 30, 2022. The increases in both periods were due to higher spending on the open-label treatment in Cushing's syndrome study for Recorlev and higher September 30, 2022 driven by lower product development costs. Research and development expenses were flat in the nine months ended September 30, 2023 compared to the same period ended September 30, 2022.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $4.7 million $2.8 million or 14.1% 8.1% and $2.3 million $5.1 million or 3.4% 5.0% for the three and six nine months ended 2023, respectively, compared to the same periods ended June 30, 2022 September 30, 2022, due to higher personnel costs marketing expenses and rent expenses related to the new lease commenced in April 2023.

Amortization of intangible assets

For the three and six nine months ended June 30, 2023 September 30, 2023 and June 30, 2022 September 30, 2022, amortization of intangible assets were both $2.7 million and both $5.4 million $8.1 million, respectively.

Other income (expense)

For the three and six nine months ended June 30, 2023 September 30, 2023, interest expense increased $3.1 million $2.9 million or 89.3% 71.6% and $5.8 million $9.9 million or 82.9% 101.2% compared to the three and six nine months ended June 30, 2022 September 30, 2022, respectively. The increases in both periods were primarily due to a higher principal amount and increased interest rates related to the loan under the Hayfin loan. Loan Agreement.

Other expense in the three and nine months ended September 30, 2023 included a $2.8 million loss on extinguishment of debt related to the exchange of 2025 Convertible Notes for 2028 Convertible Notes, which was completed in September 2023. Other expense in the nine months ended September 30, 2022 included a $1.2 million loss on extinguishment of debt related to the Oxford Loan Agreement with the Prior Lenders, which fully repaid in March 2022.

For the three and six nine months ended June 30, 2023 September 30, 2023, change in fair value of contingent value rights was a gain of $0.8 million $0.9 million and $2.1 million $3.1 million, respectively, compared to a gain of $0.1 million and a loss of $4.9 million and $7.7 million $7.6 million for the three and six nine months ended June 30, 2022 September 30, 2022, respectively. The gains in both periods in 2023 were primarily due to changes in revenue assumptions based on recent trends adjusted for management's estimates of future sales.

Liquidity and Capital Resources

Our primary uses of cash are to fund costs related to the manufacturing, marketing and selling of products, the research and development of our product candidates, general and administrative expenses and working capital requirements. Historically, we have funded our operations primarily through private placements of convertible preferred stock, public equity offerings of common stock, and issuance of debt. 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 Oxford 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. In August 2019, we filed a shelf registration statement on Form S-3 with the SEC, which covered the offering, issuance and sale by us of up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units. We simultaneously entered into a Sales Agreement with Jefferies LLC, as sales agent, to provide for the offering, issuance and sale by us of up to $50.0 million of our common stock from time to time in "at-the-market" offerings under the shelf. We 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.

In February 2020, we completed an equity offering and sold 10,299,769 shares of common stock. Net proceeds from this equity offering were $39.8 million after deducting underwriting discounts and commissions as well as other equity offering expenses. In June 2020, we completed a public notes offering and sold $86.3 million aggregate principal amount of 5.00% Convertible Senior Notes,

including $11.3 million pursuant to the underwriters' option to purchase additional notes which was fully exercised in July 2020. Concurrently with the public notes offering, in June 2020, we completed an equity offering and sold 8,510,000 shares of common stock, including 1,110,000 shares pursuant to the underwriters' option to purchase additional shares of common stock which was also fully exercised in July 2020. Net proceeds from both June 2020 offerings (including the net proceeds from the exercise of the underwriters' over-allotment options in July 2020) were $102.8 million after deducting underwriting discounts and commissions as well as other offering expenses. During the second half of 2020, $39.1 million in principal amount of Convertible Notes were converted into 13,171,791 shares of our common stock. In March 2021, we completed a registered direct offering of 6,553,398 shares of our common stock, the net proceeds of which were $26.9 million. As of June 30, 2023, the outstanding balance of Convertible Notes was $47.2 million. In October 2020, we entered into a fourth amendment to the Oxford Loan Agreement which provided for an additional $3.5 million term loan which was drawn in November 2020. On January 2, 2022, we entered into a securities purchase agreement in connection with the private placement of our common stock with Armistice for aggregate gross proceeds of approximately $30.0 million and completed the transaction on January 3, 2022. In January 2022, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on February 7, 2022, and which covers the offering, issuance and sale by us of up to an aggregate of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units.

In March 2022, we, Xeris Pharma and certain subsidiary guarantors, entered into a Credit Agreement and Guaranty (the "Hayfin Loan Agreement") with the lenders from time to time parties thereto (the "Lenders") and Hayfin Services LLP, as administrative agent for the Lenders, pursuant to which we and our subsidiaries party thereto granted a first priority security interest on substantially all of our assets, including intellectual property, subject to certain exceptions. The Hayfin Loan Agreement provided for the Lenders to extend $100.0 million in term loans to us on the closing date and up to an additional $50.0 million in delayed draw term loan(s) during the one year period immediately following the closing date (collectively, the "Loans"). On December 28, 2022, we borrowed the full amount of such $50.0 million delayed draw term loan under the Hayfin Loan Agreement. In conjunction with the execution of the Hayfin Loan Agreement, the Oxford Loan Agreement balance of $43.5 million was repaid in full and fees of $2.1 million in connection with the loan repayment were paid. In addition to utilizing the proceeds to repay the obligations under the Oxford Loan Agreement in full, the proceeds will were otherwise be used for general corporate purposes. After repayment, the Loans may not be re-borrowed. On September 29, 2022, the Company and Xeris Pharma entered into Amendment No. 1 to Credit Agreement and Guaranty, which provides for the Lenders' consent to and allows for the issuance of the letter of credit that was issued to the landlord under the Amended and Restated Lease dated September 29, 2022. On January 19, 2023, the Company and Xeris Pharma entered into Amendment No. 2 to Credit Agreement and Guaranty, which provides for the Lenders' consent to and allows for the execution and delivery of a letter of financial support to the Company's Australian subsidiary. On April 21, 2023, the Company and Xeris Pharma entered into Amendment No. 3, Waiver and Consent to Credit and Guaranty Agreement, which, amongst other things, permitted the Company to replace certain accounts and letters of credit previously maintained at or issued by, as applicable, Silicon Valley Bank with similar products maintained at or issued by Wells Fargo, N.A. On September 26, 2023, the Company and Xeris Pharma entered into the Consent to Credit and Guaranty Agreement, which subject to the terms and conditions set forth therein provides for the Lenders' consent to and allows for the exchange of the Convertible Notes and amends the amount of balance sheet cash on hand that the Company or Xeris Pharma is permitted to utilize to redeem and discharge the Convertible Notes.

In September 2023, we completed the exchange of $32.0 million in aggregate principal amount of the 2025 Convertible Notes for $33.6 million in aggregate principal amount of the 2028 Convertible Notes. As of September 30, 2023, the outstanding balance of the 2025 Convertible Notes was $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million.

Capital Resources and Funding Requirements

We have incurred operating losses since inception, and we have an accumulated deficit of $591.4 million $603.6 million at June 30, 2023 September 30, 2023. Based on our current operating plans and existing working capital at June 30, 2023 September 30, 2023, we believe that our cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months. We expect to incur substantial additional expenditures in the near term to support the marketing and selling of Gvoke, Keveyis and Recorlev as well as our ongoing research and development activities. We expect to continue to incur net losses for at least the next 12 months. Our ability to fund marketing and selling of Gvoke, Keveyis and Recorlev, as well as our product development and clinical operations, including completion of future clinical trials, will depend on the amount and timing of cash received from product revenue and potential future financings. Our future capital requirements will depend on many factors, including: including, but not limited to:

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

As we continue the marketing and selling of Gvoke, Keveyis and Recorlev, we may not generate a sufficient amount of product revenue to fund our cash requirements. Accordingly, we may need to obtain additional financing in the future which may include public or private debt and/or equity financings. As detailed in "Note 1 – Liquidity and capital resources" above, there can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to successfully market and sell Gvoke, Keveyis and Recorlev.

Cash Flows

(in thousands)	(in thousands)	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	(in thousands)	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Net cash used in operating activities	Net cash used in operating activities	$ (39,884)	$ (69,018)	Net cash used in operating activities	$ (54,494)	$ (86,772)
Net cash (used in)/provided by investing activities	Net cash (used in)/provided by investing activities	(35,527)	18,584	Net cash (used in)/provided by investing activities	(20,872)	25,293
Net cash (used in)/provided by financing activities	Net cash (used in)/provided by financing activities	(307)	78,504	Net cash (used in)/provided by financing activities	(379)	78,317

Operating activities

Net cash used in operating activities was $39.9 million $54.5 million for the six nine months ended June 30, 2023 September 30, 2023, compared to $69.0 million $86.8 million for the six nine months ended June 30, 2022 September 30, 2022. The decrease in net cash used in operating activities was primarily driven by reduced working capital usage, partially offset by changes to the fair value of contingent value rights.

Investing activities

Net cash used in investing activities was $35.5 million $20.9 million for the six nine months ended June 30, 2023 September 30, 2023, compared to net cash provided by investing activities of $18.6 million $25.3 million for the six nine months ended June 30, 2022 September 30, 2022. Cash used in investing activities in 2023 was primarily due to the purchase of short-term investments. In the first six nine months of 2022, we used the majority of investments that matured to fund operations instead of re-investing.

Financing activities

Net cash used in financing activities was $0.3 million $0.4 million for the six nine months ended June 30, 2023 September 30, 2023, compared to net cash provided by financing activities of $78.5 million $78.3 million for the six nine months ended June 30, 2022 September 30, 2022. The cash provided by financing activities in six nine months ended June 30, 2022 September 30, 2022 was primarily due to the net proceeds of $30.0 million from the January 2022 private placement of our common stock with an affiliate of Armistice, proceeds net of debt issuance costs of $92.9 million from Hayfin Loan Agreement, partially offset by the payoff of the outstanding principal under the Oxford Loan Agreement of $43.5 million in March 2022.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES AND ASSUMPTIONS

Our Annual Report on Form 10-K for the year ended December 31, 2022 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, 2022.

NEW ACCOUNTING STANDARDS

Refer to "Note 2 - Basis of presentation and summary of significant accounting policies and estimates", estimates," a description of recent accounting pronouncements applicable to our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

Cash, Cash Equivalents restricted cash and Investments—We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash, cash equivalents, restricted cash and investments. A hypothetical one-percentage point increase or decrease in interest rates applicable to our cash, cash equivalents, restricted cash and investments outstanding at June 30, 2023 September 30, 2023 would increase or decrease interest income by approximately $0.8 million $0.7 million on an annual basis.

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

Foreign Exchange Risk

We contract with research organizations outside the United States at times. We may be subject to fluctuations in foreign currency exchange rates in connection with certain of these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of June 30, 2023 September 30, 2023, we had immaterial liabilities denominated in the Australian Dollar. Net foreign currency gains and losses did not have a material effect on our results of operations for the six nine months ended June 30, 2023 September 30, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based on such evaluation, our chief executive officer and chief financial officer have concluded that the disclosure controls and procedures were effective as of June 30, 2023 September 30, 2023 to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the United States Securities and Exchange Commission's ("SEC") rules and forms, and to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its chief executive and chief financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2023 September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

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

Historically, we have funded our operations primarily through private placements of convertible preferred stock, public offerings of common stock and convertible notes, and debt issuances. We have five pharmaceutical products that were commercially launched in the past six years, i.e., Keveyis (2017), Gvoke PFS (2019), Gvoke HypoPen (2020), Recorlev (2022) and Gvoke Kit (2022). We are in the early stages of commercializing our biopharmaceutical products and have a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies prior to and at the early stages of commercialization of any product candidates, especially biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to successfully execute our commercialization strategy and may not be successful in doing so. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have incurred significant losses in every fiscal year since inception. For the six nine months ended June 30, 2023 September 30, 2023 and 2022, we reported a net loss of $36.7 million $48.9 million and $59.9 million $81.7 million, respectively. In addition, our accumulated deficit as of June 30, 2023 September 30, 2023 was $591.4 million $603.6 million.

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

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

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

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

We may never be profitable and we may not be able to continue operations without additional fundings.

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

- obtain commercial quantities of our products at acceptable cost levels;
- successfully manage inventory;
- sell and distribute our products on terms acceptable to us;
- achieve an adequate level of market acceptance of our products in the medical community and with third-party payors, including placement in accepted clinical guidelines for the conditions for which our product candidates are intended to target;
- obtain and maintain third-party coverage and adequate reimbursement for our products;
- compete effectively against our competitors; and
- launch and commercialize our products utilizing our own sales force or by entering into partnership or co-promotion arrangements with third parties.

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

Risks Related to Future Financial Condition

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

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

We may be required to or choose to obtain further funding through public equity offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing obtained by us would be senior to our common stock, would likely cause us to incur significant interest expense or other costs, and could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may increase our expenses and make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions and in-licensing opportunities. Under our existing credit facility dated March 8, 2022, as amended (the "Hayfin Loan Agreement"), with the lenders from time to time parties thereto (the "Lenders"), Hayfin Services LLP, as administrative agent for the Lenders, Xeris Pharmaceuticals, Inc. and, Xeris Biopharma Holdings, Inc., as amended (the "Hayfin Loan Agreement"), and our subsidiaries party thereto, we are restricted in our ability to incur additional indebtedness and to pay dividends. Any additional debt financing that we may secure in the future could include similar or more restrictive covenants relating to our capital raising activities, buying or selling assets and other financial and operational matters, which may make it more difficult for us to obtain additional capital, manage our business and pursue business opportunities. We may also be required to secure any such debt obligations with some or all of our assets. For example, our Hayfin Loan Agreement is secured by substantially all of our property and assets, including our intellectual property assets, subject to certain exceptions.

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

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due, or to repurchase our Convertible Notes for cash following a fundamental change, if required, and our existing and future indebtedness may limit our ability to repurchase the Convertible Notes.

On June 30, 2020, we completed a public offering of $86.3 million aggregate principal amount of our 5.00% Convertible Senior Notes due 2025 (the "Convertible "2025 Convertible Notes"), including $11.3 million pursuant to the underwriters' option to purchase additional notes which was exercised in July 2020. A total principal amount of $39.1 million of Convertible Notes converted into equity in the second

half of 2020. On September 29, 2023, we completed the exchange of $31,975,000 in aggregate principal amount of the 2025 Convertible Notes for $33,574,000 in aggregate principal amount of new 8.00% Convertible Senior Notes due 2028 (the "2028 Convertible Notes" and together with the 2025 Convertible Notes, the "Convertible Notes"). As of June 30, 2023 September 30, 2023, the outstanding balance of the 2025 Convertible Notes was $47.2 million $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million. The 2025 Convertible Notes are governed by the terms of a base indenture for senior debt securities dated June 30, 2020 (the "Base "2025 Base Indenture"), as supplemented by the first supplemental indenture thereto dated June 30, 2020 and the second supplemental indenture thereto dated October 5, 2021 ("the (the "2025 Supplemental Indentures" and together with the 2025 Base Indenture, the "Indenture" "2025 Indenture"), each between us and United States U.S. Bank Trust Company, National Association (f/k/a U.S. Bank National Association), as trustee. The 2028 Convertible Notes are governed by the terms of an indenture for senior debt securities dated September 29, 2023 (the "2028 Indenture" and together with the 2025 Indenture, the "Indentures") between us and U.S. Bank Trust Company, National Association, as trustee. Failure to satisfy our current and future debt obligations under the Indenture Indentures could result in an event of default and, as a result, all of the amounts outstanding could immediately become due and payable. In the event of an acceleration of amounts due under the Indenture Indentures as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness.

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

In addition, we have $150.0 million of term loans outstanding under our Hayfin Loan Agreement as of June 30, 2023 September 30, 2023. All obligations under our Hayfin Loan Agreement are secured by substantially all of our property and assets, including our intellectual property assets, subject to certain limited exceptions. The term loans and the Convertible Notes may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. Failure to satisfy our current and future debt obligations under our Hayfin Loan Agreement could result in an event of default thereunder and, as a result, our lenders could accelerate all amounts due. Events of default also include our failure to comply with customary affirmative and negative covenants as well as a default under any indenture or other agreement governing convertible indebtedness permitted by the Hayfin Loan Agreement, including the Indenture. Indentures. The Hayfin Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict our ability to incur additional indebtedness, grant liens, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. In the event of an acceleration of amounts due under our Hayfin Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

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

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

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

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

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

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

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

Risks Related to Commercialization and Marketing

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

To date, we have expended significant time, resources, and effort on the development of our product candidates, and a substantial portion of our resources recently has been and will continue to be focused on marketing and commercializing our approved products, Gvoke, Keveyis and Recorlev, in the United States. Our business and future success are substantially dependent on our ability to generate and increase product revenue in the near term. Our estimates of the potential market opportunity for Gvoke, Keveyis, Recorlev and our product candidates include several key assumptions of the current market size and current pricing for commercially available products and are based on industry and market data obtained from industry publications, studies conducted by us, our industry knowledge, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, the actual market for our product and product candidates could be smaller than our estimates of our potential market opportunity. Our product candidates are in various stages of development and subject to the risks of failure inherent in developing drug products. Any delay or setback in the regulatory approval, product launch, commercialization or distribution of any of our product candidates will adversely affect our business. The infrastructure, systems, processes, policies, relationships and materials we have built for the commercialization of Gvoke, Keveyis and Recorlev may not be sufficient for us to achieve success at the levels we expect. Further, our products may contain undetected manufacturing defects, including mislabeling, which might require product replacement, re-labeling or product recalls, which could further harm our business. For more information, see the section entitled, "*Business — Coverage and Reimbursement*" *Reimbursement*" in our Annual Report on Form 10-K for the year ended December 31, 2022.

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

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

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

- regulatory authorities may withdraw approvals of such product, require us to take our approved product off the market or ask us to voluntarily remove the product from the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications or the issuance of field alerts to physicians and pharmacies;
- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy ("REMS") including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions;
- we may be required to change the way a product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or products liability claims; and
- our reputation may suffer.

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

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

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

For example, Gvoke has numerous competitors in the severe hypoglycemia market, which currently include Amphastar's Baqsimi, an intranasal glucagon dry powder, Zealand Pharma's Zegalogue, a dasiglucagon outlicensed to Novo Nordisk, Novo Nordisk's GlucaGen HypoKit, Fresenius Kabi's glucagon emergency kit for low blood sugar, and Amphastar's generic Glucagon for Injection Emergency Kit. At any time, these or other industry participants may develop alternative treatments, products, or procedures for the treatment of severe hypoglycemia that compete directly or indirectly with Gvoke. 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.

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

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

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

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

We intend to leverage the sales and marketing capabilities that we have established for our approved products to commercialize additional product candidates for the management of other conditions, if approved by the FDA, in the United States. If we are unable to do so for any reason, we would need to expend additional resources to establish commercialization capabilities for those product candidates, if approved. In the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of our product candidates could be delayed which would negatively impact our ability to generate product revenue.

In addition, we intend to continue to establish collaborations to commercialize our product candidates outside the United States, if approved by the relevant regulatory authorities. Therefore, our future success outside the United States will depend, in part, on our ability to enter into and maintain collaborative relationships, 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 forces or exert the extent level of effort that we depend on third parties for would if we were marketing and distribution, any revenues we receive will depend upon selling the efforts of such third parties, and such efforts may not be successful. product ourselves.

Risks Related to Third-Parties Actions and Market Acceptance

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

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

Our third-party suppliers may not be able to produce sufficient inventory to meet commercial demand in a timely manner, or at all, and we continue to experience longer long lead times for certain components and materials used in the production of our products and product candidates. Our third-party suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our products. As a result, we may not obtain sufficient quantities of products, components or other key materials in the future, which could have a material adverse effect on our business as a whole. Any disruption to the facilities or operations of our third-party suppliers resulting from weather-related events, epidemics, including global health concerns, fire, acts of terrorism, political instability, war, labor or geopolitical issues, or any other cause could materially impair our ability to manufacture our products and to distribute our products to customers. For example, we We have a global supply chain and manufacture some components of our products outside the United States, including without limitation, Taiwan. Taiwan and Israel. The current war between Israel and Hamas could directly and indirectly affect our operations. For example, the Israel-Hamas war could result in disruptions to the facilities or operations of our third-party suppliers, including, but not limited to, the manufacturing of Keveyis, may result in longer lead times

which may cause exports out of Israel to be delayed or restricted or could result in other adverse events (such as damage or destruction to the facility used to manufacture and store Keveyis) which we cannot predict with any certainty. Any interruption or other delay in the production or delivery of our supplies could reduce sales of our products and increase our costs and any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

Gvoke and some of our product candidates are drug-device combination products that are regulated under the drug regulations of the Federal Food, Drug, & Cosmetic Act ("FDCA") based on their primary mode of action as a drug. Third-party manufacturers may fail to comply with the current Good Manufacturing Practice ("CGMP") regulatory requirements applicable to drug-device combination products, including applicable provisions of the FDA's drug CGMP regulations, device CGMP requirements embodied in the Quality System Regulation ("QSR" (the "QSR") or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our products and product candidates, re-labeling or re-packaging of our products, operating restrictions and criminal prosecutions, any of which could significantly affect the supply of our products and product candidates. The facilities used by our contract manufacturers to manufacture our products and product candidates must be registered with the FDA and are subject to inspections conducted by the FDA to ensure compliance with CGMPs. 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 the QSR. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or circumstances where the contractor may not be able to maintain compliance with the applicable CGMP or the QSR. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications, CGMP and/or the QSR and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or such foreign regulatory authorities do not approve these facilities for the manufacture of our products or product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to market our products or develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

- our suppliers may fail to comply with regulatory requirements or make errors in manufacturing raw materials, components or products that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;
- we may be subject to price fluctuations due to terms within long-term supply arrangements with suppliers or lack of long-term supply arrangements for key materials and products;
- given the long lead times to change suppliers, existing suppliers may utilize that as leverage in negotiations with us in a manner that is adverse to our business;
- our suppliers may lose access to critical services or sustain damage to a facility, including losses due to natural disasters, geo-political events, or epidemics that may result in a sustained interruption in the manufacture and supply of our products;
- fluctuations in demand for our products or a supplier's demand from other customers may affect their ability or willingness to deliver materials or products in a timely manner or may lead to long-term capacity constraints at the supplier;
- we may not be able to find new or alternative sources or reconfigure our products and manufacturing processes in a timely manner if necessary raw materials or components become unavailable;
- our suppliers may encounter financial or other hardships unrelated to our demand for materials, products and services, which could inhibit their ability to fulfill our orders and meet our requirements; and
- the possibility of breach or termination of a manufacturing agreement or purchase order by the third party.

In addition, we could be forced to secure new materials or develop alternative third-party suppliers, which can be difficult given our product complexity, long development lead-times and global regulatory review processes.

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

Reimbursement decisions by third-party payors and consolidation within the healthcare industry and among competitors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used and pricing pressure may impact our ability to sell our products at prices necessary to support our current business strategies.

Our future revenues and profitability will be adversely affected if the United States and foreign governmental, private third-party insurers and payors and other third-party payors, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products on behalf of patients. If these entities do not provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for some patients to afford and physicians may not prescribe them. In addition, limitations on the amount of reimbursement for our products may also reduce our profitability. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. There have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our products or product candidates for which we obtain marketing approval. As the healthcare industry consolidates, competition to provide products and services to industry participants has become more intense and may intensify as the potential purchasers of our products or third-party payors use their purchasing power to exert competitive pricing pressure and other terms favorable to them. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our potential purchasers. If competitive forces drive down the prices we are able to charge for our products, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business. For more information, see the sections entitled, "*Business — Coverage and Reimbursement*" *Reimbursement*" and *"Business*"*Business — Healthcare Reform*" *Reform*" in our most recent Annual Report on Form 10-K.

Government and other third-party payors are also challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. 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 and (ii) third-party payors are increasingly requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement;

and many pharmaceutical manufacturers must calculate and report certain price metrics to the government, such as average manufacturer price, or AMP, and Best Price. Penalties may apply when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

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

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

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

We depend on a relatively small number of customers for the majority of our revenue. As further discussed in "Note 2 - Basis of presentation and summary of significant accounting policies and estimates" to our condensed consolidated financial statements, for the six nine months ended June 30, 2023 September 30, 2023 and 2022, four customers accounted for over 90% of the Company's gross product revenue. At June 30, 2023 September 30, 2023 and December 31, 2022, the same four customers accounted for over 95% 85% of the trade accounts receivable, net. We expect to continue to depend upon a relatively small number of customers for a high percentage of our revenue. If we lose any of these customers and are unable to establish new customer relationships, our business, prospects, financial condition and results of operations could be materially and adversely affected. Additionally, if one or more of our major customers experiences financial difficulties, the adverse impact on us could be substantial.

Risk Related to our Dependence on Third Parties for Clinical Trials

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

We depend on independent clinical investigators, clinical research organizations ("CROs"), academic institutions and other third-party service providers to conduct clinical trials with and for our product candidates. Although we rely heavily on these parties for successful execution of our clinical trials, we are ultimately responsible for the results of their activities and many aspects of their activities are beyond our control. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, but the independent clinical investigators may prioritize other projects over ours or may fail to timely communicate issues regarding our products to us. Further, conducting clinical trials in foreign countries, as we have done and may do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. The delay or early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials, or our reliance on results of trials that we have not directly conducted or monitored could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition.

We maintain compliance programs related to our clinical trials through our clinical operations and development personnel. Our clinical trial vendors are required to monitor and report to us issues with the conduct of our clinical trials, and we monitor our clinical trial vendors through our clinical, regulatory, and quality assurance staff and other service providers. Our clinical trial vendors or personnel may not timely and fully discover and report any fraud or abuse or other issues that may occur in connection with our clinical trials to us. Such fraud or abuse or other issues, if they occur and are not successfully remediated, could have a material adverse effect on our research, development, and commercialization activities and results.

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

Risks Related to Regulatory Approval

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

We have devoted significant financial resources and business efforts to the development of our product candidates. We cannot be certain that any of our product candidates will receive marketing approval.

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

NDAs and BLAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs and BLAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. Any delay or setback in the regulatory approval or commercialization of any of our product candidates will adversely affect our business.

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

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway or other pathways we have selected, as applicable, for our product candidates;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval, including any findings that the clinical and other benefits of our product candidates do not outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as any of our product candidates (as applicable);
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may audit some or all of our clinical research and human factors study sites to determine the integrity of our data and may reject any or all of such data;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials or implementation of a REMS;
- may change its criteria for approval, policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

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

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

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

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

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

We are pursuing a regulatory pathway pursuant to Section 505(b)(2) of the FDCA for the approval of certain of our product candidates, which allows us to rely on submissions of existing clinical data for the drug. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman

Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval.

If the FDA determines that our product candidates do not meet the requirements of Section 505(b)(2), we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. In March 2010, former President Obama signed into law legislation creating an abbreviated pathway for approval under the Public Health

Service Act, or PHS Act, of biological products that are similar to other biological products that are approved under the PHS Act. The legislation also expanded the definition of biological product to include proteins such as insulin. The law contains transitional provisions governing protein products such as insulin, that, under certain circumstances, might permit companies to seek approval for their insulin products as biologics under the PHS Act. Specifically, on March 23, 2020, a small subset of "biological products" approved under the FDCA, such as insulin, which historically were approved as drugs, transitioned to being regulated as biological products. Being regulated as biological products enables transition products to serve as the reference product for biosimilar or interchangeable products approved through the abbreviated licensure pathway. The transition is a regulatory action in which the approved drug application for a transition biological product will be "deemed" to be a biologics license application. Thus, our XeriSol pramlintide-insulin co-formulation, which would have previously been reviewed through a 505(b)(2) NDA, is instead required to be approved under the PHS Act. If our other product candidates do not meet the requirements of Section 505(b)(2) or are otherwise ineligible or become ineligible for approval via the Section 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, our product candidates may not receive the requisite approvals for commercialization.

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

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

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

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

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

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

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

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

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

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

We have received orphan drug designation from the FDA for five indications for our products and product candidates, which are our ready-to-use glucagon for post-bariatric hypoglycemia ("PBH") and Congenital Hyperinsulinism ("CHI"), our ready-to-use diazepam for acute repetitive seizures and Dravet syndrome, and for Recorlev, for the treatment of adult patients with endogenous Cushing's syndrome for whom surgery is not an option or has not been curative. We may pursue such designation for others in specific orphan indications in which there is an unmet medical need. We relied on orphan drug exclusivity in the marketing and sale of Keveyis until it expired on August 7, 2022 and with respect to the marketing and sale of Recorlev, intend to rely on orphan drug exclusivity through December 30, 2028. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Although we may seek orphan drug designation for certain additional indications, we may never receive such designation. Moreover, obtaining orphan drug designation for one indication does not mean we will be able to obtain such designation for another indication.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective or makes a major contribution to patient care. In assessing whether a drug provides a "major contribution to patient care" over and above the currently approved drugs, which is evaluated by the FDA on a case-by-case basis, there is no one objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration. However, such a demonstration to overcome the seven-year market exclusivity may be difficult to establish with limited precedents and there can be no assurance that we will be successful in these efforts if and where we pursue them. Even with respect to the indications for which we have received orphan designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of our product candidates could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity for the same drug and same condition. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off-label in our approved indication, and different drugs for the same condition may already be approved and commercially available.

In 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. Legislation has been proposed by the European Commission that, if implemented, has the potential in some cases to shorten the ten-year period of orphan marketing exclusivity. We have received orphan drug designation from the EMA for our ready-to-use glucagon for the treatment of CHI and NIPHS, which includes patients with PBH.

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

We do not have any products other than Gvoke, Keveyis, and Recorlev approved for sale in the United States, nor any products or product candidates other than Ogluo approved for sale in any international markets, and we do not have experience in obtaining regulatory approval in international markets outside of the EU and the UK. In order to market products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain clearance or approval in the United States.

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

requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any drug we develop will be unrealized.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products or product candidates for which we obtain marketing approval. For more information, see the section entitled, "*Business — Healthcare Reform*" *Reform*" in our Annual Report on Form 10-K for the year ended December 31, 2022.

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

The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for approved products. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products and product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval of those product candidates for which we seek marketing approval, as well as subject us to more stringent labeling and post-marketing testing and other requirements.

Risks Related to Product Development

Our failure to successfully identify, develop and market additional product candidates, or acquire additional product candidates or enter into collaborations or other commercial agreements could impair our ability to grow.

As part of our growth strategy, we intend to identify, develop and market additional product candidates leveraging our formulation science, and evaluate other commercial relationships through collaborations or other strategic agreements. We are exploring various therapeutic opportunities for our pipeline programs. We may spend several years completing our development of any particular current or future internal product candidates, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. Gvoke, which delivers ready-to-use glucagon via a pre-filled syringe or auto-injector, was approved by the FDA in 2019 for the treatment of severe hypoglycemia in pediatric (aged two years and above) and adult patients with diabetes. While we have identified several additional potential applications of our ready-to-use glucagon, there is no guarantee that we will be able to utilize our formulation science to obtain approval of additional product candidates.

In the future, we may be dependent upon other pharmaceutical companies, academic scientists and other researchers to sell or license product candidates, approved products or the underlying technology to us. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. In addition, we expect to seek one or more collaborators for the development and commercialization of one or more of our products or product candidates, particularly with respect to our pipeline product candidates or foreign geographies. We face significant competition in seeking appropriate collaborators. We

have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies or enter into collaborations or other strategic arrangements and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates or approved products on terms that we find acceptable, or at all.

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

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

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

Risks Related to our Industry and Ongoing Legal and Regulatory Requirements

Risks Related to Ongoing Regulatory Obligations

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

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

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

Regulatory agencies may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA, the Federal Trade Commission and other agencies and government entities, including the Department of Justice ("DOJ") and the Office of Inspector General of the United States Department of Health and Human Services, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we, or any future collaborators, do not market any of our products for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to 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 June 7, 2023, we received an untitled letter from FDA's Office of Prescription Drug Promotion ("OPDP") regarding specific sections of the Recorlev consumer website. The letter raised concerns that the webpages made false or misleading claims about the safety and efficacy of Recorlev that misbrand Recorlev within the meaning of the FDCA. We have submitted a response to the FDA regarding our plan to revise those sections of the webpages at issue issue. The FDA completed evaluation of our response and are issued a close-out letter in discussions with August 2023 stating that it appears that we have addressed all the FDA related to that remediation. concerns contained in the untitled letter.

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

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

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

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our arrangements with investigators, healthcare practitioners, consultants, third-party payors and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. For more information, see the section entitled, "*Business — Other Healthcare Laws and Compliance Requirements" Requirements*" in our Annual Report on Form 10-K for the year ended December 31, 2022.

Efforts to ensure that our business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom may receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. Defending against any such actions can be costly and time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. The United States government has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide copay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, copay, and co-

insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance. Further, it is possible that changes in insurer policies regarding copay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current United States presidential administration may reverse or otherwise change these measures, both the current United States presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict how the implementation of and any further changes to this rule will affect our business.

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

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

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

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

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

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

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

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

Various laws, regulations and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non-United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside the United States, we are required to dedicate additional resources to comply with laws and regulations in each new jurisdiction in which we are operating or plan to operate, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates 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 United States government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor.

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

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

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries can further reduce prices. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies, which is time consuming and costly. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement

and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Risks Related to Industry Competition

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

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA"). FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our products or product candidates, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our products or product candidates. In some cases, even this limited bioequivalence testing can be waived by the FDA. Laws have also been enacted to facilitate the development of generic drugs and biologics based off recently approved NDAs and BLAs. The Creating and Restoring Equal Access to Equivalent Samples Act

("CREATES Act") was enacted in 2019 requiring sponsors of approved NDAs and BLAs to provide sufficient quantities of product samples on commercially reasonable, market-based terms to eligible product developers. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. Providing product samples and allocating additional resources to respond to such requests or any legal challenges under this law, could adversely impact our business. Competition from generic equivalents to our products or product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products or product candidates. For example, Amphastar's ANDA for generic Glucagon for Injection Emergency Kit was approved by the FDA on December 29, 2020 for the treatment of severe hypoglycemia and while we previously relied on orphan drug exclusivity in the marketing and sale of Keveyis through the expiration of orphan drug exclusivity, Torrent Pharmaceuticals Limited's ANDA for generic dichlorphenamide was approved on December 29, 2022. We intend to rely on orphan drug exclusivity and if available, NCE exclusivity in the marketing and sale of Recorlev. While we applied for NCE exclusivity for Recorlev under section 505(u) of the FDCA, the FDA may determine that the Recorlev application does not meet the eligibility criteria under 505(u) for NCE exclusivity.

Risks Related to Our Intellectual Property

Risks Related to Protecting Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries with respect to the use, formulation and structure of our proprietary product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we may in the future also license or purchase patents or applications owned by others. The patent application and approval process is expensive and time consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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

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

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

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

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

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

Pending and future patent applications may not result in patents being issued which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property Litigation

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

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

We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of Gvoke, Keveyis, Recorlev, or our product candidates. Generally, we do not conduct independent reviews of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. Because patent applications can take up to 18 months after filing to become public, and many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

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

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

A third party or former employee or collaborator may claim an ownership interest in one or more of our patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing, and marketing of the affected product or products. A third party could assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel.

If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Furthermore, any potential intellectual property litigation also could force us to do one or more of the following:

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

The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation.

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

We may also be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors. Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade

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

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

We expect to submit NDAs under Section 505(b)(2) of the FDCA for most of our product candidates. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies and/or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. An NDA under Section 505(b)(2) would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for a previously approved drug. For NDAs submitted under Section 505(b)(2), the patent certification and related provisions of the Hatch-Waxman Act apply.

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

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

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

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

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

We may not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products and product candidates.

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

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

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

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover,

there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Risk Related to Intellectual Property Laws

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and are therefore costly, time consuming and inherently uncertain. Changes in patent statutes, regulations promulgated under them, and court holdings interpreting the statutes and regulations could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition. Depending on future actions by the United States Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Further, for a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. Alternatively, a petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to the United States patents in lawsuits in the United States federal courts and uses a lower burden of proof than used in litigation in the United States federal courts. Therefore, it is generally considered easier and less costly for a competitor or third party to have a United States patent invalidated in a USPTO post-grant review or inter partes review proceeding than in a litigation in a United States federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which could result in a loss of the challenged patent right to us.

Risks Related to Employee Matters, Managing Growth and Ongoing Operations

Risks Related to Potentially Under-resourced Regulatory Authorities

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

The ability of the FDA 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 United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. 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 pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should the 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 adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risk Related to Employment Matters

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

We are dependent upon the continued services of key members of our executive management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our executive management team, including Paul Edick, our Chief Executive Officer, Steven Pieper, our Chief Financial Officer, John Shannon, our President and Chief Operating Officer, Ken Johnson, our Senior Vice President, Global Development and Medical Affairs, and Beth Hecht, our Chief Legal Officer and Corporate Secretary. The loss of any one of these individuals could disrupt our operations or our strategic plans. Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

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

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

Risks Related to Our Common Stock

Risks Related to Investment in Securities

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

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

- our ability to successfully commercialize Gvoke, Keveyis, and Recorlev;
- regulatory actions with respect to our products and product candidates;
- regulatory actions with respect to our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of our pipeline product candidates;
- commencement or termination of collaborations for our development programs;
- the results of our efforts to develop additional product candidates or products;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure or discontinuation of any of our development programs;
- the pricing and reimbursement of Gvoke, Keveyis, Recorlev or any of our product candidates that may be approved;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including impacts from inflation, interest rate increases, major bank failure or sustained financial market illiquidity; and
- any ongoing indirect impacts from public health crisis, such as a resurgence of the COVID-19 pandemic.

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

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us in connection with volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business. On August 4, 2023 November 6, 2023, the closing price of a share of our common stock was $2.64 $1.85 per share.

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

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

The Convertible Notes are convertible into shares of common stock at any time at the option of the holder subject to certain conditions. We have reserved a sufficient number of shares of common stock for issuance upon conversion of the Convertible Notes, CVRs and warrants. During the second half of 2020, $39.1 million in principal amount of Convertible Notes were converted into 13,171,791 shares of our common stock. As of June 30, 2023 September 30, 2023, the outstanding balance of Convertible Notes was $47.2 million $48.8 million. If any

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 is 326.7974 shares of our common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $3.06 per share of common stock, and is subject to adjustment under the terms of the Convertible Notes. In the event of certain circumstances, we will increase the

conversion rate, provided that the conversion rate will not exceed 367.6470 shares of our common stock per $1,000 principal amount of Convertible Notes in the case of the 2025 Convertible Notes and 549.4505 shares of our common stock per $1,000 principal amount of Convertible Notes in the case of the 2028 Convertible Notes. Because the conversion rates of the Convertible Notes adjust upward upon the occurrence of certain events, our existing shareholders may experience more dilution if any or all of the Convertible Notes are converted into shares of common stock after the adjusted conversion rate became effective.

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

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

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

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

Risks Related to Tax

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

As of June 30, 2023 September 30, 2023, we had federal net operating loss carryforwards of $501.4 million and various state net operating loss carryforwards of $345.3 million. If not utilized, the federal net operating losses generated in taxable years beginning on or before December 31, 2017 will expire at various dates between 2025 and 2037, and these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Federal net operating losses generated in taxable years beginning after December 31, 2017 can be carried forward indefinitely; however, such net operating losses may only offset up to 80% of taxable income in taxable years beginning after June 30, 2023 September 30, 2023. As of June 30, 2023 September 30, 2023, we had $6.7 million and $3.1 million of federal and state income tax credits, respectively, to reduce future tax liabilities. If not utilized, the $5.4 million in federal income tax credits will begin to expire in 2025, and the $2.5 million of state research and development credits will begin to expire in 2022, and these tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Code") and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Our existing net operating losses or credits may be subject to limitations arising from previous ownership changes, and if we undergo future ownership changes, many of which may be outside of our control, our ability to utilize our net operating losses or credits could be further limited by Sections 382 and 383 of the Code. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits.

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

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

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

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

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

- establish a classified board of directors such that all members of the board are not elected at one time; allow the authorized number of our directors to be changed only by resolution of our board of directors; and limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws; and
- establish a Delaware Forum Provision (as defined below) or a Federal Forum Provision (as defined below).

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the

person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in our stockholders' best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

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

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

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of or based on a fiduciary duty owed by any of our current or former directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended. In addition, our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision").

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

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

General Risk Factors

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

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

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

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

We may face liability claims related to the use or misuse of our products and product candidates. These claims may be expensive to defend and may result in large judgments against us. During the course of treatment, patients using our products and product candidates could suffer adverse medical effects for reasons that may or may not be related to our products and product candidates. Any of these events could result in a claim of liability. Any such claims against us, regardless of their merit, could result in significant costs to defend or awards against us that could materially harm our business, financial condition or results of operations. In addition, any such claims against us could result in a distraction to management, decreased demand for our products, an adverse effect on our public reputation, and/or difficulties in commercializing our products. To date, we have not received notice of any products liability claims against us. We maintain total products liability insurance coverage of $15.0 million.

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

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

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

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

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act ("JOBS Act") enacted in April 2012, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an "emerging growth company" for up to five years from the date of our IPO. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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

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

During the course of our ongoing review and testing of our internal controls, we may identify deficiencies and may incur significant costs to remediate such deficiencies, including material weaknesses, if any, that we identify through these efforts. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

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

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

The trading market for our common stock is influenced by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. Analysts who publish information about our common stock may have relatively little experience covering our company, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. If any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

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 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 the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years.

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 the last business day of our second quarter in any given year, which would allow us to continue to take advantage of these exemptions. As of June 30, 2023, we determined that we will no longer qualify as a "smaller reporting company" in 2024.

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

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

We may be subject to the United States federal and state, European, UK and other foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). We have personnel located in Ireland and have conducted and may in the future conduct clinical trials in the EU European Economic Area ("EEA") and/or the UK subjecting us to additional privacy restrictions and data protection requirements. The collection and use of personal data (including health data data) in the EU EEA and the UK are governed by the provisions of the EU General Data Protection Regulation ("EU GDPR"), as well as other national data protection legislation in force in relevant Member States, (including with respect to the EU GDPR as it forms part of EEA, and the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union

(Withdrawal) Act 2018 UK General Data Protection Regulation (the "UK GDPR", GDPR," together with the EU GDPR the "GDPR") and the UK Data Protection Act 2018 in with respect to the UK). UK. These laws impose a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the European Economic Area, EEA or EEA (or in the case of the UK, GDPR, outside of the UK), providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals' requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EEA and UK data protection rules. regimes. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Although

The GDPR prohibits the UK is regarded as a third country under the EU's GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers international transfer of personal data originating in the EEA to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK ("third countries") which are not deemed as adequate for the transfers of personal data by competent authorities, unless a derogation exists or adequate safeguards must be (for example, the European Commission approved Standard Contractual Clauses ("EU SCCs") and the UK International Data Transfer Agreement/Addendum ("UK IDTA")) are implemented in compliance with European EEA and UK data protection laws. On June 4, 2021, Where relying on the EC issued new forms of standard contractual clauses EU SCCs or UK IDTA for data transfers, from controllers or processors we may also be required to carry out transfer impact assessments on transfers made pursuant to the EU SCCs and the UK IDTA, on a case-by-case basis to ensure the law in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). As of December 27, 2022, the new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive for all transfers outside of the EEA. The UK is not subject to the European Commission's new standard contractual clauses but has published the UK International Data Transfer Agreement data importer's country and International Data Transfer Addendum to the new standard contractual clauses (the "IDTA"), which enable transfers from the UK. For new transfers, the IDTA already needs to be in place, and must be in place for all existing transfers from the UK from March 21, 2024. Following a ruling from the Court of Justice of the EU, in Data Protection Commissioner v Facebook Ireland Limited and Maximillian Schrems, Case C-311/18 ("Schrems II"), companies relying on standard contractual clauses to govern transfers of personal data to third countries (in particular the United States) will need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR. This assessment includes assessing whether third party vendors can also ensure these guarantees. The same assessment is required for transfers governed by the IDTA. We will be required to implement these new safeguards when conducting restricted data transfers international transfer obligations under the GDPR EEA and doing so UK data protection regimes will require significant effort and cost. cost, and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data from the EEA and UK to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position.

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

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

It is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term.Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. In addition, EEA Member States have adopted national laws to implement the EU GDPR that may partially deviate from the EU GDPR. Further, the competent authorities in the EEA Member States may interpret the EU GDPR obligations slightly differently from country to country and therefore we do not expect to operate in a uniform legal landscape in the EEA. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of European personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA.

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

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. The UK government has announced plans to reform the data protection legal framework in the UK in its Data Reform Bill but those have been put on hold. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EU.

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

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

Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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

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

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

Economic uncertainty in various global markets caused by political instability and conflict and economic challenges caused by has in the COVID-19 pandemic has past resulted, and may continue to result, in weakened demand for our products. Political developments impacting government spending and international trade, including potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-economic conditions. The effects of these events may continue due to potential United States government shutdowns and the transition in administrations, and the United States' ongoing trade disputes with China and other countries. In addition, the current military conflict conflicts between Russia and Ukraine and Israel and Hamas could disrupt or otherwise adversely impact our operations and related sanctions, export controls or other actions that may be initiated by nations including the United States, the EU, Russia or Russia countries or actors in the Middle East (e.g., potential cyberattacks, disruption of energy flows, etc.) could adversely affect our business and/or our supply chain or those of our third party service providers. The United States and other countries could impose wider sanctions and take other actions that may adversely affect our business should the conflict conflicts further escalate. It is not possible to predict the broader consequences of this conflict, these conflicts, which could include further sanctions, embargoes, regional instability, prolonged periods of higher inflation, international trade disruptions, supply disruptions, geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations. The continuing effect of any or all of these events could adversely impact demand for our products, harm our operations and weaken our financial results.

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

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

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

Our cash held in non-interest bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") limits and is predominantly held at one institution, Wells Fargo Bank, N.A. If such banking institution or any future banking institutions where we maintain our cash were to fail, we could lose all or a portion of those amounts held in excess of such insurance limits. For example, the recent closures of Silicon Valley Bank, where we maintained a portion of our cash, Signature Bank and First Republic Bank and their placement into receivership with the Federal Deposit Insurance Corporation ("FDIC") FDIC created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, future adverse developments with respect to *specific* financial institutions or the broader financial services industry, including concerns or rumors about any events of these kinds or similar risks, may lead to market-wide liquidity shortages and the FDIC may elect not to make all account holders whole. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds and could have a material adverse effect on our business and financial condition.

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

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

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

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

ITEM 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
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
3.2	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K12B (File No. 001-40880) filed with the Securities and Exchange Commission on October 5, 2021)
4.1	Indenture, dated as of September 29, 2023, between the Company, the Guarantor and the Trustee (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (file No. 001-40880) filed with the Securities and Exchange Commission on September 29, 2023)
4.2	Form of 8.00% Convertible Senior Notes due 2028 (included in Exhibit 4.1)
10.1*	Amendment No 3, Waiver Consent to Credit and Consent to Credit and GuarantyAgreement, , dated as of April September21, 26, 2023, among Xeris Pharmaceuticals, Inc., the Registrant, the lenders party thereto and Hayfin Services LLP, as administrative agent
10.2*† 10.2	Amendment 5Form of Exchange Agreement between the Company, the Guarantor and certain holders of the Existing Notes (incorporated by reference to Exhibit 10.1 to the QualityAssurance Agreement, dated as of May 22, 2023, between Bachem AG Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Xeris Pharmaceuticals, Inc. Exchange Commission on September 27, 2023
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
32.1*+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

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

SIGNATURES

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

Xeris Biopharma Holdings, Inc.

Date: August 8, November 9, 2023

By /s/ Paul R. Edick

Paul R. Edick

Chief Executive Officer and Chairman

(Principal Executive Officer)

Date: August 8, November 9, 2023

By /s/ Steven M. Pieper

Steven M. Pieper

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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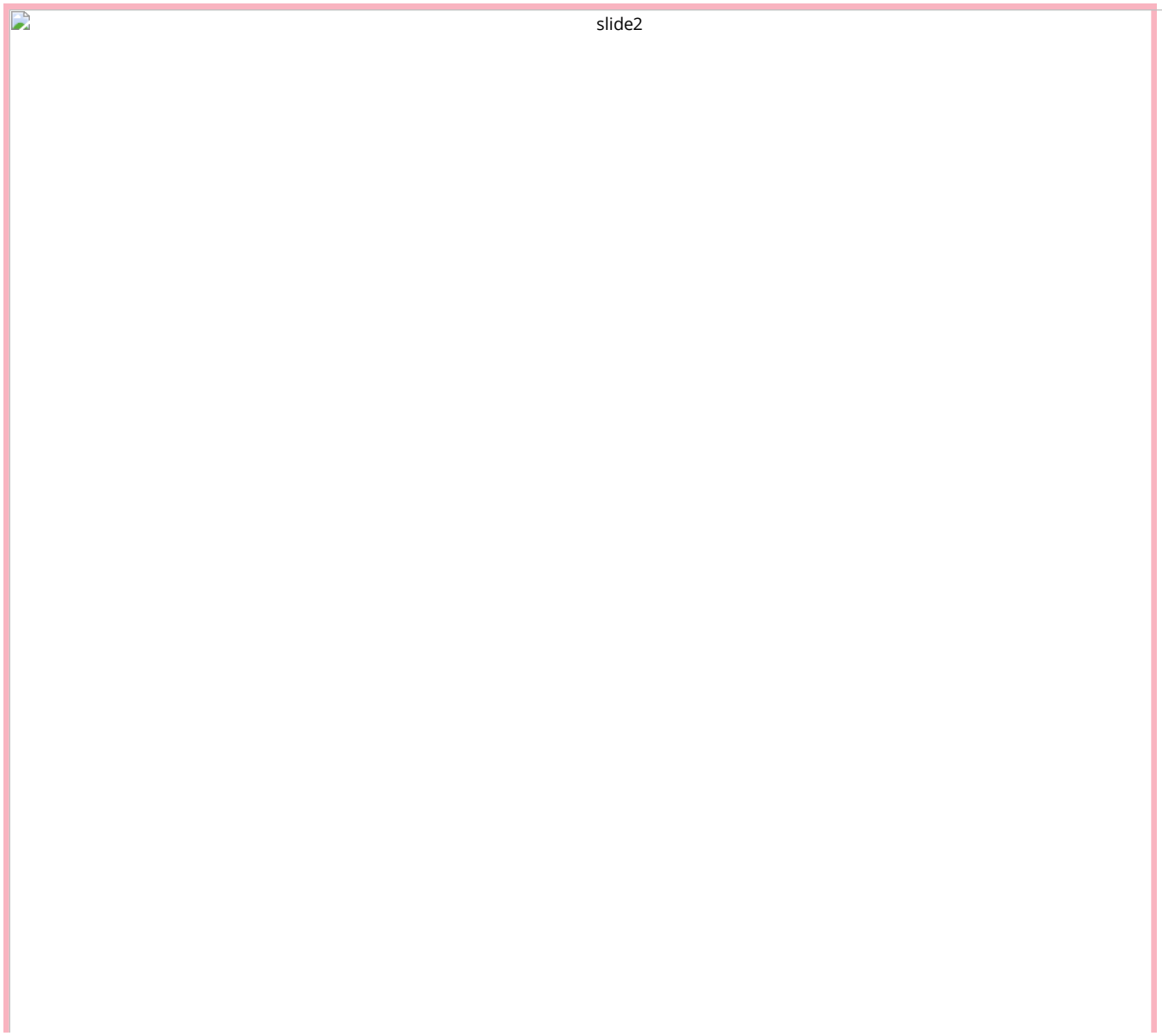
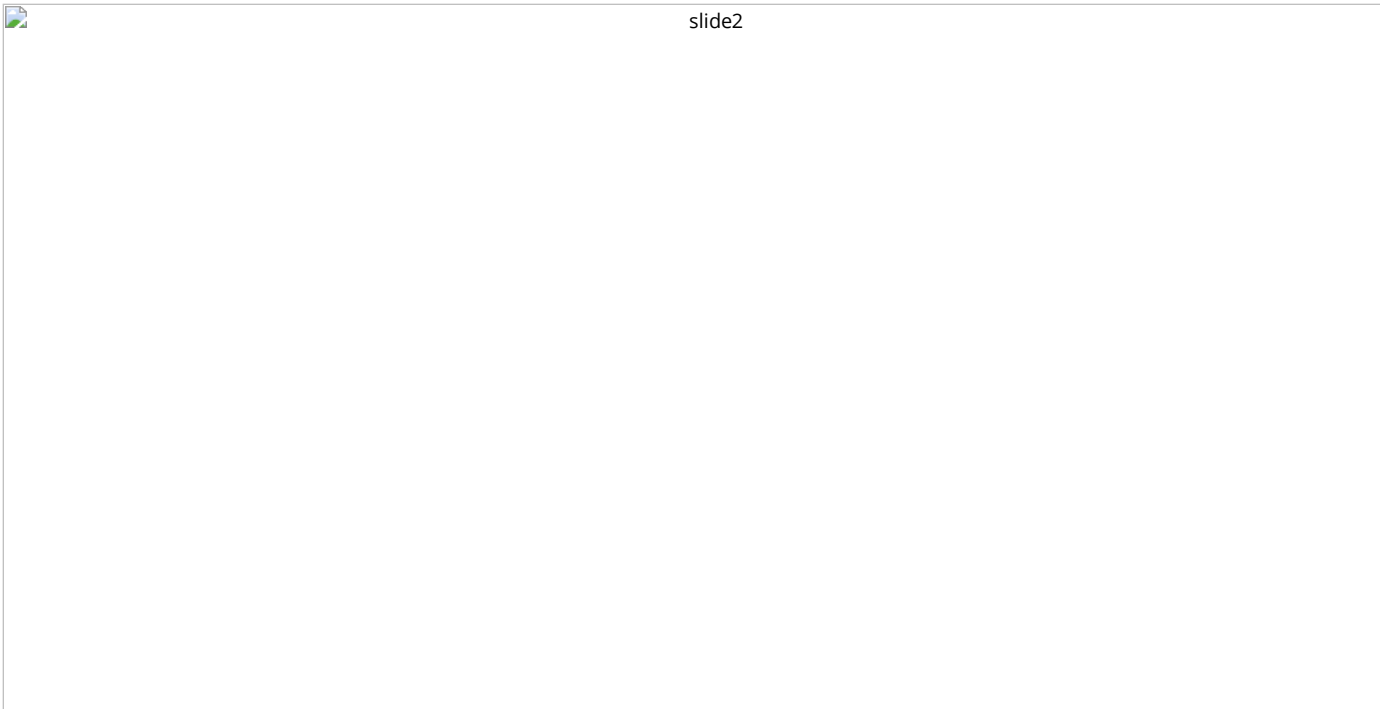
1 AMENDMENT NO. 3, WAIVER AND AMENDMENT NO. 3, WAIVER AND April 21,
2023 September 26, 2023 "Amendment" "Consent"

change exchange, pursuant to one or more exchange agreements substantially in depository of certain Controlled Accounts listed on form attached hereto as (such agreements, the "Exchange Agreements"), a portion of the Existing Convertible Notes for new convertible promissory notes (the "New Convertible Notes") that qualify as Permitted Convertible Indebtedness, such New Convertible Notes to be issued pursuant to an indenture substantially in the form attached from Silicon Valley Bank, a Division of First-Citizens Bank & Trust Company (successor as Exhibit B (the "Indenture"; the transactions contemplated purchase to Federal Deposit Insurance Corporation as Receiver for Silicon Valley Bridge Bank, N.A. (as successor to Silicon Valley Bank)) ("SVB") to Wells Fargo Bank, N.A. ("Wells Fargo") (such change, Exchange Agreements and "Accounts Change" and such new Deposit Accounts, Indenture. "Wells Fargo Bank Accounts" "Convertible Note Refinancing" the Credit Agreement, such Permitted Convertible Indebtedness is required to meet certain conditions, including, among other requirements, (i) that such Indebtedness will be subject to terms that are customary and typical for unsecured convertible debt of such type; and (ii) that such Indebtedness will not include terms that are more restrictive on the Obligors than the provisions of the Credit Agreement; WHEREAS, pursuant to 8.17 8.19 among other cash management comply with certain redemption maintain at all times all Deposit Accounts as Controlled Accounts; regarding any Relevant Existing Convertible Notes; and (i) Accounts Change notwithstanding that convertible Note Refinancing and, subject to Wells Fargo Bank Accounts will not constitute Controlled Accounts upon the opening thereof terms (ii) permit the Obligors a period of forty-five (45) days after the opening of each Wells Fargo Bank Account to cause such Wells Fargo Bank Account to constitute a Controlled Account (each, a "Specified Account Period" and collectively, the "Specified Accounts Period"); WHEREAS the Obligors have requested that the Agent and the Lenders waive the requirements condition in Section 8.17 of the Credit Agreement during the Specified Accounts Period and solely with respect to the Wells Fargo Bank Accounts; WHEREAS, the Obligors have also informed the Agent that they desire to change the issuer of certain letters of credit listed on Exhibit B hereto (the "SVB L/Cs") from SVB to Wells Fargo (the "L/C Change"); WHEREAS, pursuant to Section 9.01(p) of the Credit Agreement, the Obligors shall not have Indebtedness under any letters of credit in an aggregate face amount in excess of $2,000,000; provided such amount shall be automatically increased to (i) $4,800,000 so long as the Borrower Exhibit 10.1



2 is required to cause a letter of credit to be issued to the lessor under the lease for the premises located at 1375 W. Fulton Street, Chicago, IL 60607 or (ii) if the aggregate face amount of such letter of credit described in clause (i) above is reduced after the date of issuance thereof, $4,800,000 less the amount of such reduction; WHEREAS, to consummate the L/C Change, the Obligors desire to cause the issuance of new letters of credit by Wells Fargo (the "Wells Fargo L/Cs") to the current beneficiaries of the SVB L/C's, thereby exceeding the amount of Indebtedness under letters of credit permitted by Section 9.01(p) of the Credit Agreement until such time such beneficiaries return the SVB L/C's to SVB in cancellation thereof (the "L/C Terminations"); WHEREAS, the Obligors have requested that the Lenders and the Agent (i) consent to the L/C Change and (ii) waive compliance with Section 9.01(p) of the Credit Agreement for a period of thirty days after the issuance of each of the Wells Fargo L/Cs to permit the Obligors to complete the L/C Terminations (the "Specified L/C Period"); WHEREAS, the Obligors have informed the Lenders and the Agent that they have provided cash collateral in support of certain permitted credit card Indebtedness in violation of Section 9.02 of the Credit Agreement (the "Cash Collateral Event"); WHEREAS, the Obligors wish to amend the Credit Agreement to permit the providing of cash collateral with respect to certain permitted credit card Indebtedness of the Obligors; and WHEREAS, herein (i) consent to the Accounts Change and the L/C Change (ii) waive compliance with Section 8.17, Section 9.01(p) and Section 9.02(l) of the Credit Agreement, respectively, solely for the purpose of permitting the Obligors to consummate grant transactions, (iii) amend the Credit Agreement to permit the Obligors to provide cash collateral in support of permitted credit card Indebtedness, and (iv) waive any Default or Event of Default arising directly or indirectly as a result of the Cash Collateral Event (the "Specified Defaults"), in each case, on the terms and subject to the conditions set forth herein, including, without limitation, the compliance by the Obligors with the post-closing covenants set forth in Section 1.01(f) hereof (the "Post-Closing Covenants"). consent. ARTICLE I AMENDMENT, WAIVERS AND CONSENT SECTION 1.01. Amendment, Waivers and Consent; Agreements. (a) Effective as of the Effective Date, Section 9.02 of the Credit Agreement is hereby amended by: (i) (x) deleting the text "and" appearing at the end of clause (r) thereof, (y) deleting the text "." appearing at the end of clause (s) thereof and adding in its place the text "and;", and (z) adding a new clause (t) immediately after clause (s) thereof to read in its entirety as follows: Exhibit 10.1



3 "cash collateral accounts serving as collateral in connection with Indebtedness permitted pursuant to Section 9.01(o) in an amount up to 105% of such Indebtedness." (ii) replacing the text "(s)" appearing in the last sentence thereof with the text "(t)". (b) Effective as of the Effective Date, the Agent and the Lenders hereby (i) consent to the Accounts Change and (ii) waive compliance with Section 8.17 of the Credit Agreement solely with respect to the Wells Fargo Bank Accounts and solely during the applicable Specified Account Period. An Event of Default under Section 11.01(d) of the Credit Agreement shall occur if the Obligors fail to comply with clause (ii) of the Post-Closing Covenants set forth in Section 1.01(f) in the time period set forth therein. Upon written request of the Borrower prior to the end of any Specified Account Period, the Agent may, in its sole discretion, agree to extend such Specified Account Period. (c) ARTICLE I CONSENT SECTION 1.01. Consent; Agreements. (a) contained Credit Agreement or any other Document. Documents, waive the Specified Defaults. (d) Effective as of the Effective Date, the Agent and the Lenders hereby (i) L/C Change Convertible Note Refinancing, it being understood (ii) waive compliance agreed that, notwithstanding the foregoing, Section 9.01(p) respect to any Existing Convertible Notes that are not exchanged for New Convertible Notes pursuant to the Convertible Note Refinancing (such non-exchanged Existing Convertible Notes being the "Non- Exchanged Existing Convertible Notes"): (i) such Non-Exchanged Existing Convertible Notes (A) for which the maturity date therefor has been not been extended to a date not earlier than September 4, 2027 Section 9.02(l) (B) that remain outstanding on January 15, 2025, will qualify as (and will be treated as) Relevant Existing Convertible Notes for all purposes solely to complete the L/C Terminations (such that the basket capacity thereunder will be increased by no more than the face amount (including for purposes Wells Fargo L/Cs) definition of Maturity Date); (ii) Sections 8.19 solely during the Specified L/C Period. An Event of Default under Section 11.01(d) 9.06(f) occur if continue to apply to such Non-Exchanged Existing Convertible Notes; (iii) for purposes of satisfying Obligors fail requirement comply deposit Subject Cash into a Controlled Account In accordance (iii) (ii)(y) Post-Closing Covenants set forth definition of Maturity Date (the "Non-Exchanged Defeasance Account"), (A) the Non-Exchanged Defeasance Account, together with the Subject Cash to be deposited therein, shall be separate and distinct from, and Section 1.01(f) in the time period set forth therein. Upon written request of the Borrower prior addition end of the Specified L/C Period, the Agent may, in its sole discretion, agree Controlled Accounts required extend the Specified L/C Period. (e) Any term or provision hereof be maintained pursuant the contrary notwithstanding, the waivers, amendments and other modification contemplated hereby relate solely to the specific sections or provisions Section 10.01 expressly referenced herein relate solely to the periods or transactions expressly referenced herein, and (B) other or additional waiver, amendment or other modification is made, implied or intended to be made with respect to any other term or provision of any Loan Document, or any Obligation of any Obligor or any rights or remedies of any Secured Party under any Loan Document, whether now existing or occurring amount on deposit future, including, but not limited to, the right to declare all or any portion Non-Exchange Defeasance Account shall be counted for purposes the outstanding principal amount of the Loans and other Obligations to be immediately due and payable, imposing a default rate of interest in respect of the Obligations in accordance determining compliance 3.02(b) 10.01 Agreement Agreement; and (iv) any Stated Interest and/ pursuing any or all other rights and remedies available Special Interest (as each such term is defined in the Existing Convertible Notes as in effect immediately prior any Secured Party as a secured party under JCC, effectiveness of this Amendment) that has accrued (or would accrue) on such Existing Convertible Notes prior to Security Documents or any other date of the consummation of the Indenture (the "Existing Interest Accrual End Date") that is paid after the Existing Interest Accrual End Date shall be disregarded for purposes of determining the interest rate applicable to the New Convertible Notes for purposes of the Document. (f) The Parent and Documents. (b) Without limiting Borrower shall: (i) upon requirements set forth in opening proviso to Section 1.01(a) above, notwithstanding the $15,000,000 limitation set forth in the proviso set forth in the definition each Wells Fargo Bank Account, promptly (and in any event within one (1) Business Day thereafter) notify Subject Cash, in writing (it being acknowledged by hereby consents to increase such limitation to $15,600,000 from and after Agent that Consummation of Wells Fargo Banks Accounts ending in and have been notified to the Agent); Convertible Note Refinancing,

4 (ii) prior to the end of each Specified Account Period, cause the applicable Wells Fargo Bank Account to constitute a Controlled Account by executing and delivering to and in favor of the Agent a customary "springing" account control agreement, in form and substance reasonably acceptable to the Agent; (iii) prior to the end of the Specified L/C Period, complete the L/C Terminations; and (iv) upon the cancellation of the SVB L/Cs, promptly (and in any event, within three (3) Business Days thereafter) notify the Agent in writing.

Amendment, Consent.

amended modified Amendment, Consent.

Amendment, Consent.

Amendment, Consent.

Amendment Consent.

Amendment Consent

Amendment, Consent.

Amendment Consent

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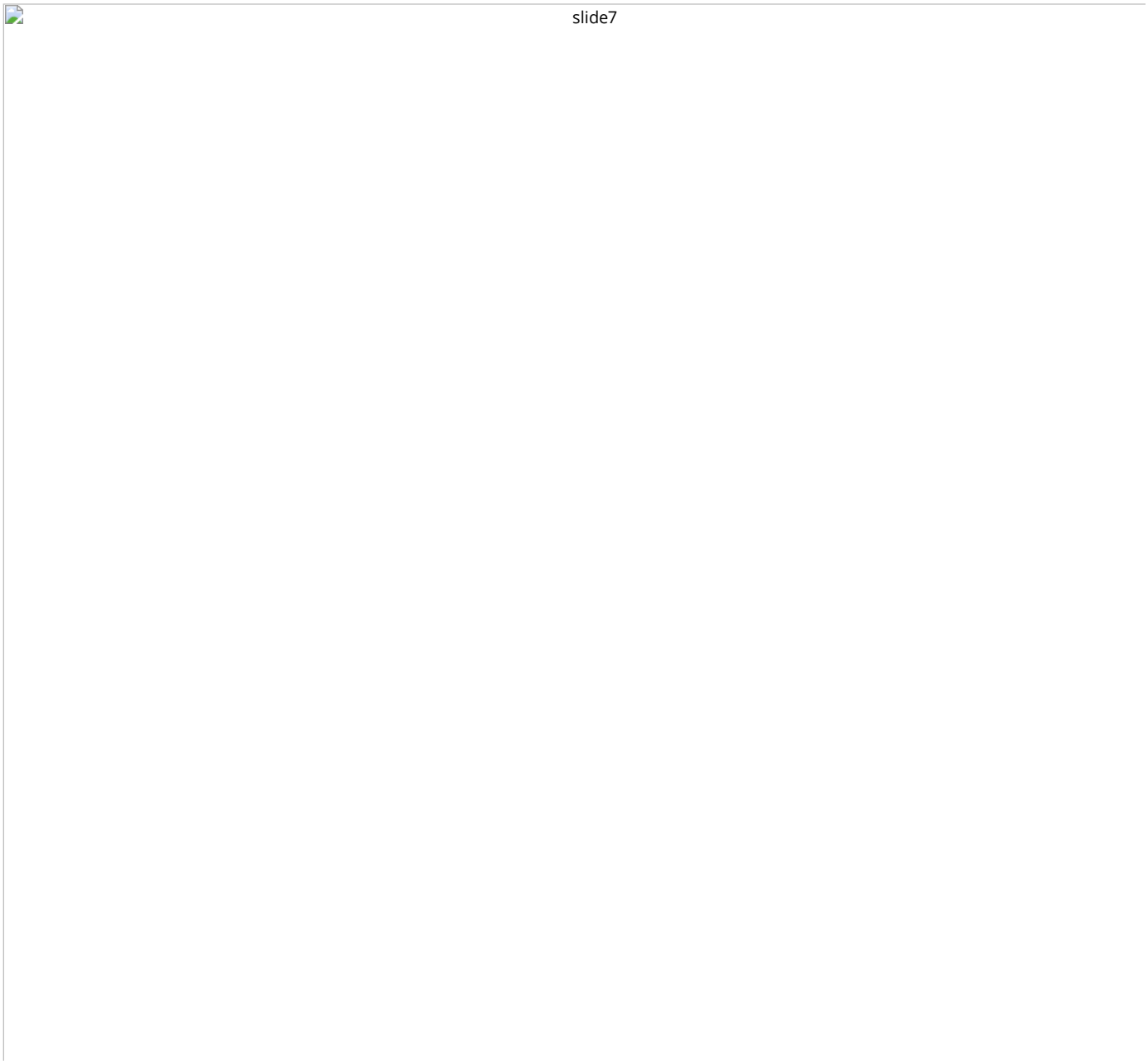
Waiver Consent Amendment Consent Costs and Expenses, Etc Non-Exchanged Existing Convertible Notes Threshold Agent shall have received for its account and the account of each Lender all reasonable and documented fees, costs and expenses due and payable to them pursuant to Section 14.03(a) aggregate principal amount Credit Agreement (including Non-Exchanged Existing Convertible Notes shall, upon Agent's and each Lender's reasonable and documented (in reasonable detail) legal fees and out-of-pocket expenses), consummation of the Convertible Note Refinancing, not exceed $15,200,000.00. Amendment Consent

Waiver Consent On and after the Amendment Effective Date, each reference in any Loan Document (other than this Consent) to the Credit Agreement shall mean and be a reference to the Credit Agreement as modified by this Consent. (b) Amendment Consent

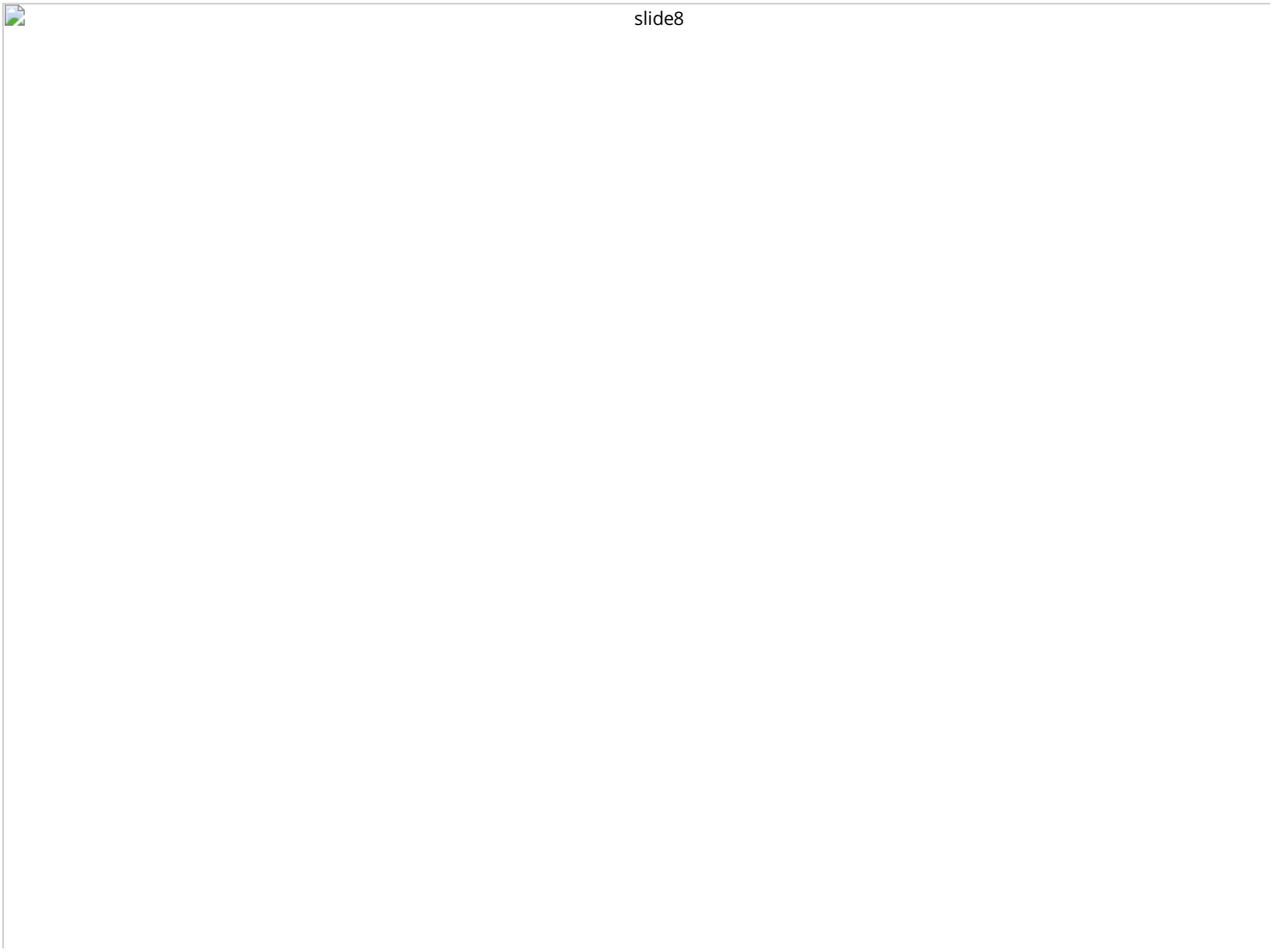
Amendment Consent

The amendments, waivers, consents and modifications set forth herein shall be limited precisely as provided for herein to the provisions expressly amended herein or otherwise modified, waived or consented to hereby and shall not be deemed to be an amendment to, waiver of, consent to or modification of any other term or provision of the Credit Agreement or any other Loan Document or of any transaction or further or future action on the part of any Obligor which would require the consent of the Lenders or the Agent under the Credit Agreement or any other Loan Document, or a waiver of any Default or Event of Default or non-compliance with any term or condition contained in the Credit Agreement.

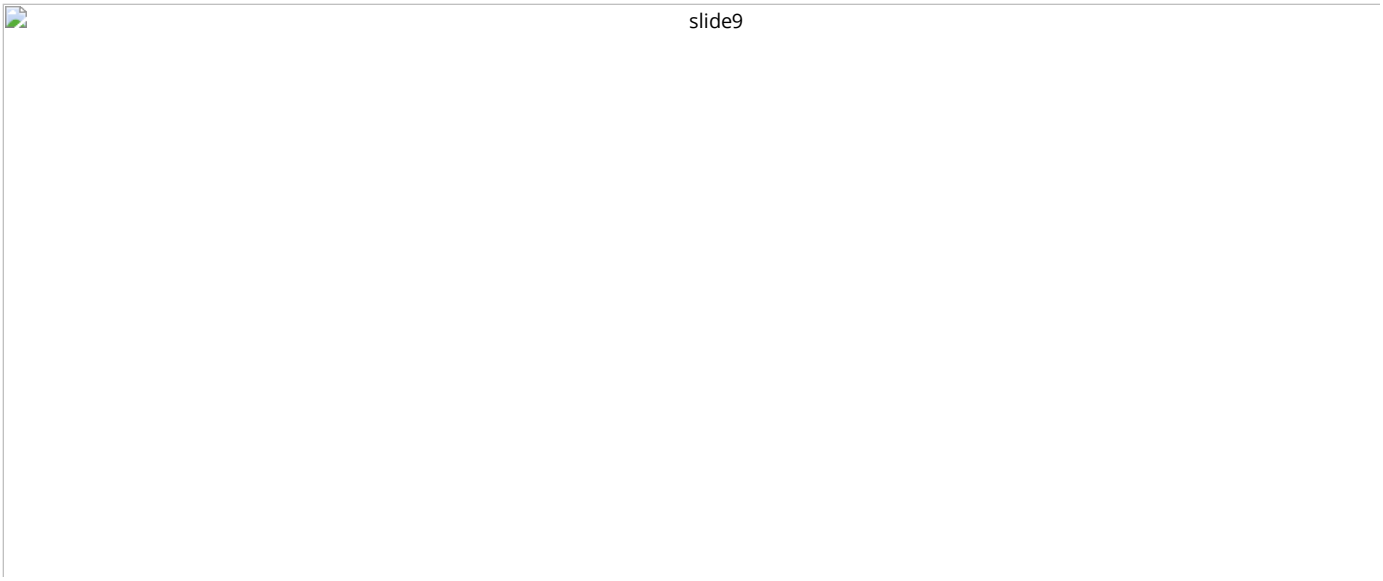
7 Amendment Consent



8 /s/ O'Regan O'Regan O'Regan O'Regan

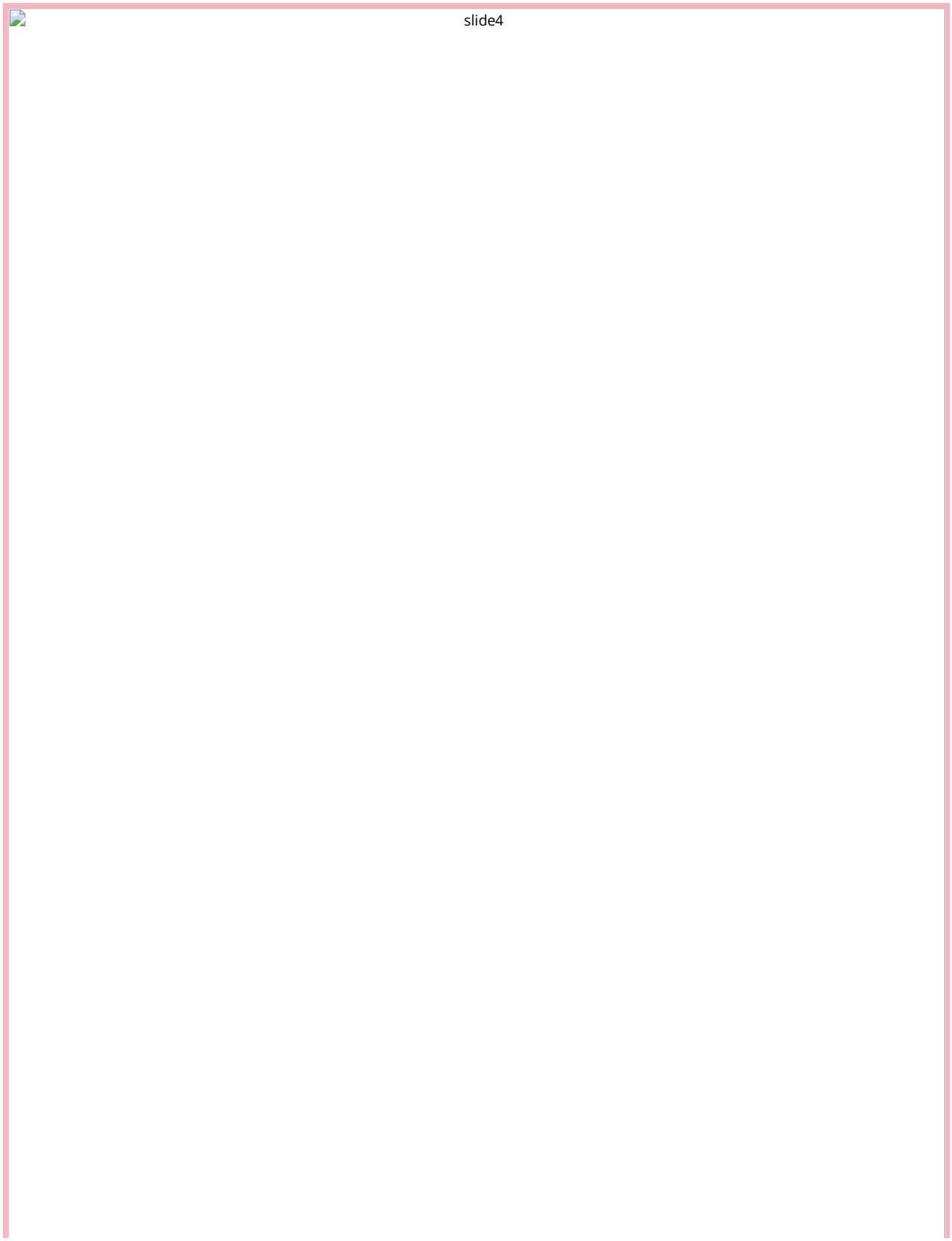


CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED Amendment 5 to the Quality Assurance Agreement This Amendment 5 (the "Amendment 5") is made as of February 24, 2023 (the "Effective Date") by and between Bachem AG, an entity organized under the laws of Switzerland, with its principal place of business at Hauptstrasse 144, CH-4416 Bubendorf, Switzerland ("Bachem"), and Xeris Pharmaceuticals, Inc., an entity organized under the laws of Delaware, with its principal place of business at 1375 W. Fulton Street, Suite 1300, Chicago, IL 60607 USA ("Xeris"). PREAMBLE WHEREAS, Bachem and Xeris have entered into a Quality Assurance Agreement between the Parties effective as of November 20, 2015, an amendment 1 to the Quality Assurance Agreement dated October 31, 2016 ("Amendment 1"), an amendment 2 to the Quality Assurance Agreement dated January 26, 2017 ("Amendment 2"), an amendment 3 to the Quality Assurance Agreement dated February 26, 2020 ("Amendment 3") and an amendment 4 to the Quality Assurance Agreement dated May 05, 2021 ("Amendment 4"), collectively comprising the "Quality Assurance Agreement"; WHEREAS, Bachem and Xeris now mutually desire to amend, modify and restate certain terms and conditions of the Quality Assurance Agreement. NOW THEREFORE, the Parties hereto, intending to be legally bound, agree as follows: 1. DEFINITIONS The capitalized terms used in this Amendment 5 shall have the meaning ascribed to such terms in the Quality Assurance Agreement, unless otherwise stated. 2. AMENDMENTS The Parties agree that, as of the Effective Date, the Quality Assurance Agreement is amended as set forth in this Section 2. 2.1 Section 3.2 of the Quality Assurance Agreement, Notices to Bachem shall be deleted in its entirety and replaced by the following: "Section 3.2 Notices to Bachem. Any notice to Bachem shall be addressed to: Bachem AG Hauptstrasse 144, CH-4416 Bubendorf, Switzerland [***] [***] [***] [***]" 2.2 Section 3.3 of the Quality Assurance Agreement, Notices to Xeris shall be deleted in its entirety and replaced by the following: "Section 3.3 Notices to Xeris. Any notice to Xeris shall be addressed to: Xeris Pharmaceuticals, Inc. 1375 W. Fulton Street, Suite 1300, Chicago, IL 60607 10.2 A (See attached).



Bachem/ Xeris - Amendment 5 to the Quality Assurance Agreement - Confidential 2/4 [***] [***] [***] [***]" 2.3 Section 5.14 Shipping and packaging of the Product shall be added immediately following Section 5.13 of the Agreement to ensure that the Product is delivered at the storage temperature stated in the Specification. Therefore, Section 5.14 shall be added as follows: "Section 5.14 Shipping and packaging of the Product. Bachem shall be responsible for the packaging of the Product and for including a data logger for the temperature monitoring. Furthermore, Bachem shall be responsible for the shipment of the Product to the agreed point of delivery." 2.4 Article 10 Specific Responsibilities shall be amended by adding a new row in the table to indicate [***] responsibility for shipping and packaging. Therefore, the following row shall be added as the last row in the table "Responsibility" thereof as follows: RESPONSIBILITY Bachem Xeris Packaging and Shipment Packaging of the Product and shipping to the agreed point of delivery with data logger [***] [***] " 3. MISCELLANEOUS 3.1. In the event of any conflict between the terms of this Amendment 5 and the terms of the Quality Assurance Agreement, the terms of this Amendment 5 shall prevail. 3.2. Except as expressly modified by this Amendment 5, the terms and provisions of the Quality Assurance Agreement remain and shall remain in full force and effect. 3.3. The terms of Article 12 (Miscellaneous) of the Quality Assurance Agreement shall apply to this Amendment 5 directly as if incorporated herein. 3.4. This Amendment 5 may be entered into any number of counterparts, each of which when signed (whether in original or electronic form) and delivered shall constitute one single agreement between the Parties hereto. As an alternative to handwritten signatures on a hardcopy, electronic signatures of duly authorized representatives of the Parties shall have the full force and effect of an original signature. In case this Amendment 5 is signed electronically (e.g. with DocuSign), only the electronic version of this document is valid. Each printout is for reference only. The signature page follows.

Bachem/ Xeris - Amendment 5 to the Quality Assurance Agreement - Confidential 3/4 IN WITNESS WHEREOF, the Parties have caused this Amendment 5 to the Quality Assurance Agreement to be duly executed by their authorized representatives on the Effective Date. Bubendorf, _____ Bachem AG By: [***] By:_ [***] Chicago, IL USA, _____ Xeris Pharmaceuticals, Inc. By: /s/Brian Conner_____ Name: Brian Conner Function: Chief Compliance Officer



Bachem/ Xeris - Amendment 5 to the Quality Assurance Agreement - Confidential 4/4 CHANGE HISTORY OF THE QUALITY AGREEMENT Customer: Xeris Product: Glucagon Agreement / Amendment No. Date Change description Agreement 20.11.2015 Quality Agreement established between Bachem and Xeris Amendment 1 31.10.2016 Section 3.3: Xeris's contact details updated Amendment 2 26.01.2017 Annex 1: Specifications updated Amendment 3 26.02.2020 Section 3.3: Xeris's contact details updated Annex 1: Specifications updated Annex 2: Approved Contract Laboratories updated Amendment 4 05.05.2021 Section 3.3: Xeris's contact details updated Section 12.7: Number of copies and electronic signature updated Amendment 5 The date of the last signature. Section 3.2: Bachem's contact details updated Section 3.3: Xeris's contact details updated Section 5.14: "Shipping and packaging of the Product" added Article 10: A new row with responsibilities for shipping and packaging added. Exhibit B (See attached).

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: August 8, November 9, 2023

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: August 8, November 9, 2023

By: /s/ Steven M. Pieper
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 June 30, 2023 September 30, 2023 (Periodic Report) to which this statement is an exhibit fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

2. Information contained in the Periodic Report fairly presents, in all material aspects, the financial condition and results of operations of Xeris Biopharma Holdings, Inc.

Date: August 8, 2023 November 9, 2023

/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)

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