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 March 31, 2023

or

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

For the transition period from _____ to _____

Commission file number: 001-40880

XERIS BIOPHARMA HOLDINGS, INC.

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

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

(844) 445-5704

(Registrant's telephone number, including area code)

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 May 1, 2023, 137,311,468 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 expect 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 would force us to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our business depends entirely on the commercial success of our products and product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed.
- 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, and a limited number of options for alternate sources for Gvoke, Keveyis, and Recorlev or our product candidates could harm our ability to develop our product candidates or to 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.
- Our business may continue to be adversely affected by impacts resulting from Coronavirus ("COVID-19") pandemic.
- 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.

Index to Quarterly Report on Form 10-Q

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

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2023	December 31, 2022
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 50,984	$ 121,966
Short-term investments	44,118	—
Trade accounts receivable, net	30,860	30,830
Inventory	29,039	24,735
Prepaid expenses and other current assets	10,512	9,287
Total current assets	165,513	186,818
Property and equipment, net	6,477	5,516
Operating lease right-of-use assets	3,886	3,992
Goodwill	22,859	22,859
Intangible assets, net	117,896	120,607
Other assets	4,729	4,730
Total assets	$ 321,360	$ 344,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,983	$ 4,606
Current operating lease liabilities	1,448	1,580
Other accrued liabilities	20,149	36,786
Accrued trade discounts and rebates	16,874	16,818
Accrued returns reserve	13,254	11,173
Current portion of contingent value rights	14,958	—
Other current liabilities	2,757	2,658
Total current liabilities	81,423	73,621
Long-term debt, net of unamortized debt issuance costs	187,623	187,075
Non-current operating lease liabilities	9,346	9,402
Non-current contingent value rights	9,371	25,688
Deferred tax liabilities	3,518	3,518
Other liabilities	31	31
Total liabilities	291,312	299,335
Commitments and contingencies (Note 15)		
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 March 31, 2023 and December 31, 2022, respectively	—	—
Common stock—par value $0.0001, 350,000,000 shares and 350,000,000 shares authorized as of March 31, 2023 and December 31, 2022, respectively; 137,291,277 and 136,273,090 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	14	14
Additional paid in capital	601,667	599,966
Accumulated deficit	(571,604)	(554,770)
Accumulated other comprehensive loss	(29)	(23)
Total stockholders' equity	30,048	45,187
Total liabilities and stockholders' equity	$ 321,360	$ 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 March 31,	
	2023	**2022**
Product revenue, net	$ 32,265	$ 21,910
Royalty, contract and other revenue	931	163
Total revenue	33,196	22,073
Costs and expenses:		
Cost of goods sold	5,319	6,273
Research and development	4,838	6,250
Selling, general and administrative	33,605	35,913
Amortization of intangible assets	2,711	2,711
Total costs and expenses	46,473	51,147
Loss from operations	(13,277)	(29,074)
Other income (expense):		
Interest and other income	1,300	68
Interest expense	(6,216)	(3,521)
Change in fair value of warrants	—	1,221
Change in fair value of contingent value rights	1,359	(2,816)
Total other expense	(3,557)	(5,048)
Net loss before benefit from income taxes	(16,834)	(34,122)
Benefit from income taxes	—	408
Net loss	$ (16,834)	$ (33,714)
Other comprehensive loss, net of tax:		
Unrealized gains (losses) on investments	(6)	(35)
Comprehensive loss	$ (16,840)	$ (33,749)
Net loss per common share - basic and diluted	$ (0.12)	$ (0.25)
Weighted average common shares outstanding - basic and diluted	137,142,565	135,032,782

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2021	124,873,316	$ 13	$ 555,359	$ (31)	$ (460,110)	$ 95,231
Net loss	—	—	—	—	(33,714)	(33,714)
Issuance of common stock related to Armistice equity offering	10,238,908	1	29,999	—	—	30,000
Issuance of warrants related to loan agreement	—	—	2,080	—	—	2,080
Exercise of stock options	11,228	—	8	—	—	8
Vesting of restricted stock units (net of 197,257 shares withheld for tax)	404,743	—	(416)	—	—	(416)
Stock-based compensation	—	—	3,301	—	—	3,301
Other comprehensive loss	—	—	—	(35)	—	(35)
Balance, March 31, 2022	135,528,195	$ 14	$ 590,331	$ (66)	$ (493,824)	$ 96,455

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2022	136,273,090	$ 14	$ 599,966	$ (23)	$ (554,770)	$ 45,187
Net loss	—	—	—	—	(16,834)	(16,834)
Vesting of restricted stock units (net of 743,677 shares withheld for tax)	1,018,187	—	(863)	—	—	(863)
Stock-based compensation	—	—	2,564	—	—	2,564
Other comprehensive loss	—	—	—	(6)	—	(6)
Balance, March 31, 2023	137,291,277	$ 14	$ 601,667	$ (29)	$ (571,604)	$ 30,048

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (16,834)	$ (33,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	364	321
Amortization of intangible assets	2,711	2,711
Amortization of premium/discount on investments	(382)	50
Amortization of debt discount and debt issuance costs	548	219
Amortization of operating right-of-use assets	106	—
Stock-based compensation	2,564	3,301
Loss on extinguishment of debt	—	1,323
Change in fair value of warrants	—	(1,221)
Change in fair value of contingent value rights	(1,359)	2,816
Changes in operating assets and liabilities:		
Trade accounts receivable	(30)	(5,927)
Prepaid expenses and other current assets	(1,225)	(58)
Inventory	(3,817)	(157)
Accounts payable	6,935	2,168
Other accrued liabilities	(13,931)	(13,658)
Accrued trade discounts and rebates	56	(48)
Accrued returns reserve	2,081	1,431
Supply agreement liabilities	(3,838)	(5,280)
Operating lease liabilities	(188)	—
Other	99	(2,686)
Net cash used in operating activities	(26,140)	(48,409)
Cash flows from investing activities:		
Capital expenditures	(238)	16
Purchases of investments	(43,741)	—
Sales and maturities of investments	—	6,700
Net cash (used in) provided by investing activities	(43,979)	6,716
Cash flows from financing activities:		
Proceeds from equity offerings	—	30,000
Proceeds from issuance of debt	—	97,295
Repayment of debt	—	(43,496)
Payments of debt issuance costs	—	(4,360)
Payments for loss on extinguishment of debt	—	(837)
Proceeds from exercise of stock awards		8
Repurchase of common stock withheld for taxes	(863)	(416)
Net cash (used in) provided by financing activities	(863)	78,194
Effect of exchange rate changes on cash, cash equivalents and restricted cash	—	(1)
Increase in cash, cash equivalents and restricted cash	(70,982)	36,500
Cash, cash equivalents and restricted cash, beginning of year	126,314	67,271
Cash, cash equivalents and restricted cash, end of year	$ 55,332	$ 103,771

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

	Three Months Ended March 31,	
	2023	**2022**
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 9,826	$ 3,769
Supplemental schedule of non-cash activities:		
Issuance of warrants related to loan agreement	$ —	$ 2,080
Initial operating lease right-of-use assets for adoption of ASU 2016-02	$ —	$ (6,277)
Initial current and non-current operating lease liabilities for adoption of ASU 2016-02	$ —	$ 14,013

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):

	March 31,	
	2023	**2022**
Cash flows from operating activities:		
Cash and cash equivalents	$ 50,984	$ 103,771
Restricted cash included in Other assets	4,348	—
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 55,332	$ 103,771

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.

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, approved by the Food and Drug Administration ("FDA") in December 2021, a cortisol synthesis inhibitor for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome. The Company also has a pipeline of development programs to bring new products forward using its proprietary formulation 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 $571.6 million as of March 31, 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 March 31, 2023, the Company believes that its cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months from the issuance date of these 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 COVID-19, geopolitical instability resulting from the ongoing military conflict between Russia and Ukraine, rising interest rates, inflationary pressures, 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 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").

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 months ended March 31, 2023 and 2022, four customers accounted for 96% and 93% of the Company's gross product revenue, respectively. At March 31, 2023 and December 31, 2022, the same four customers accounted for 98% 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, 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 March 31,	
	2023	**2022**
Product revenue (in thousands):		
Gvoke	$ 15,033	$ 12,452
Keveyis	12,755	9,324
Recorlev	4,477	134
Product revenue, net	32,265	21,910
Royalty, contract and other revenue	931	163
Total revenue	$ 33,196	$ 22,073

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 March 31, 2023, consist of U.S. government securities, all with remaining maturities of less than one year. Debt securities as of March 31, 2023 had an average remaining maturity of 0.5 years. The debt securities are reported at fair value with unrealized gains or losses recorded in accumulated other comprehensive income (loss) in the condensed consolidated balance sheets. 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", 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 March 31, 2023 (in thousands):

	March 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:				
U.S. government securities	$ 44,124	$ 5	$ (11)	$ 44,118
Total available-for-sale investments	$ 44,124	$ 5	$ (11)	$ 44,118

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, the Company first assesses whether they are intended to sell, 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 months ended March 31, 2023.

Note 5. Inventory

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

	March 31, 2023	December 31, 2022
Raw materials	$ 10,909	$ 7,410
Work in process	5,890	11,367
Finished goods	12,240	5,958
Inventory	$ 29,039	$ 24,735

Inventory reserves were $0.6 million and $1.3 million at March 31, 2023 and December 31, 2022, respectively.

Note 6. Property and equipment

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

	March 31, 2023	December 31, 2022
Lab equipment	$ 3,967	$ 3,841
Furniture and fixtures	1,742	1,355
Computer equipment	707	474
Office equipment	64	8
Software	353	307
Leasehold improvements	5,542	5,065
Total property and equipment	12,375	11,050
Less: accumulated depreciation and amortization	(5,898)	(5,534)
Property and equipment, net	$ 6,477	$ 5,516

Depreciation and amortization expense relating to property and equipment were $0.4 million and $0.3 million for the three months ended March 31, 2023 and 2022, respectively.

Note 7. Intangible assets

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

		March 31, 2023			December 31, 2022		
	Life (Years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Definite-lived intangible asset - Keveyis	5	$ 11,000	$ (3,300)	$ 7,700	$ 11,000	$ (2,750)	$ 8,250
Definite-lived intangible asset - Recorlev	14	121,000	(10,804)	110,196	121,000	(8,643)	112,357
Total intangible assets		$ 132,000	$ (14,104)	$ 117,896	$ 132,000	$ (11,393)	$ 120,607

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

2023 remaining	8,132
2024	10,843
2025	10,843
2026	10,293
2027	8,643
Thereafter	69,142
Total	$ 117,896

Note 8. Other accrued liabilities

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

	March 31, 2023	December 31, 2022
Accrued employee costs	$ 8,761	$ 13,400
Supply agreement - current portion	2,882	6,720
Accrued supply chain costs	440	562
Accrued marketing costs	1,099	2,593
Accrued research and development costs	1,067	1,411
Accrued restructuring charges	1,694	2,799
Accrued interest expense	498	4,656
Accrued other costs	3,708	4,645
Other accrued liabilities	$ 20,149	$ 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 three months ended March 31, 2023 (in thousands):

	Restructuring Costs
Balance accrued at December 31, 2022	2,799
Payments	(1,105)
Balance accrued at March 31, 2023	$ 1,694

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 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 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 Convertible Notes. At any time before the close of business on the second scheduled trading day immediately before the maturity date, holders of Convertible Notes may convert their Convertible Notes at their option into shares of the Company’s common stock, together, if applicable, with cash in lieu of any fractional share, at a conversion rate of 326.7974 shares of the Company's common stock per $1,000 principal amount of Convertible Notes. In the second half of 2020, $39.9 million in principal amount of Convertible Notes were converted into 13,171,791 shares of Xeris Pharma’s common stock.

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

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

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

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

The fair value of the convertible senior notes is determined from using current interest rates based on credit ratings and the remaining term of maturity. As of March 31, 2023, the fair value of the convertible senior notes was approximately $41.1 million. The fair value of the convertible debt was estimated using inputs for volatility, the Company's stock price, time to maturity, the risk-free rate and the Company's credit spread, some of which are considered Level 3 inputs in the fair value hierarchy disclosed in "Note 12 - Fair value measurement".

Loan Agreement

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

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

In March 2022, the Company, Xeris Pharma and certain subsidiary guarantors of the Company entered into a Credit Agreement and Guaranty (as amended, modified or amended and restated from time to time, the "Hayfin Loan Agreement") with the lenders from time to time parties thereto (the "Lenders") and Hayfin Services LLP, as administrative agent for the Lenders (in such capacity, together with its successors and assigns, the "Agent"), pursuant to which the Company and its subsidiaries party thereto granted a first priority security interest on substantially all of their assets, including intellectual property, subject to certain exceptions. The Hayfin Loan Agreement provided for the Lenders to extend $100.0 million in term loans to the Company on the closing date and up to an additional $50.0 million in delayed draw term loans during the one year period immediately following the closing date (collectively, the "Loans"). On December 28, 2022, the Company borrowed the full amount of such $50.0 million delayed draw term loan under the Hayfin Loan Agreement. In conjunction with the execution of the Hayfin Loan Agreement, the Oxford Loan Agreement remaining balance of $43.5 million and fees of $2.1 million in connection with the loan repayment were paid. In addition to utilizing the proceeds to repay the obligations under the Oxford Loan Agreement in full, the proceeds will 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 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 Convertible Notes are outstanding as of such date and either (i) the maturity date thereof has not been extended to a date on or after September 4, 2027 or (ii) the Company has not received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.0 million of cash on hand, is sufficient to redeem and discharge the Convertible Notes in full.

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

	March 31, 2023	December 31, 2022
Convertible Notes	$ 47,175	$ 47,175
Loan facility	144,746	144,487
Less: unamortized debt issuance costs	(4,298)	(4,587)
Long-term debt, net of unamortized debt issuance costs	$ 187,623	$ 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	$	—
2024		—
2025		47,175
2026		—
2027		150,000
	$	197,175

For the three months ended March 31, 2023 and 2022, the Company recognized interest expense of $6.2 million and $3.5 million, respectively, of which $0.5 million and $0.2 million, respectively, related to the amortization of debt discount and issuance costs and a $1.3 million loss on extinguishment of debt in the three months ended March 31, 2022 related to the Oxford Loan Agreement with the Prior Lenders, which ceased 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", 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 March 31, 2023, the following warrants were outstanding:

	Outstanding Warrants	Exercise Price per Warrant	Expiration Date
Warrants classified as liabilities:			
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 of $1,000 related to the 2018 Term A Warrants and gains of $1,000 related to the 2018 Term B Warrants upon the change in fair value of the warrants during the three months ended March 31, 2023. The Company recognized gains

of $1.2 million, $12,000 and $8,000 upon the change in fair value of the warrants during the three months ended March 31, 2022 related to the assumed Strongbridge private placement warrants, which expired in June 2022, 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.

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 March 31, 2023 and December 31, 2022 (in thousands):

	Total as of March 31, 2023	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 50,984	$ 50,984	$ —	$ —
Investments:				
U.S. government securities	$ 44,118	$ 44,118	$ —	$ —
Liabilities				
Current portion of contingent value rights	$ 14,958	$ —	$ —	$ 14,958
Non-current contingent value rights	$ 9,371	$ —	$ —	$ 9,371
Warrant liabilities	$ 9	$ —	$ —	$ 9

	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	$ —	$ —
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		(1,359)
Balance at March 31, 2023	$	24,329
Balance at Current portion of contingent value rights	$	14,958
Balance at Non-current contingent value rights		9,371
Balance at March 31, 2023	$	24,329

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 March 31, 2023, there were 3,851,526 shares of common stock available for future issuance under the 2018 Plan.

The 2018 Employee Stock Purchase Plan (the "ESPP") was adopted by the Board of Directors in April 2018 and approved by the Company's stockholders in June 2018 to issue up to 193,000 shares of common stock to participating employees. Through the ESPP, eligible employees may authorize payroll deductions of up to 15% of their compensation to purchase up to the number of shares of common stock determined by dividing $25,000 by the closing market price of Xeris common stock on the offering date. The purchase price per share at each purchase date is equal to 85% of the lower of (i) the closing market price per share of Xeris common stock on the employee’s offering date or (ii) the closing market price per share of Xeris common stock on the purchase date. Each offering period has a six-month duration and purchase interval with a purchase date of the last business day of June and December each year. As of March 31, 2023, there were 577,860 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 March 31, 2023, there were 347,079 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 March 31, 2023, there were 2,425,706 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.

There were no stock options granted during the first quarter of 2023.

Stock option activity under the 2011 Plan, 2018 Plan, Inducement Plan and Assumed Plans for the three months ended March 31, 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	—	—	
Forfeited	(2,041)	5.95	
Expired	(130,366)	12.42	
Outstanding - March 31, 2023	9,567,754	$ 5.27	4.57
Vested and expected to vest at March 31, 2023	9,567,754	$ 5.27	4.57
Exercisable - March 31, 2023	8,978,290	$ 5.34	4.34

At March 31, 2023, there was a total of $1.3 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 1.2 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 three months ended March 31, 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	7,133,900	1.24
Vested	(1,761,864)	3.81
Forfeited	(66,247)	2.17
Unvested balance - March 31, 2023	10,561,349	$ 1.80

As of March 31, 2023, there was $16.9 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over the weighted-average remaining vesting period of 2.5 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 March 31,	
	2023	2022
Research and development	$ 322	$ 547
Selling, general and administrative	2,242	2,754
Total stock-based compensation expense	$ 2,564	$ 3,301

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 extend and 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. The estimated initial operating lease liability related to the expansion portion of the premises leased pursuant to the amended and restated lease is approximately $22.8 million and upon commencement of the expansion space term on April 1, 2023, the operating lease right-of-use asset is approximately $17.4 million.

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. Most of the real estate leases include one or more options to renew, with renewal terms that can extend the lease term from one to five years or more. 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 March 31, 2023, the Company's operating leases had a weighted-average remaining lease term of 10.2 years and a weighted-average discount rate of 11.4%.

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

	Three Months Ended March 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 478	$ 445

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 March 31,	
Lease cost	2023	2022
Operating lease expense	$ 413	$ 467
Variable lease cost	350	225
Sublease income	(54)	(52)
Total lease cost	$ 709	$ 640

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

2023 remaining	$ 1,105
2024	1,556
2025	1,820
2026	1,869
2027	1,918
Thereafter	10,674
Total lease payments	18,942
Less: Effect of discounting to net present value	(8,148)
Present value of lease liabilities	$ 10,794
Operating lease liabilities, current	1,448
Operating lease liabilities, non-current	9,346
Total operating lease liabilities	$ 10,794

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 March 31, 2023, the Company had unused letters of credit of $4.3 million, which were issued primarily to secure leases. These letters of credit are collateralized by $4.3 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 March 31, 2023, management was not aware of any existing, pending or threatened legal actions that would have a material impact on the financial position or results of operations of the Company.

Long Term Debt

In the event the Convertible Notes are still outstanding as of January 15, 2025 and the maturity date thereof has not been extended to a date on or after September 4, 2027, then unless the Company has received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.0 million of cash on hand, is sufficient to redeem and discharge the Convertible Notes in full, 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 March 31,	
	2023	**2022**
Shares to be issued upon conversion of Convertible Notes	15,416,667	15,416,667
Vested and unvested stock options	9,567,754	10,456,601
Restricted stock units	10,561,349	5,302,517
Warrants	8,362,270	12,808,695
Total anti-dilutive securities excluded from EPS computation [1]	43,908,040	43,984,480

[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," "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, continuing impacts resulting from the coronavirus pandemic, and other factors discussed in Item 1A of Part II of this Quarterly Report on Form 10-Q. Any forward-looking statements contained herein speak only as of the date hereof, and Xeris expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

Unless otherwise indicated, references to "Xeris," the "Company," "we," "our" and "us" in this Quarterly Report on Form 10-Q refer to Xeris 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 178 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 the 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.

For the three months ended March 31, 2023 and March 31, 2022, we reported net losses of $16.8 million and $33.7 million, respectively. We have not been profitable since inception, and, as of March 31, 2023, our accumulated deficit was $571.6 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.

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 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.

Components of our Results of Operations

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

Product revenue, net

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

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.

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

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 months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		Change	
	2023	2022	$	%
Product revenue:				
Gvoke	$ 15,033	$ 12,452	$ 2,581	20.7
Keveyis	12,755	9,324	3,431	36.8
Recorlev	4,477	134	4,343	nm
Product revenue, net	32,265	21,910	10,355	47.3
Royalty, contract and other revenue	931	163	768	nm
Total revenue	33,196	22,073	11,123	50.4
Cost and expenses:				
Cost of goods sold, excluding amortization of intangible assets	5,319	6,273	(954)	(15.2)
Research and development	4,838	6,250	(1,412)	(22.6)
Selling, general and administrative	33,605	35,913	(2,308)	(6.4)
Amortization of intangible assets	2,711	2,711	—	nm
Total cost and expenses	46,473	51,147	(4,674)	(9.1)
Loss from operations	(13,277)	(29,074)	15,797	(54.3)
Other income (expense):				
Interest and other income	1,300	68	1,232	nm
Interest expense	(6,216)	(3,521)	(2,695)	76.5
Change in fair value of warrants	—	1,221	(1,221)	nm
Change in fair value of contingent considerations	1,359	(2,816)	4,175	nm
Total other expense	(3,557)	(5,048)	1,491	(29.5)
Net loss before benefit from income taxes	(16,834)	(34,122)	17,288	(50.7)
Benefit from income taxes	—	408	(408)	nm
Net loss	$ (16,834)	$ (33,714)	$ 16,880	(50.1)

[1] nm: not meaningful

Product revenue, net

Gvoke net revenue increased by $2.6 million or 20.7% for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. Gvoke prescriptions grew approximately 50% in the first quarter of 2023 compared to the same period of 2022. The growth in product demand was partially offset by a decrease in net pricing.

Keveyis net revenue increased by $3.4 million or 36.8% for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. This increase was 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 $4.5 million for the three months ended March 31, 2023, driven primarily by increases in the number of patients on therapy.

Cost of goods sold

Cost of goods sold was $5.3 million and $6.3 million for the three months ended March 31, 2023 and 2022, respectively. The decrease was attributable to a one-time contract credit and product mix offset by higher product sales.

Research and development expenses

Research and development expenses decreased $1.4 million or 22.6% for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. The decrease was primarily driven by lower product development costs.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased $2.3 million or 6.4% for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. The decrease was primarily driven by lower costs related to the restructuring plan that commenced in 2021 and was fully expensed by 2022.

Amortization of intangible assets

For the three months ended March 31, 2023 and 2022, amortization of intangible assets were both $2.7 million.

Other income (expense)

For the three months ended March 31, 2023, interest expense increased $2.7 million or 76.5% compared to the three months ended March 31, 2022. The increase was primarily due to a higher principle amount and increased interest rate related to the Hayfin loan.

Liquidity and Capital Resources

Our primary uses of cash are to fund costs related to the manufacturing, marketing and selling of products, the research and development of our product candidates, general and administrative expenses and working capital requirements. Historically, we have funded our operations primarily through private placements of convertible preferred stock, public equity offerings of common stock, and issuance of debt. In June 2018, we completed our IPO of 6,555,000 shares of our common stock at a price of $15.00 per share for aggregate net proceeds of $88.9 million after deducting underwriting discounts and commissions as well as other equity offering expenses. In February 2019, we completed an equity offering and sold an aggregate of 5,996,775 shares of common stock at a price of $10.00 per share. Net proceeds from this equity offering were $55.5 million after deducting underwriting discounts and commissions as well as other equity offering expenses. In September 2019, we entered into the 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 March 31, 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 otherwise be used for general corporate purposes. After repayment, the Loans may not be re-borrowed. On September 29, 2022, the Company 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 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.

Capital Resources and Funding Requirements

We have incurred operating losses since inception, and we have an accumulated deficit of $571.6 million at March 31, 2023. Based on our current operating plans and existing working capital at March 31, 2023, we believe that our cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months. We expect to incur substantial additional expenditures in the near term to support the marketing and selling of Gvoke, Keveyis and Recorlev as well as our ongoing research and development activities. We expect to continue to incur net losses for at least the next 12 months. Our ability to fund marketing and selling of Gvoke, Keveyis and Recorlev, as well as our product development and clinical operations, including completion of future clinical trials, will depend on the amount and timing of cash received from product revenue and potential future financings. Our future capital requirements will depend on many factors, including:

- our degree of success in commercializing Gvoke, Keveyis and Recorlev;
- the 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**)	**Three Months Ended March 31,**	
	2023	**2022**
Net cash used in operating activities	$ (26,140)	$ (48,409)
Net cash (used in)/provided by investing activities	(43,979)	6,716
Net cash (used in)/provided by financing activities	(863)	78,194

Operating activities

Net cash used in operating activities was $26.1 million for the three months ended March 31, 2023, compared to $48.4 million for the three months ended March 31, 2022. The decrease in net cash used in operating activities was primarily driven by reduced working capital usage.

Investing activities

Net cash used in investing activities was $44.0 million for the three months ended March 31, 2023, compared to net cash provided by investing activities of $6.7 million for the three months ended March 31, 2022. Cash used in investing activities in 2023 was primarily due to the purchase of short-term investments. In the first quarter 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 $0.9 million for the three months ended March 31, 2023, compared to net cash provided by financing activities of $78.2 million for the three months ended March 31, 2022. The cash used in the first quarter of 2023 was mainly due to the repurchase of common stock withheld for taxes upon the restricted stock unit vesting. The cash provided by financing activities in the first quarter of 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", 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 March 31, 2023 would increase or decrease interest income by approximately $1.0 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 Convertible Notes is assessed at a fixed rate of 5.0% annually and therefore does not subject us to interest rate risk.

Foreign Exchange Risk

We contract with 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 March 31, 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 three months ended March 31, 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 March 31, 2023 to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the United States Securities and Exchange Commission's ("SEC") rules and forms, and to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its chief executive and chief financial officers, as appropriate, to allow timely decisions regarding required disclosure.

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 March 31, 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 expect to incur losses over the next few years and may not be able to achieve or sustain revenues or profitability in the future.

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

We have incurred significant losses in every fiscal year since inception. For the three months ended March 31, 2023 and 2022, we reported a net loss of $16.8 million and $33.7 million, respectively. In addition, our accumulated deficit as of March 31, 2023 was $571.6 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 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 would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Biopharmaceutical development is a time consuming, expensive and uncertain process that takes years to complete. We are incurring significant commercialization expenses related to product sales, marketing, manufacturing, packaging and distribution of Gvoke, Keveyis and Recorlev and expect to continue to incur such expenses for our products, as well as for any of our product candidates, if approved. We expect to require additional capital to complete the clinical trials associated with our product candidates and begin commercialization efforts, if approved. Accordingly, we may need additional funding in connection with our continuing operations. In the future, if we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs and/or sales and marketing activities. Market volatility, 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 interest expense, and could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may increase our expenses and make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions and in-licensing opportunities. Under our existing credit facility dated March 8, 2022, with the lenders from time to time parties thereto (the "Lenders"), Hayfin Services LLP, as administrative agent for the Lenders, Xeris Pharmaceuticals, Inc. and Xeris Biopharma Holdings, Inc., as amended (the "Hayfin Loan Agreement"), we are restricted in our ability to incur additional indebtedness and to pay dividends. Any additional debt financing that we may secure in the future could include similar or more restrictive covenants relating to our capital raising activities, buying or selling assets and other financial and operational matters, which may make it more difficult for us to obtain additional capital, manage our business and pursue business opportunities. We may also be required to secure any such debt obligations with some or all of our assets. For example, our Hayfin Loan Agreement is secured by substantially all of our property and assets, including our intellectual property assets, subject to certain exceptions.

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

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due, or 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 Notes"), including $11.3 million pursuant to the underwriters' option to purchase additional notes which was exercised in July 2020. A total principal amount of $39.1 million of Convertible Notes converted into equity in the second half of 2020. As of March 31, 2023, the outstanding balance of Convertible Notes was $47.2 million. The Convertible Notes are governed by

the terms of a base indenture for senior debt securities dated June 30, 2020 (the "Base Indenture"), as supplemented by the first supplemental indenture thereto dated June 30, 2020 and the second supplemental indenture thereto dated October 5, 2021 ("the Supplemental Indentures" and together with the Base Indenture, the "Indenture"), each between us and United States Bank National Association, as trustee. Failure to satisfy our current and future debt obligations under the Indenture could result in an event of default and, as a result, all of the amounts outstanding could immediately become due and payable. In the event of an acceleration of amounts due under the Indenture as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness.

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

In addition, we have $150.0 million outstanding under our Hayfin Loan Agreement as of March 31, 2023. All obligations under our Hayfin Loan Agreement are secured by substantially all of our property and assets, including our intellectual property assets, subject to certain limited exceptions. The term loans and the Convertible Notes may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. Failure to satisfy our current and future debt obligations under our Hayfin Loan Agreement could result in an event of default and, as a result, our lenders could accelerate all amounts due. Events of default also include our failure to comply with customary affirmative and negative covenants as well as a default under any indenture or other agreement governing convertible indebtedness permitted by the Hayfin Loan Agreement, including the Indenture. The Hayfin Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict our ability to incur additional indebtedness, grant liens, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. In the event of an acceleration of amounts due under our Hayfin Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

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

On April 21, 2020, we entered into the 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 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*" in our most recent Annual Report on Form 10-K.

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

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

Additionally, if, after 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, we anticipate that companies will dedicate significant resources to developing products competitive to our product candidates.

For example, Gvoke has numerous competitors in the severe hypoglycemia market, which currently include Eli Lilly’s Baqsimi, an intranasal glucagon dry powder, 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 is an oral carbonic anhydrase inhibitor, that was approved in the United States to treat hyperkalemic, hypokalemic and related variants of PPP. Torrent Pharmaceuticals Limited’s ANDA for generic dichlorphenamide was approved on December 29, 2022 and competes with Keveyis, which may adversely impact our revenue. In addition, due to the end of orphan drug exclusivity, additional generic competition may compete with Keveyis and sales of Keveyis could be negatively affected and our results of operations could suffer. 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 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 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 will depend, in part, on our ability to enter into and maintain collaborative relationships for such efforts, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, such collaborators may not have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and such efforts may not be successful.

Risks Related to Third-Parties Actions and Market Acceptance

Our reliance on third-party suppliers, including single-source suppliers, and a limited number of options for alternate sources for Gvoke, Keveyis, and Recorlev 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. ("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 are experiencing significantly longer lead times for certain components and materials used in the production of our products and product candidates. Our third-party suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our products. As a result, we may not obtain sufficient quantities of products, components or other key materials in the future, which could have a material adverse effect on our business as a whole. For example, impacts to global supply chains from the COVID-10 pandemic could continue to disrupt our and our suppliers' ability to procure sufficient supplies for the manufacture of our commercial products or our product candidates. Any disruption to the facilities or operations of our third-party suppliers resulting from weather-related events, epidemics, including global health concerns, fire, acts of terrorism, political instability or any other cause could materially impair our ability to manufacture our products and to distribute our products to customers. For example, we have a global supply chain and manufacture some components of our products outside the United States, including without limitation, Taiwan. Any interruption or other delay in the production or delivery of our supplies could reduce sales of our

products and increase our costs and any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

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

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

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

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

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

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

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

Reimbursement decisions by third-party payors and consolidation within the healthcare industry and among competitors 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"* and *"Business — Healthcare Reform"* in our most recent Annual Report on Form 10-K.

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

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the 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 other product candidates will be dependent on its 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 three months ended March 31, 2023 and 2022, four customers accounted for over 90% of the Company’s gross product revenue. At March 31, 2023 and December 31, 2022, the same four customers accounted for over 95% 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.

Risk Related to the Impact of the COVID-19 Pandemic

Our business may continue to be adversely affected by impacts resulting from COVID-19 pandemic and its effects or a future widespread public health epidemic.

The effects of the COVID-19 pandemic continue to affect many businesses, including ours. In addition, future public health epidemics or widespread outbreaks of contagious diseases could adversely impact our business. Any outbreak of contagious diseases, and other adverse public health developments, such as the COVID-19 pandemic, could impact our operations depending on future developments, which are highly uncertain, largely beyond our control and cannot be predicted with certainty. These uncertain factors include the duration of the outbreak, new information which may emerge concerning the severity of the diseases and the actions taken to contain or treat its impact, could adversely impact our operations, including among others, conduct of our clinical trials, employee mobility and productiveness, temporary closure of facilities, including clinical trial sites, manufacturing facilities and customer locations, and third party service providers such as CROs and contract manufacturing organizations (“CMOs”), any of which could have an adverse impact on our business and financial results. For example, we currently rely on third-party suppliers and CMOs for the manufacturing of Gvoke, Keveyis, and Recorlev, as well as to perform third-party logistics functions, including warehousing and distribution of Gvoke, Keveyis, and Recorlev. In addition, we rely on third parties to perform quality testing and supply other goods and services to run our business. Certain of our third party suppliers in our supply chain for materials have been adversely impacted by restrictions resulting from the COVID-19 pandemic or supply chain issues, including staffing shortages, production slowdowns and disruptions in delivery systems, and may continue to be impacted such that our supply chain may be disrupted, limiting our ability to manufacture commercial quantities of our products.

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 MAA to the EMA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate revenue.

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

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

If the FDA determines that our product candidates do not meet the requirements of Section 505(b)(2), we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. In March 2010, former President Obama signed into law legislation creating an abbreviated pathway for approval under the Public Health Service Act, or PHS Act, of biological products that are similar to other biological products that are approved under the PHS Act. The legislation also expanded the definition of biological product to include proteins such as insulin. The law contains transitional provisions governing protein products such as insulin, that, under certain circumstances, might permit companies to seek approval for their insulin products as biologics under the PHS Act. Specifically, on March 23, 2020, a small subset of "biological products" approved under the Federal Food, Drug, and Cosmetic Act, such as insulin, which historically were approved as drugs, transitioned to being regulated as biological products. Being regulated as biological products enables transition products to serve as the reference product for biosimilar or interchangeable products approved through the abbreviated licensure pathway. The transition is a regulatory action in which the approved drug application for a transition biological product will be "deemed" to be a biologics license application. Thus, our XeriSol pramlintide-insulin co-formulation, which would have previously been reviewed through a 505(b)(2) NDA, was instead required to be approved under the PHS Act. If our other product candidates do not meet the requirements of Section 505(b)(2) or are otherwise ineligible or become ineligible for approval via the Section 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, our product candidates may not receive the requisite approvals for commercialization.

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

significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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

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

Gvoke, 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.

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

To date, patients treated with our ready-to-use glucagon have experienced drug-related side effects typically observed with glucagon products, including nausea, vomiting and headaches. In our clinical trials of Recorlev, the most common adverse reactions (incidence > 20%) were nausea/vomiting, hypokalemia, hemorrhage/contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain/dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia/sleep disturbances, and peripheral edema. In the Keveyis clinical trial, the most common adverse reactions (incidence > 10%) were paresthesia, cognitive disorder, dysgeusia, and confusional state. These adverse events can be dose-dependent and may increase in frequency and severity if we increase the dose to increase efficacy. It is possible that there may be side effects associated with our product candidates' use. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects of our product candidates could affect patient recruitment or the ability of enrolled patients to complete the trial or could also adversely affect physician or patient acceptance thereof. Any of these occurrences may harm our business, financial condition and prospects.

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

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

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

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

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

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective or makes a major contribution to patient care. In assessing whether 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. We have received orphan drug designation from the EMA for our ready-to-use glucagon for the treatment of CHI and NIPHS, which includes patients with PBH.

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

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

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

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

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

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

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable debate, and members of Congress have indicated that they will address such costs through new legislative measures. To date, there have been several recent 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 rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease 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 effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known.

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 QSRs. Accordingly, we and our third-party suppliers must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse 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.

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*" in our most recent Annual Report on Form 10-K.

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 United States Department of Veterans Affairs, Federal Supply Schedule, or FSS, pricing program, and the Tricare Retail Pharmacy program, and have obligations to report the average sales price for certain of our drugs to the Medicare program. For calendar quarters beginning January 1, 2022, manufacturers will need to

start reporting the average sales price for drugs under the Medicare program regardless of whether they are enrolled in the Medicaid Drug Rebate Program. Currently, only manufacturers participating in the Medicaid Drug Rebate Program are obligated to do so.

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, which can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program 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 average sales price, 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. The Centers for Medicare & Medicaid Services, or CMS, could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results. CMS issued a final regulation, which became effective in April 2016, to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. In December 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); and provided definitions for “line extension,” “new formulation,” and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula (beginning in 2022). Regulatory and legislative changes, and judicial rulings relating to the Medicaid Drug Rebate Program and related 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.

The HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective in January 2019. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated this regulation or other requirements of the program could negatively impact our financial results. Moreover, HRSA newly established an administrative dispute resolution, or ADR, process under a final regulation effective January 2021, for claims by covered entities that a manufacturer engaged in overcharging, including claims that a manufacturer limited the ability of a covered entity to purchase the manufacturer’s drugs at the 340B ceiling price, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. This ADR regulation has been challenged in separate litigation instituted by PhRMA and by pharmaceutical manufacturers in multiple federal courts. Under the ADR final rule which became effective in January 2021, an ADR proceeding could potentially subject us to discovery by covered entities and other onerous procedural requirements and could result in additional liability. HRSA could also decide to terminate a manufacturer’s agreement to participate in the 340B program for a violation of that agreement or other good cause shown, in which case the manufacturer’s covered outpatient drugs may no longer be eligible for federal payment under the Medicaid or Medicare Part B program. In November 2022, HRSA issued a proposed rule to revise the ADR procedures contained in its January 2021 final regulation for disputes arising under the 340B drug pricing program between covered entities and manufacturers.

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 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.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pursuant to applicable law, knowing provision of false information in connection with price reporting under the United States Department of Veterans Affairs, FSS or Tricare Retail Pharmacy, or Tricare, programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, 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 False Claims Act 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.

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

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

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

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

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

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

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

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will not: (a) be sufficient to protect our technology, (b) provide us with a basis for commercially viable products and/or (c) provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under 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, Steven Prestrelski, our Chief Scientific Officer and Co-Founder, John Shannon, our President and Chief Operating Officer, Ken Johnson, our Senior Vice President, Global Development and Medical Affairs, and Beth Hecht, our Chief Legal Officer and Corporate Secretary. The loss of any one of these individuals could disrupt our operations or our strategic plans. Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

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

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

Risks Related to Our Common Stock

Risks Related to Investment in Securities

Our stock price has been and will likely continue to be volatile, and you may 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
- ongoing impacts from 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 May 5, 2023, the closing price of a share of our common stock was $2.40 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 March 31, 2023, the outstanding balance of Convertible Notes was $47.2 million. If

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

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

Upon completion of the acquisition 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 March 31, 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 March 31, 2023. As of March 31, 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 for our Convertible Notes, Charter and Bylaws

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

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

- establish a classified board of directors such that all members of the board are not elected at one time; allow the authorized number of our directors to be changed only by resolution of our board of directors; and limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws; and
- 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 governing our Convertible Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then noteholders will have the right to require us to repurchase their notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the notes and the indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that noteholders or holders of our common stock may view as favorable.

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

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

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

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

General Risk Factors

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

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

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Despite our implementation of security measures, our information systems 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.

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 and/or the UK subjecting us to additional privacy restrictions and data protection requirements. The collection and use of personal health data in the EU are governed by the provisions of the EU General Data Protection Regulation ("EU GDPR"), as well as other national data protection legislation in force in relevant Member States (including the EU GDPR as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (the “UK GDPR”, together with the EU GDPR the “GDPR”) and the Data Protection Act 2018 in the UK). These laws impose a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the European Economic Area, or EEA (or in the case of the UK GDPR, outside of the UK), providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals’ requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Although the UK is regarded as a third country under the EU’s GDPR, the European Commission has issued a 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. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the 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 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 under the GDPR and doing so will require significant effort and cost.

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 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) million or 4% of the data controller’s or data processor’s total worldwide global turnover for the preceding fiscal year, whichever is higher, and violations of the GDPR may also lead to damages claims by data controllers and data subjects. Such penalties are in addition to any civil litigation claims by data controllers, clients, and data subjects. As such, we will need to take steps to cause our processes to continue to be compliant with the applicable portions of the GDPR, but we cannot assure you that we will be able to implement changes in a timely manner or without significant disruption to our business, or that such steps will be effective, and we may face the risk of liability under the GDPR.

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.

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 between Russia and Ukraine, could adversely affect our business and financial performance.

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

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

The United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, for example due to increases in the costs of labor and supplies, or remain at a historically high rate, it will affect our expenses, such as employee compensation, supply costs and research and development expenses. Additionally, the United States is experiencing an acute workforce shortage, which in turn, has created a very competitive wage environment that may increase our operating costs. To the extent inflation 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") 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.

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)
10.1*	Amendment No 2. to Credit Agreement and Guaranty, dated as of January 19, 2023, among Xeris Pharmaceuticals, Inc., the Registrant, the lenders party thereto and Hayfin Services LLP, as administrative agent
10.2*†	Amendment No. 4 to Commercial Supply Agreement, dated as of January 26, 2023 between Pyramid Laboratories Inc. and Xeris Pharmaceuticals, Inc.
10.3*†	Amended and Restated Product Supply Agreement, effective as of January 30, 2023, by and between Xeris Pharmaceuticals, Inc. and SHL Pharma LLC
10.4*†	Statement of Work #1 – Device, effective as of January 30, 2023, between Xeris Pharmaceuticals, Inc. and SHL Pharma, LLC
10.5*†	Statement of Work #2 – Product, effective as of January 30, 2023, between Xeris Pharmaceuticals, Inc. and SHL Pharma, LLC
10.6*†	Omnibus Assignment and Assumption Agreement and Amendment No. 1 to Asset Purchase Agreement and Supply Agreement, effective as of March 13, 2023, among Xeris Pharmaceuticals, Inc., Strongbridge Dublin Limited and Taro Pharmaceuticals North America, Inc.
10.7*†	Omnibus Amendment No. 2 to Asset Purchase Agreement and Supply Agreement, effective as of March 13, 2023, between Xeris Pharmaceuticals, Inc. and Taro Pharmaceuticals North America, Inc.
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: May 9, 2023

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

Date: May 9, 2023

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

Exhibit 10.1

Execution Version

AMENDMENT NO. 2 TO CREDIT AGREEMENT AND GUARANTY

This AMENDMENT NO. 2 TO CREDIT AGREEMENT AND GUARANTY, dated as of January 19, 2023 (this "***Amendment***"), is by and among XERIS PHARMACEUTICALS, INC., a Delaware corporation (the "***Borrower***"), and XERIS BIOPHARMA HOLDINGS, INC., a Delaware corporation ("***Parent***"), the Lenders party hereto, and HAYFIN SERVICES LLP, as administrative agent for the Lenders (in such capacity, together with its successors and assigns, the "***Agent***"). Reference is made to the Credit Agreement and Guaranty, dated as of March 8, 2022, among the Borrower, Parent, certain subsidiaries of Parent from time to time party thereto, the lenders from time to time party thereto (the "***Lenders***") and the Agent (as amended, supplemented or otherwise modified from time to time, the "***Credit Agreement***"). Capitalized terms used herein without definition shall have the same meanings as set forth in the Credit Agreement, as amended by this Amendment.

RECITALS

WHEREAS, the Borrower has informed the Agent and the Lenders that (i) it intends to execute and deliver a Letter of Financial Support (in the form set forth on **Exhibit A** hereto) to the Board of Xeris Pharmaceuticals Australia Pty Ltd, a wholly-owned Subsidiary of the Borrower (the "***New Letter of Financial Support***") and (ii) it has previously executed and delivered a Letter of Financial Support, dated as of November 18, 2021 to the Board of Xeris Pharmaceuticals Australia Pty Ltd (the "***Previous Letter of Financial Support***");

WHEREAS, Parent and the Borrower have requested that the Agent and the Lenders amend certain provisions of the Credit Agreement to permit the execution and delivery of the New Letter of Financial Support; and

WHEREAS, the Agent and the Lenders are willing to do so on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, the parties hereto hereby agree as follows:

ARTICLE I
AMENDMENTS TO CREDIT AGREEMENT

SECTION 1.01. Amendments to the Credit Agreement. As of the Amendment Effective Date, the Credit Agreement is hereby amended as follows:

(a) Sections 9.01(d) of the Credit Agreement is hereby amended and restated in its entirety to read as follows:

> "(d) (i) Guaranties by an Obligor (other than Cortendo) of the Indebtedness of another Obligor (other than Cortendo) to the extent such Indebtedness is otherwise permitted hereunder and (ii) Guaranties by the Borrower of the Indebtedness of Xeris Australia pursuant to any Letter of Financial Support (in the form set forth on Exhibit A to Amendment No. 2 to Credit Agreement and Guaranty, dated as of January 19, 2023 or in such other form as is reasonably satisfactory to the Agent) executed and delivered by the

Borrower to the Board of Xeris Australia from time to time (a copy of which shall be concurrently provided to the Agent) (a "***Letter of Financial Support***"); provided that in the case of this **clause (ii)** any payments thereon shall be deemed to be an Investment by the Borrower in Xeris Australia to be made in accordance with **Section 9.05(k)**, or, at the Borrower's option, **Section 9.05(r)** and in any event subject to the limitations set forth therein; provided further that, in the case of **clauses (i)** and **(ii)** above, any subrogation claims of any such guarantying Obligor shall be subordinated to the Obligations pursuant to the Intercompany Subordination Agreement;"

(b) Sections 9.01(t) of the Credit Agreement is hereby amended and restated in its entirety to read as follows:

"(t) Permitted Refinancings of Indebtedness otherwise permitted pursuant to this **Section 9.1** (other than **Section 9.1(a)**, **(d)**, **(l)**, the proviso in **(p)**, **(t)** and **(u)**); and"

(c) The last sentence of Section 9.01 of the Credit Agreement is hereby amended and restated in its entirety to read as follows:

"Any term or provision of this Agreement to the contrary notwithstanding, in no event shall Cortendo or any Subsidiary that is not a Subsidiary Guarantor incur or permit to remain outstanding Indebtedness from any Obligor (other than pursuant to **clauses (b). (d)(ii)** or **(r)** above)."

(d) Section 9.05 of the Credit Agreement is hereby amended by (i) deleting the text " and" appearing at the end of clause (q) thereof, (ii) deleting the text "." appearing at the end of clause (r) thereof and adding in its place the text "and", and (iii) adding a new clause (s) immediately after clause (r) thereof to read in its entirety as follows:

"(s) Investments by the Borrower in Xeris Australia in the form of a Letter of Financial Support permitted pursuant to **Section 9.01(d)(ii)**; provided that any payments thereon shall be made in accordance with **Section 9.05(k)**, or, at the Borrower's option, **Section 9.05(r)** and in any event subject to the limitations set forth therein."

ARTICLE II
ACKNOWLEDGEMENT, AGREEMENT AND CONSENT AND REPRESENTATIONS AND WARRANTIES

SECTION 2.01. Each Obligor party hereto confirms and agrees that, notwithstanding the effectiveness of this Amendment, the obligations of such Obligor under each Loan Document to which such Obligor is a party shall not be impaired and each Loan Document to which such Obligor is a party is, and shall continue to be, in full force and effect and is hereby confirmed and ratified in all respects.

SECTION 2.02. Each Obligor party hereto hereby acknowledges and agrees that the Guaranteed Obligations will include all Obligations under, and as defined in, the Credit Agreement as amended by this Amendment.

SECTION 2.03. To induce the Agent and the Lenders to execute and deliver this Amendment, each Obligor party hereto represents and warrants to the Agent and the Lenders party hereto that as of the date hereof, each of the following statements are true and correct:

(a) The execution and delivery of this Amendment, and the performance of this Amendment and the Credit Agreement as amended hereby, by each Obligor party hereto has been duly authorized by all necessary corporate or other organizational action on the part of such Obligor and this Amendment and the Credit Agreement as amended hereby each constitutes a legal, valid and binding agreement of such Obligor, enforceable against such Obligor in accordance with their respective terms, except as enforcement may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights generally and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(b) The execution and delivery of this Amendment, and the performance of this Amendment and the Credit Agreement as amended hereby, in each case by any Obligor party hereto, does not (i) violate or conflict with any Law, (ii) result in the creation of any Lien (other than Permitted Liens) on any asset of such Obligor or any of its Subsidiaries or (iii) violate, or result in a default under, any Material Agreement binding upon Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect.

(c) No authorization or approval or other action by, and no notice or filing with, any Governmental Authority or any other Person (other than those that have been duly obtained or made and which are in full force and effect) is required for the due execution and delivery of this Amendment and the performance of this Amendment and the Credit Agreement as amended hereby, in each case by each Obligor party hereto, except for filings and recordings in respect of perfecting or recording the Liens created pursuant to the Security Documents.

(d) Parent and its Subsidiaries, on a consolidated basis, are, and immediately after giving effect to this Amendment, will be Solvent.

(e) Immediately before and after giving effect to this Amendment, no event has occurred and is continuing that constitutes a Default or an Event of Default.

ARTICLE III
CONDITIONS PRECEDENT

SECTION 3.01. Conditions to Effectiveness of this Amendment. This Amendment shall become effective only upon, and shall be subject to, the prior or simultaneous satisfaction or waiver of each of the following conditions precedent in a manner reasonably satisfactory to the Agent (the date satisfaction of such conditions being referred to as the "***Amendment Effective Date***"):

(a) **Executed Amendment**. The Agent shall have received this Amendment, duly executed by the Borrower, Parent, the Agent and each of the Lenders.

(b) **Executed Letter of Financial Support**. The Agent shall have received the New Letter of Financial Support, duly executed by the Borrower.

(c) **Costs and Expenses, Etc**. The 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) of the Credit Agreement (including the Agent's and each Lender's reasonable and documented (in reasonable detail) legal fees and out-of-pocket expenses).

ARTICLE IV
MISCELLANEOUS

SECTION 4.01. Governing Law; Jurisdiction; Jury Trial. This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; provided that Section 5-1401 and 5-1402 of the New York General Obligations Law shall apply. The jurisdiction, service of process, venue and waiver of jury trial provisions set forth in Sections 14.10 and 14.11 of the Credit Agreement, respectively, are incorporated herein by reference *mutatis mutandis*.

SECTION 4.02. Effect of Amendment.

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

(b) This Amendment shall constitute a Loan Document for all purposes of the Credit Agreement. The Obligors party hereto agree that all of the representations, warranties, terms, covenants, conditions and other provisions of the Credit Agreement and other Loan Documents shall, except as expressly set forth in this Amendment, remain unchanged and shall continue to be, and shall remain, in full force and effect in accordance with their respective terms. 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. Except as expressly set forth in this Amendment, the Credit Agreement and the other Loan Documents are and shall continue to be in full force and effect and are hereby in all respects ratified and confirmed.

(c) The execution, delivery and effectiveness of this Amendment shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the Agent or any Lender under any Loan Document or applicable Law, nor constitute a waiver of any provision of the Credit Agreement except as expressly set forth herein.

SECTION 4.03. No Novation. This Amendment is not intended by the parties to be, and shall not be construed to be, a novation of the Credit Agreement or the other Loan Documents.

SECTION 4.04. Counterparts; Electronic Signatures. This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same

instrument and any of the parties hereto may execute this Amendment by signing any such counterpart. Delivery of an executed signature page of this Amendment by facsimile transmission or electronic transmission (in PDF format) shall be effective as delivery of a manually executed counterpart hereof. Any signature (including, without limitation, (x) any electronic symbol or process attached to, or associated with, a contract or other record and adopted by a person with the intent to sign, authenticate or accept such contract or record and (y) any facsimile or .pdf signature) hereto or to any other certificate, agreement or document related to this transaction, and any contract formation or record-keeping, in each case, through electronic means, shall have the same legal validity and enforceability as a manually executed signature or use of a paper-based record-keeping system to the fullest extent permitted by applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any similar state law based on the Uniform Electronic Transactions Act, and the parties hereto hereby waive any objection to the contrary.

SECTION 4.05. Binding Nature. The provisions of this Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns permitted by the Loan Documents; provided that no Obligor may assign or otherwise transfer any of its rights or obligations hereunder without the prior written consent of the Agent.

SECTION 4.06. Captions. The captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Amendment.

SECTION 4.07. Severability. If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by any applicable Law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof.

SECTION 4.08. Integration. This Amendment constitutes the entire agreement among the parties with respect to the subject matter hereof and supersedes any and all previous agreements and understandings, oral or written, relating to the subject matter hereof.

[Signature pages to follow]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the date hereof.

PARENT:

XERIS BIOPHARMA HOLDINGS, INC.

By /s/ Steven M. Pieper

Name: Steven M. Pieper
Title: Chief Financial Officer

BORROWER:

XERIS PHARMACEUTICALS, INC.

By /s/ Steven M. Pieper

Name: Steven M. Pieper
Title: Chief Financial Officer

AGENT, on behalf of the Lenders:

HAYFIN SERVICES LLP

By /s/ Nicola O'Regan
Name: Nicola O'Regan
Title: Authorised Signatory

Exhibit A

Letter of Financial Support

See attached.

180 North LaSalle Street, Suite 1600, Chicago, IL 60601

Date: January 19, 2023

The Board of Directors
Xeris Pharmaceuticals Australia Pty Ltd
58 Gipps Street,
Collingwood VIC 3066

Dear Directors

Letter of Financial Support

I hereby declare that Xeris Pharmaceuticals, Inc. warrants and undertakes:

(a) To provide such financial support to Xeris Pharmaceuticals Australia Pty Ltd ("**the Company**") that is required from time to time to ensure that any debts incurred by the Company are met as and when they fall due;
(b) Indemnify the Company in relation to any claims which are made against it for damages in relation to any product or service which the Company delivers in Australia; and
(c) That it has sufficient assets and income from which to honour this indemnity in favour of the Company.

This undertaking is provided for a minimum of 12 months from the date of this letter.

For and on behalf of Xeris Pharmaceuticals, Inc.:

Yours faithfully,

/s/ Steven M. Pieper

Name: Steven M. Pieper
Xeris Pharmaceuticals, Inc.

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 NO. 4 TO Commercial Supply Agreement

This Amendment No. 4 to the Commercial Supply Agreement (this "Amendment") has been made and entered into as of January 26, 2023 (the "Effective Date") between PYRAMID Laboratories Inc. ("PYRAMID") and Xeris Pharmaceuticals, Inc. ("Client"). This Amendment amends that certain Commercial Supply Agreement dated as of May 14, 2018, as amended by Amendment No. 1 dated as of September 1, 2018, Amendment No. 2 dated as of May 13, 2021 and Amendment No. 3 dated as of August 31, 2022, the "Agreement"), by and between the parties to this Amendment. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Agreement.

NOW, THEREFORE, the parties intending to be legally bound, hereby agree as follows:

1. Schedule A. The Agreement is hereby amended as of the Effective Date such that Schedule A thereto is deleted in its entirety and replaced with Schedule A attached hereto.

2. Miscellaneous. Except as expressly amended hereby, the terms of the Agreement (including the schedules thereto) shall remain in full force and effect, and the Agreement, as amended by this Amendment, is binding on each of the parties to this Amendment.

* * *

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the Effective Date.

PYRAMID Laboratories, Inc.:

By:_____/s/Medhat Gorgy_____
Name: Medhat Gorgy
Title: President & CEO

Xeris Pharmaceuticals, Inc.:

By: /s/ Peter Valentinsson_____
Name: Peter Valentinsson
Title: SVP, Product Development/Technical Operations

Schedule A

Batch Size, Dosage, Yield*, Volume, Pricing

I. [***]

[***]					
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
[***]					
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
[***]					
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
[***]					
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]	[***]

[***]

Pricing Assumptions:

1. Standard Batch [***].
2. Standard batch size estimates based on [***] theoretical yield per dosage; yield assumptions and batch sizes shall be adjusted annually based on actual production history.
3. Batch size/yield/price independent [***].
4. Pricing subject to annual adjustments as defined under Section 3.3.2, [***].
5. Pricing for Validation Batches shall be adjusted as defined under Section 3.3.3 [***].

Schedule A (continued)

6. Price includes [***].

7. Price includes [***].

8. Price excludes [***].

II. [***]

[***]

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]			
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

* [***]

Schedule A (continued)

Batch Size, Dosage, Yield, Volume Pricing

Pricing Assumptions:

1. Standard Batch [***].
2. Standard batch size estimates based on [***] theoretical yield per dosage; yield assumptions and batch sizes shall be adjusted annually based on actual production history.
3. Pricing subject to annual adjustments as defined under Section 3.3.2, [***].
4. Pricing for Validation Batches shall be adjusted as defined under Section 3.3.3 [***].
5. Price includes [***].
6. Price includes [***].
7. Price excludes [***].

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

AMENDED AND RESTATED PRODUCT SUPPLY AGREEMENT

This **AMENDED AND RESTATED PRODUCT SUPPLY AGREEMENT** (the "Agreement"), effective as of January 30, 2023 (the "Effective Date"), is made by and between **SHL Pharma, LLC**, a private limited liability company existing under the laws of Florida, with offices at 588 Jim Moran Boulevard, Deerfield Beach, Florida 33442 ("SHL"), and **Xeris Pharmaceuticals, Inc.,** a Delaware corporation, with its principal office at 180 N. LaSalle Street, Suite 1600, Chicago, Illinois, 60601 ("Customer"), collectively the "Parties" and each individually a "Party".

RECITALS

WHEREAS, Customer is engaged in the research, development, and commercialization of products for patients with unmet medical needs; and

WHEREAS, Customer owns and possesses certain materials, intellectual property rights, information, and know-how related to the Drug Products (as defined below), and related research programs;

WHEREAS, SHL is engaged in the design, development, and manufacture of drug delivery devices, and assembly of combination drug products involving delivery devices, including auto-injectors and pen injectors;

WHEREAS, Customer and SHL's Affiliate (defined below), Scandinavian Health Limited, a private company existing under the laws of Hong Kong, with its registered office at Room 810, Argyle Centre, Phase 1, 688 Nathan Road, Kowloon, Hong Kong ("SHL HK") entered into a Joint Development Agreement effective as of January 29th, 2016 (the "Joint Development Agreement") under which, SHL HK developed an auto-injector device based on SHL's [***]for use with Customer's Primary Packaging (defined below) when converted into assembled Product (defined below);

WHEREAS, Customer, SHL HK, and SHL Medical AG, a private company existing under the laws of Switzerland with its registered office at Gubelstrasse 22, Zug 6300 and an

Affiliate of SHL, agreed that as of October 1, 2018, all rights and obligations of SHL HK under the Joint Development Agreement were transferred to and assumed by SHL Medical AG.

WHEREAS, Customer and SHL entered into a Product Supply Agreement effective as of August 1, 2018, as amended by the First Amendment to the Product Supply Agreement effective as of June 24, 2020 (as amended, the "Supply Agreement"), pursuant to which SHL manufactures the Devices through its Affiliate, SHL Taiwan (defined below), as a qualified supplier of SHL, and SHL assembles the Device together with Customer's Primary Packaging into a fully assembled Product;

WHEREAS, SHL and Customer wish to enter into this Agreement for the purpose of amending and restating, in its entirety, the Supply Agreement and to set forth the terms and conditions upon which Customer shall engage SHL to have the Devices manufactured and to provide the Services related to the above-mentioned Device, Primary Packaging, and Product; and

NOW, THEREFORE, for and in consideration of the foregoing promises and the mutual covenants and obligations contained herein, the Parties do agree as follows:

TERMS AND CONDITIONS

1. DEFINITIONS

1.1 "Affiliate" means, with respect to a Party, any corporation, company, partnership, joint venture, or other business entity controlled by, controlling, or under common control with such Party. For purposes of this definition, "control" means the direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in an entity, or such other relationship as, in fact, constitutes actual control.

1.2 "Agreement" shall be as defined in the preamble.

1.3 "Background Intellectual Property" means Intellectual Property owned, licensed to, or otherwise controlled by one of the Parties hereto prior to the performance of the Joint Development Agreement or developed, licensed, or otherwise controlled by one of the Parties outside the scope of the Joint Development Agreement or this Agreement or the Services and provided (whether hereto before or after the Effective Date) by that Party to the other for use in the Services within the scope of this Agreement.

1.4 "Best Practices" shall have the definition stated in Section 2.12.

1.5 "Capacity Commitment" shall have the definition stated in Section 5.1.6 and the applicable SOW.

1.6 "Commercially Reasonable Efforts" means, in the case of a Party, with respect to any activity means the level of efforts and resources (including the standard of care and skill and manner and quality) that would be used in the performance of the relevant activity in compliance with applicable laws, regulations and if applicable, GMP, by a person or entity (engaged in the manufacture and supply or commercialization of pharmaceutical products, as applicable) of comparable size and resources as the applicable Party with regard to a product at a similar stage in its product life taking into account the following factors to the extent reasonable and relevant: issues of safety and efficacy, quality, product profile, duration of exclusivity or other proprietary position of the product, the nature and length of supply relationship, the regulatory environment and status of such product, and other relevant scientific, technical and commercial factors, all as measured by the facts and circumstances at the time such efforts are due. Where this Agreement requires a Party to use Commercially Reasonable Efforts, such efforts and resources that are used by such Party's Affiliates, agents, sublicensees and licensees, as relevant, shall also be attributed to such Party. For clarity, "Commercially Reasonable" has a correlative meaning.

1.7 "Components Colors" means the specific combination of colors of the surface of any specific components of the Device, chosen or accepted by Customer and approved by SHL in writing, to apply to the Device. For avoidance of doubt, typical surface elements may include but are not limited to the cap, needle shield, plunger rod, body, and rear cap of the Device. The Components Colors do not include the industrial design of the Device and do not therefore extend to the ornamental configuration, surface decoration features, or look and feel features of the Device.

1.8 "Confidential Information" means all confidential and proprietary information disclosed or provided hereunder to one Party by or on behalf of the other Party, its employees, consultants or advisors or any of the other Party's Affiliates and its Affiliates' employees, including, but not limited to: (i) written records, business plans, operational information (such as administration, human resource, employee(s) or financial information), individual lists, research, notes,

manuals, notebooks, documentation, program listings, flow charts, magnetic media, disks, diskettes and tapes, (ii) products and services, (iii) machines, articles of manufacture and computer programs, (iv) designs and configurations, (v) analyses, (vi) drawings, sketches, models, apparatuses, photographs and reports, (vii) computer software, including operating systems, applications and program listings, (viii) data bases, (ix) inventions, devices, new developments, methods, processes, systems, formulations, configurations and uses, whether patentable or unpatentable and whether or not reduced to practice, (x) other copyrightable works, (xi) all technology, Know-How, and trade secrets and (xii) all similar and related information, data, records and materials in whatever form. Confidential Information shall also include all reports, analyses, notes or records taken about the Confidential Information or other information that are based on, contain or reflect any Confidential Information.

1.9 "Customer Materials" means Primary Packaging and any other materials that Customer provides to SHL in order for SHL to carry out the Services and to produce the Product and Deliverables. Solely when such term is used in connection with Services for assembly of the Products, "Customer Materials" shall include Devices for purposes of Section 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.8, and 3.9 and only after Devices have been (i) supplied by SHL Taiwan as a qualified supplier of SHL and (ii) received by SHL at the Facility located in Deerfield Beach, Florida. For the avoidance of doubt, the term "Customer Materials" shall not include the Devices for purposes of the intellectual property provisions set forth in Article 12 or the indemnification provisions set forth in Article 15.

1.10 "Defense Action" shall have the meaning stated in Section 12.13.

1.11 "Deliverables" shall mean the Devices and Products to be sourced by and delivered by SHL, and any other deliverable identified in this Agreement.

1.12 "Device" means a single-use injection device based on SHL's [***] in the form of sub-assemblies sourced from SHL Taiwan and developed for Customer under the Joint Development Agreement, suitable for housing the Primary Packaging, inclusive of all components, assembly steps and quality release steps, to be manufactured in accordance with Product requirements defined in the applicable Statement of Work, and Product specifications and Device specifications in the Quality Agreement. For purposes of clarity, the Device includes any past or future versions of the Device supplied hereunder and does not include the Primary Packaging or the Drug Product contained therein.

1.13 "Disclosing Party" shall have the meaning stated in Section 10.1.

1.14 "Drug Product" means [***].

1.15 "Effective Date" shall be as defined in the preamble to this Agreement.

1.16 "Enforcement Action" shall have the meaning stated in Section 12.14.

1.17 "Facility(ies)" means: (i) with respect to the manufacturing of the Devices, SHL Taiwan (defined below)'s facility located at 136 Guosheng 2nd Street, Taoyuan, Taiwan; (ii) with respect to the assembly of the Devices and Primary Packaging to produce Products, SHL's facility located at 588 Jim Moran Boulevard, Deerfield Beach, Florida; (iii) with respect to storage Services, SHL's facilities located at 951 Clint Moore Road, Suite A, Boca Raton, Florida 33487 and at 750 NW 33rd Street, Suite B, Pompano Beach, Florida 33064; or (iv) any facility operated by SHL or its Affiliates and approved in writing by Customer in accordance with the Quality Agreement.

1.18 "FDA" means the United States Food and Drug Administration or any comparable directorate of food and drugs administration of any jurisdiction of the Territory into which Customer desires to file a regulatory submission.

1.19 "Fee" or "Fees" means the service fees charged by SHL for the Services as set forth in the applicable Statement of Work.

1.20 "Field" means the treatment of moderate to severe hypoglycemia in adult or pediatric patients with type 1 diabetes.

1.21 "Force Majeure Event" shall have the definition stated in Article 23.

1.22 "Foreground Intellectual Property" means all information, Intellectual Property, works, discoveries, and creations that have been or are made, conceived or identified in the course of the performance of the Joint Development Agreement or the Services.

1.23 "Good Manufacturing Practices" or "Current Good Manufacturing Practices" ("GMP" or "cGMP") means those practices laid down in international guidelines and regulations such as the cGMP rules of the World Health Organization, ISO 13485, the United States Code of Federal Regulations (Title 21, Parts 210-211, as well as Parts 808, 812 820 (QSR)), applicable Guidance(s) for Industry and

FDA Staff (e.g. cGMP Requirements for Combination Products), and the European Union Guide to Good Manufacturing Practice including Annexes in the production of Pharmaceutical Products, and any subsequent or future revisions of such guidelines and regulations.

1.24 "Indemnified Party" is defined in Section 15.3.

1.25 "Indemnifying Party" is defined in Section 15.3.

1.26 "Intellectual Property" means all rights, whether registered or unregistered, in patents, patent applications, inventions, Know-How, trade secrets and other confidential information, trade dress, designs, copyrights (including, without limitation, rights in computer software), data, database rights and *sui generis* rights, rights affording equivalent protection to copyrights, semiconductor topography rights, trademarks, service marks, trade dress, logos, domain names, business names, trade names, brand names, certification marks, assumed names and other indicators or origin, rights in any drawings, designs, plans, specifications, manuals, computer software, assets, inventor's certificates and invention disclosures, writings and other works of authorship, whether copyright or not, bills of material, moral rights and all other industrial or intellectual property or other rights or forms of protection of a similar nature or having similar effect in any part of the world and rights in and in relation to them and, where appropriate, applications for any of them in any country or jurisdiction, rights in the nature of unfair competition rights, rights to sue for passing-off or dilution, the right to apply for any of them and all other information necessary for the technical exploration of any of the same and all registrations of or for the same.

1.27 "Joint Development Agreement" is defined in the preamble to this Agreement.

1.28 "JSC" is defined in Section 4.1.

1.29 "Know-How" means unpatented, unpublished, technical information (including, without limitation, information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, materials, formulae, formulations, processes, research or experimental results, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain.

1.30 "Latent Defect" shall mean a hidden flaw, weakness or imperfection of the Device or Product (other than any such flaw, weakness or imperfection related to or stemming from the Primary Package and/or the Drug Product) that cannot be readily ascertained from the mere observation or a reasonable or customary inspection of the Product. Latent Defects do not include defects of the Product that were caused by wear and tear, gradual deterioration or contamination.

1.31 "Long Term Forecast" shall have the definition stated in Section 5.1.1.

1.32 "Material Adverse Event" means the occurrence of, as shown based on one or more objective factors, any adverse circumstances or set of circumstances when taken individually or together with all other adverse changes or effects, which would make it commercially unreasonable to continue the Services.

1.33 "Minimum Order Quantity" or "MOQ" means the average manufacturing batch quantity for the Device or Product which would be the minimum for a single Purchase Order. The standard MOQ shall not be less than the batch size set forth in the applicable Statement of Work except as noted herein and with the agreement of SHL, and, in any event, Purchase Orders shall be a whole number multiple of the applicable batch size. For clarity, Customer shall be allowed to order smaller quantities of Product from time to time, to minimize obsolescence or to supply bulk unlabeled Product to partners in the Territory (e.g., [***] Products for sale in the United Kingdom or the European Economic Area).

1.34 "Price" means the price charged by SHL for the Device as set forth in the applicable Statement of Work.

1.35 "Primary Packaging" means a 1.0 mL long pre-filled syringe to be supplied by Customer and containing a dosage of 0.5mg or 1.0mg of Customer's injectable Drug Product.

1.36 "Product" means the combination of the Primary Packaging and the Device, inclusive of labelling and bulk secondary packaging. For the avoidance of doubt, once fully assembled, the Product includes Customer's Drug Product contained in the Primary Packaging, the Device, a Product label, and secondary bulk packaging and labeling approved in writing by Customer and provided by SHL.

1.37 "Purchase Order" shall have the definition stated in Section 5.2.1.

1.38 "Quality Agreement" means the Quality Agreement entered into between the

Parties effective as of October 8, 2021, as amended, which amended and restated the prior Quality Agreement dated April 14, 2020 and amended June 25, 2020. The Quality Agreement includes relevant Device and Product specifications, as applicable, and shall be amended from time-to-time as required. In the event of inconsistencies between this Agreement and the Quality Agreement, this Agreement shall control except for matters related to quality, compliance, or regulatory affairs.

1.39 "Receiving Party" shall have the meaning stated in Section 10.1.

1.40 "Receiving Party's Representatives" shall have the meaning stated in Section 10.2.

1.41 "Renewal Term" shall have the meaning stated in Section 14.1.

1.42 "Rolling Forecast" shall have the meaning stated in Section 5.1.2.

1.43 "Scale-Up Plan" shall have the meaning stated in Section 2.13.

1.44 "Services" means (i) the manufacturing and supply of Devices by SHL's Affiliate, SHL Taiwan, at the Facility located in Taoyuan, Taiwan; (ii) the applicable testing and quality release of the Devices by SHL's Affiliate, SHL Taiwan, at the Facility located in Taoyuan, Taiwan; (iii) the transportation of the Devices from the Facility located in Taoyuan, Taiwan to the Facility located in Deerfield Beach, Florida; (iv) incoming inspection and release of Devices and the assembly of the Devices and the Primary Packaging into Products by SHL at the Facility located in Deerfield Beach, Florida; (v) the labeling and secondary bulk packaging of Products by SHL at the Facility located in Deerfield Beach, Florida; (vi) the applicable testing, handling, and storage of the Devices, Primary Packaging and Products by SHL at the Facility located in Deerfield Beach, Florida; and (vii) other services to be provided by SHL to Customer as specified in this Agreement or the applicable Statement of Work. The Services identified in (i)-(vii) above are further described in the applicable SOW.

1.45 "Safety Stock" means a stock of SHL Materials at a level mutually agreed to by the Parties as specified in the applicable SOW.

1.46 "SHL Materials" means, other than Customer Materials, any additional labelling and bulk packaging materials that are reasonably required for the performance of the Services, as further defined in the applicable Statement of Work. For

purposes of this definition, "Devices" shall be considered SHL Materials unless they are considered "Customer Materials" pursuant to the definition thereof.

1.47 "SHL Taiwan" means Scandinavian Health Limited, one of SHL's Affiliates and a qualified supplier for SHL, duly established under the laws of Taiwan (R.O.C.) with its registered office at No. 36, Liufu Rd., Luzhu Dist., Taoyuan City, Taiwan.

1.48 "Statement of Work" or "SOW" shall have the meaning stated under Section 2.1.

1.49 "Term" shall have the definition stated under Section 14.1.

1.50 "Territory" means the United States, the United Kingdom, the European Union, Israel, the territory administered by the Palestinian Authority and any additional jurisdictions as agreed to in writing by the Parties. In addition, for purposes of the Customer's named patient program, the Territory is global but limited to territories where the Product has not been authorized by the applicable health authority.

1.51 "Working Group" is defined in Section 4.5 of this Agreement.

2. SERVICES

2.1 During the Term, Customer shall request and SHL shall perform the Services, including without limitation by (i) ordering, transporting, importing and supplying the Devices from SHL Taiwan, (ii) conducting the applicable testing, quality release and storage of the Devices, (iii) assembling the Devices with the Primary Packaging into Products, (iv) labeling Products and conducting applicable testing and quality release of the Products, and (v) delivering any other Deliverables or performing any other Services as described in this Agreement and separate statements of work (each, a "Statement of Work" or "SOW") entered into by the Parties referencing this Agreement. For purposes of clarity, SHL shall source the Device from SHL Taiwan, a qualified supplier of SHL, and SHL shall be responsible for all transportation, importation, quality testing and release of the Device and life cycle management, in accordance with this Agreement, each applicable SOW and the Quality Agreement. SHL shall be obligated to make available production capabilities sufficient to satisfy the Capacity Commitment and Customer shall be obligated to purchase all Devices, Products, and Deliverables duly ordered, produced, tested and released in accordance with this Agreement, any applicable Statements of Work and the

Quality Agreement. The specific activities and details in connection with the supply of the Devices and provision of the other Services shall be memorialized by way of Statements of Work. Once executed by both Parties hereto, each SOW becomes part of this Agreement, although the terms in a SOW will govern only Services described in that SOW. In the event of any conflict between the terms of this Agreement and any SOW, the terms of this Agreement shall govern unless otherwise specifically set forth in such SOW.

2.2 Each Statement of Work will include relevant Device or Product specific operating assumptions and parameters, the Device description, Product description, Primary Packaging description, secondary and bulk packaging description, batch sizes, order quantities, capacity requirements, other SHL Materials to be supplied or produced, storage conditions, Services to be performed and Deliverables to be delivered, Prices, Fees, and, if applicable, other compensation therefor, and JSC representation. SHL or its Affiliates shall perform the Services as described and identified herein or therein. All appendices and other exhibits hereto shall be deemed to be incorporated herein by reference.

2.3 SHL will produce and supply Devices from SHL Taiwan, its qualified supplier, and complete required stability studies to ensure Devices will have remaining shelf-life of at least [***] at the time of Device assembly and release at SHL Taiwan.

2.4 SHL perform the Services at the Facilities in compliance with the Quality Agreement, applicable laws and regulations, including applicable legislation concerning health, safety, and environmental protection, and GMP, in effect on or after the Effective Date. All Deliverables made available to the Customer for delivery in accordance with this Agreement shall have been produced in accordance with the Quality Agreement and all applicable laws, the provisions of this Agreement, SHL's standard operating procedures, and GMP.

2.5 Customer shall ensure that SHL is the sole provider of Services for the Product.

2.6 SHL represents and warrants that SHL and its Affiliates have, and shall maintain throughout the Term, the capabilities and necessary certifications to provide the Services in accordance with applicable laws, regulations and GMP. SHL further represents that SHL and its Affiliates have, and shall maintain throughout the Term, all necessary authorization to manufacture the Devices and SHL and its

Affiliates have all necessary authorizations to assemble the Products.

2.7 SHL shall not subcontract any part of this Agreement to any third party or entity unless allowed by the Quality Agreement or otherwise consented to in writing by Customer, which consent shall not be unreasonably withheld. If such consent is given, SHL shall only subcontract with those parties that have executed a supply agreement and quality agreement containing provisions of the character and scope of this Agreement and the Quality Agreement applicable to the Services. Customer acknowledges that in SHL's performance of this Agreement and each SOW, SHL may subcontract portions of its obligations hereunder and thereunder to its Affiliates as identified in this Agreement and in the Quality Agreement and that SHL shall ensure that such Affiliates comply with applicable provisions herein and therein, including without limitation its compliance obligations, through SHL's supplier qualification and management program.

2.8 SHL shall ensure that its and its Affiliates' employees, subcontractors, and agents abide by the terms and conditions of this Agreement, and any breach by any of its and its Affiliates' employees, subcontractors, or agents of any such terms or conditions shall be deemed a breach of this Agreement by SHL.

2.9 SHL shall cause SHL Taiwan to not take, or to fail to take, any action that would be inconsistent with SHL's performance of its obligations under this Agreement.

2.10 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, CUSTOMER AND SHL MAKE NO OTHER REPRESENTATION OR WARRANTY, EXPRESS, OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PURPOSE.

2.11 Customer and SHL or its Affiliates shall review and update the Quality Agreement from time to time, as required. The Quality Agreement shall in no way determine liability or financial responsibility of the Parties for the responsibilities set forth therein or under this Agreement. In the event of a conflict between the terms of this Agreement and the Quality Agreement, this Agreement shall control except for matters related to quality, compliance and regulatory affairs, which shall be controlled by the Quality Agreement. Separate from this Agreement and the Quality Agreement, SHL shall maintain a quality agreement with SHL's Affiliate, SHL Taiwan, to manage the manufacturing, supply and quality of Devices purchased by Customer for use in the Product,

and the terms of such quality agreement shall be comparable to those in Customer's Quality Agreement with SHL.

2.12 SHL warrants that neither SHL and its Affiliates, nor any of the employees or agents performing Services under this Agreement: (i) have been debarred, and to the best of the SHL's knowledge, are not under consideration to be debarred, by the FDA from working in or providing services to any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992 or any other equivalent or successor statutes, rules or regulations, whether foreign or domestic; or (ii) have been excluded, debarred, suspended or are otherwise ineligible to participate in federal healthcare programs or in federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)) or convicted of a criminal offense related to the provision of healthcare items or services, but has not yet been debarred, suspended, proposed for debarment or otherwise determined to be ineligible to participate in federal healthcare programs.

2.13 The Device and Product manufactured hereunder shall be subject to SHL's lifecycle management program and SHL will regularly reevaluate the Device and Product in accordance with the then-applicable standards and best practices, regulatory requirements, and contemporary technology for "emergency use" auto-injectors (the "Best Practices"). The current Best Practices that SHL considers the Device and Product should meet during the lifecycle of the Device and Product will be outlined in a production scale-up plan ("Scale-Up Plan") and the Quality Agreement, which shall be updated from time to time. Such Best Practices updates may come from, inter alia, new or adjusted requirements by FDA or comparable regulatory authority or relevant market complaints. SHL may, in its reasonable determination, determine from time to time that certain ongoing operational activities (e.g., heightened inspection), extra layers of risk mitigation activities due to potential post market incident(s), or other requirements, will be needed in order to enable the Device and Product to meet the current Best Practices. Parties agree that as such Best Practices requirements evolve, the Best Practices may need to be reviewed and updated as required. Should the Device or Product not meet the updated Best Practices, the Parties acknowledge and agree that the Device or Product may have to be reassessed by both Parties, and that Customer shall bear the cost of related feasibility studies or testing required for such reassessment. The Parties further acknowledge that

in such circumstances, the design of the Device or Product may need to be modified or an entirely new auto-injector may need to be developed to conform with the updated Best Practices, or it may be determined that the current Device or Product may no longer be feasible given the then current Best Practices.

In the event that a Party believes a new Best Practice requirement is necessary or believes that the Device or Product does not meet the requirements of the Best Practices, such Party will provide written notice, which notice shall include reasonable supporting detail, to the other Party specifying the proposed Best Practice requirement, the rationale therefor and the manner in which the Device or Product does not meet such requirements. Following such notification, the Parties will promptly discuss the proposed Best Practices requirement and negotiate in good faith any changes to the Device or Product and related project scope, timelines, and additional fees and expenses necessary to bring the Device or Product and related manufacturing processes into compliance with the proposed Best Practices. While changes to Best Practices and changes to related project scope, timelines, and additional fees and expenses necessary to bring the Device or Product and related manufacturing processes into compliance with the proposed Best Practices shall be discussed and negotiated in good faith by the Parties, the final decision as to any changes to Best Practices and changes to related project scope, timelines, and additional fees and expenses necessary to bring the Device or Product and related manufacturing processes into compliance with the proposed Best Practices shall be at the reasonable discretion of SHL acting in good faith. The Quality Agreement shall be amended by the Parties to reflect any such changes in Best Practices.

In the event that Customer does not agree to the changes of the Best Practices requirement or in the event that the Parties cannot reach an agreement on any related changes in project scope, timelines or additional fees and expenses necessary to bring the Device or Product and related manufacturing processes into compliance with the updated Best Practices within [***] of initiation of such negotiations, Customer shall be entitled to elect to approve a deviation from the Best Practices and SHL's lifecycle management program, provided such deviation meets all regulatory obligations of SHL and Customer in connection with the Device and Product. Under such circumstance, (i) Customer shall document such election via a variance letter in writing, (ii) the variance letter Customer provided under (i) above shall provide that Customer shall be

responsible for all risk, liability, and cost resulting from any such deviation from SHL's recommended lifecycle management program (including the Best Practices), and shall fully indemnify SHL against any third party damages resulting from such deviation (such indemnification to include this ninety (90)-day decision making period); and, (iii) except as otherwise expressly set forth in the variance letter Customer provided under (i) above, SHL's obligations under this Agreement and each SOW, including its obligation to manufacture the Device and Product, shall remain in full force and effect notwithstanding such deviation.

In the event Customer does not agree to the changes of the Best Practices requirements or the Parties cannot reach an agreement on any related changes in project scope, timelines or additional fees and expenses necessary to bring the Device or Product and related manufacturing processes into compliance with the updated Best Practices and Customer does not provide SHL with said variance letter or in the event, all manufacturing activities will be suspended, pending successful completion of said negotiations, with an understanding that time is of the essence. SHL shall be entitled to any Fees for the Services rendered and materials prepared up to the date of said suspension under this Agreement and the applicable SOW.

3. SUPPLY OF CUSTOMER MATERIALS

3.1 Customer agrees to provide SHL and its Affiliates with quantities of Customer Materials and related quality documentation, as necessary or useful for SHL and its Affiliates and in sufficient quantities necessary to conduct the Services, as needed by SHL and its Affiliates for: (i) the release tests of the Devices, (ii) the assembly of the Products, and (iii) the testing and release of the Products. Unless otherwise agreed to in writing by the Parties, deliveries of Customer Materials to be used in the Devices shall be made at least [***] prior to the delivery date of such Devices and deliveries of Customer Materials to be used in the Products shall be made at least [***] prior to the delivery date of such Products. Customer shall deliver such Customer Materials to SHL [***] Facility (Incoterms 2020), either to the Facility located at Deerfield Beach, Florida, or at the Facility located at Taoyuan, Taiwan, as indicated in writing by SHL. Customer Materials will be stored free of charge for up to [***] after delivery to SHL and thereafter shall be subject to the storage fee set forth in the applicable SOW; provided, however, that the storage fee shall be waived with respect to any Customer Materials

which must be stored for more than [***] due to SHL's delay for the duration of the delay. SHL and its Affiliates shall use Customer Materials solely for the performance of this Agreement within the Facility and may not use the Customer Materials for any other purpose. By way of example, SHL and its Affiliates shall not produce any modified or unmodified derivatives of the Customer Materials and shall not attempt to analyze the Customer Materials for its chemical composition or microbiological aspect. Customer acknowledges that sufficient and timely supply of Customer Materials is crucial for completion of the Services in a timely fashion.

3.2 If applicable, the Parties will cooperate with and assist each other as may be reasonably necessary to permit the import of Customer Materials into the jurisdiction where the Services will be performed.

3.3 SHL shall not distribute or release any Customer Materials to any third party unless allowed by the Quality Agreement or otherwise instructed by Customer in writing. In addition, Customer Materials shall be used solely by SHL's or SHL's Affiliates' employees and agents who are working directly on the performance of this Agreement and the applicable SOW. SHL or its Affiliates may not file for patent protection or other similar governmental rights on any invention encompassing, utilizing, or disclosing any Customer Materials.

3.4 All right, title, and interest in and to the Drug Product, Primary Packaging, and Customer Materials, and all Intellectual Property embodied therein, shall remain in Customer notwithstanding the transfer to and use by SHL or its Affiliates hereunder of the Customer Materials. Except for the right to use Customer Materials as expressly described herein, there are no grants of any right, license, or privilege to any Intellectual Property of Customer nor any rights thereunder to SHL or its Affiliates. SHL recognizes that Customer provides Customer Materials "as is". CUSTOMER MAKES NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO CUSTOMER MATERIAL AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE.

3.5 Within [***] after receiving any Customer Materials, SHL or its Affiliates will inspect such Customer Materials and will promptly notify Customer to the extent such Customer Materials do not conform to the applicable specifications;

provided, however, that within [***] of receipt, SHL shall notify Customer of any apparent transportation damage.

3.6 Any loss of or damage to the Customer Materials, caused as a result of SHL's or its Affiliates' negligence or intentional misconduct from the time the Customer Materials arrive at the applicable Facility shall be borne by SHL or in the case of Devices constituting Customer Materials, caused as a result of SHL's or its Affiliates' manufacturing quality, transportation, negligence or intentional misconduct shall be borne by SHL. SHL's risks of loss and damage over the Customer Materials (other than non-conforming Devices) shall cease upon the delivery of the Products to Customer. For purposes of clarity, SHL's risks of loss and damage with respect to (i) the Customer Materials (other than non-conforming Devices) shall be limited to the replacement cost of the lost or damaged Customer Materials and shall be subject to the terms of Section 15.5 and Article 11 and (ii) non-conforming Devices shall be as set forth in Section 7.4.

3.7 Customer shall ensure that clear handling, use, and storage instructions are provided to SHL for all Customer Materials in accordance with this Agreement, the applicable SOW and the Quality Agreement (in particular the Primary Packaging and the Drug Product), and including any precautions or other special measures that SHL should be made aware of.

3.8 SHL or its Affiliates shall handle, use, and store the Customer Materials in accordance with the applicable SOW, the Quality Agreement, and all applicable laws, regulations, and GMP.

3.9 At the request of Customer, SHL shall return or destroy any Customer Materials in its possession, with written certification of such destruction provided upon Customer's request, upon completion of the Services or the termination or expiration of this Agreement, subject to the terms of Section 3.10. Except as set forth in Section 7.4, any costs associated with such request shall be borne by the Customer. For the avoidance of doubt, in the case of Devices constituting Customer Materials, SHL shall not destroy any Devices unless instructed in writing by Customer.

3.10 Customer acknowledges that, in accordance with applicable laws, SHL may not be able to return to Customer certain Customer Materials upon completion of the Services, expiry or termination of this Agreement. Should SHL be unable to

return the Customer Materials upon completion of the Services, expiry or termination of this Agreement, SHL shall notify Customer in advance, destroy the materials at Customer's cost and expense, and provide Customer with a certificate of destruction. Customer may not seek any compensation or refund upon the occurrence of such discarding or destruction.

4. PROJECT GOVERNANCE

4.1 Joint Steering Committee: As soon as reasonably practicable after the Effective Date, the Parties shall establish an executive lead team to be known as the joint steering committee (the "JSC") to oversee, review, and coordinate the Services and Deliverables. All other committees or Working Groups established under this Agreement shall be subordinate to the JSC. The JSC will be comprised of representatives designated by SHL (including representatives from SHL's Affiliate SHL Taiwan, as desired) and Customer, appointed at the sole discretion of the respective Parties. Substitute representatives may be appointed at any time upon written notice to the other Party. The JSC will be chaired by joint chairpersons appointed by the Parties. The initial composition of the JSC is provided in the applicable Statement of Work.

4.2 Responsibilities: The JSC shall be responsible for: (i) overseeing, managing, and providing strategic direction to the collaboration; (ii) reviewing and monitoring the activities and progress of Working Groups established under this Agreement; (iii) overseeing the integration and coordination of the Services and Deliverables, and associated legal matters; (iv) reviewing and monitoring the strategies and plans for the Services and Deliverables, and overseeing and managing the implementation of such plans; (v) overseeing and managing changes to the budgets, Long Term Forecast, Rolling Forecast, Capacity Commitment, capital expenditures, Fees, and Prices; (vii) ensuring quality, regulatory and compliance matters, including Device design and Product assembly change controls, are addressed as defined in the Quality Agreement; (viii) resolving disputes, disagreements, and deadlocks that are not resolved; (ix) determining whether the Services and the Deliverables should proceed in the event of a Material Adverse Event; and (x) undertaking or approving such other matters as are specifically provided for the JSC under this Agreement.

4.3 Meetings of JSC: The JSC will meet [***] or as often as the Parties agree is reasonably necessary to accomplish its purpose, on a mutually agreeable date

and at a mutually agreeable place. Additional representatives of SHL or Customer, or both, in addition to members of the JSC, may attend such meetings at the invitation of either Party.

4.4 Decision Making of JSC: A minimum number of [***] JSC members, representing both Parties in an equal manner, are required for decision making purposes, unless otherwise agreed to by the Parties. Decisions of the JSC shall be made by the members present in person or by other means (e.g., teleconference) at any meeting, with each Party having [***] vote (regardless of the number of attendees of that Party) and at least [***]) representative from each Party participating in such vote. In the event that the JSC is unable to reach consensus with respect to a particular matter, each JSC co-chairperson will appoint a representative to resolve the conflict within [***], and the proposed resolution will be presented to the JSC. In the event a dispute cannot be resolved by the JSC, then the matter will be resolved in accordance with Article 22. The minutes will be circulated and agreed upon by the Parties.

4.5 Working Groups: The JSC may designate working groups to address specific projects, planning or issues arising under this Agreement ("Working Groups") regarding Services or Deliverables as required. Working Groups may be focused on specific areas, including: (i) quality, compliance and regulatory affairs, (ii) Device and Product design, tooling, equipment and assembly processes, (iii) operations and facilities, (iv) procurement, forecasting and capacity planning, (v) product development, (vi) project management and support, or (vii) any additional area deemed necessary by the JSC. Working Groups will meet as agreed by the Parties and will be responsible and report to the JSC.

5. FORECASTS / ORDERS / INVENTORY

5.1 Forecasts

5.1.1 Before the end of January of each calendar year, Customer shall provide SHL with a written, non-binding, long range forecast for the next [***] of Customer's anticipated requirements ("Long Term Forecast") for the Devices and Products respectively, as further described in this Agreement.

5.1.2 Customer shall provide SHL, at the beginning of each month with an [***] rolling forecast of its requirements respectively for the Device and Product (the "Rolling Forecast"):

a) The [***] of the most recent Rolling Forecast shall constitute a firm and binding order period, subject to the terms of Section 5.1.4 and 5.1.5.

b) Months [***] of the most recent Rolling Forecast shall be non-binding.

The Rolling Forecast shall be aligned with Customer's production plan for Primary Packaging and quantities shall be in multiples of Primary Packaging batch quantities as listed in the applicable SOW, and subject to Capacity Commitments and forecast variances as described in Sections 5.1.5, 5.1.6, and the applicable SOW.

5.1.3 Each Rolling Forecast shall be accompanied by a set of new Purchase Orders, one for Devices and one for Products.

5.1.4 To the extent Customer fails to provide a Long Term Forecast or Rolling Forecast as required hereunder, the last applicable Long Term Forecast or Rolling Forecast previously provided by Customer shall be deemed to be the latest and current Long Term Forecast or Rolling Forecast provided by Customer. SHL has the right to adjust the level of capacity based on changes to the Long Term Forecast and Rolling Forecast.

5.1.5 Customer shall align production plans for the Device and Primary Packaging, the Rolling Forecast, and open Purchase Orders. Customer shall provide SHL with commercially reasonable advance notice of any significant Primary Packaging batch yield variance or delay that could impact the Rolling Forecast or open Purchase Orders, and in no event longer than [***]after such variance or delay is known to Customer. The [***] of any Rolling Forecast represent commitments to purchase the amounts provided in the Rolling Forecast for those [***]. Customer shall not incur a penalty for any batch yield variance less than [***] below the Primary Packaging batch multiples agreed to in the applicable SOW. For any batch yield variance greater than [***] agreed to in the applicable SOW, Customer shall incur a [***] delivered under that Purchase Order. This shall be in addition to any other penalties or costs applied pursuant to this Agreement.

5.1.6 At the beginning of each year, the JSC shall review SHL's monthly and annual maximum capacity available for the Device and Product ("Capacity Commitment"), as specified in the applicable SOW. Any conflict between the Long Term Forecast and the Capacity Commitment shall be reviewed

and resolved by the JSC as required.

5.2 Purchase Orders

5.2.1 Customer shall submit one or more Purchase Orders to satisfy the binding portion of the Rolling Forecast (each a "Purchase Order") as described in Section 5.1.2 above. The Purchase Orders shall reflect the total number of Devices and Products, respectively, required by Customer for all purposes, based on whole batch quantities, except as otherwise provided herein. SHL will use Commercially Reasonable Efforts to confirm Purchase Orders within [***] including confirmation of the quantity, Fees, Price, and other relevant information, and to deliver the Devices and Products within the timeframe specified on the confirmation of receipt of the Purchase Orders. In any event, Customer must provide Purchase Orders to SHL at least [***] before the desired delivery date for the Device and Product (as the case may be). For avoidance of doubt, Customer shall be allowed to occasionally sub-divide batches of Primary Packaging into smaller batches of Product to minimize obsolescence or supply Product to business partners, in accordance with the applicable SOW.

5.2.2 Absent of Customer's receipt of written notice to the contrary from SHL within [***] after issuance of the Purchase Order, each Purchase Order shall be deemed accepted by SHL.

5.2.3 In the event SHL rejects a Purchase Order, SHL and Customer shall promptly discuss such rejection in good faith with a view to agreeing upon an amended Purchase Order reasonably acceptable to Customer and SHL.

5.2.4 Customer shall be responsible for aligning production plans for the Device, Primary Packaging, the Rolling Forecast, and open Purchase Orders. Customer shall deliver the Customer Materials to SHL at least [***] prior to the applicable Purchase Order delivery date for which such Customer Materials are to be used. If Customer delivers Primary Packaging less than [***] prior to the applicable Purchase Order delivery date, Customer shall not be penalized except as noted herein. If Customer delivers a batch of Primary Packaging less than [***] before the applicable Purchase Order delivery date, Customer shall be responsible for a rescheduling charge of [***] applied to the then current Price or Fees for quantities delivered under such applicable Purchase Order, which shall be in addition to any other

penalties or costs applied pursuant to this Agreement. For deliveries of Primary Packaging made less than [***] before the then current Purchase Order delivery date, SHL shall use Commercially Reasonable Efforts to reschedule Purchase Order delivery within [***] of Customer's actual delivery of the Primary Packaging. For the avoidance of doubt, SHL shall have no late delivery liability for shipping delays if Customer delivers Primary Packaging less than [***] prior to a Purchase Order delivery date and any such delays shall not constitute a breach of this Agreement by SHL. For the avoidance of doubt, the foregoing does not apply to delayed delivery of Customer Materials if such delay is due to SHL's delays in delivery of Devices.

5.3 Within [***] after the end of each month, SHL shall provide Customer with an inventory report showing quantities and batch numbers for Devices, Customer Materials, SHL Materials, and Product at the Facility in Deerfield Beach, Florida, in a format Parties have agreed upon.

5.4 Customer shall modify open Purchase Orders in accordance with adjustments to the Rolling Forecast as described in Section 5.1.5 subject to provisions therein.

6. DELIVERY

6.1 Title and risk of loss shall pass to Customer at time of delivery of Device or Products per the delivery term set forth in the applicable SOW. For the avoidance of doubt, SHL shall hold title and risk of loss for the Device until the Device has been delivered to SHL at its Facility located in Deerfield Beach, Florida as further described in the applicable SOW. SHL shall be responsible for selecting the carrier to transport Devices from SHL Taiwan's Facility in Taoyuan, Taiwan to SHL's Facility in Deerfield Beach, Florida which such carrier shall be a qualified supplier of SHL. Customer shall be responsible for selecting the carrier to transport the Products from the Facility to Customer's facilities or contractors. SHL shall cooperate in a Commercially Reasonable manner with Customer and its selected carrier to arrange pick up for shipments as necessary to accommodate Customer's Purchase Orders and business needs. SHL will notify Customer at least [***] prior to the date when SHL intends to deliver the Devices and Products. SHL shall not release Products to the Customer arranged carrier without written confirmation from Customer that the Product has been accepted for release and SHL is authorized to ship the Products, and such

written confirmation from Customer shall not be unreasonably withheld.

6.2 SHL shall deliver the Device and Product to Customer as specified in the applicable SOW and Quality Agreement, including certificates of compliance for each batch of Device and Product and, in the case of each batch of Devices, the incoming release documentation. In the event that SHL fails to meet the delivery date specified in the confirmed Purchase Order (including Purchase Orders accepted pursuant to Section 5.2.2) or has reason to believe that it will fail to meet such delivery date, SHL shall provide Customer with prompt written notice of such failure, identifying in such notice the earliest available date to make up for such failure.

6.3 SHL is responsible for maintaining and operating the Facilities and all equipment used to manufacture the Devices and assemble the Products in an acceptable state of repair in accordance with applicable law and GMP. SHL is responsible for validating all such Facilities and equipment using SHL's standard procedures. For the avoidance of doubt, SHL shall ensure SHL's Affiliate, SHL Taiwan, complies with the provisions herein through SHL's supplier qualification and management program.

6.4 In order for SHL to produce the Devices and Products and perform the Services, Customer acknowledges that certain Device- or Product-specific capital expenditures may be necessary in respect to equipment or the Facilities. Any such specific capital expenditures must be agreed to by the Parties and JSC, and by amending the applicable SOW or entering into a separate dedicated equipment purchase agreement, which shall address the ownership of such Device-specific or Product-specific equipment, cost sharing obligations, and any other restrictions and obligations related thereto. Capital expenditures that are not Device-specific or Product-specific, including but not limited to maintaining regulatory compliance or expanding capacity, shall be borne by SHL.

6.5 All Devices and Products shall be labeled and packed in accordance with the applicable SOW.

6.6 Except as provided under Article 23 and Section 5.2.3, if at any time during the Term, SHL is or expects that it will be unable, in full or in part, to fulfill Customer's Device and Product Purchase Orders for any reason, SHL shall immediately notify Customer, detailing the extent to which it will not meet such requirements and provide Customer with the expected date of arrival of the

Devices or Products. If Customer, in good faith, cannot accept the new date specified for delivery by SHL, or if the shipment fails to dispatch from the Facility within [***] after the delivery date specified on the original or revised Purchase Order, Customer shall be entitled to [***] reduction in Fee for assembly of the Product or the Price for the Device, as applicable, delivered under that order. For the absence of doubt, SHL is not responsible for delivery delays and/or failure to ship correct quantities of Devices or Product where such delays and failures are due to delays or short-falls in delivery of Customer Materials pursuant to Section 3 (it being understood that for purposes of this sentence, "Customer Materials" shall not include Devices).

6.7 Upon Customer's written request, SHL will store the (1) Products at the Facility at no additional charge for a period of up to [***] after providing manufacturing or product batch records and testing and release documentation for the Products to Customer or (2) Devices at the Facility located in Deerfield Beach, Florida at no additional charge for a period of up to [***] after delivery of such Devices as described in the applicable SOW, in each case unless otherwise agreed to by the Parties. In the event that any of the foregoing documentation require Customer's approval, such approval may not be unreasonably withheld. SHL may charge Customer a storage Fee as set forth in the applicable SOW for storage beyond that specified above or in the applicable SOW. SHL shall use Commercially Reasonable Efforts to protect the stored Devices or Products from damage, deterioration, loss, or theft. SHL will store all Devices and Products under the appropriate temperature and storage conditions as provided in the Quality Agreement and applicable SOW. SHL shall not grant, nor permit any creditor or other third party to acquire any security interest, lien, or other interest in or encumbrance on the Products. SHL shall reimburse Customer for any loss of or damage to the stored Devices or Products caused by SHL's intentional misconduct or gross negligence.

6.8 In the event that SHL is unable to deliver the Devices or Product due to a non-conformance issue associated with the Primary Packaging or for any cause that cannot be directly imputed to SHL's performance of this Agreement or the applicable SOW (such as delay or failure to deliver Customer Material pursuant to Section 3), SHL will store inventory of the Devices, Primary Packaging, or the Products at the Facilities for such period of time required to resolve the non-conformance issue associated with the Primary Packaging or the cause

preventing the delivery of the Devices or Products. In the event that SHL is required to store excess inventory of the Devices, Primary Packaging, or Products for Customer in accordance with this section, SHL shall: (i) charge Customer a storage fee as set forth in the applicable SOW or for Primary Packaging, in the amount to be specified by SHL at a later date; (ii) retain title to the Devices and Products only; and (iii) store the Devices, Primary Packaging, and Products under the appropriate temperature and storage conditions set forth in the Quality Agreement and the applicable SOW. For the avoidance of doubt, any delivery issue related to Devices or Products as a result of a Device non-conformance (i) shall be the responsibility of SHL to resolve, and (ii) Customer shall not be charged for any related Device or Product storage Fees until resolved by SHL.

6.9 In the event that inventories related to the Devices or Products need to be disposed of due to delays described in Section 6.7, or changes in the design of Device or Product, Customer shall be responsible for the costs related to replacing and/or disposing of such inventories, except for limitations to SHL inventory as otherwise stated herein. In such an event, Customer shall not be liable for more than [***] of SHL printed components inventory as applicable to the then current Rolling Forecast.

6.10 SHL shall in no event be responsible for temperature management or physical control of Product after SHL delivers the Product to Customer's carrier under Section 6.1 of this Agreement. SHL shall be responsible for temperature management and physical control of Devices and Product until SHL delivers the Product to Customer's carrier under Section 6.1 of this Agreement.

7. CONFORMANCE

7.1 Unless as otherwise stated in the Quality Agreement, prior to delivering Devices or Product, SHL shall:

7.1.1 confirm Devices conform to specifications and perform local Quality reviews and batch release at their Facilities according to applicable laws and GMP; and

7.1.2 confirm Products conforms to the specifications and perform a local Quality review and batch release according to applicable laws and GMP; and

7.1.3 provide Customer with a certificate of compliance, deviation and

investigation reports, and any other Product batch documentation required for Customer review, acceptance, and release; and

7.1.4 retain and store Devices and Products at the Facility under proper conditions until Customer has reviewed, accepted and provided written release for a Product batch; and

7.1.5 SHL will retain samples for each batch of Devices and Products.

7.2 SHL represents and warrants to Customer that, at the time of delivery, with the exception of the Primary Packaging, the Devices and Products will conform to and will have been processed in conformance with applicable specifications, change controls, Quality Agreement, and laws, including GMP and be free from all liens, encumbrances and defects in the title other than those that arise directly as a result of actions taken by Customer.

7.3 The remaining shelf life of a Device batch, once assembled into Product, shall be a minimum of [***] from the date of Product assembly. The shelf life of a Product batch shall be the shelf life assigned to the Primary Packaging batch used in the Product, as determined by Customer or Customer's contractor, unless otherwise limited by the remaining shelf life of the Device at the time of Product assembly, in accordance with the Quality Agreement. For the avoidance of doubt, the shelf life of the assembled Product shall not exceed the [***] assembled shelf-life of the Device, unless the Parties agree the assembled Device shelf life can be extended beyond [***] in accordance with the Quality Agreement.

7.4 In the event that any Devices or Products delivered fail to conform to the applicable specifications or any of the warranties provided in this Agreement, Customer may reject the same by giving notice thereof to SHL, for any defects other than Latent Defects, within [***] after delivery, and for Latent Defects, within the shelf life of the Devices or Products, which notice shall specify the manner in which the Devices or Products fail to conform to any applicable specifications. All rejected Devices or Products will be returned to SHL or destroyed at SHL's option and expense, if such rejection is related to the Device manufacture or Product assembly. In the event Customer's rejection is justified, the Devices or Products rejected in accordance with this section will be replaced as soon as practically possible by SHL with Devices or Products that meet the specifications and quality requirements set forth in this Agreement at no cost to Customer, to the exception of any Primary Packaging-related expenses;

provided, however, that in the case of non-conforming Devices, Customer may in its sole discretion further elect to (i) withhold payment for such Devices until delivery of replacement Devices that meet the specifications and quality requirement herein, or (ii) request, and SHL shall promptly provide, a full refund of all amounts paid with respect to such non-conforming Devices, including without limitation, the Price of such Devices and any associated Fees, freight charges, or other expenses but excluding the 4-cavity surcharge described in the applicable SOW, in lieu of receiving replacement Devices. Other than with respect to SHL's indemnification obligations pursuant to Section 15.2, the foregoing remedy is Customer's exclusive remedy with respect to SHL's failure to deliver Devices or Products that meet the specifications and quality requirements set forth in this Agreement.

7.5 If the Parties disagree as to whether a Device or Product conforms to the applicable specifications or the warranties provided in this Agreement, the Parties shall cooperate to have the Device or Product in dispute analyzed by an independent testing laboratory commonly selected or agreed to by the Parties, as defined in the Quality Agreement. The results of such testing shall be final and binding on the Parties on the issue of conformance. If the Device or Product is determined to conform to the specifications and the warranties, Customer shall bear the cost of the testing and pay for the Device or Product. If the Device or Product is determined not to conform to the specifications and the warranties, SHL shall bear the cost of the testing and provide the remedies described in Section 7.4.

7.6 In the event that Customer initiates a Product recall that can be attributed to a Latent Defect associated with the Device or Product and that is directly attributed to SHL's performance of this Agreement or the applicable SOW, such recalled Product shall be replaced as soon as practically possible by SHL with Device or Product that meets the specifications and quality requirements set forth in this Agreement and the Quality Agreement at [***]. For the avoidance of doubt, this Section 7.6 shall not serve to limit any remedies available to Customer pursuant to Section 15 hereunder.

8. INSPECTIONS AND AUDITS

8.1 In accordance with the Quality Agreement, SHL shall advise Customer within [***] from the receipt of the official request if an authorized agent of any

regulatory authority visits a Facility for an inspection concerning the Device or Product, or if a regulatory authority issues a request concerning the Device or Product. Upon written request, SHL shall allow Customer to review, at the Facility, a copy of the report with respect to any such visit by such regulatory authority, if any, within [***] of SHL's receipt of such report, provided that such review shall be subject to the provisions of Article 10 of this Agreement and that Customer shall not be allowed to make any copy of the documents reviewed. Prior to SHL submitting a response to any Device-specific or Product-specific regulatory authority regarding an inspection or request, Customer has the right to review any such response prior to submission to a regulatory authority. Customer's right to review reports, data or documents under this section shall be subject to (i) SHL's confidentiality obligations toward third parties, and (ii) SHL's right to refuse to disclose proprietary data or information, to be exercised at SHL's discretion, based on the nature of such data or information. The costs and expense of any regulatory audits that are specific to the Device or Product shall be borne by Customer.

8.2 In accordance with the Quality Agreement, Customer shall have the right, either by itself or through SHL approved independent outside auditors or consultants, which approval shall not be unreasonably withheld, not more than [***] during the Term to inspect and audit areas at each Facility where Services are performed by SHL; provided however, in situations where reasonable cause is shown, Customer shall have the right to audit more frequently for such situations. Such an audit may include the examination of production or quality records or performance of a general GMP audit, but excludes the right to make any copy of the documents reviewed or to take any photograph of the Facility visited. All such audits and any activity related to such shall be at Customer's sole expense and shall (i) require at a minimum [***] advance written notice, (ii) occur during normal business hours as coordinated with SHL, and (iii) be scheduled in a manner that does not interfere unreasonably with operations. A condition of any such audit is that any such auditor or consultant shall enter into an agreement with the Parties on terms pursuant to which such independent auditor or consultant shall agree to maintain the confidentiality of the information obtained during the course of such audit. Customer related costs and expenses of any such audits that are specific to the Device or Product shall be borne by Customer.

8.3 Nothing in this article or in this Agreement grants Customer a right to audit or

inspect SHL's financial and/or accounting records relating to this Agreement or SHL's business overall.

8.4 SHL will cooperate with the Authorities, in accordance with applicable laws and regulations, if such Authorities request to carry out unannounced inspections related to the Device or the Product at the Facilities; and in accordance with the Quality Agreement, SHL shall notify Customer as soon as reasonably possible and no later than [***] after any unannounced inspections by FDA or other Authority.

9. FEES AND PRICES

9.1 Fees and Prices stated in the applicable Statement of Work shall be valid within the initial period set forth therein. After such initial period, the Fees and Prices shall be automatically adjusted in accordance with the [***], during the preceding [***] (the "PPI"). SHL shall, once a year starting in [***] and no later than [***], provide Customer with the updated Fees and Prices for the period between [***]reflecting the foregoing PPI adjustment. Customer shall have until [***] to challenge the calculation of the updated Fees and Prices. SHL shall then provide Customer with the confirmed updated Fees and Prices on [***]. The updated yearly Fees and Prices shall apply to Devices or Products ordered between [***]. Notwithstanding the foregoing, if an unexpected economic event causes SHL's documented manufacturing or assembly costs for the Devices or Products to increase by more than [***] within [***], Parties agree to meet in good faith to negotiate a revised Fee or Price, as applicable, deemed equitable by both Parties. In the event Parties cannot agree on a revised Fee or Price by [***], Parties shall have remedies as further described under Articles 14 and 22. Prior to the Parties agreeing on the updated Fee or Price, the then current Fee or Price shall continue to apply until the Parties reach an agreement.

9.2 SHL shall submit invoices to Customer for Devices or Product at the time specified in the applicable Statement of Work. SHL shall separately invoice Customer for any storage or other Fees as described in the applicable SOW. Invoices shall be due and payable within [***] after Customer's receipt thereof. Invoices shall be sent to Customer at: payables@xerispharma.com.

9.3 All invoices must reference a valid Customer Purchase Order number. All payments to SHL shall be made by wire transfer.

9.4 All payments shall be exclusive of applicable taxes, including but not limited to sales tax, value added tax or withholding taxes. Any such applicable tax, including withholding taxes required under applicable law to be paid or withheld, shall be an expense of, and borne solely by, Customer. In the event any withholding tax is levied on the Services in any jurisdiction, Customer shall increase the sum effectively paid to SHL so that the amount received by SHL after withholding tax is deducted is the full amount SHL would have received if no withholding or deduction had been made. SHL shall assist Customer in any effort by Customer in claiming any exemption and/or credit from such taxes under any double taxation or similar agreement or treaty from time to time in force, and in minimizing the amount required to be so withheld. In order to assist Customer in minimizing its withholding tax liability, upon reasonable request, SHL shall cooperate with Customer in providing necessary and reasonable documentation.

9.5 Notwithstanding the foregoing, Customer may contest any invoice or portion thereof if it reasonably believes that the charges reflected therein are inappropriate or questionable (paying all charges that are appropriate). For any invoice or portion of an invoice that Customer contests, Customer shall provide, within [***] of receipt of the invoice, written notification to SHL of such and SHL shall thereafter have [***] to respond to Customer. The Parties shall work together in good faith to resolve any such dispute within [***] of SHL providing its written response. Should the Parties be unable to resolve the matter within that time period, the Parties shall submit the matter to a mutually agreed third party for a binding determination regarding the disputed amount. The Parties agree that the third party shall have [***] to review, investigate, and make a determination. The costs arising during such dispute, including third party's fees, administrative costs, attorney's fees, and any other foreseeable and reasonable fees and expenses shall be paid within [***] after announcement of the determination by the Party determined by the third party not be the prevailing party. Once the matter is resolved, Customer shall pay any outstanding charges within [***] thereafter.

9.6 In the event of early termination of this Agreement or any of the SOWs, SHL shall invoice Customer, its complete full and final settlement for such terminated work, a sum equal to its actual direct costs for the terminated work satisfactorily performed as of the effective date of termination, plus an allowance for

reasonable overhead and profit on such direct cost. SHL shall, upon request provide a financial accounting of all costs incurred and other supporting documentation for completion of payments by Customer to SHL prior to Customer incurring any obligation to pay such settlement amount. The time frames stated in Section 9.2 apply to any such settlements. For the avoidance of doubt, Customer shall be obligated to purchase all Safety Stock upon termination.

9.7 SHL may charge Customer an annual interest rate at [***] above ninety [***] for undisputed invoices not paid after the due date.

9.8 If any undisputed invoice is not paid by Customer in accordance with the provisions of Article 9, SHL may, at its discretion: (i) suspend the performance of the Services until the invoice is settled, provided that in such case, SHL will not be held responsible for any delay caused by such suspension; and (ii) exercise its right of lien or retention on any Deliverable that is still in SHL's possession for which title has not already transferred to Customer, including Deliverables ordered by Customer and manufactured by SHL pursuant to any Purchase Order issued in accordance with Section 5.2, whether the unpaid invoice relates to such Deliverables or such Purchase Order or is unrelated to them. SHL's remedies under this section shall cease to be effective upon receipt by SHL of Customer's payment in full of all amounts that remain due under this Agreement.

10. CONFIDENTIAL INFORMATION

10.1 During the Term, each Party (the "Disclosing Party") may disclose to the other Party (the "Receiving Party") Confidential Information. Confidential Information does not include information that: (a) at the time of disclosure is published, known publicly, or is otherwise in the public domain, (b) is, at the time of disclosure or later, becomes publicly known under circumstances involving no breach of this Agreement, (c) is, as evidenced by the Receiving Party's written records, lawfully and in good faith made available to the Receiving Party by a third party that did not (directly or indirectly) derive it from, or develop it for, the Disclosing Party, or (d) is, as evidenced by the Receiving Party's written records, independently developed by the Receiving Party without the aid, use, or application of any of the Disclosing Party Confidential Information.

10.2 The Receiving Party (i) shall not disclose the Disclosing Party's Confidential Information to any third party without first obtaining the express written permission of the Disclosing Party; (ii) shall use the Disclosing Party's Confidential Information only as is necessary to fulfill its obligations pursuant to this Agreement, (iii) shall not reverse engineer or decompile any item containing Confidential Information, and (iv) except as expressly stated above, shall limit such disclosure to its officers, employees, consultants, auditors, lenders, advisors, and approved subcontractors (such persons or entities to receive Confidential Information, collectively, the "Receiving Party's Representatives") that are bound by confidentiality and non-use provisions at least as restrictive as those found herein on a need-to-know basis for purposes of fulfilling its obligations hereunder. The Receiving Party shall bear full liability towards the Disclosing Party for any conduct of the Receiving Party's Representatives that would breach the terms of this Article 10. In addition, the Parties shall not disclose the existence of this Agreement or its terms to any third party without prior written consent of the other Party, which shall not be unreasonably withheld. The obligations of confidentiality and non-use set forth herein shall remain in effect for a period of [***] after the termination or expiration of this Agreement. Notwithstanding the foregoing, with respect to any trade secret information within the Confidential Information, the confidentiality obligations hereunder shall continue for so long as such information remains a trade secret.

10.3 Prior to the approved disclosure of the Disclosing Party's Confidential Information to a third party, the Receiving Party shall obtain from any such third party a legally enforceable written agreement (other than with respect to a Party's attorneys who are bound by professional duties of confidentiality not to disclose such information) not to disclose the Disclosing Party's Confidential Information, or knowledge or Know-How derived therefrom, to any third party or use such Confidential Information for any purposes other than those contemplated by this Agreement. Both Parties shall take Commercially Reasonable Efforts to protect the other Party's Confidential Information from disclosure or misappropriation (but in no event shall such Party use less than a reasonable degree of care) and shall be responsible for entering into written confidentiality agreements with any third parties that are no less restrictive than the provisions of this Agreement and for enforcing such agreements. Upon request, each Party shall provide to the other evidence of any confidentiality

agreement it required to be executed by a third party.

10.4 The existence of this Agreement, each of its terms and conditions, and all information required to be provided from one Party to another under the terms and conditions of this Agreement shall be deemed Confidential Information that is subject to the non-disclosure provisions of Article 10.

10.5 THE PARTIES ACKNOWLEDGE THAT EACH OF THEIR CONFIDENTIAL INFORMATION IS PROVIDED TO THE OTHER ON AN "AS IS" BASIS. NEITHER PARTY MAKES WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE OTHER'S CONFIDENTIAL INFORMATION AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

10.6 The confidentiality obligations of the Receiving Party under this Article 10 shall not apply solely to the extent that any information is required to be publicly disclosed pursuant to a governmental, securities or judicial requirement, or other requirement of law, but only after notifying the Disclosing Party of such requirement, if legally permitted, and, if requested by the Disclosing Party, using reasonable efforts to minimize such disclosure and to obtain confidential treatment for all or relevant portions of the Confidential Information to be disclosed.

10.7 Subject to any license rights granted hereunder, upon request of a Party, and in any case upon expiration or termination of this Agreement, each Party shall promptly delete and or destroy any electronic or magnetic copies and return to the other Parties all tangible copies of the other Party's Confidential Information. Each Party shall confirm in writing to the other Party that Confidential Information has been deleted or destroyed.

10.8 The Parties hereto acknowledge and agree that a breach of this Article 10 could give rise to irreparable harm for which money damages would not be an adequate remedy and accordingly the Parties agree that, in addition to any other remedies, each Party shall be entitled to obtain preliminary or injunctive relief and to enforce the terms of this Article 10 by a decree of specific performance.

11. INSURANCE

Each Party shall maintain during the Term of the Agreement, at its own cost, general

commercial insurance as well as any other insurance, excluding contractual liability insurance, which may be required by local regulations or by the scope and nature of Services being provided. SHL shall secure property insurance for the Facility in Deerfield Beach, Florida with coverage for individual damage up to [***].

12. INTELLECTUAL PROPERTY RIGHTS

12.1 Background Intellectual Property: It is recognized and understood that the existing Background Intellectual Property of either Party is their separate property, respectively, and ownership of such existing Background Intellectual Property is not affected by this Agreement, and neither Party shall have any claims to, or rights in, such Background Intellectual Property of the other Party. It is expressly agreed that neither Party transfers by operation of this Agreement to the other Party any interest in Background Intellectual Property other than expressly granted herein.

12.2 Foreground Intellectual Property: The Parties acknowledge and agree that, in connection with the Device, no Intellectual Property has been jointly created or shall be jointly owned by the Parties. As between the Parties, SHL shall own all Foreground Intellectual Property embodied in or related solely to the Device, including Intellectual Property embodied in Device molds and tooling fabricated for Customer in support of the Device. SHL shall also own without limitation the right to sue and collect damages for past, present, and future infringement or misappropriation of all Intellectual Property rights solely embodied in or related to the Device. Customer shall promptly disclose to SHL on a confidential basis any invention or discovery concerning any aspects of the Device conceived, or conceived and reduced to practice, in the performance of the Services under this Agreement. Customer shall require its employees and/or, its agents performing under this Agreement to promptly report and assign such Intellectual Property to SHL. Upon receipt of a written request delivered by SHL, within [***] of the disclosure of such invention as stated under this section, Customer shall execute, without charge to SHL, an irrevocable assignment of all such rights, title and interest in and to such invention to SHL. Customer further agrees to use its Commercially Reasonable Efforts to assist SHL, at SHL's request, cost, and expense, to file patent, prosecute, and maintain applications and patents on such invention. Nothing in this Agreement gives Customer or its Affiliates the right to file for patent protection or other similar governmental rights (including but not limited to Reference Listed Drug filings such as the

FDA's Orange and Purple Books) claiming any invention encompassing, utilizing, or disclosing any SHL Materials.

12.3 Customer Materials: Customer shall own all Foreground Intellectual Property embodied in or related to the Customer Materials, including but not limited to any forms or formulations of the Drug Product, methods of using the Drug Product, dosage regimens, treatments employing the Drug Product, or improvements to the Drug Product, and any improvements in or to any of the preceding. Subject to Section 12.2 above, Customer may pursue patent or other legal protection of its Intellectual Property at its discretion. SHL shall promptly disclose to Customer on a confidential basis any invention or discovery directly related to the Customer Materials, including the Drug Product conceived, or conceived and reduced to practice, in the performance of the Services under this Agreement. SHL shall require its employees and/or, its agents performing under this Agreement to promptly report and assign such Intellectual Property to Customer. Upon receipt of a written request delivered by Customer, within [***] of the disclosure of such invention as stated under this section, SHL shall execute, without charge to Customer, an irrevocable assignment to Customer of all such rights, title and interest in and to such invention. SHL further agrees to use its Commercially Reasonable Efforts to assist Customer, at Customer's request, cost and expense, to file patent, prosecute and maintain applications and patents on such invention. Nothing in this Agreement gives SHL or its Affiliates the right to file for patent protection or other similar governmental rights (including, but not limited to, Reference Listed Drug filings such as the FDA's Orange and Purple Books) claiming any invention encompassing, utilizing or disclosing any Customer Materials.

12.4 Industrial Design

12.4.1 Customer does not request the creation of a specific industrial design for the Device. The Parties acknowledge that no specific design has been created as part of the Services. The design of the shell and of the cap components of the Device shall be under the current standard industrial design of the Device platform, which has not been specifically created by SHL for Customer. The industrial design shall be part of SHL's Background Intellectual Property.

12.4.2 Customer requests the use of Components Colors as described in the

applicable Statement of Work. SHL agrees that SHL and its Affiliates will not manufacture, have manufactured, provide, or assist any third party to manufacture any device based on the same technology [***] that has components of the same color combination as the Components Colors, when such device is to be used in connection with the Drug Product, in the Field, and in the Territory.

12.5 Licenses

12.5.1 Subject to the terms and conditions of this Agreement, SHL hereby grants, and causes its Affiliates to grant, to Customer, and Customer hereby accepts, a royalty free, fully paid-up, non-transferable, non-exclusive license covering the distribution, use, sale, offering for sale, promotion, marketing, exportation, and importation of the Device for the sole purpose of Product in the therapeutic Field and this Agreement. This license shall be exclusive of any right to manufacture the Device and Product. This license may not be sub-licensed by Customer to any person or entity except to (i) its Affiliates; (ii) third parties (other than competitors of SHL) but solely for the purpose of providing non-manufacturing services, including but not limited to testing or assembly services, on behalf of Customer or its Affiliates with respect to the Product and solely for the purpose of this Agreement; and (iii) its licensees, customers and distributors of the Drug Product or the Product in the Territory in connection with obtaining and maintaining regulatory approvals, and the distribution, use, selling, offering for sale, promotion, marketing, exportation, and importation of the Device and Product, by such licensees, customers and distributors of the Drug Product or the Product. Any license granted hereunder shall automatically terminate upon the expiration or termination of this Agreement without need of any further writing between the Parties; provided, however, that Customer may continue to exercise such license to the extent necessary for the sale by Customer of any remaining inventory of Product.

12.5.2 Subject to the terms and conditions of this Agreement, Customer hereby grants to SHL, and SHL hereby accepts, a royalty-free, fully paid-up, non-transferable, non-sub-licensable, and non-exclusive license to use the Customer Materials to perform the Services pursuant to this Agreement. This license shall be exclusive of any right to manufacture, develop or create

derivative works of the Drug Product, the Primary Packaging or other Customer Materials. This license may not be sub-licensed by SHL to any person or entity except to (i) its Affiliates or (ii) third parties (other than competitors of Customer) but, in each case, solely for the purpose of providing manufacturing testing or assembling the Device, on behalf of SHL or its Affiliates with respect to the Product and solely in connection with this Agreement. Any license granted hereunder shall automatically terminate upon the expiration or termination of this Agreement without need of any further writing between the Parties.

12.5.3 All licenses or other rights to use, by one Party, the Intellectual Property of the other Party as granted under this Agreement shall be limited to the specific Drug Product, Device, Field and Territory as specified in this Agreement and no such license shall be deemed to grant a Party access to Intellectual Property for any application to or use with a particular drug, device, field and/or indication that has not been previously identified in this Agreement.

12.6 SHL owns and shall retain all right, title, and interest in and to all SHL's Confidential Information and SHL's Intellectual Property. Except otherwise stated within this Agreement, no Intellectual Property, right, license or privilege is granted to Customer under this section.

12.7 Customer owns and shall retain all right, title, and interest in and to all Customer's Confidential Information and Customer's Intellectual Property. Except otherwise stated within this Agreement, no Intellectual Property, right, license or privilege is granted to SHL under this section.

12.8 Patenting: Customer shall control the filing, prosecution, and maintenance of any patent applications claiming any Customer's Intellectual Property, and shall be responsible for paying all costs associated therewith. SHL shall control the filing, prosecution, and maintenance of any patent applications claiming any SHL's Intellectual Property, and shall be responsible for paying all costs associated therewith.

12.9 Upon request, SHL may provide only to Customer's appointed patent attorney for review only by such Customer's attorney, the freedom to operate assessment conducted by SHL and/or its outside patent counsel related to the Device provided that SHL, Customer, and Customer's patent attorney or outside

counsel have entered into confidentiality agreement as restrictive as set forth herein. Such review shall take place at a time mutually agreed by the Parties.

12.10 Customer shall provide SHL with artwork, copy or other material developed or produced in support of the Product labels, printed packaging, materials and Product inserts or leaflets. SHL will not make any change to the artwork, copy, or other materials submitted to the FDA by Customer without the prior written approval of Customer. Customer shall have the right to specify any Commercially Reasonable individual or bulk package sizes and types. SHL disclaims any responsibility with respect to any such artwork, copy or other material developed or produced in support of the Products' labels, printed packaging materials and inserts or leaflets. Customer shall have no rights to use the artwork, trademarks, service marks, trade names, and logos owned by or licensed to SHL without SHL's prior written consent.

Customer warrants that labels and printed packaging materials related to the Product shall not infringe, copy, or free ride, in whole or in part, upon the labels, trade dress, or printed packaging materials of third parties.

12.11 Except as specifically set forth herein, the Parties expressly acknowledge and agree that neither intends to convey any rights, licenses, assignments or grants to the other, by implication, estoppel or otherwise, as a result of this Agreement. Nothing in this Agreement shall be construed as conveying any rights, license, assignments or grants (implied or mandated by law, equity or otherwise) in either Party's Intellectual Property, including without limitation any Know-How, statutory or non-statutory rights, and in any other drug or pharmaceutical product besides the Product. The Parties shall execute and deliver, and shall cause to be executed and delivered, such further documents and take or cause to be taken such further actions as may be necessary or appropriate to effectuate more fully this Agreement and to carry out the business contemplated by this Agreement, including without limitation any Intellectual Property licenses or assignments, grants, or powers-of-attorney, as may be commercially reasonable and required.

12.12 If either Party becomes aware of any circumstance, claim, or proceeding that relates to the Intellectual Property of the other Party that is embodied in the Device or Product that may adversely affect the validity, title, or enforceability of such Intellectual Property, or any actual, alleged, or threatened infringement

of such Intellectual Property, or any actual, alleged, or threatened misappropriation or misuse of such Intellectual Property, such Party shall promptly notify the other Party thereof in writing.

12.13 If any Intellectual Property embodied in the Product becomes the subject of a third party claim of Intellectual Property infringement, misappropriation, or misuse, SHL, with respect to the Device Intellectual Property, and Customer, with respect to the Customer Materials Intellectual Property, may, at its cost and expense, defend against such claim or initiate any declaratory judgment action or bring any other action necessary to protect such Intellectual Property (a "Defense Action"). If a Partly commences any such Defense Action as provided hereunder, the other Party may, at its option, elect to join such Party in such Defense Action, in which case such other Party shall bear its own out-of-pocket expenses (including the fees and expenses of any separate counsel) arising from such election to join. In connection with any such Defense Action and subject to the provisions of Section 12.16, the Parties shall cooperate fully and shall provide each other with any information or assistance that either reasonably requests.

12.14 If a third party infringes, misappropriates, or misuses any of SHL's Intellectual Property embodied in the Device, SHL may institute, at its sole cost and expense, any actions against such third party for any such infringement, misappropriation, or misuse of SHL's Intellectual Property (each an "Enforcement Action"). If SHL fails or decides not to institute or to continue an Enforcement Action, Customer does not have the right to institute an Enforcement Action with respect to SHL's Intellectual Property as Customer has no standing. The Customer has no recourse against SHL should SHL fail or decides not to institute or continue an Enforcement Action with respect to SHL's Intellectual Property. If SHL decides to institute such an Enforcement Action, the Parties shall discuss in good faith to determine if SHL on its own or both Parties jointly will bring the action to terminate such infringement or misappropriation. The cost of such Enforcement Action (including attorney's and other professionals' fees) shall be borne by SHL if bringing the Enforcement Action on its own or as the Parties may agree in writing if bringing the Enforcement Action jointly.

12.15 Each Party shall make Commercially Reasonable Efforts to cooperate and execute or cause to be executed all necessary documents and take or cause to be taken all appropriate actions, at the expense of the prosecuting Party, to: (i) allow

the other Party to exercise a Defense Action, and (ii) institute and prosecute such Enforcement Action. In connection with any such Defense Action or Enforcement Action, the Parties shall fully cooperate and shall provide each other with any information or assistance that either reasonably requests. Each Party shall keep the other informed of developments in any such Defense Action or Enforcement Action.

12.16 Neither Party may settle any Defense Action or Enforcement Action or consent to the entry of any judgment or settlement or otherwise compromise any such action or suit in any way that may adversely affect the other Party's rights or interests, without the other Party's prior written consent.

12.17 Any award paid by a third party as a result of any Defense Action or Enforcement Action contemplated under Section 12.13 or 12.14, as applicable, whether by way of settlement as contemplated by Section 12.16 or otherwise, shall be allocated first pro rata to the reimbursement of any expenses incurred by the Parties in such Defense Action or Enforcement Action, and any remaining amounts shall be allocated to the Party that instituted such Defense Action or Enforcement Action.

12.18 To the best knowledge of the Parties as of the Effective Date, neither the entering of this Agreement nor fulfilling their obligations in connection with this Agreement will infringe the Intellectual Property, contractual, or other proprietary rights of any third party. Further, SHL represents and warrants to Customer that, to SHL's knowledge, as of the Effective Date, the use and sale of the Device or any other technology used and associated with such Device, will not infringe the valid Intellectual Property or other proprietary rights of any third party. Customer represents and warrants to SHL that, to Customer's knowledge, as of the Effective Date, the use of the Customer Materials will not infringe the Intellectual Property or other proprietary rights of any third party.

13. USE OF NAME

Except as required by applicable law or regulation, neither Party will use the name, logo, or trademarks of the other Party or its Affiliates in any publicity, regulatory filing, advertising, or news release without the prior written approval of an authorized representative of the other Party.

14. TERM AND TERMINATION

14.1 The Initial Term of this Agreement shall end upon the fifth (5th) anniversary of the Effective Date (the "Initial Term"). This Agreement shall automatically renew for successive two (2) year periods (each a "Renewal Term", and all such Renewal Terms together with the Initial Term, collectively the "Term"), unless either Party notifies the other Party in writing, at least [***] prior to the expiration of the then current Term that such Party does not wish to renew this Agreement for an additional Renewal Term. In addition, unless otherwise expressly specified in a SOW, each SOW hereunder shall have the same Term as this Agreement and shall terminate when this Agreement is terminated or expires.

14.2 Termination for cause.

14.2.1 Either Party may terminate this Agreement or any SOW hereunder for cause prior to the completion of the Term. If a Party fails to perform any material obligation or otherwise breaches a material provision of this Agreement or a SOW, the non-breaching Party may provide written notice thereof, specifying in detail the nature of the breach and indicating its intent to terminate if such breach is not cured. A Party in breach of this Agreement or a SOW shall have [***] from receipt of such notice to remedy such breach. If the breach is not cured within [***], the non-breaching Party may elect to terminate this Agreement or such SOW immediately by written notice to the breaching Party.

14.2.2 Customer may terminate this Agreement or any SOW at any time during the Term if (i) except as provided under Article 23, SHL voluntarily delays the performance of the Services for a continuous period of [***], or (ii) SHL has [***] or more late Purchase Order deliveries during any [***]which were not the result of Customer's failure to deliver Primary Packaging on-time, or (iii) Customer provides SHL with a copy of the notice received from the FDA informing it of a refusal, cancellation or withdrawal of the regulatory authorization that would have allowed Customer to commercialize the Product or the Drug Product in the Territory.

14.2.3 Either Party may terminate this Agreement or any SOW effective upon issuance of written notice if, at any time, the other Party files a petition in bankruptcy, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent.

14.2.4 In the event there is a material change to FDA or comparable regulatory authority requirements, or other applicable laws, which makes the manufacturing of the Device or Product for the intended use impossible to achieve by using commercially reasonable personnel or financial resources, the Parties will enter into good faith discussions to resolve such matter in accordance with Section 14.4.3 of this Agreement. In the event the Parties are not able to reach an agreement on how to resolve such matter within [***] of initiation of such negotiations, either Party may terminate this Agreement or any SOW by providing [***] prior written notice to the other Party.

14.3 Termination without cause. This Agreement or any SOW can be terminated without cause by one Party providing written notice to the other Party at least [***] prior to the expiration of the Initial Term or the expiration of any subsequent Renewal Term, as provided for in Section 14.1.

14.4 Effect of termination or expiration.

14.4.1 Upon termination or expiration of, as applicable, this Agreement, SHL shall immediately discontinue its use of Customer Materials and performance of the Services as directed by Customer, except as otherwise required to complete Services described herein.

14.4.2 If expiration or termination of this Agreement or SOW is due to a material breach as described in Section 14.2.1, the terminating Party shall not have any obligation to make any further payments to the other, except for any amount that would remain due to the other Party as of the date of termination or expiration of this Agreement or SOW. In the event of expiration or any termination (other than a termination due to a material breach by SHL) occurring prior to the completion of the Services, Customer shall not be relieved of its obligation to: (i) accept delivery of conforming Devices or Products manufactured or in the process of being manufactured for Purchase Orders opened prior to the date of termination or expiration; (ii) pay for all conforming Devices or Products manufactured or in the process of being manufactured for open Purchase Orders prior to the date of termination or expiration; and (iii) cover all costs related to work in process and the raw materials to be specifically used in the performance of this Agreement or the applicable SOW and that were purchased or stored

by SHL in accordance with Customer's binding and non-binding forecast in accordance with Section 5.1.2, including but not limited to, any Safety Stock maintained pursuant to this Agreement and Device work in process produced by SHL prior to the date of termination or expiration of this Agreement.

14.4.3 If expiration or termination of this Agreement or any SOW is not due to a material breach by either Party as described in Section 14.2.1, Customer shall have the option to: (i) secure additional Product from SHL at the then applicable Price or Fee set forth in the applicable SOW for quantities up to [***] of the latest Rolling Forecast for delivery at a mutually agreeable time; and (ii) purchase Devices required to assemble Product at the then applicable Price or Fee set forth in the applicable SOW at another manufacturing site for a minimum of [***] after SHL Services at the Facilities have been completed. For the avoidance of doubt, the Fee and Price hereunder shall be subject to Section 9.1.

14.4.4 Upon the expiration or termination of this Agreement and upon receipt by SHL, in full, of all fees and expenses due by Customer, each Party shall promptly and in any event within [***], return to the other its Confidential Information and tangible embodiments of its Intellectual Property and tangible copies thereof as well as destroy all electronic copies thereof in that Party's possession, custody or control; provided, however, that each Party may retain a copy of such information as necessary for archival purposes. Each Party shall, upon request, provide to the other a written confirmation that all the foregoing information or materials have been either returned to the Party to whom they belong or have been lost or destroyed such that no copy, electronic or otherwise, exists in the confirming Party's possession, custody or control.

14.4.5 Upon the expiration or termination of this Agreement, any licenses to Intellectual Property shall be deemed cancelled and revoked without need of any further writing between the Parties. Such cancellation and revocation shall not apply to Products already delivered, and the Devices therein, or Devices purchased and provided under Section 14.4.3.

14.4.6 Termination or expiration of this Agreement or any SOW shall not waive any other remedies or continuing obligations as set forth herein or in the

Quality Agreement, including, but not limited to those regarding quality, Confidential Information and Intellectual Property.

15. INDEMNIFICATION AND LIABILITY

15.1 Customer shall defend and indemnify SHL and its Affiliates, and its officers, agents, and employees, from and against all third party claims, losses, damages, injuries, costs, or expenses that may be sustained, suffered, or incurred by any of the foregoing, including without limitation, expenses of litigation and reasonable attorneys' fees for: (i) any breach of Customer's representations, warranties, or obligations under this Agreement, or non-fulfillment of or failure to perform any covenant or agreement made by Customer in this Agreement, which breach of representations shall include, for the avoidance of doubt, the infringement of any third party's Intellectual Property by the use of Customer Materials by SHL, as permitted hereunder; (ii) any personal injury, death or property damage caused by the possession, use of Customer Materials or consumption by any person of the Drug Product to the extent such injury, death, or damage was not caused by a defect or malfunction of the Device or Product, as applicable; (iii) any manufacturing defect in the Drug Product or the Primary Packaging; (iv) the use of any Primary Packaging or Drug Product supplied to SHL by Customer; and (v) any other intentional act, negligent act or omission on the part of Customer or its respective employees or agents, in each case, to the extent any such losses are not the result of the negligence or willful misconduct of SHL.

15.2 SHL shall defend and indemnify Customer and its Affiliates, and its officers, agents, and employees, from and against all third party claims, losses, damages, injuries, costs, or expenses that may be sustained, suffered, or incurred by any of the foregoing, including without limitation, expenses of litigation and reasonable attorneys' fees for (i) any breach of SHL's representations, warranties, or obligations under this Agreement, or non-fulfillment of or failure to perform any covenant or agreement made by SHL in this Agreement, which breach of representations shall include, for the avoidance of doubt, the infringement of any third party's valid Intellectual Property by the manufacture, use, sale, importation, assembly or distribution of the Device in the Territory by Customer; (ii) any personal injury, death or property damage caused by the possession, use or consumption by any person of the Device that is a result of SHL's actions or inactions, to the extent such personal injury, death or property

damage was not caused by the possession, or use of any of the Customer Materials or consumption of the Drug Product; and (iii) any other intentional act, negligent act or omission on the part of SHL or its employees or agents, including, without limitation, SHL's failure to comply with all applicable laws, rules and regulatory requirements within the Territory concerning the Device, except if any such claim arises from a negligent act or omission or the intentional misconduct of Customer or from one of Customer's named patient programs as a result of the Product not being authorized by the applicable health authority.

15.3 In the event that any claim is asserted against any Party hereto, or any Party hereto is made a Party defendant in any action or proceeding, and such claim, action or proceeding involves a matter which is subject to a claim for indemnification under this Article 15, then such Party (an "Indemnified Party") shall promptly give written notice to the other Party (the "Indemnifying Party") of such claim, action or proceeding, and such Indemnifying Party shall have the right to join in the defense of said claim, action or proceeding, at such Indemnifying Party's own cost and expense, and if the Indemnifying Party agrees in writing to be bound by and to promptly pay the full amount of any final judgment from which no further appeal may be taken and if the Indemnified Party is reasonably assured of the Indemnifying Party's ability to satisfy such agreement, then at the option of the Indemnifying Party, such Indemnifying Party may take over the defense of such claim, action or proceeding, except that, in such case, the Indemnified Party shall have the right to approve any attorney or counsel selected by the Indemnifying Party (which approval shall not be unreasonably delayed or withheld) and to join in the defense of said claim, action or proceeding at its own cost and expense. In no event shall either Party institute, settle, or otherwise resolve any claim or potential claim, action or proceeding relating to the Product or Intellectual Property of or licensed by SHL under the terms of this Agreement, without the prior written consent of the other Party.

15.4 In no event shall either Party be liable to the other Party or its Affiliates under this Agreement for: (i) any indirect, consequential, incidental, punitive, or special damages; and (ii) lost profits, loss of use, loss of data, loss of revenue, or damages resulting from value added to the Product.

15.5 In no event shall either Party's total liability to the other Party arising under this Agreement, including any indemnification paid by either Party pursuant to

Sections 15.1 and 15.2 of this Agreement, exceed the total amount received by SHL from Customer under this Agreement during any [***] beginning on the Effective Date, or the sum of [***], whichever is lesser.

16. SURVIVAL

Termination of this Agreement by either Party or its expiration shall not affect the rights and obligations of the Parties accrued prior to the date of the termination or expiration. The rights and obligations of the following Articles and Sections shall survive the expiration or termination of this Agreement: 1, 2.9, 2.10, 3.4, 3.6, 3.9, 3.10, 7, 8.1, 10, 11, 12, 13, 14.4, 15, 16, 17, 18, 19, 20, 21, 22 and 25; except, SHL's obligation to continue performing the activities in this Agreement shall not survive.

17. SEVERABILITY

If a court or other tribunal of competent jurisdiction should hold any term or provision of this Agreement to be excessive, invalid, void, or unenforceable, the offending term or provision shall be deleted, and if possible, replaced by a term or provision which, so far as practicable achieves the legitimate aims of the Parties. Any invalidity or unenforceability of any article or provision of this Agreement shall not affect the remainder of the Agreement.

18. RELATIONSHIP BETWEEN THE PARTIES

18.1 SHL and Customer, for all purposes related to this Agreement, shall be deemed independent contractors. Nothing in this Agreement shall be deemed to create a relationship of employment or agency or to constitute the Parties as partners or joint ventures.

18.2 This Agreement shall not be deemed to confer any rights or remedies upon any person not a Party hereto.

18.3 SHL and Customer shall bear the sole responsibility for all compensation and benefits of their respective employees, subcontractors, and agents.

19. NO WAIVER

The failure of either Party to require performance by the other Party of any of that other Party's obligations hereunder shall in no manner affect the right of such Party to enforce the same at a later time. No waiver by any Party hereto of any condition, or of the breach of any provision, term, representation or warranty contained in this

Agreement shall be deemed to be or construed as a further or continuing waiver of any such condition or breach, or of any other condition or of the breach of any other provision, term, representation, or warranty hereof.

20. NOTICES

Any notices given under this Agreement shall be in writing and shall be deemed delivered when received. Any notice under this Agreement shall be sent by: (i) first-class mail, postage prepaid; (ii)by electronic delivery with confirming transmission and receipt; (iii) courier; or (iv) hand delivery; and addressed to the addresses shown below (or any other address as the Parties may notify each other in writing):

For SHL:
SHL Pharma, LLC
588 Jim Moran Boulevard
Deerfield Beach, FL 33442
Attention: Managing Director
Phone: [***]
Email: [***]

With a copy to:
SHL Medical AG
Gubelstrasse 22
6300 Zug
Switzerland
Attention: Chief Legal Officer
Email: [***]

For Customer:
On or before May 1, 2023:
Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1600
Chicago, Illinois, 60601
After May 1, 2023:
Xeris Pharmaceuticals, Inc.
1375 West Fulton Street, Suite 1300
Chicago, Illinois 60607
Attention: John Shannon
Email: [***]

With a copy to:
Attention: Ron de Vera
Email: [***]

And to:
Attn: Legal Department
Email: [***]

21. GOVERNING LAW

This Agreement shall be governed by and construed in accordance with the laws of the state of New York and the United States of America without regard to choice of law provisions.

22. DISPUTE RESOLUTION

If any dispute arises between the Parties hereto relating to this Agreement, they agree to promptly enter into negotiations by and between executives with full authority to settle such dispute within [***] following delivery of written notice of such dispute. If the executives cannot resolve the dispute, then either Party can resort and seek judicial remedy with venue of the dispute vested in the state courts of New York City, New York. The Parties hereby consent to the personal and exclusive jurisdiction and venue of these courts.

23. FORCE MAJEURE

No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement or the applicable Statement of Work if, and only to the extent that, such failure or delay results from causes beyond the reasonable control of the affected Party, including but not limited to acts of God, earthquakes, floods, fires, typhoons, tornados, disruptions of essential services and utilities, strikes, epidemics, war, acts of terrorism, riots, sabotage, or other occurrence which is beyond the control of the Party making the claim (a "Force Majeure Event"). The Party claiming a Force Majeure Event must provide prompt written notice to the other Party of the Force Majeure Event. Such non-performance will be excused for [***] or longer if by written agreement between the Parties; the Party claiming a Force Majeure Event shall exercise Commercially Reasonable Efforts to eliminate or limit the effects of a Force Majeure Event and to resume performance of its affected obligations as soon as practicable.

24. ASSIGNMENT

24.1 No Party may assign this Agreement, including any SOW, in whole or in part, to any third party without the consent of the other, which shall not be unreasonably withheld except that Customer may assign this Agreement and any SOW in connection with the sale of all or substantially all of its assets or Product assets. The Parties' Affiliates shall not be considered third parties for the purposes of this section. No assignment of this Agreement or any SOW under this section may relieve the assigning Party of its obligations under this Agreement or such SOW.

24.2 The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefits of, the Parties hereto and their respective permitted

successors and assigns.

25. REMEDIES

Except as otherwise expressly provided herein, the remedies accorded to the Parties under this Agreement are cumulative and in addition to those provided by law, in equity or elsewhere in this Agreement.

26. COUNTERPARTS

This Agreement, including any SOW hereunder, may be executed in one or more counterparts, each of which when executed and delivered will be deemed an original and all of which together will constitute one and the same agreement. A signed copy of this Agreement, including any SOW hereunder, delivered by facsimile, e-mail or other means of electronic transmission is deemed to have the same legal effect as delivery of an original signed copy of this Agreement or SOW.

27. ELECTRONIC SIGNATURE

The Parties agree that this Agreement, including any SOW hereunder, may be electronically signed and that the electronic signatures appearing on this Agreement or any SOW are the same as handwritten signatures for the purposes of validity, enforceability, and admissibility.

28. ENTIRE AGREEMENT

This Agreement, the appendixes attached hereto, each SOW and the Quality Agreement constitute the entire agreement between the Parties concerning the subject matter contained in this Agreement and supersede all written or oral prior agreements or understanding with respect thereto. No variation or modification of any of the terms or appendixes of this Agreement or any waiver of the terms or provisions hereof shall be valid unless in writing and signed by an authorized representative of each Party.

29. Non-discrimination.

If applicable, SHL shall abide by the requirements of 41 CFR Sections 60-1.4(a), 60-300.5(a) and 60-741.5(a). These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities and prohibit discrimination against all individuals based on their race, color religion, sex, sexual orientation, gender identity, or national origin. Moreover, these

regulations require that covered service provider and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, protected veteran status or disability. This subcontract may also be subject to Executive Order 13496.

Signatures begin on the next page.

IN WITNESS WHEREOF, the Parties intending to be legally bound have caused this Agreement to be executed by their duly authorized officers or representatives.

Xeris Pharmaceuticals, Inc.	**SHL Pharma, LLC**
By: /s/ John Shannon	By: /s/Kimberlee Steele
Name: John Shannon	Name: Kimberlee Steele Title:
Title: President & COO	Managing Director

Exhibit 10.4

Statement of Work No. 1 - Device

This **Statement of Work No. 1** (this "SOW" or "Statement of Work") is effective as of January 30, 2023 (the "SOW Effective Date") between **SHL Pharma, LLC**, a company existing under the laws of Florida, with offices at 588 Jim Moran Boulevard, Deerfield Beach, Florida 33442 ("SHL"), and **Xeris Pharmaceuticals, Inc.,** a corporation existing under the laws of Delaware, with an office at 180 North LaSalle Street, Suite 1600, Chicago, IL 60601, United States ("Customer"), and upon execution will be incorporated into the Amended and Restated Product Supply Agreement entered into as of January 30, 2023 (the "Agreement") between SHL and Customer. If any item in this Statement of Work conflicts with the Agreement, the terms of the Agreement will control unless this Statement of Work expressly refers to the parties' intent to supersede the terms of the Agreement. Notwithstanding the foregoing, in any event, the Agreement shall control with respect to any provisions related to confidentiality, intellectual property rights, or indemnification.

All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement.

1. **Device Specifications**

[***]	[***]

The Device is based on [***] in the form of sub-assemblies sourced by SHL from SHL Taiwan, suitable for housing Customer's Primary Packaging, inclusive of all components, assembly steps, and quality release steps, and as developed under the Joint Development Agreement. Devices manufactured under the Agreement and this SOW shall meet the applicable specifications according to the Quality Agreement.

2. Customer will order and purchase the Device pursuant to the Agreement and this SOW. SHL will manufacture the Device at its qualified supplier, SHL Taiwan, pursuant to the Device specifications and the Quality Agreement.

3. SHL will complete required stability studies to ensure Devices have minimum shelf-life of at least [***] at the time of Device assembly and release at SHL Taiwan and, at a cost to be agreed by the Parties, will work on completing stability studies to support shelf-life of at least [***].

4. **Primary Packaging**

[***]	[***]
[***]	[***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

All Devices shall be packed in bulk secondary packaging provided by SHL. SHL shall be responsible for safe and adequate packaging, transportation and warehousing of the Devices, which shall conform to Device specifications and requirements. Each batch of Devices will be shipped with all relevant material information and documentation, as specified in the Quality Agreement.

5. Customer Materials

In accordance with Section 3.1, 3.2, and 5.2.4 of the Agreement, Customer shall provide [***]. Customer shall provide such Customer Materials to SHL [***] at SHL's Facility at Taoyuan, Taiwan (Incoterms® 2020). SHL Taiwan will be the Importer of Record for shipments of Customer Materials into the SHL Facility at Taoyuan, Taiwan. Notwithstanding the foregoing, all duties and taxes shall be charged to Customer as [***].

6. SHL Materials

SHL is responsible for the manufacture of the Devices through its Affiliate, SHL Taiwan. Trays, packaging materials, shipper boxes and any materials other than Customer Materials will be provided by SHL in sufficient quantities as needed for the manufacture of the Device.

7. Prices of the Device and Fees

(a) The Price of the Device shall be as follows, on a per-unit basis, inclusive of all release testing:

Description	Unit Price (USD, tax excluded)
[***]	[***]
[***]	[***]

[***]	[***]

- The above pricing is valid from the Effective Date to [***]. Any reimbursable costs shall be [***]has been expressly agreed to in writing by the Parties.
- For purposes of Section 6.1 of the Agreement and this SOW, "delivery" shall mean delivery of the Devices by SHL Taiwan to the Facility located in Deerfield Beach, Florida [***] (Incoterms® 2020). Pursuant to Section 9.2 of the Agreement, invoices for Devices will be issued upon the delivery of such Devices .
- Pricing will be adjusted per Section 9.1 of the Agreement.
- For the avoidance of doubt, the above Prices shall include the following:
  i. Manufacturing of the Device, including all necessary materials other than any Customer Materials;
  ii. Quality Control testing of Devices via generally accepted statistical methods and SHL release of Device;
  iii. Certificate of analysis/Certificate of conformance;
  iv. GMP-required retention samples of the Devices;
  v. Any and all scrap costs related to the production of the Device;
  vi. Routine sampling, analysis and release as part of Device manufacturing; and
  vii. Routine maintenance and calibration of equipment and Facility.

Beginning with the first shipments of Devices produced using the new full set of 4-cavity production tools and additional SKD-4 assembly equipment, SHL shall apply a surcharge of [***] per set until Customer has ordered and purchased [***] sets of Device. After such quantity of Devices have been ordered, such surcharge shall cease and the pricing shall revert to the then-current Price. To the extent Customer has not paid the surcharge with respect to [***] sets on or before the second anniversary of the SOW Effective Date, Customer shall make a one-time payment to SHL in the amount of the difference between (i) [***] and (ii) the aggregate amount of surcharge paid by Customer. For purposes of invoicing, SHL shall separately note the amount of surcharge applicable to a shipment of Devices.

(b) Storage Fees

If a storage fee is applicable to Customer Material storage pursuant to Section 3.1 of the Agreement, the Customer Material storage Fee shall be [***]; provided, however, that there shall be no storage Fee for storage of any Customer Materials requested by SHL for quality control testing at SHL's Facility in Taiwan.

Pursuant to Section 6.7 of the Agreement, Fees for storing the Devices for a period of [***] after delivery are included within the above pricing. Customer shall pay an additional Fee for storage of Devices beyond said period in an amount of [***] per specified product storage conditions (a segment of less than [***] shall be counted as [***]).
Invoices for the storage Fees will be issued upon the completion of the storage services. For the avoidance of doubt, Customer shall not be responsible for storage fees for any Device batches not released due to shipping damage or failure to meet Device specifications.

(c) Freight charges
The Parties agree that as of the Effective Date, all taxes, duties, and freight charges of the Devices will be invoiced as a passed-through cost; provided, however, that such freight charges shall be approved in advance by Customer, such approval not to be unreasonably withheld or delayed.

(d) Release Test Sampling
Devices will be sampled in accordance with current design documentation and approved specifications in accordance with the Quality Agreement.

(e) Delivery of the Device
All Devices and samples are delivered by SHL [***] SHL Facility at Deerfield Beach, Florida (Incoterms® 2020). Title and risk of loss and damages to the Devices shall transfer to Customer upon such delivery. For the avoidance of doubt, Section 7.4 of the Agreement governs the incoming inspection, potential defect of the Devices, and the remedy therefor.

8. Minimum Batch and Order Quantity (MOQ)

Customer shall use good faith efforts to forecast and order quantities of Devices consistent with multiples of the expected batch yields (assuming not more than a [***] yield loss) from SHL Taiwan manufacturing.

9. Capacity Commitment

The Parties understand that SHL's capacity commitment is contingent upon Customer's timely replacement or investment in applicable Device equipment and tools. The JSC shall review Customer's Long Term Forecast and the Capacity Commitment annually and the Parties agree to work together in good faith to adjust the Capacity Commitment to support Customer's Long Term Forecast. To the extent SHL believes it will not be able to meet Customer's production demand as set forth in Customer's Long Term Forecast, SHL shall promptly notify Customer thereof, including the reasons therefor, and the Parties shall work together in good faith to meet such production demand as promptly as

commercially reasonable and negotiate a subsequent amendment.

As of the SOW Effective Date, monthly Capacity Commitment for the Device shall not be less than [***] sets of the Device in each [***], [***] sets of the Device in each [***], and [***] sets of the Device in each [***].

10. Storage Conditions

[***].

11. JSC Composition

Customer Member / Title	SHL Member /Title
	Managing Director, SHL Pharma
SVP, Global Technical Operations	CQRO
VP, CMC	Director, Quality
VP, Quality	Director Process Development
Senior Director, Pharmaceutical Manufacturing	Managing Director, SHL Taiwan
Director, Supply Chain	Director Project Management
Senior Director, Accounting or Senior Director, Finance	Director Development
	Director Operations
	Associate Director/Director Supply Chain (FL/TW)
	Sr Manager Project Management (TW)
	Director Account Management

All other terms and conditions of the Agreement will apply to this Statement of Work.

Signature page follows.

IN WITNESS WHEREOF, the Parties intending to be legally bound have caused this SOW to be executed by their duly authorized officers or representatives.

Xeris Pharmaceuticals, Inc.	**SHL Pharma, LLC**
By: /s/ John Shannon	By: /s/Kimberlee Steele
Name: John Shannon	Name: Kimberlee Steele
Title: President & COO	Title: Managing Director

Exhibit 10.5

Statement of Work No. 2 - Product

This **Statement of Work No. 2** (this "SOW" or "Statement of Work") is effective as of January 30, 2023 (the "SOW Effective Date") between **SHL Pharma, LLC**, a company existing under the laws of Florida, with offices at 588 Jim Moran Boulevard, Deerfield Beach, Florida 33442 ("SHL"), and **Xeris Pharmaceuticals, Inc.,** a corporation existing under the laws of Delaware, with an office at 180 North LaSalle Street, Suite 1600, Chicago, IL 60601, United States ("Customer"), and upon execution will be incorporated into the Amended and Restated Product Supply Agreement entered into as of January 30, 2023 (the "Agreement") between SHL and Customer. If any item in this Statement of Work conflicts with the Agreement, the terms of the Agreement will control unless this Statement of Work expressly refers to the parties' intent to alter the terms of the Agreement. Notwithstanding the foregoing, in any event, the Agreement shall control with respect to any provisions related to confidentiality, intellectual property rights, or indemnification.

All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement.

1. **Product Overview**

   [***].

2. Customer will order and purchase the Product pursuant to the Agreement and this SOW. SHL will (i) inspect and release incoming Devices and assemble the Devices and the Primary Packaging into Products at the Facility located in Deerfield Beach, Florida; (ii) label the assembled Product and bulk package Products at the Facility located in Deerfield Beach, Florida; (iii) perform the applicable testing, handling, and storage of the Devices, Primary Packaging and Products at the Facility located in Deerfield Beach, Florida; and (iv) perform the other Services described herein each in accordance to the Product specifications and the Quality Agreement.

3. **Product Shelf-Life**
   SHL will support an assembled Device and Product shelf-life of at least [***] at the time of Product assembly.

4. **Primary Packaging**

[***]	[***]
[***]	[***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

5. Labelling and Bulk Packaging

Customer-approved label will be placed on the assembled Product. The labelled Product shall be placed in plastic trays and the trays shall then be placed into a foil bag [***]. Storage and shipment of the sealed trays/pouches shall be in accordance with Product specifications set forth in the Quality Agreement.

All Products shall be labeled and packed in bulk secondary packaging provided by SHL. SHL shall be responsible for safe and adequate labelling and packaging of the Products for warehousing and shipping, which shall conform to Customer's Product specification and requirements and the carrier's requirements. Each Product will be bulk packaged and shipped with all relevant material information and documentation, as specified in the Quality Agreement.

6. Customer Materials

In accordance with Section 3.1, 3.2, and 5.2.4 of the Agreement, Customer shall provide [***]. In addition, Customer shall order Devices such that they can be available to SHL at least [***]; provided, however, that the foregoing does not apply to delayed delivery of Customer Materials if such delay is due to SHL's delays in delivery of Devices. Customer shall provide such Customer Materials [***] to SHL [***] at SHL's Facility at Deerfield Beach, FL (Incoterms® 2020) and order sufficient quantities of Devices which will be delivered as set forth in SOW 1. SHL will be the Importer of Record for shipments of Devices into the Facility at Deerfield Beach, Florida (it being understood that such duties and taxes shall be charged to Customer as set forth in Section 7(c) of SOW 1). For the avoidance of doubt, Device shall be deemed Customer Material upon the transfer of title as set forth in Section 7 (e) of SOW 1. Upon SHL's receipt of the Devices, SHL shall promptly, but in no event later than [***] after receipt thereof, complete incoming release testing of such Devices and notify Customer of the results thereof.

SHL shall be entitled to invoice Customer for any Product batch failure resulting from or otherwise attributed to the Primary Packaging, absent any contributory fault, negligence or willful misconduct of SHL in performing the Services (i.e. the Fees that would have been payable if the batch had not failed due to the Primary Packaging for the Services actually performed). Except as set forth in Section 3.6 of the Agreement, destruction and discarding fees of any expired, obsolete, or unusable Customer Materials required as a result of any Product batch failure resulting from or otherwise attributed to the Primary Packaging as described in the immediately preceding sentence shall be borne by Customer at [***]. Similarly, as further described in Section 7.4 of the Agreement Customer shall be entitled to receive a full refund or replacement Devices at no additional cost to Customer as set forth in Section 7.4, including for any Product batch failure resulting from or otherwise attributed to the Device. The loss or damage to other Customer Materials shall be governed by Section 3.6 of the Agreement.

7. SHL Materials

SHL is responsible for the assembly of the Products using released Devices from SHL Taiwan, Product labels and labeling.

In the event that: (i) Customer decides to change any label or bulk packaging that has been agreed between the Parties, or (ii) any label or bulk packaging component expires, Customer shall bear all cost associated with such labels and bulk packaging at [***]; provided, however, that in the case of clause (ii), Customer shall not be responsible for destruction or discarding fees for any components in excess of [***] inventory.

8. Services and Fees

(a) The Fees for the Product, including the assembly, labeling and pouching thereof, shall be as follows, inclusive of all release testing, as shown below on a per unit basis:

Description of Services	Fees (USD/unit, tax excluded)
Assembly of Devices and Primary Packaging into a Product	[***]
Labelling and pouching	[***]
Total	[***]

- The above Fees are valid from the Effective Date to [***]. For the avoidance of doubt, the above Fees shall be subject to Section 9.1 of the Agreement. Any reimbursable costs shall be [***] has been expressly agreed to in writing by the Parties.

- The above Fees exclude additional lot set-up/changeover fees of [***] for lot sizes between [***]units, or [***]for lot sizes less than [***].
- The above Fees for labelling and pouching includes the costs for all SHL Materials.
- Any costs for permits, licenses, inspections, or otherwise, that are specific to the Products and not generally required or reasonably expected by SHL as a contract manufacturer of regulated drugs or devices in the Territory, shall be borne by Customer at cost.
- Pursuant to Section 9.2 of the Agreement, invoices for Products will be issued [***] after SHL provides Customer with the batch records of such Product.
- For the avoidance of doubt, the above Fees shall include the following:
  (a) Incoming inspection and release of Devices and assembly of the Primary Packaging and Devices into Products;
  (b) Applying a label, batch number, and expiration date on the outside of the assembled Product (including label and printing inspection/verification);
  (c) Packaging labelled Products into bulk foil pouches, labeling bulk pouches, packing bulk pouches into corrugated shippers, and palletization;
  (d) Quality Control sampling and testing of Product via generally accepted statistical methods and SHL release of Product;
  (e) Certificate of analysis/Certificate of conformance;
  (f) GMP-required retention samples of the Products;
  (g) Routine sampling, analysis and release as part of Product assembly; and
  (h) Routine maintenance and calibration of equipment and Facility.

(b) Storage Fees

If a storage fee is applicable to Customer Material storage pursuant to Section 3.1 of the Agreement, the Customer Material storage Fee shall be [***].

Pursuant to Section 6.7 of the Agreement, Fees for storing the Products for a period of up to [***] after SHL provides Customer with the manufacturing or product batch records and testing and release documentation for the Products are included within the above pricing. Customer shall pay a Fee for storage of Products beyond said period in an amount of [***] per specified Product storage conditions.

For the avoidance of doubt, a segment of less than [***] shall be counted as [***]. Invoices for the storage Fees will be issued upon the completion of the storage services. SHL will store the Customer Material and Products at the Facility located in Deerfield Beach, Florida or otherwise approved third party in accordance with the Quality Agreement.

(c) Release Test Sampling:
Product will be sampled in accordance with current design documentation and approved specifications in accordance with the Quality Agreement.

(d) Delivery of Product

- All Product and samples are delivered to Customer (or Customer's designee) [***] Facility at Deerfield Beach, Florida (Incoterms® 2020).
- For any Product or sample delivered other than [***] Facility at Deerfield Beach, Florida (Incoterms® 2020) to Customer (or Customer's designee), a shipping fee will be charged as a [***] of the shipping costs incurred by SHL. Invoices of said shipping fee will be issued upon the completion of the shipment.
- Title and risk of loss to the Products shall transfer to Customer when SHL provides manufacturing or product batch records and testing and release documentation for such Products to Customer.

9. Minimum Batch and Order Quantity (MOQ)

Customer shall use good faith efforts to forecast and order quantities of Product consistent with the Minimum Order Quantity.

10. Capacity Commitment

The Parties understand that SHL's capacity commitment is contingent upon Customer's timely replacement or investment in applicable Device equipment and tools. The JSC shall review Customer's Long Term Forecast and the Capacity Commitment annually and the Parties agree to work together in good faith to adjust the Capacity Commitment to support Customer's Long Term Forecast. To the extent SHL believes it will not be able to meet Customer's production demand as set forth in Customer's Long Term Forecast, SHL shall promptly notify Customer thereof, including the reasons therefor, and the Parties shall work together in good faith to meet such production demand as promptly as commercially reasonable and negotiate a subsequent amendment.

As of the SOW Effective Date, monthly Capacity Commitment for the Product shall not be less than [***] units of the Product in each [***], [***] units of the Product in each [***] and [***] units of the Product in each [***].

11. Safety Stock

SHL shall maintain a minimum of [***] of Safety Stock of Product labels and Product bulk packaging based upon the monthly average derived from the [***] of the Customer's latest Rolling Forecast at no charge to Customer. Upon termination of this SOW for any reason, Customer shall be obligated to purchase such Safety Stock.

12. Storage Conditions

[***].

13. JSC Composition

Customer Member / Title	SHL Member /Title
SVP, Global Technical Operations	Managing Director, SHL Pharma
VP, CMC	CQRO
VP, Quality	Director, Quality
Senior Director, Pharmaceutical Manufacturing	Director, Process Development
Director, Supply Chain	Sr. Manager/Director, Project Management
Senior Director, Accounting or Senior Director, Finance	Director, Operations
	Associate Director/Director, Supply Chain
	Director, Account Management

All other terms and conditions of the Agreement will apply to this Statement of Work.

Signature page follows.

IN WITNESS WHEREOF, the Parties intending to be legally bound have caused this SOW to be executed by their duly authorized officers or representatives.

Xeris Pharmaceuticals, Inc.	**SHL Pharma, LLC**
By: /s/ John Shannon	By: /s/Kimberlee Steele
Name: John Shannon	Name: Kimberlee Steele
Title: President & COO	Title: Managing Director

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

Execution Version

OMNIBUS ASSIGNMENT AND ASSUMPTION AGREEMENT AND AMENDMENT NO. 1 TO ASSET PURCHASE AGREEMENT AND SUPPLY AGREEMENT

This **OMNIBUS ASSIGNMENT AND ASSUMPTION AGREEMENT AND AMENDMENT NO. 1 TO ASSET PURCHASE AGREEMENT AND SUPPLY AGREEMENT** (this "***Assignment and Amendment***"), effective as of March 13, 2023 (the "***Amendment Effective Date***"), is entered into by and amongst Strongbridge Dublin Limited, having an address at Fitzwilliam Hall, Suite 206, Fitzwilliam Place, Dublin 2, Ireland (as successor-by-transfer of Strongbridge Biopharma plc, "***Assignor***") and Xeris Pharmaceuticals, Inc., having an address at 180 N. LaSalle St., Suite 1600, Chicago, Illinois 60601 ("***Assignee***" or "***Buyer***"), and Taro Pharmaceuticals North America, Inc., having an address at Harbour Place, 103 South Church Street, Grand Cayman KY1-1202, Cayman Islands ("***Taro***" or "***Seller***"). Assignor, Assignee and Taro are each referred to herein as a "***Party***" and collectively as the "***Parties***."

W- I- T-N- E- S- S- E- T- H

WHEREAS, Assignor and Taro entered into that certain (i) Asset Purchase Agreement effective December 12, 2016 (the "***Purchase Agreement***") and (ii) Supply Agreement effective December 12, 2016 (the "***Supply Agreement***" and, together with the Purchase Agreement, the "***Agreements***");

WHEREAS, as of the Amendment Effective Date, Assignor desires to assign its rights, duties and obligations under the Agreements to Assignee, and Assignee desires to assume all of Assignor's rights, duties and obligations under the Agreements;

WHEREAS, based on the foregoing representations and those set forth below, Assignor, Assignee and Taro desire to consent to and acknowledge such assignment; and

WHEREAS, the Parties wish to amend the Agreements in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. Assignment and Delegation of Duties. Assignor hereby conveys, transfers and assigns to Assignee all of Assignor's rights, title, and interests under and to each Agreement and Assignor hereby delegates all of Assignor's duties and obligations under such Agreement to Assignee, effective as of the Amendment Effective Date.

2. Assumption. Effective as of the Amendment Effective Date, Assignee hereby (i) accepts the assignment set forth in Section 1 and (ii) agrees to assume and be bound by and perform all duties and obligations of Assignor in accordance with the terms and conditions of each Agreement.

3. Amendment of Purchase Agreement. As of the Amendment Effective Date, the Parties agree that the Purchase Agreement is hereby amended as follows:

(a) All references in the Purchase Agreement to an Agreement means such Agreement as amended by this Assignment and Amendment.

(b) All references in the Purchase Agreement to "Strongbridge" are changed to "Xeris".

(c) Section 2.6 of the Purchase Agreement is deleted in its entirety and new Section 2.6 is added as follows:

"2.6 Non-Compete.

(a) For the duration of the Term (as defined in the Supply Agreement), Taro and its Affiliates shall not, directly or indirectly (other than through Xeris), (i) Commercialize a Competitive Product in the Territory, (ii) promote any product in the Indication in the Territory, or (iii) undertake or have undertaken any clinical activities in the Territory with respect to a Competitive Product in the Territory for the Indication.

(b) For the duration of the Term (as defined in the Supply Agreement), Taro and its Affiliates shall not, directly or indirectly (other than through Xeris), itself or by assisting any Third Party (including by sharing any Confidential Information related to the Product therewith), Commercialize a product in the Territory for the Indication or promote any product in the Indication in the Territory, provided that:

(i) Taro may only Commercialize a product containing the API if such product would not reasonably be expected to have a material impact on the market for the Product (including by taking into account potential off-label prescribing of such product);

(ii) In the event that the Parties disagree regarding a potential material impact on the market for the Product, the provisions of Section 8.12(a) other than the last sentence thereof shall apply to resolution of such disagreement, and if it remains unresolved thereafter, the Parties shall submit such disagreement for resolution by an independent third-party expert having at least fifteen (15) years of experience as a senior executive in the pharmaceutical industry with responsibility for marketing strategies for pharmaceutical products and reasonably acceptable to both Parties. The Parties shall simultaneously submit their arguments in written form along with any supporting written evidence to the expert within ten (10) Business Days after the end of the process set forth in Section 8.12(a) other than the last sentence thereof, for decision on such written arguments and evidence. The expert shall render its decision within thirty (30) days of receipt of the written arguments and evidence. The decision of the expert shall be final and binding on the Parties and the costs and expenses of such expert shall be borne by the Party against whom the expert's decision is rendered.

(c) Notwithstanding the foregoing, Xeris acknowledges in the event that Taro or any of its Affiliates acquires any business (or assets) which is Commercializing a Competitive Product at the time of such acquisition, Taro shall not be in violation of its obligations under this Section 2.6 if Taro or its applicable Affiliate ceases Commercializing such Competitive Product within twelve (12) months from the effective date of the closing of the acquisition.

(d) In addition, if Taro or any of its Affiliates are acquired by or merged with a Third Party that is Commercializing a Competitive Product at the time of such acquisition or merger, such Third Party and its other Affiliates will not have any obligations under this Section 2.6; provided that the division, subsidiary or business group of the surviving party in such change of control that Commercializes such Competitive Product shall not have access to, and shall not refer to, rely upon or use in any manner, the Intellectual Property Rights owned by Taro or its Affiliates that are necessary for the Commercialization of the Product under the NDA provided to Xeris on the Closing Date with respect to such Competitive Product."

(d) Section 8.1 of the Purchase Agreement is deleted in its entirety and new Section 8.1 is inserted in lieu thereof as follows:

"8.1 Notices. Notices required or permitted under this Agreement shall be in writing and sent by prepaid registered or certified air mail or by overnight express mail (e.g., FedEx) or by electronic mail confirmed by electronic mail (including an electronic "read receipt" notice) and shall be deemed to have been

properly served to the addressee (A) upon delivery in the case of prepaid registered or certified air mail or by overnight express mail or (B) upon receipt of written confirmation in the case of electronic mail, to the following addresses of the Parties or such other address(es) as such Party may hereafter specify by written notice to the other Party in accordance herewith:

If to Xeris on or before May 1, 2023:
Xeris Pharmaceuticals, Inc.
180 N. LaSalle St., Suite 1600
Chicago, IL 60601
Attention: Legal Department
Attention: Technical Operations

With a copy to: [***]

If to Xeris after May 1, 2023:
Xeris Pharmaceuticals, Inc.
1375 West Fulton Street, Suite 1300
Chicago, IL 60607
Attention: Legal Department
Attention: Technical Operations

With a copy to: [***]

If to Taro:

Taro Pharmaceuticals North America, Inc.
Harbour Place
103 South Church Street
Grand Cayman KY1-1202
Cayman Islands
Attention: General Manager

With a copy to:

Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, NY 10532
Attention: General Counsel"

(e) Section 8.12(a) of the Purchase Agreement is amended by deleting the first sentence thereof in its entirety and inserting in lieu thereof a new sentence as follows:

"The Parties will attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between senior representatives of each Party appointed by such Party."

4. Amendment of Supply Agreement. As of the Amendment Effective Date, the Parties agree that the Supply Agreement is hereby amended as follows:

(a) All references in the Supply Agreement to an Agreement means such Agreement as amended by this Assignment and Amendment.

(b) All references in the Supply Agreement to "Strongbridge" are changed to "Xeris".

(c) Section 1.1 of the Supply Agreement is amended by inserting in alphabetical order a new defined term as follows:

"Unlabeled Product" means Product which has not yet been Labeled, i.e. "brite stock", which Buyer has requested Seller store unLabeled at Seller's Affiliate's Facility until such time as Buyer instructs Seller to Label such product and deliver it to Buyer pursuant to Section 3.7 of this Agreement."

(d) Section 3.1 of the Supply Agreement is amended by inserting new clause (d) immediately following clause (c) thereof as follows:

"(d) Upon the request of Buyer, Seller shall Label Unlabeled Product in accordance with this Agreement for a labeling fee to be agreed in writing by the Parties. Following Labeling, the Product shall be delivered to Buyer in accordance with Section 3.7 of this Agreement."

(e) Section 3.7(c) of the Supply Agreement is amended by deleting such section in its entirety and inserting in lieu thereof new Section 3.7(c) as follows:

"(c) Title and risk of loss of Product shall automatically transfer to Buyer when Seller loads the shipment onto Buyer's designated carrier's transport vehicle and Buyer shall bear all risk of loss associated with the Product thereafter; provided, however, that title and risk of loss of Unlabeled Product shall automatically transfer to Buyer upon Buyer's quality assurance acceptance of such Unlabeled Product following Buyer's receipt of complete and accurate manufacturing and primary packaging records from Seller, provided that Buyer should confirm its quality assurance acceptance within [***] of its receipt thereof. In addition, Seller (or its Affiliate) shall provide an invoice to Buyer for each lot of Unlabeled Product upon Buyer's quality assurance acceptance thereof. Seller will store Product and for a storage fee to be agreed by the Parties in writing, Unlabeled Product, at its Affiliate's Facility or such other location as the Parties may agree from time to time in writing in accordance with the Quality Agreement. Seller will send Buyer electronic copies of the batch records, certificates of analysis and certificate of conformance (i) relating to the Product on or before the date of delivery and, (ii) other than with respect to the certificate of conformance which will only be delivered following Labeling, relating to the Unlabeled Product prior to storage."

(f) Section 6.2(b) of the Supply Agreement is amended by deleting the first sentence thereof in its entirety and inserting in lieu thereof a new sentence as follows:

"The Parties shall not disclose, directly or indirectly, in any manner whatsoever to any Third Parties any Confidential Information received from the other Party (or its Affiliates, as applicable) (the "Disclosing Party") without first obtaining the written consent of the Disclosing Party, and the other Party ("Recipient") shall keep confidential, all of the Disclosing Party's Confidential Information that is disclosed to Recipient except that Recipient may disclose Confidential Information (a) as otherwise agreed in writing by the Disclosing Party, (ii) as expressly permitted by this Section 6.2 and (iii) to third parties who are not competitors of the Disclosing Party or its Affiliates in connection with due diligence or similar investigations by such third parties, and disclosures to potential third party investors and lenders in confidential financing or loan documents, provided, in each case, that any such third party agrees to be bound by reasonable obligations of confidentiality and non-use and such third party is not a competitor of the Disclosing Party or its Affiliates."

(g) Section 7.1 of the Supply Agreement is amended by deleting the first sentence thereof in its entirety and inserting in lieu thereof a new sentence as follows:

"This Agreement shall become effective as of the Effective Date and, unless sooner terminated pursuant to Section 7.2 below, shall continue in full force and effect thereafter until March 13, 2027 (the "Initial Term") and, thereafter, shall automatically renew for additional two (2) year periods ("Extension Term")

on the same terms unless at least nine (9) months prior to the expiration of the then current Term: (a) a Party makes a written request to the other Party to discuss in good faith new terms for the Agreement for the Extension Term; or (b) a Party notifies the other Party in writing that it desires to terminate the Agreement."

(h) Section 8.2(a) of the Supply Agreement is amended by deleting the first sentence thereof in its entirety and inserting in lieu thereof a new sentence as follows:

"The Parties will attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between senior representatives of each Party appointed by such Party."

(i) Section 9.10 of the Supply is deleted in its entirety and new Section 9.10 is inserted in lieu thereof as follows:

"9.10 Notices. Notices required or permitted under this Agreement shall be in writing and sent by prepaid registered or certified air mail or by overnight express mail (e.g., FedEx) or by electronic mail confirmed by electronic mail (including an electronic "read receipt" notice) and shall be deemed to have been properly served to the addressee (A) upon delivery in the case of prepaid registered or certified air mail or by overnight express mail or (B) upon receipt of written confirmation in the case of electronic mail, to the following addresses of the Parties or such other address(es) as such Party may hereafter specify by written notice to the other Party in accordance herewith:

If to Buyer on or before May 1, 2023:
Xeris Pharmaceuticals, Inc.
180 N. LaSalle St., Suite 1600
Chicago, IL 60601
Attention: Legal Department
Attention: Technical Operations

With a copy to: [***]

If to Buyer after May 1, 2023:
Xeris Pharmaceuticals, Inc.
1375 West Fulton Street, Suite 1300
Chicago, IL 60607
Attention: Legal Department
Attention: Technical Operations

With a copy to: [***]

If to Seller:

Taro Pharmaceuticals North America, Inc.
Harbour Place
103 South Church Street
Grand Cayman KY1-1202
Cayman Islands
Attention: General Manager

With a copy to:

Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive

Hawthorne, NY 10532
Attention: General Counsel"

5. Joinder. By executing this Assignment and Amendment, each of Taro, the Assignor and the Assignee agrees as of the Amendment Effective Date to be bound by the terms of that certain Mutual Confidential Disclosure Agreement dated July 13, 2016, between Taro Pharmaceuticals U.S.A., Inc. ("***Taro USA***") and Strongbridge plc as if Taro, Assignor and Assignee were each an original signatory thereto.

6. Authority. Each Party represents and warrants that it has the necessary power and authority to enter into and perform its obligations under this Assignment and Amendment and the Agreements, as amended by this Assignment and Amendment, and upon execution, this Assignment and Amendment will be a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms. Each Party further represents and warrants that the execution, delivery and performance of this Assignment and Amendment and the Agreements, as amended by this Assignment and Amendment, do not and will not (i) require any consent or approval of its stockholders, (ii) violate any provision of any Applicable Law (as defined in the Supply Agreement) or any provision of its certificate of incorporation, by-laws or other founding document, or (iii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected. In addition, each Party represents and warrants that it (and its Affiliates) are not currently debarred, suspended or otherwise excluded by any government agency from receiving government contracts in the Territory (as defined in the Supply Agreement), nor is it, or its Affiliates or any of its employees debarred under the applicable provisions of the Food, Drug, and Cosmetic Act.

7. Assignor Assistance. Assignor agrees that, upon request and without any compensation, Assignor will cooperate and do all actions, including without limitation, the execution of papers that may be necessary or reasonably requested by Assignee or Taro to assist in the transition of the services from Assignor to Assignee.

8. Consent. Taro hereby consents to the assignment set forth in Section 1 above. Taro agrees to continue to be bound by Taro's respective obligations under the Agreements, including after giving effect to this Assignment and Amendment.

9. Governing Law. This Assignment and Amendment shall be governed by and construed in accordance with the laws of the State of New York, United States without regard to its conflicts of laws principles.

10. Amendments. This Assignment and Amendment may not be amended, waived or terminated without the written consent of all Parties.

11. Successors. This Assignment and Amendment shall be binding upon and inure to the benefit of the Parties hereto and their respective heirs, successors and assigns.

12. Entire Agreement. Each Party acknowledges that this Assignment and Amendment constitutes the entire agreement of the Parties relating to the subject matter hereof and supersedes all previously writings and understandings, whether written or oral, with respect to the subject matter hereof.

13. Severability. If any part of this Assignment and Amendment is declared invalid by any legally governing authority having jurisdiction over a Party, then such declaration shall not affect the remainder of this Assignment and Amendment and the Parties shall revise the invalidated part in a manner that will render such provision valid without impairing the Parties' original intent.

14. Recitals. The recitals set forth above are incorporated into and made part of this Assignment and Amendment.

15. Full Force and Effect. Except as amended herein, each Agreement shall remain unchanged and in full force and effect in accordance with such Agreement's original terms.

SIGNATURES ON NEXT PAGE

IN WITNESS WHEREOF, the Parties have each caused a duly authorized representative to execute this Assignment and Amendment as of the Amendment Effective Date.

Strongbridge Dublin Limited, Assignor:

/s/John Shannon

Authorized Signature

John Shannon

Typed or Printed Name

Director

Title

3/13/2023
Date

Xeris Pharmaceuticals, Inc., Assignee:

/s/John Shannon

Authorized Signature

John Shannon

Typed or Printed Name

Director

Title

3/13/2023
Date

Taro Pharmaceuticals North America, Inc.:

/s/Avi Avramoff

Authorized Signature

Avi Avramoff

Typed or Printed Name

VP Head of R&D

Title

3/10/2023
Date

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

Execution Version

OMNIBUS AMENDMENT NO. 2 TO ASSET PURCHASE AGREEMENT AND SUPPLY AGREEMENT

This **OMNIBUS AMENDMENT NO. 2 TO ASSET PURCHASE AGREEMENT AND SUPPLY AGREEMENT** (this "***Amendment***"), effective as of March 13, 2023 (the "***Amendment Effective Date***"), is entered into by and amongst Xeris Pharmaceuticals, Inc., having an address at 180 N. LaSalle St., Suite 1600, Chicago, Illinois 60601 (as successor-by-assignment to Strongbridge Dublin Limited as successor-by-transfer to Strongbridge Biopharma plc, "***Xeris***" or "***Buyer***"), and Taro Pharmaceuticals North America, Inc., having an address at Harbour Place, 103 South Church Street, Grand Cayman KY1-1202, Cayman Islands ("***Taro***" or "***Seller***"). Xeris and Taro are each referred to herein as a "***Party***" and collectively as the "***Parties***."

W- I- T-N- E- S- S- E- T- H

WHEREAS, Xeris and Taro entered into that certain (i) Asset Purchase Agreement effective December 12, 2016, as amended by the Ominibus Assignment and Assumption Agreement and Amendment No. 1 effective as of March 13, 2023 (the "***Purchase Agreement***") and (ii) Supply Agreement effective December 12, 2016, as amended by the Ominibus Assignment and Assumption Agreement and Amendment No. 1 effective as of March 13, 2023 (the "***Supply Agreement***" and, together with the Purchase Agreement, the "***Agreements***");

WHEREAS, the Parties wish to amend the Agreements in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. Amendment of Purchase Agreement. As of the Amendment Effective Date, the Parties agree that the Purchase Agreement is hereby amended as follows:

(a) By updating all references in the Purchase Agreement to an Agreement to mean such Agreement as amended by this Amendment.

(b) By inserting in Section 1.1 in alphabetical order a new defined term as follows:

"Second Amendment Effective Date" means March 13, 2023.

(c) By deleting the defined term "Product" in Section 1.1 of the Purchase Agreement in its entirety and inserting in lieu thereof a new defined term "Product" as follows:

"Product" means the pharmaceutical product approved for Commercialization in the U.S. under the NDA and marketed (x) under the Product Trademark in the Territory and, as applicable, (y) after the Second Amendment Effective Date, as an authorized generic in the Territory; provided, however, that for purposes of Sections 2.3, 4.1 and 4.2 the term "Product" shall not include this clause (y)."

(d) By inserting new clause (e) immediately following clause (d) of Section 2.6 as follows:

"(e) For the avoidance of doubt, Section 2.6 shall not survive the termination or expiration of this Agreement."

(e) The last sentence in Section 4.3(a) of the Purchase Agreement is deleted and replaced by the following sentence:

"Commencing on January 15, 2018 and on each anniversary thereafter through January 15, 2027, Xeris will provide reasonable documentation demonstrating its compliance under Schedule 4.3."

(f) Schedule 4.3 of the Purchase Agreement is deleted in its entirety and new Schedule 4.3 hereto is inserted in lieu thereof.

2. Amendment of Supply Agreement. As of the Amendment Effective Date, the Parties agree that the Supply Agreement is hereby amended as follows:

(a) By updating all references in the Supply Agreement to an Agreement to mean such Agreement as amended by this Amendment.

(b) By inserting in Section 1.1 in alphabetical order a new defined term as follows:

"Authorized Generic" has the meaning set forth in the defined term "Product"."

(c) By deleting the defined term "Product" in Section 1.1 of the Supply Agreement in its entirety and inserting in lieu thereof a new defined term "Product" as follows:

"Product" means, as the context requires, the following finished products Manufactured for sale in the Territory: (x) KEVEYIS® (dichlorophenamide) 50 mg tablets in labeled final packaging in accordance with the Specifications and/or (y) dichlorophenamide 50 mg tablets in labeled final packaging in accordance with the Specifications and marketed without the Product Trademark as an authorized generic (the "Authorized Generic").

(d) By deleting the penultimate sentence in Section 3.1(a) and inserting in lieu thereof a new sentence as follows:

"Buyer agrees to exclusively purchase from Seller and Seller agrees to exclusively sell to Buyer, the Product for sale in the Territory."

(e) By inserting at the end of the first sentence of Section 3.2(a) immediately before the period the following new text:

", including the quantity of Product which shall constitute Unlabeled Product or Authorized Generic"

(f) By deleting the first two sentences of Section 3.2(c) of the Supply Agreement in their entirety and inserting in lieu thereof a new second sentence as follows:

"Except as otherwise specified below, Buyer shall deliver a purchase order not less than one hundred twenty (120) days prior to the requested delivery date for the Product ("Purchase Order"). Each Purchase Order shall specify the quantities of Product requested (including any quantities of Unlabeled Product or Authorized Generic requested) and except in the case of Unlabeled Product, the delivery date and the destination for delivery of the Product. In the case of Unlabeled Product which is in storage, Buyer shall deliver to Seller a subsequent Purchase Order specifying the Labeling, delivery date and the destination for delivery of the Product not less than forty-five (45) days prior to the requested delivery date for the Unlabeled Product."

(g) By inserting new clause (vii) immediately following clause (vi) in Section 3.3 as follows:

"(vii) Contract Years 2023-2026: For each Contract Year, the number of Units of Product equal to (i) prior to the first sale of a Generic Product, [***] Units of Product and (ii) following the first sale of a Generic Product in the Territory[***] of the Units of Product purchased by Buyer hereunder during the immediately preceding Contract Year (e.g. if in Contract Year 2022, Buyer purchased [***] Units of Product and a Generic Product sale takes place in 2023, then the Minimum Order Quantity for Contract Year 2023 would be [***] Units (i.e., [***] of [***] Units) of Product)."

(h) By deleting clause (b) of Section 3.3 and inserting in lieu thereof new clause (b) as follows:

"[Reserved]."

(i) By inserting at the end of Section 3.6 the following new sentence:

"The process for determining the initial Product labelling, the Authorized Generic labelling and the process for changing any such labelling (including any artwork changes) is set forth on Schedule 3.6. The Parties will use their Commercially Reasonably Efforts to implement any labeling changes within thirty (30) days of the date the labeling change was requested."

(j) By deleting Schedule 3.6 in its entirety and inserting in lieu thereof Schedule 3.6 hereto.

3. Authority. Each Party represents and warrants that it has the necessary power and authority to enter into and perform its obligations under this Amendment and the Agreements, as amended by this Amendment, and upon execution, this Amendment will be a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms. Each Party further represents and warrants that the execution, delivery and performance of this Amendment and the Agreements, as amended by this Amendment, do not and will not (i) require any consent or approval of its stockholders, (ii) violate any provision of any Applicable Law (as defined in the Supply Agreement) or any provision of its certificate of incorporation, by-laws or other founding document, or (iii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected. In addition, each Party represents and warrants that it (and its Affiliates) are not currently debarred, suspended or otherwise excluded by any government agency from receiving government contracts in the Territory (as defined in the Supply Agreement), nor is it, or its Affiliates or any of its employees debarred under the applicable provisions of the Food, Drug, and Cosmetic Act.

4. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of New York, United States without regard to its conflicts of laws principles.

5. Amendments. This Amendment may not be amended, waived or terminated without the written consent of all Parties.

6. Successors. This Amendment shall be binding upon and inure to the benefit of the Parties hereto and their respective heirs, successors and assigns.

7. Entire Agreement. Each Party acknowledges that this Amendment constitutes the entire agreement of the Parties relating to the subject matter hereof and supersedes all previously writings and understandings, whether written or oral, with respect to the subject matter hereof.

8. Severability. If any part of this Amendment is declared invalid by any legally governing authority having jurisdiction over a Party, then such declaration shall not affect the remainder of this Amendment and the Parties shall revise the invalidated part in a manner that will render such provision valid without impairing the Parties' original intent.

9. Recitals. The recitals set forth above are incorporated into and made part of this Amendment.

10. Full Force and Effect. Except as amended herein, each Agreement shall remain unchanged and in full force and effect in accordance with such Agreement's original terms.

SIGNATURES ON NEXT PAGE

IN WITNESS WHEREOF, the Parties have each caused a duly authorized representative to execute this Amendment as of the Amendment Effective Date.

Xeris Pharmaceuticals, Inc.:

/s/John Shannon

Authorized Signature

John Shannon

Typed or Printed Name

Director

Title

3/13/2023

Date

Taro Pharmaceuticals North America, Inc.:

/s/Avi Avramoff

Authorized Signature

Avi Avramoff

Typed or Printed Name

VP Head of R&D

Title

3/10/2023

Date

SCHEDULE
4.3
MARKETING COMMITMENT

	2017	2018	2019	2020	2021	2022 - 2027
Xeris SG&A Target*	[***]	[***]	[***]	[***]	[***]	[***]

* in millions of US dollars and as measured by GAAP accounting on Xeris Biopharma Holdings, Inc.'s Financial statements

SCHEDULE
3.6
PROCEDURE FOR INITIAL LABELING
AND ANY LABELING CHANGE

Initial Product Labeling/Authorized Generic Labeling

Xeris provides files and artwork to Taro to design and/or implement changes to existing Product labels or to create Authorized Generic Label(s).

If Xeris Changing:

1. Taro provides files to Xeris to review and make DRAFT revisions
2. Taro receives artwork and Regulatory Reviews
3. Taro Regulatory responds with any further correction or revision requests depending on Xeris alterations
4. If no change request, routing within Taro internal artwork system is initiated within Production, Marketing and further Regulatory
5. If change requested, than first step is visited above and process continues through each point until agreed and approved
6. Artwork then sent to Xeris for Approval
7. Artwork then FTP'd and routed to vendor to create Proof
8. Proof sent to Xeris for approval
9. After approval vendor will print

If Taro Changes:

1. Taro graphics team seeks graphics material from Xeris (text or branding requirements)
2. Taro graphics team makes proper DRAFT revisions
3. Taro Regulatory Reviews for any corrections or further revision needs
4. Taro sends artwork for Xeris to review for comment, approval and regulatory assessment to determine NDA reporting category
5. If no change request, routing within Taro internal artwork system is initiated within Production, Marketing and further Regulatory
6. If change request from Xeris, than step 2 is visited above and process continues through each point until agreed and approved
7. Artwork then FTP'd and routed to vendor for print

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: May 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: May 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 March 31, 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: May 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)