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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2024
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
Commission file number: 001-40880

XERIS BIOPHARMA HOLDINGS, INC.

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

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

(844) 445-5704
(Registrant's telephone number, including area code)
Not applicable
(Former name, former address and former fiscal year, if changed since last report)
Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of July 31, 2024, 148,998,825 shares, par value $0.0001 per share, of common stock were outstanding.

XERIS BIOPHARMA HOLDINGS, INC.

Index to Quarterly Report on Form 10-Q

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2024	December 31, 2023
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 57,604	$ 67,449
Short-term investments	19,964	5,002
Trade accounts receivable, net	42,440	39,197
Inventory	42,977	38,838
Prepaid expenses and other current assets	7,355	5,778
Total current assets	170,340	156,264
Property and equipment, net	5,833	5,971
Operating lease right-of-use assets	22,864	23,204
Goodwill	22,859	22,859
Intangible assets, net	104,343	109,764
Other assets	5,494	4,540
Total assets	$ 331,733	$ 322,602
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,798	$ 11,565
Current operating lease liabilities	5,307	3,495
Other accrued liabilities	23,494	23,510
Accrued trade discounts and rebates	23,275	22,149
Accrued returns reserve	16,197	14,198
Current portion of contingent value rights	420	19,109
Other current liabilities	997	1,167
Total current liabilities	75,488	95,193
Long-term debt, net of unamortized debt issuance costs	230,481	190,932
Non-current operating lease liabilities	34,016	34,764
Non-current contingent value rights	—	1,379
Deferred tax liabilities	3,324	2,268
Other liabilities	7,710	4,848
Total liabilities	351,019	329,384
Commitments and contingencies (Note 14)		
Stockholders' equity (deficit):		
Preferred stock—par value $0.0001, 25,000,000 shares and 25,000,000 shares authorized and no shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Common stock—par value $0.0001, 350,000,000 shares and 350,000,000 shares authorized as of June 30, 2024 and December 31, 2023, respectively; 148,936,727 and 138,130,715 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	15	14
Additional paid in capital	631,740	610,254
Accumulated deficit	(651,010)	(617,025)
Accumulated other comprehensive loss	(31)	(25)
Total stockholders' equity (deficit)	(19,286)	(6,782)
Total liabilities and stockholders' equity (deficit)	$ 331,733	$ 322,602

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Product revenue, net	$ 46,512	$ 36,893	$ 86,775	$ 69,158
Royalty, contract and other revenue	1,553	1,115	1,928	2,046
Total revenue	48,065	38,008	88,703	71,204
Costs and expenses:				
Cost of goods sold	7,790	7,555	13,761	12,874
Research and development	5,759	6,087	13,580	10,925
Selling, general and administrative	39,993	37,635	78,373	71,240
Amortization of intangible assets	2,710	2,710	5,421	5,421
Total costs and expenses	56,252	53,987	111,135	100,460
Loss from operations	(8,187)	(15,979)	(22,432)	(29,256)
Other income (expense):				
Interest and other income	1,291	1,223	3,214	2,523
Debt refinancing costs	—	—	(2,690)	—
Interest expense	(7,964)	(6,528)	(14,996)	(12,744)
Change in fair value of warrants	3	(14)	7	(14)
Change in fair value of contingent value rights	601	781	3,968	2,140
Total other expense	(6,069)	(4,538)	(10,497)	(8,095)
Net loss before income taxes	(14,256)	(20,517)	(32,929)	(37,351)
Income tax (expense) benefit	(749)	675	(1,056)	675
Net loss	$ (15,005)	$ (19,842)	$ (33,985)	$ (36,676)
Other comprehensive loss, net of tax:				
Unrealized losses on investments	5	(49)	(5)	(55)
Foreign currency translation adjustments	1	—	—	—
Comprehensive loss	$ (14,999)	$ (19,891)	$ (33,990)	$ (36,731)
Net loss per common share - basic and diluted	$ (0.10)	$ (0.14)	$ (0.24)	$ (0.27)
Weighted average common shares outstanding - basic and diluted	148,345,549	137,338,071	144,372,512	137,250,465

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	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
Net loss	—	—	—	—	(19,842)	(19,842)
Exercise of stock options	14,036	—	32	—	—	32
Vesting of restricted stock units (net of 13,525 shares withheld for tax)	129,033	—	(25)	—	—	(25)
Stock-based compensation	—	—	2,928	—	—	2,928
Issuance of common stock through employee stock purchase plan	577,784	—	549	—	—	549
Other comprehensive loss	—	—	—	(49)	—	(49)
Balance, June 30, 2023	138,012,130	$ 14	$ 605,151	$ (78)	$ (591,446)	$ 13,641

	Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2023	138,130,715	$ 14	$ 610,254	$ (25)	$ (617,025)	$ (6,782)
Net loss	—	—	—	—	(18,980)	(18,980)
Issuance of common stock to settle contingent value rights	7,525,048	1	15,802	—	—	15,803
Exercise of stock options	229,417	—	459	—	—	459
Vesting of restricted stock units (net of 1,437,592 shares withheld for tax)	2,339,223	—	(3,434)	—	—	(3,434)
Stock-based compensation	—	—	3,767	—	—	3,767
Other comprehensive loss	—	—	—	(11)	—	(11)
Balance, March 31, 2024	148,224,403	$ 15	$ 626,848	$ (36)	$ (636,005)	$ (9,178)
Net loss	—	—	—	—	(15,005)	(15,005)
Vesting of restricted stock units (net of 23,230 shares withheld for tax)	340,417	—	(51)	—	—	(51)
Stock-based compensation	—	—	4,233	—	—	4,233
Issuance of common stock through employee stock purchase plan	371,907	—	710	—	—	710
Other comprehensive gain	—	—	—	5	—	5
Balance, June 30, 2024	148,936,727	$ 15	$ 631,740	$ (31)	$ (651,010)	$ (19,286)

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (33,985)	$ (36,676)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	607	750
Amortization of intangible assets	5,421	5,421
Amortization of premium/discount on investments	(482)	(812)
Amortization of debt discount and debt issuance costs	1,380	1,107
Amortization of operating right-of-use assets	340	373
Deferred income tax expense (benefit)	1,056	(675)
Stock-based compensation	8,000	5,492
Change in fair value of contingent value rights	(3,968)	(2,140)
Changes in operating assets and liabilities:		
Trade accounts receivable	(3,243)	605
Prepaid expenses and other current assets	(1,577)	827
Inventory	(4,597)	(11,250)
Accounts payable	(6,063)	7,015
Other accrued liabilities	442	(11,206)
Accrued trade discounts and rebates	1,126	216
Accrued returns reserve	1,999	147
Supply agreement liabilities	—	(6,720)
Operating lease liabilities	1,064	5,961
Other	1,829	1,681
Net cash used in operating activities	(30,651)	(39,884)
Cash flows from investing activities:		
Capital expenditures	(561)	(1,786)
Purchases of investments	(29,486)	(43,741)
Sales and maturities of investments	15,000	10,000
Net cash used in investing activities	(15,047)	(35,527)
Cash flows from financing activities:		
Proceeds from debt refinancing	50,000	—
Payment of debt discount	(11,831)	—
Proceeds from issuance of employee stock purchase plan shares	710	549
Proceeds from exercise of stock awards	459	32
Repurchase of common stock withheld for taxes	(3,485)	(888)
Net cash provided by (used in) financing activities	35,853	(307)
Decrease in cash, cash equivalents and restricted cash	(9,845)	(75,718)
Cash, cash equivalents and restricted cash, beginning of year	71,674	126,314
Cash, cash equivalents and restricted cash, end of year	$ 61,829	$ 50,596

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

	Six Months Ended June 30,	
	2024	**2023**
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 8,320	$ 15,206
Supplemental schedule of non-cash activities:		
Issuance of common shares in settlement of CVR liability	$ 15,803	$ —

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

	As of June 30,	
	2024	**2023**
Cash flows from operating activities:		
Cash and cash equivalents	$ 57,604	$ 46,170
Restricted cash included in Other assets [(1)]	4,225	4,426
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 61,829	$ 50,596

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

See accompanying notes to condensed consolidated financial statements.

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

Note 1. Organization and nature of the business

Nature of business

Xeris Biopharma Holdings, Inc. ("Xeris Biopharma" or the "Company") is a growth-oriented biopharmaceutical company committed to improving 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; Recorlev, a cortisol synthesis inhibitor for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome approved by the Food and Drug Administration ("FDA") in December 2021; and Keveyis, the first therapy approved in the United States to treat hyperkalemic, hypokalemic, and related variants of Primary Periodic Paralysis ("PPP"). The Company also has a pipeline of development programs to bring new products forward using its proprietary formulation science, XeriSol and XeriJect.

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

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

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

Liquidity and capital resources

The Company has incurred operating losses since inception and has an accumulated deficit of $651.0 million as of June 30, 2024. 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 and existing working capital at June 30, 2024, 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, Recorlev and Keveyis. Market volatility resulting from geopolitical instability resulting from the ongoing military conflicts between Russia and Ukraine and Israel and Hamas, rising interest rates, inflationary pressures, the tightening of lending standards, 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, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on March 6, 2024.

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.

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

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").

Some items in the prior year financial statements may have been reclassified to conform to the current presentation. Reclassification had no effect on prior year net income or stockholders' equity.

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, Recorlev and Keveyis in the United States only.

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

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

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 both the three and six months ended June 30, 2024, four customers accounted for 97% of the Company's gross product revenue. For the three and six months ended June 30, 2023, four customers accounted for 97% and 96% of the Company's gross product revenue, respectively. At June 30, 2024 and December 31, 2023, the same four customers accounted for 96% and 99% of the trade accounts receivable, net, respectively.

New accounting pronouncements

Adopted accounting standard

In July 2023, the FASB issued ASU 2023-03, *Presentation of Financial Statements (Topic 205), Income Statement - Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation - Stock Compensation (Topic 718)*. This standard amends various SEC paragraphs in the Accounting Standards Codification to primarily reflect the issuance of SEC Staff Accounting Bulletin No. 120. Staff Accounting Bulletin No. 120 provides guidance to companies issuing share-based awards shortly before announcing material, nonpublic information to consider such material nonpublic information to adjust observable market prices if the release of material nonpublic information is expected to affect the share price. The standard does not provide any new guidance so there is no transition or effective date associated with it and therefore, the Company adopted this standard with no impact on the Company's financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This standard eliminates certain accounting models to simplify the accounting for convertible instruments, expands the disclosure requirements related to the terms and features of convertible instruments, and amends the guidance for the

derivatives scope exception for contracts settled in an entity's own equity. Consequently, more convertible debt instruments will be reported as a single liability instrument and more convertible preferred stock as a single equity instrument with no separate accounting for embedded conversion features. 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. The Company adopted ASU 2020-06 on January 1, 2024. Adoption of ASU 2020-06 did not impact the Company's financial position, results of operations or cash flows since the Company did not separately present in equity an embedded conversion feature in such debt but accounted for the convertible debt instrument wholly as debt.

Pending accounting standards

In March 2024, the FASB issued ASU 2024-02, *Codification Improvements - Amendments to Remove References to the Concept Statements*. This standard amends the Codification to remove references to various concepts statements and impacts a variety of topics in the Codification. The amendments apply to all reporting entities within the scope of the affected accounting guidance, but in most instances the references removed are extraneous and not required to understand or apply the guidance. Generally, the amendments in this standard are not intended to result in significant accounting changes for most entities. The standard is effective January 1, 2025 and is not expected to have a material impact on the Company's financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* This standard expands the requirements for income tax disclosures in order to provide greater transparency. The amendments are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The amendments should be applied prospectively. The Company is evaluating the timing and effects of the adoption of this standard on the Company's disclosures.

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

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements - Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative.* This Standard modifies the disclosure or presentation requirements of a variety of Topics in the Codification to align with the SEC's regulations. The ASU also makes those requirements applicable to entities that were not previously subject to the SEC's requirements. The ASU is effective for the Company two years after the effective date to remove the related disclosure from Regulation S-X or S-K. As of the date these financial statements have been made available for issuance, the SEC has not yet removed any related disclosure. The Company does not expect the adoption of this standard to have a material impact on the Company's financial statements.

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 does not expect the adoption of this standard to have a material impact on the Company's financial statements.

Note 3. Disaggregated revenue

Disaggregated revenue by product (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Product revenue:				
Gvoke	$ 20,046	$ 15,638	$ 36,625	$ 30,671
Keveyis	13,128	14,088	26,213	26,843
Recorlev	13,338	7,167	23,937	11,644
Product revenue, net	46,512	36,893	86,775	69,158
Royalty, contract and other revenue	1,553	1,115	1,928	2,046
Total revenue	$ 48,065	$ 38,008	$ 88,703	$ 71,204

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

Note 4. Short-term investments

The Company classifies investments in debt securities as available-for-sale. Debt securities are comprised of liquid investments that are highly rated securities and, as of June 30, 2024, consist of U.S. government securities, all with remaining maturities of less than one year. Debt securities as of June 30, 2024 had an average remaining maturity of 0.2 years. The debt securities are reported at fair value with unrealized gains or losses recorded in accumulated other comprehensive income (loss) in the condensed consolidated balance sheets. The cost of short-term investments is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion, as well as interest income, are included in interest and other income in the condensed consolidated statements of operations and comprehensive loss. Refer to "Note 11 - Fair value measurements," for information related to the fair value measurements and valuation methods utilized.

The following table represents the Company's short-term investments by major security type (in thousands):

	June 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Investments:				
U.S. government securities	$ 19,971	$ —	$ (7)	$ 19,964
Total available-for-sale investments	$ 19,971	$ —	$ (7)	$ 19,964

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

Allowance for Credit Losses

For available-for-sale securities in an unrealized loss position, the Company first assesses whether they are intended to be sold, or if it is more likely than not that the Company will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For available-for-sale securities that do not meet the above criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, market conditions, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive loss on the statements of operations and comprehensive loss. No credit loss allowance was recorded in the three and six months ended June 30, 2024 and 2023.

Note 5. Inventory

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

	June 30, 2024	December 31, 2023
Raw materials	$ 23,910	$ 17,404
Work in process	11,302	10,959
Finished goods	7,765	10,475
Inventory	$ 42,977	$ 38,838

Inventory reserves were $3.9 million and $2.4 million at June 30, 2024 and December 31, 2023, respectively.

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Note 6. Property and equipment

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

	June 30, 2024	December 31, 2023
Lab equipment	$ 4,600	$ 4,153
Furniture and fixtures	539	539
Computer equipment	826	860
Office equipment	97	97
Software	374	374
Leasehold improvements	6,040	5,984
Total property and equipment	12,476	12,007
Less: accumulated depreciation and amortization	(6,643)	(6,036)
Property and equipment, net	$ 5,833	$ 5,971

Depreciation and amortization expense relating to property and equipment was $0.3 million and $0.4 million for the three months ended June 30, 2024 and 2023, respectively. Depreciation and amortization expense relating to property and equipment was $0.6 million and $0.8 million for the six months ended June 30, 2024 and 2023, respectively.

Note 7. Intangible assets

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

		June 30, 2024			December 31, 2023		
	Life (Years)	Gross assets	Accumulated amortization	Net	Gross assets	Accumulated amortization	Net
Definite-lived intangible asset - Keveyis	5	$ 11,000	$ (6,050)	$ 4,950	$ 11,000	$ (4,950)	$ 6,050
Definite-lived intangible asset - Recorlev	14	121,000	(21,607)	99,393	121,000	(17,286)	103,714
Total intangible assets		$ 132,000	$ (27,657)	$ 104,343	$ 132,000	$ (22,236)	$ 109,764

As of June 30, 2024, expected amortization expense for intangible assets subject to amortization for the next five years and thereafter is as follows (in thousands):

2024 remaining	$ 5,422
2025	10,843
2026	10,293
2027	8,643
2028	8,643
Thereafter	60,499
Total	$ 104,343

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Note 8. Other accrued liabilities

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

	June 30, 2024	December 31, 2023
Accrued employee costs	$ 12,825	$ 16,956
Accrued interest expense	6,670	1,374
Accrued supply chain costs	441	523
Accrued marketing costs	803	598
Accrued research and development costs	621	960
Accrued other costs	2,134	3,099
Other accrued liabilities	$ 23,494	$ 23,510

Note 9. Long-term debt

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

	June 30, 2024	December 31, 2023
Convertible senior notes	$ 49,256	$ 49,306
Less: unamortized debt issuance costs	(1,186)	(1,400)
Loan agreement	184,722	145,569
Less: unamortized debt issuance costs	(2,311)	(2,543)
Long-term debt, net of unamortized debt issuance costs	$ 230,481	$ 190,932

Convertible senior notes

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

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

On September 29, 2023, the Company completed the exchange of $32.0 million in aggregate principal amount of the 2025 Convertible Notes for $33.6 million in aggregate principal amount of new 8.00% Convertible Notes due 2028 (the "2028 Convertible Notes" and together with the 2025 Convertible Notes, the "Convertible Notes"). As of June 30, 2024, the outstanding balance of the 2025 Convertible Notes was $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million.

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

The Convertible Notes are senior, unsecured obligations and are equal in right of payment with the issuer'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,

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including trade payables, and (to the extent the Company or Xeris Pharma is not a holder thereof) preferred equity, if any, of the Company's direct and indirect subsidiaries other than Xeris Pharma.

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

The fair value of the Convertible Notes is determined using current interest rates based on credit ratings and the remaining term of maturity. As of June 30, 2024, the fair value of the Convertible Notes was approximately $53.5 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 11 - Fair value measurement."

Loan agreement

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

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

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

On March 5, 2024, the Company, Xeris Pharma and certain subsidiary guarantors of the Company entered into an Amended and Restated Credit Agreement and Guaranty (the "Amended and Restated Credit Agreement") with the lenders from time to time parties thereto (the "New Lenders") and Hayfin Services LLP, as administrative agent for the New Lenders, pursuant to which the Company and its subsidiaries party thereto granted a first priority security interest on substantially all of their assets, including intellectual property, subject to certain exceptions. The Amended and Restated Credit Agreement amends and restates in its entirety the Hayfin Loan Agreement. The Amended and Restated Credit Agreement provided for the New Lenders to extend $200.0 million in term loans (the "Tranche 1 Loans") to Xeris Pharma on the closing date and $15.2 million in additional term loans (the "Tranche 2 Loans" and, together with the Tranche 1 Loans, the "2029 Loans") on any date after the closing date and through July 15, 2025. The Tranche 2 Loans may only be used to redeem the 2025 Convertible Notes. In conjunction with the execution of the Amended and Restated Credit Agreement, the aggregate principal balance of $150.0 million plus all accrued and unpaid interest outstanding under the Hayfin Loan Agreement was continued under the Amended and Restated Credit Agreement as Tranche 1 Loans. In addition to utilizing the proceeds to repay the obligations under the Hayfin Loan Agreement in full, the proceeds of the Tranche 1 Loans will otherwise be used for general corporate purposes. After repayment, the 2029 Loans may not be re-borrowed.

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

The 2029 Loans incur interest at a floating per annum rate in an amount equal to the sum of (i) 6.95% (or 5.95% if the replacement rate is in effect) plus (ii) the greater of (x) the forward-looking term rate based on SOFR for a three month tenor (or the replacement rate, if applicable), and (y) 2.00% per annum. The remaining balance of unamortized debt issuance costs have been reflected as a direct reduction to the loan balance. The effective interest rate of the 2029 Loans, including the amortization of debt discount and debt

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issuance costs, amounts to approximately 11.4%. The debt outstanding under the 2029 Loans approximates fair value due to the variable interest rate on the debt.

The Amended and Restated Credit Agreement allows Xeris Pharma to voluntarily prepay the outstanding amounts thereunder. Xeris Pharma is subject to an early prepayment fee equal to (i) for any prepayment that occurs on or prior to the second anniversary of the closing date, the applicable make-whole amount, (ii) for any prepayment that occurs after the second anniversary of the closing date but on or prior to the fourth anniversary of the closing date, the product of (x) the amount of any principal so prepaid, multiplied by (y) for any prepayment that occurs (A) after the second anniversary of the closing date and on or prior to the third anniversary of the closing date, five percent (5.00%), (B) after the third anniversary of the closing date and on or prior to the fourth anniversary of the closing date, three percent (3.00%), and (C) after the fourth anniversary of the closing date, zero percent (0.00%).

The Amended and Restated Credit Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's (and its subsidiaries) ability to incur additional indebtedness, grant liens, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions.

The Amended and Restated Credit Agreement was accounted for as a modification of debt in accordance with ASC 470-50, *Debt - Modifications and Extinguishments*, thus there was no gain or loss recognized on the transaction.

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

2024 remaining	$	—
2025		15,200
2026		—
2027		—
2028		33,574
Thereafter		200,000
	$	248,774

For the three and six months ended June 30, 2024, the Company recognized interest expense of $8.0 million and $15.0 million, respectively, of which $0.8 million and $1.4 million, respectively, related to the amortization of debt discount and issuance costs, respectively. For the three and six months ended June 30, 2023, the Company recognized interest expense of $6.5 million and $12.7 million, respectively, of which $0.6 million and $1.1 million, respectively, related to the amortization of debt discount and issuance costs, respectively. Debt refinancing costs related to advisory and legal fees of $2.7 million were recorded in the condensed consolidated statements of operations and comprehensive loss for the six months ended June 30, 2024.

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Note 10. Warrants

As of June 30, 2024, the following warrants were outstanding:

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

Note 11. 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.

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The following tables present the Company's fair value hierarchy for those assets and liabilities measured at fair value as of June 30, 2024 and December 31, 2023 (in thousands):

	Total as of June 30, 2024	Level 1	Level 2	Level 3
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 57,604	$ 57,604	$ —	$ —
Investments:				
U.S. government securities	$ 19,964	$ 19,964	$ —	$ —
Other assets:				
Restricted cash	$ 4,225	$ 4,225	$ —	$ —
Liabilities				
Contingent value rights - current	$ 420	$ —	$ —	$ 420
Warrant liabilities	$ 1	$ —	$ —	$ 1

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

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.

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As of June 30, 2024, there were approximately 74.4 million CVRs outstanding. Up to 8.1 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 2023 Keveyis milestone was achieved, triggering a milestone payment to CVR holders. In settlement of the milestone payment obligation, the Company issued 7,525,048 shares of common stock. The 2023 Recorlev Milestone was not achieved. A gain of $3.0 million from the remeasurement of the CVR liability was recorded in the first quarter of 2024 in the condensed consolidated statements of operations and comprehensive loss as a result of changes in the Company's stock price prior to the issuance of the common stock in settlement of the CVR.

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, 2023	$	20,488
CVR settlement		(16,100)
Change in fair value of CVRs		(3,968)
Balance at June 30, 2024	$	420

Note 12. Stock compensation plan

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

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

As of June 30, 2024, there were 1.8 million shares of common stock available for future issuance under the 2018 Plan.

The 2018 Employee Stock Purchase Plan (the "ESPP") was adopted by the Board of Directors in April 2018 and approved by the Company's stockholders in June 2018 to issue up to 193,000 shares of common stock to participating employees. Through the ESPP, eligible employees may authorize payroll deductions of up to 15% of their compensation to purchase up to the number of shares of common stock determined by dividing $25,000 by the closing market price of Xeris common stock on the offering date. The purchase price per share at each purchase date is equal to 85% of the lower of (i) the closing market price per share of Xeris common stock on the employee's offering date or (ii) the closing market price per share of Xeris common stock on the purchase date. Each offering period has a six-month duration and purchase interval. As of June 30, 2024, there were 14.2 thousand shares available for issuance under the ESPP.

The Equity Inducement Plan (the "Inducement Plan") was adopted by the Board of Directors in February 2019. The Inducement Plan allows the Company to make stock option or restricted stock unit awards to prospective employees of the Company as an inducement to such individuals to commence employment with the Company. The Company uses this Inducement Plan to help it attract and retain prospective employees who are necessary to support the commercialization of products and the expansion of the Company generally. As of June 30, 2024, there were 1.6 million shares of common stock available for future issuance under the Inducement Plan.

Assumed Plans

On the acquisition date of Strongbridge, the Company assumed all then-outstanding stock options and shares available and reserved for issuance under some legacy equity incentive plans of Strongbridge, including the Strongbridge 2015 equity compensation plan and Strongbridge 2017 inducement plan (collectively, the "Assumed Plans"). Shares reserved under the Assumed Plans will be available for future grants. The Company also assumed all then-outstanding stock options from the rest of the legacy equity incentive plans of Strongbridge without assuming the shares available and reserved for issuance under these plans. The number of shares subject to stock options outstanding under all Strongbridge legacy equity incentive plans are included in the tables below. As of June 30, 2024, there were 102.1 thousand shares reserved for future grants under the Assumed Plans.

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Stock options

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

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

Stock option activity under the 2011 Plan, 2018 Plan, Inducement Plan and Assumed Plans for the six months ended June 30, 2024 was as follows:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)
Outstanding - December 31, 2023	9,199,744	$5.22	3.84
Exercised	(229,417)	2.00	
Forfeited	(190)	4.98	
Expired	(26,962)	5.44	
Outstanding - June 30, 2024	8,943,175	$5.29	3.31
Vested and expected to vest at June 30, 2024	8,943,175	$5.29	3.31
Exercisable - June 30, 2024	8,840,519	$5.30	3.27

At June 30, 2024, there was a total of $0.3 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 0.5 years.

Restricted Stock Units

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

A summary of outstanding RSU awards and the activity for the six months ended June 30, 2024 was as follows:

	Number of Units	Weighted Average Grant Date Fair Value Per Share
Unvested balance - December 31, 2023	11,579,548	$ 1.83
Granted	9,614,250	2.45
Vested	(4,140,462)	2.15
Forfeited	(287,447)	2.02
Unvested balance - June 30, 2024	16,765,889	$ 2.10

As of June 30, 2024, there was $28.0 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over the weighted-average remaining vesting period of 2.0 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 382	$ 632	719	954
Selling, general and administrative	3,851	2,296	7,281	4,538
Total stock-based compensation expense	$ 4,233	$ 2,928	$ 8,000	$ 5,492

Note 13. Leases

The Company has non-cancellable operating leases for office and laboratory space, which expire at various times in 2031 and 2036. The non-cancellable lease agreements provide for monthly lease payments, which increase during the term of each lease agreement.

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

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

As the interest rate implicit in the lease is not readily determinable, the Company uses the incremental borrowing rate as the discount rate. The Company considers observable inputs as of the effective date of the ASC 842 adoption including the credit rating, existing borrowings and other relevant borrowing rates, such as risk-free rates like the United States Treasury rate, and then adjusting as necessary for the appropriate lease term. The incremental borrowing rate is reassessed if there is a change to the lease term or if a modification occurs and it is not accounted for as a separate contract. As of June 30, 2024, the Company's operating leases had a weighted-average remaining lease term of 11.2 years and a weighted-average discount rate of 11.9%.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows for operating leases	$ 839	$ 440	$ 1,204	$ 918
Right of use assets obtained in exchange for new lease obligations:				
Operating leases	$ —	$ 20,043	$ —	$ 20,043

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Lease cost	2024	2023	2024	2023
Operating lease expense	$ 1,340	$ 1,350	$ 2,680	$ 1,763
Variable lease cost	325	302	566	652
Sublease income	(52)	(54)	(105)	(108)
Total lease cost	$ 1,613	$ 1,598	$ 3,141	$ 2,307

As of June 30, 2024, maturities of lease liabilities are summarized as follows (in thousands):

2024 remaining	$ 2,290
2025	6,080
2026	6,232
2027	6,389
2028	6,549
Thereafter	45,441
Total lease payments	72,981
Less: Effect of discounting to net present value	(33,658)
Present value of lease liabilities	$ 39,323

Operating lease liabilities, current	$ 5,307
Operating lease liabilities, non-current	34,016
Total operating lease liabilities	$ 39,323

Note 14. Commitments and contingencies

Commitments

Commitments to Taro

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

Leases

As of June 30, 2024, the Company had unused letters of credit of $4.2 million, which were issued primarily to secure leases. These letters of credit are collateralized by $4.2 million of restricted cash, which is recorded in other assets in the condensed consolidated balance sheets.

Contingencies

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of June 30, 2024, 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 (i) the 2025 Convertible Notes are still outstanding as of January 15, 2025 or (ii) the 2028 Convertible Notes are still outstanding as of January 15, 2028 and, in each case, the maturity date has not been extended to a date not earlier than September 5, 2029, then unless the Company has received net cash proceeds from one or more permitted equity raises or permitted raises of convertible debt which, together with no more than $15.6 million of cash on hand, is sufficient to redeem and discharge the 2025 Convertible Notes or 2028 Convertible Notes, as applicable, in full, the loans outstanding under the Amended and Restated Credit

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Agreement will mature on January 15, 2025 in the case of outstanding 2025 Convertible Notes and January 15, 2028 in the case of outstanding 2028 Convertible Notes. As disclosed in "Note 9 - Long-term debt", the Amended and Restated Credit Agreement provided for the New Lenders to extend $15.2 million Tranche 2 Loans on any date after March 5, 2024 and through July 15, 2025 solely for the purpose of redeeming the 2025 Convertible Notes.

Note 15. Net loss per common share

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

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

	As of June 30,	
	2024	**2023**
Shares to be issued upon conversion of Convertible Notes	15,939,216	15,416,667
Vested and unvested stock options	8,943,175	9,307,846
Restricted stock units	16,765,889	10,602,771
Warrants	8,362,270	8,362,270
Total anti-dilutive securities excluded from EPS computation [(1)]	50,010,550	43,689,554

[(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 6, 2024 with the U.S. Securities and Exchange Commission. In addition to financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. All statements in this document other than statements of historical fact are, or could be, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "will," "would," "may," "should," "expects," "focus," "goal," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," and terms of similar meaning are also generally intended to identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including without limitation, the regulatory approval of our product candidates, our ability to market and sell our products and product candidates if approved, and factors discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2023 and elsewhere in 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.

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.

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.

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

Our proprietary formulation capabilities

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

Development of product candidates

Once Weekly Subcutaneous Injection of Levothyroxine (XP-8121)

XP-8121 is a novel formulation for subcutaneous administration that could potentially mitigate many of the challenges associated with oral formulations, such as identification of an ideal dose due to absorption variation and medication adherence for patients who have difficulty maintaining a stable, therapeutic serum level. Preclinical studies of XP-8121 showed a sustained plasma exposure profile and similar highest concentration of a drug in the blood, or Cmax, when compared with equivalent doses of the oral formulation. We conducted a Phase 1 study of XP-8121 to evaluate the pharmacokinetics, safety and tolerability, and potential for weekly dosing in the treatment of hypothyroidism.

Levothyroxine and Hypothyroidism

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

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

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

In October 2022, we reported positive topline Phase 1 data of XP-8121. The data showed that subjects receiving XP-8121 subcutaneous had slower absorption, lower peak plasma, and higher extended exposure compared to Synthroid PO at the comparable dose of 600 µg. In addition, exposure was proportional over the range of ascending XP-8121 doses studied. Simulations based on a population pharmacokinetic model indicated that exposure from weekly XP-8121 1200 µg SC doses overlapped daily Synthroid PO 300 µg suggesting a dose conversion factor of 4x. Importantly, single SC doses of XP-8121 at all doses were generally well-tolerated and the XP-8121 doses studied were generally comparable to Synthroid 600 µg PO with respect to the safety findings. In June 2023, we initiated a non-randomized, open-label, single arm, self-controlled Phase 2 study to determine a target dose conversion factor from stably dosed oral levothyroxine to XP-8121 in patients with hypothyroidism and also assess the safety and tolerability after once-weekly subcutaneous injections. The data established an average once-weekly SC dose of XP-8121 and confirmed previous Phase 1 study of a 4x target dose conversion factor when switching from once-daily oral administration of levothyroxine. Participants who completed the study rated higher treatment satisfaction with XP-8121 compared to oral and a majority (72%) indicated a strong

preference for the subcutaneous route of administration. An FDA End-of-Phase 2 interaction to facilitate a Phase 3 pivotal study program is expected by year-end.

Patents

We currently own 178 patents issued globally, including composition of matter patents covering our ready-to-use glucagon formulation that expire in 2036. Included in the total patents, we have 64 granted patents globally related to our platform technologies and 8 patents granted in the United States and listed in the United States FDA Orange Book covering proprietary formulations of levoketoconazole (the active pharmaceutical ingredient in Recorlev) and the uses of such formulations in treating certain endocrine-related diseases and syndromes. The latter includes United States Patent Nos. 11,020,393, 11,278,547 and 11,903,940, which were granted on June 1, 2021, March 22, 2022, and February 20, 2024, respectively, and which provide patent protection through 2040 for the use of Recorlev in the treatment of certain patients with persistent or recurrent Cushing's syndrome.

Financing

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

For the six months ended June 30, 2024 and June 30, 2023, we reported net losses of $34.0 million and $36.7 million, respectively. We have not been profitable since inception, and, as of June 30, 2024, our accumulated deficit was $651.0 million. In the near term, we expect to continue to incur significant expenses, operating losses and net losses as we:

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

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

Components of our Results of Operations

The following discussion sets forth certain components of the statement of operations of Xeris for the three and six months ended June 30, 2024 and 2023 as well as factors that impact those items.

Product revenue, net

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

Royalty, contract and other revenue

Royalty and contract revenue is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured. Revenue generated from various collaboration and technology partnerships are included in this line.

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 products and product candidates. We recognize research and development expenses as incurred. Expenses that are paid in advance of performance are capitalized until services are provided or goods are delivered. We track external research and development costs by project, however, personnel related expenses related to research and development are not allocated by project. Research and development expenses include:

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

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

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

Selling, general and administrative expenses

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

Amortization of intangible assets

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

Other income (expense)

Other income (expense) consists primarily of interest expense related to our convertible debt, senior secured credit facility, interest income earned on deposits and investments, debt refinancing costs and gains and losses on the change in fair value of the CVRs.

Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2024	2023	$	%	2024	2023	$	%
Product revenue:								
Gvoke	$ 20,046	$ 15,638	$ 4,408	28.2	$ 36,625	$ 30,671	$ 5,954	19.4
Keveyis	13,128	14,088	(960)	(6.8)	26,213	26,843	(630)	(2.3)
Recorlev	13,338	7,167	6,171	86.1	23,937	11,644	12,293	105.6
Product revenue, net	46,512	36,893	9,619	26.1	86,775	69,158	17,617	25.5
Royalty, contract and other revenue	1,553	1,115	438	39.3	1,928	2,046	(118)	(5.8)
Total revenue	48,065	38,008	10,057	26.5	88,703	71,204	17,499	24.6
Cost and expenses:								
Cost of goods sold, excluding amortization of intangible assets	7,790	7,555	235	3.1	13,761	12,874	887	6.9
Research and development	5,759	6,087	(328)	(5.4)	13,580	10,925	2,655	24.3
Selling, general and administrative	39,993	37,635	2,358	6.3	78,373	71,240	7,133	10.0
Amortization of intangible assets	2,710	2,710	—	—	5,421	5,421	—	—
Total cost and expenses	56,252	53,987	2,265	4.2	111,135	100,460	10,675	10.6
Loss from operations	(8,187)	(15,979)	7,792	(48.8)	(22,432)	(29,256)	6,824	(23.3)
Other income (expense):								
Interest and other income	1,291	1,223	68	5.6	3,214	2,523	691	27.4
Debt refinancing costs	—	—	—	nm	(2,690)	—	(2,690)	nm
Interest expense	(7,964)	(6,528)	(1,436)	22.0	(14,996)	(12,744)	(2,252)	17.7
Change in fair value of warrants	3	(14)	17	(121.4)	7	(14)	21	(150.0)
Change in fair value of contingent value rights	601	781	(180)	(23.0)	3,968	2,140	1,828	85.4
Total other expense	(6,069)	(4,538)	(1,531)	33.7	(10,497)	(8,095)	(2,402)	29.7
Net loss before benefit from income taxes	(14,256)	(20,517)	6,261	(30.5)	(32,929)	(37,351)	4,422	(11.8)
Income tax (expense) benefit	(749)	675	(1,424)	(211.0)	(1,056)	675	(1,731)	(256.4)
Net loss	$ (15,005)	$ (19,842)	$ 4,837	(24.4)	$ (33,985)	$ (36,676)	$ 2,691	(7.3)

nm: not meaningful

Product revenue, net

Gvoke

Net revenue increased by $4.4 million or 28.2% for the three months ended June 30, 2024 compared to the same period ended June 30, 2023. This change was due to an increase in volume ($3.7 million or 23.8%), primarily driven by prescription growth, and net pricing ($0.7 million or 4.4%).

Net revenue increased by $6.0 million or 19.4% for the six months ended June 30, 2024 compared to the same period ended June 30, 2023. This change was due to an increase in volume ($5.1 million or 16.6%), primarily driven by prescription growth, and net pricing ($0.9 million or 2.8%).

Keveyis

Net revenue decreased by $1.0 million or 6.8% for the three months ended June 30, 2024 compared to the same periods ended June 30, 2023. The decrease was due to lower volume ($1.3 million or 9.4%) partially offset by an increase in net pricing ($0.3 million or 2.6%).

Net revenue decreased by $0.6 million or 2.3% for the six months ended June 30, 2024 compared to the same periods ended June 30, 2023. The decrease was due to lower volume ($2.2 million or 8.3%) partially offset by an increase in net pricing ($1.6 million or 6.0%).

Recorlev

Net revenue increased by $6.2 million or 86.1% for the three months ended June 30, 2024 compared to the same period ended June 30, 2023. The increase was due to higher volume ($4.9 million or 67.9%) and an increase in net pricing ($1.3 million or 18.2%).

Net revenue increased by $12.3 million or 105.6% for the six months ended June 30, 2024 compared to the same period ended June 30, 2023. The increase was due to higher volume ($9.8 million or 84.3%) and an increase in net pricing ($2.5 million or 21.3%).

Cost of goods sold

Cost of goods sold increased by $0.2 million or 3.1% and $0.9 million or 6.9% for the three and six months ended June 30, 2024 compared to the same periods ended June 30, 2023, respectively.

Cost of goods sold as a percent of total product revenue decreased by 3.7%, to 16.7% for the three months ended June 30, 2024 compared to 20.5% for the same period ended June 30, 2023, primarily due to higher sales of products with a lower cost of goods sold ($0.7 million or 2.0%).

Cost of goods sold as a percent of total product revenue decreased by 2.8%, to 15.9% for the six months ended June 30, 2024 compared to 18.6% for the same period ended June 30, 2023, primarily due to higher sales of products with lower cost of goods sold ($1.3 million or 1.8%).

Research and development expenses

Research and development expenses decreased by $0.3 million or 5.4% for the three months ended June 30, 2024 compared to the same period ended June 30, 2023, primarily driven by lower spending for our pipeline ($0.5 million), primarily XP-8121 ($0.9 million) offset by other projects ($0.4 million), and our technology development ($0.6 million) offset by an increase in personnel related expenses ($0.4 million).

Research and development expenses increased by $2.7 million or 24.3% for the six months ended June 30, 2024 compared to the same period ended June 30, 2023, primarily driven by higher spending for our pipeline ($1.3 million) and personnel related expenses ($1.1 million).

The following table summarizes our research and development expenses by type for the three and six months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2024	2023	$	%	2024	2023	$	%
Project specific expenses:								
Pipeline	$ 941	$ 1,447	$ (506)	(35.0)%	$ 4,071	$ 2,782	$ 1,289	46.3 %
Technology development [1]	301	863	(562)	(65.1)%	840	1,008	(168)	(16.7)%
Personnel related expenses	3,579	3,185	394	12.4 %	7,007	5,926	1,081	18.2 %
Lab supplies and equipment depreciation	384	357	27	7.6 %	764	612	152	24.8 %
Other	554	235	319	135.7 %	898	597	301	50.4 %
Total	$ 5,759	$ 6,087	$ (328)	(5.4)%	$ 13,580	$ 10,925	$ 2,655	24.3 %

[1] Technology Development represents any investment in our proprietary technology platforms, XeriSol and XeriJect.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $2.4 million or 6.3% and $7.1 million or 10.0% for the three and six months ended June 30, 2024 compared to the same periods ended June 30, 2023, respectively, due to higher personnel costs.

Amortization of intangible assets

For the three and six months ended June 30, 2024 and June 30, 2023, amortization of intangible assets were both $2.7 million and $5.4 million, respectively.

Other income (expense)

For the three and six months ended June 30, 2024, interest expense increased $1.4 million or 22.0% and $2.3 million or 17.7% compared to the same periods ended June 30, 2023, respectively. The increases in both periods were primarily due to a higher principal amount and increased interest rates.

For the three and six months ended June 30, 2024, change in fair value of contingent value rights was a gain of $0.6 million and $4.0 million, respectively, compared to $0.8 million and $2.1 million for the three and six months ended June 30, 2023, respectively. The gain in the first half of 2024 were primarily due to the remeasurement of the CVR liability as a result of changes in our stock price prior to issuance of the common stock issued in settlement of the CVR and the revaluation of the CVR liability related to Recorlev 2024 sales milestone.

For the six months ended June 30, 2024, deferred refinancing costs were $2.7 million related to the third party debt arrangements for advisory and legal fees.

Liquidity and Capital Resources

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

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

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

In September 2023, we completed the exchange of $32.0 million in aggregate principal amount of the 2025 Convertible Notes for $33.6 million in aggregate principal amount of the 2028 Convertible Notes. As of June 30, 2024, the outstanding balance of the 2025 Convertible Notes was $15.2 million and the outstanding balance of the 2028 Convertible Notes was $33.6 million.

In March 2024, we, Xeris Pharma and certain subsidiary guarantors, entered into an Amended and Restated Credit Agreement and Guaranty (the "Amended and Restated Credit Agreement") with the lenders from time to time parties thereto (the "New Lenders") and Hayfin Services LLP, as administrative agent for the New Lenders, pursuant to which the Company and its subsidiaries party thereto granted a first priority security interest on substantially all of their assets, including intellectual property, subject to certain exceptions. The Amended and Restated Credit Agreement amended and restated the Hayfin Loan Agreement in its entirety. The Amended and Restated Credit Agreement provided for the New Lenders to extend $200.0 million in term loans to the Company on the closing date and up to an additional $15.2 million in additional term loans, which additional term loans are available only to redeem the Company's existing 2025 Convertible Notes.

Capital Resources and Funding Requirements

We have incurred operating losses since inception, and we have an accumulated deficit of $651.0 million at June 30, 2024. Based on our current operating plans and existing working capital at June 30, 2024, we believe that our cash resources are sufficient to sustain operations and capital expenditure requirements for at least the next 12 months. We expect to incur substantial additional expenditures in the near term to support the marketing and selling of Gvoke, Recorlev and Keveyis as well as our ongoing research and development activities. We expect to continue to incur net losses for at least the next 12 months. Our ability to fund marketing and selling of Gvoke, Recorlev and Keveyis, as well as our product development and clinical operations, including completion of future clinical trials, will depend on the amount and timing of cash received from product revenue and potential future financings. Our future capital requirements will depend on many factors, including, but not limited to:

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

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

Cash Flows

(**in thousands**)	Six Months Ended June 30, 2024	2023
Net cash used in operating activities	$ (30,651)	$ (39,884)
Net cash used in by investing activities	$ (15,047)	$ (35,527)
Net cash provided by/(used in) financing activities	$ 35,853	$ (307)

Operating activities

Net cash used in operating activities was $30.7 million for the six months ended June 30, 2024, compared to $39.9 million for the six months ended June 30, 2023. The decrease in net cash used in operating activities was primarily driven by reduced working capital usage, partially offset by changes to the fair value of contingent value rights. For a discussion regarding product revenue, net and increases in spending, refer to "Results of Operations" included in this "Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations" of Part I of this Quarterly Report on Form 10-Q.

Investing activities

Net cash used in investing activities was $15.0 million for the six months ended June 30, 2024, compared to net cash provided by investing activities of $35.5 million for the six months ended June 30, 2023. Cash used in investing activities in 2024 was primarily due to net purchases of short-term investments.

Financing activities

Net cash provided by financing activities was $35.9 million for the six months ended June 30, 2024, compared to net cash used in financing activities of $0.3 million for the six months ended June 30, 2023. The cash provided by financing activities in 2024 was primarily due to the net proceeds of $38.2 million of the debt refinancing from the Amended and Restated Credit Agreement.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES AND ASSUMPTIONS

Our Annual Report on Form 10-K for the year ended December 31, 2023 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, 2023.

NEW ACCOUNTING STANDARDS

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

Cash, Cash Equivalents restricted cash and Investments—We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash, cash equivalents, restricted cash and investments. A hypothetical one-percentage point increase or decrease in interest rates applicable to our cash, cash equivalents, restricted cash and investments outstanding at June 30, 2024 would increase or decrease interest income by approximately $0.8 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 Amended and Restated Credit Agreement, interest is incurred at a floating per annum rate in an amount equal to the sum of (i) 6.95% (or 5.95% if the replacement rate is in effect) plus (ii) the greater of (x) the forward-looking term rate based on SOFR for a three month tenor (or the replacement rate, if applicable), and (y) 2.00% per annum. The remaining balance of unamortized debt issuance costs have been reflected as a direct reduction to the loan balance. Interest on the 2025 Convertible Notes is assessed at a fixed rate of 5.0% annually and interest on the 2028 Convertible Notes is assessed at a fixed rate of 8.0% annually and therefore do not subject us to interest rate risk.

Foreign Exchange Risk

We contract with research organizations outside the United States at times. We may be subject to fluctuations in foreign currency exchange rates in connection with certain of these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. Net foreign currency gains and losses did not have a material effect on our results of operations for the three and six months ended June 30, 2024.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based on such evaluation, our chief executive officer and chief financial officer have concluded that the disclosure controls and procedures were effective as of June 30, 2024 to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the United States Securities and Exchange Commission's ("SEC") rules and forms, and to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its chief executive and chief financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2024 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

In addition to the information set forth in this report, you should carefully consider the risks discussed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, which could have a material adverse effect on our business or consolidated financial statements, results of operations, and cash flows. Additional risks not currently known, or risks that are currently believed to be not material, may also impair business operations. The material changes to our risk factors since the filing of our Annual Report on Form 10-K for the year ended December 31, 2023, are presented below.

Risks Related to Ongoing Regulatory Obligations

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

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

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

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

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

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

The FDA's and foreign regulatory agencies' policies are subject to change, and additional federal, state, local or non-United States governmental regulations may be enacted that could affect our ability to maintain compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that may arise from future legislation or administrative action, either in the United States or abroad. Moreover, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes.

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 John Shannon, our Chief Executive Officer, Steven Pieper, our Chief Financial Officer, Kevin McCulloch, 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.

General Risk Factors

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

We may be subject to the United States federal and state, European, UK and other foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). We have personnel located in Ireland and have conducted and may in the future conduct clinical trials in the European Economic Area ("EEA") and/or the UK subjecting us to additional privacy restrictions and data protection requirements. The collection and use of personal data (including health data) in the EEA and the UK are governed by the provisions of the EU General Data Protection Regulation ("EU GDPR") as well as other national data protection legislation in force in relevant Member States, with respect to the EEA, and the UK General Data Protection Regulation (the "UK GDPR," together with the EU GDPR the "GDPR") and the UK Data Protection Act 2018 with respect to the UK. These laws impose a broad range of

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

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

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

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

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

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

Many jurisdictions outside of Europe where we may do business or conduct trials in the future are also considering and/or have enacted comprehensive data protection legislation. In addition, we also continue to see jurisdictions imposing data localization laws. These and similar regulations may interfere with our intended business activities, inhibit our ability to expand into those markets, require modifications to our products or services or prohibit us from continuing to offer services or conduct trials in those markets without significant additional costs. In the US state laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, in California, the California Consumer Protection Act, or CCPA, which went into effect on January 1, 2020, established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope. In addition, a ballot initiative, the California Privacy Rights Act, or CPRA, was passed in November 2020 and as of January 1, 2023 has imposed additional obligations on companies covered by the legislation. The

CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information.

Similar laws have been passed and proposed in numerous other states. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law which, as of March 31, 2024, regulates the collection and sharing of health information. The Washington law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We or our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act ("AI Act") — the world's first comprehensive AI law entered into force on August 1, 2024 and, with some exceptions, shall become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. If our vendors, or our third-party partners experience an actual or perceived breach or privacy or a cybersecurity incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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

Rule 10b5-1 Trading Plan

During the three months ended June 30, 2024, none of the Company's directors or officers adopted, materially modified, or terminated any contract, instruction, or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement.

ITEM 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*†	Manufacturing and Supply Agreement dated as of January 14, 2022, between Strongbridge Dublin Limited and Regis Technologies, Inc.
10.2*†	Commercial Manufacturing Services and Supply Agreement, dated as of May 4, 2021, between Strongbridge Dublin Limited and Xcelience, LLC
10.3*†	Amendment No 1 to Commercial Manufacturing Services and Supply Agreement, dated as of May 23, 2024, between Lonza Tampa, LLC (f/k/a Xcelience, LLC) and Strongbridge Dublin Limited
10.4	First Amendment to Xeris Pharmaceuticals, Inc. 2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40880) filed with the Securities and Exchange Commission on June 5, 2024)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
32.1*+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

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

SIGNATURES

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

Xeris Biopharma Holdings, Inc.

Date: August 8, 2024

By /s/ John Shannon
John Shannon
Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 8, 2024

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

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

Manufacturing and Supply Agreement

This Manufacturing and Supply Agreement (this "Agreement") is entered into as of the 14th day of January, 2022 (the "Effective Date"), by and between **Strongbridge Dublin Limited,** a wholly-owned subsidiary of Strongbridge Biopharma Limited (f/k/a Strongbridge Biopharma plc), a company incorporated under the laws of Ireland having its registered office at Suite 206, Fitzwilliam Place, Dublin 2, D02 T292, Ireland ("Customer"), and **Regis Technologies, Inc.**, an Illinois corporation, having its principal place of business at 8210 Austin Ave., Morton Grove, IL 60053 ("Regis"). Customer and Regis may be referred to individually as a "Party" or collectively as "Parties".

PREAMBLE

Whereas, Regis is a company engaged inter-alia in the processing, manufacturing and supply of active pharmaceutical ingredients and is interested in producing commercial quantities of Product (as defined below) for Customer;

Whereas, Customer is interested in purchasing commercial quantities of Product from Regis pursuant to the terms and conditions of this Agreement; and

Whereas, the Parties desire that this Agreement will determine the general terms and conditions for the manufacture and supply of Product (as defined below) by Regis for Customer.

NOW, THEREFORE, Regis and Customer hereby agree as follows:

1. DEFINITIONS.

1.1 Definitions. As used in this Agreement, the following terms shall have the corresponding meanings set forth below:

(a) Affiliate means (i) organizations that directly or indirectly control a Party hereto, (ii) organizations that are directly or indirectly controlled by a Party hereto or (iii) organizations that are directly or indirectly controlled by the ultimate parent company of a Party hereto. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

(b) Applicable Laws means all relevant United States federal, state and local laws, statutes, rules, regulations, and ordinances and industry standards and guidelines as in effect on the Effective Date or adopted thereafter and which are applicable to a

Party's activities hereunder, including, without limitation, the applicable regulations and guidelines of any United States governmental authority including the United States Food and Drug Administration.

(c) Customer Intellectual Property shall have the meaning ascribed to it in Section 14.1(b).

(d) Contract Results shall have the meaning ascribed to it in Section 14.2.

(e) Disclosing Party shall have the meaning ascribed to it in Section 15.1.

(f) Effective Date shall mean the last date on the signature page.

(g) Firm Order Period shall have the meaning ascribed to it in Section 3.2.

(h) GMPs means, as applicable, current good manufacturing practices, including the regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act, 21 C.F.R. Part 210 et seq., as amended from time to time, applicable guidance documents issued by the FDA, and applicable documents developed by the International Conference on Harmonization (ICH) to the extent that such documents are consistent with regulations promulgated by the FDA.

(i) Intellectual Property shall mean anything that is protected by any patents, trademarks, copyrights, trade secrets, know-how and all other intellectual and industrial property rights (whether registered or unregistered and including rights in any application for any of the foregoing), including without limitation, information, work product, inventions, know-how, ideas, improvements, discoveries, enhancements, modifications, data, results, formulae, instructions, processes, protocols, techniques, methodologies, testing and control procedures, and information of every other kind and description.

(j) Regis Intellectual Property shall have the meaning ascribed to it in Section 14.1(a).

(k) [***] shall mean [***].

(l) Party means Regis or Customer, and when used in the plural, means Regis and Customer together.

(m) Product means Levoketoconazole (CAS Registry No. 142128-57-2).

(n) Product Specification means the specifications for the Product as described in Exhibit 1.

(o) Production Facility means the production facility of Regis located in Morton Grove, IL.

(p) Quality Agreement means the document entered into by the Parties in good faith and will be entered into specifying quality related details of the particular goods and

services to be provided, the main contacts, reporting arrangements, allocation and limits of responsibility for the two parties, inter-alia. If there are contradictions between the provisions of this Agreement and those of the Quality Agreement, the provisions of this Agreement will take precedence.

(q) Receiving Party shall have the meaning ascribed to it in Section 15.1.

(r) Regulatory Authority shall mean the United States Food and Drug Administration, or any successor entity thereto performing substantially similar function ("FDA") or any other recognized governmental or regulatory authority (i.e. EMA, MHRA, or MHLW) responsible for the regulation of API used in pharmaceutical products intended for human use.

(s) Term means the period from the Effective Date until termination or expiration of this Agreement in accordance with Section 17.

2. OBJECT

2.1 Regis will manufacture Product and sell Product to Customer, and Customer will buy the Product from Regis subject to the terms and conditions set forth in this Agreement.

2.2 This Agreement will form the basis of purchase orders of Customer to Regis. It will be an integral part of individual purchase orders. Any pre-printed terms set forth on any purchase order shall be disregarded and if there are contradictions between this Agreement and those of a purchase order then the provisions of this Agreement shall take precedence, unless specifically agreed in writing and signed by both Parties.

3. FORECASTING AND PURCHASE ORDERS

3.1 Forecasting. Customer will deliver to Regis for planning purposes no later than the beginning of each quarter (i.e., January 1, April 1, July 1, October 1) a non-binding rolling forecast of its estimated quarterly requirements for delivery of Product during the next [***]. The quantities of Product detailed in the [***] from the delivery date (the "Firm Order Period") of each such forecast will represent binding irrevocable purchase commitments of Customer and Regis which can only be amended by mutual agreement of the Parties and for which Customer shall place corresponding purchase orders. Forecasts shall contain a quantity in [***] batch increments and may range from [***] batches annually.

The first forecast covering a period of [***] from the Effective Date is attached hereto as Exhibit 2.

3.2 Purchase Orders. Strongbridge will provide a Purchase Order for Product [***] prior to desired delivery date. Upon receipt of the Purchase Order, Regis will order Starting Material ("SM") and invoice Strongbridge for the Starting Material Fee (the "SM Fee") as set forth in Exhibit 3. Strongbridge reserves the right to delay delivery of Product for up to [***] from the delivery date initially indicated in the Purchase Order. Notification of any delay must be in writing and received by Regis within [***] of issuance of the Purchase Order. If no written notification of

delay from Strongbridge is received during the [***] period, the delivery date becomes binding. Once binding, Strongbridge will be invoiced as follows:

(a) Commitment Fee: [***] of the Purchase Order total, less the SM Fee previously invoiced, will be invoiced at the commencement of the Firm Order Period defined in Section 3.1 above.

(b) Release Fee: The remaining balance of the Purchase Order total will be invoiced upon release of Product by Regis (adjusted for actual yield).

3.3 Customer's purchase orders shall contain Customer's purchase order number, quantity (in [***] increments to match the approximate batch size), price, invoicing address, delivery address and requested delivery dates. A purchase order template is attached hereto as Exhibit 4.

3.4 Regis shall notify Customer of acceptance of the Purchase Order within [***] from receipt and each acceptance shall include confirmation of the delivery date of the applicable quantity of Product; provided that to the extent no delivery date is included or Regis fails to issue an acceptance within the applicable time period, the order shall be deemed accepted by Regis and the applicable delivery date shall be deemed to be the delivery date and delivery location specified in the applicable Purchase Order which shall be binding on the Parties. Other than due to a force majeure event, Regis shall accept all purchase orders that are materially in compliance with this Agreement and consistent with Customer's previous [***] rolling forecast.

3.5 If Regis is unable, or anticipates that it will not be able, to supply Customer's requirements for number of batches of Product and delivery date in accordance with this Section 3 (a "Shortage of Supply"), Regis shall notify Customer in writing of the same within [***] of receipt of the applicable Purchase Orders, forecast or determination that a Shortage of Supply will exist, and shall include in such notice its best estimate of the duration of the delay, the reasons for the delay, and whether the reason impacts the validated state of the process. Regis shall, at its own cost, use commercially reasonable efforts to remedy any Shortage of Supply and resume supplying Product meeting the requirements of this Agreement to Customer as soon as possible.

3.6 Regis agrees to retest batches of Product at Customer's request and expense for batches within [***] of the retest period.

4. ANNUAL STABILITY STUDY

4.1 Regis will perform the annual stability study on one batch of Product released each calendar year. Customer will decide which batch will be placed on stability. If more than one batch needs to be placed on stability in a year, Customer will pay for the stability study with prior approval of the need for an extra stability batch in the year. If no batches are produced in a calendar year, a new stability study will not be required for that year.

4.2 The annual stability study will be run using the time points and parameters in the Exhibit 1 and Regis will provide interim annual updates of the stability data. Upon completion of

the annual stability study, Regis will provide Customer with a final report of the results. The price for each annual stability study is set forth in Exhibit 3.

4.3 Reference Standards. If requested by Customer, Regis will qualify or requalify (2S,4R)-(-)-cis-Ketoconazole as a reference standard or Regis will purchase other reference standards required for the manufacturing of Product. The price for reference standards is set forth in Exhibit 3.

5. RAW MATERIALS AND SAFETY STOCK

(a) Regis shall provide all raw and auxiliary materials required in connection with the manufacture of the Product hereunder. Regis shall procure, use and analyse the raw materials in accordance with GMPs and the regulatory filing of the Product.

(b) Upon receipt of purchase order issued by Customer, Regis will purchase sufficient Racemic Ketoconazole ("SM") from [***] or other mutually approved supplier, to produce Product. Regis will invoice Customer for the SM Fee as set forth in Exhibit 3. Customer shall provide purchase orders for SM to maintain a safety stock of no less than [***] of SM and Regis will invoice Customer the SM Fee accordingly. Regis shall procure additional safety stock of SM at the request and expense of Customer.

(c) Storage of the SM shall be the responsibility of Regis and will be included in the annual Maintenance Fee defined in Section 11.3. All SM shall be used solely for the Product. Regis shall be responsible for risk of loss to SM in its possession.

(d) Regis will have a quality agreement with [***] for SM.

(e) Within [***] following the end of each calendar month, Regis will perform and deliver to Customer a reconciliation of SM and Product inventory for the prior month.

6. MANUFACTURE OF PRODUCT, QUALITY CONTROL AND QUALITY ASSURANCE, PACKAGING

6.1 Regis shall manufacture and store the Product at the Production Facility according to the Product Specifications, the Quality Agreement, the Manufacturing Process, GMPs and all Applicable Laws, rules and regulations.

6.2 Regis will perform the quality control testing specified in the Quality Agreement. Batch review and release to Customer will be the responsibility of Regis's quality assurance group. Regis will perform its batch review and release responsibilities in accordance with Regis's standard operation procedures. Regis will provide all batch documents to Customer after release of Product. Customer shall accept or reject a batch within [***] from receipt of the relevant and complete batch documentation. If there is no written notification from Customer within the [***], the batch will be deemed accepted by Customer. Customer will have the sole responsibility for the release of products to the market.

6.3 Regis will package the Product as set out in the batch record. If additional packaging or subdivision is required, additional charges will apply.

6.4 Regis shall promptly notify and forward to Customer any information concerning any potentially serious or unexpected side effect, injury, toxicity or sensitivity reaction or any unexpected incidence or other adverse experience related to the Product (an "Adverse Experience") reported to it. Customer agrees that it shall be solely responsible to review, analyze and respond to any Adverse Experience. Regis shall have no obligation with respect to an Adverse Experience other than the obligation to notify Customer. Customer will inform Regis of any new data related to safely manufacturing product.

7. CO-OPERATION

7.1 Governmental Agencies.

Subject to Section 7.6, each Party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Product, for Regis communications, only regarding the site-specific Issues related to Product if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency. Regis specifically agrees to cooperate with any inspection by the FDA or other regulatory authority, as applicable, and Regis shall bear the costs associated with the hosting of such regulatory agency inspections. Regis shall promptly advise Customer of any notice or request that it receives from a governmental agency or regulatory authority regarding inspection of its facilities. Regulatory services will be provided at an additional fee.

7.2 Records and Accounting by Regis.

Regis will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Products that are necessary to comply with manufacturing regulatory requirements. Copies of the records and samples will also be retained by Regis in accordance with the Quality Agreement and relevant SOPs.

7.3 Inspection.

During the term of this Agreement and for [***] after its expiration or termination, Customer or its designee may inspect Regis Facility, reports and records relating to this Agreement, excluding the financial records of the company, during normal business hours and with reasonable advance notice, but a Regis representative must be present during the inspection Regis will schedule and

conduct inspections in accordance with the Quality Agreement and relevant SOPs. Inspections performed after termination of this agreement will be performed at Customer's expense.

7.4 Access.

During the term of this Agreement and for [***] after its expiration or termination, Regis will give Customer reasonable access at agreed times to the areas of the Facility in which the Product is manufactured, stored, handled, or shipped to permit Customer to verify that the manufacturing services are being performed in accordance with the Specifications, GMPs, and applicable laws. Access to the Facility, except for cause audits, necessary to determine if corrective actions were taken, will be addressed in accordance with the Quality Agreement. The right of access set forth in this Section 7.5 will not include a right to access or inspect Regis's financial records. The terms for which audits are conducted are defined in the Quality Agreement.

7.5 Reports.

Regis will supply all necessary data/documentation to Customer, at Customer's reasonable discretion, needed to maintain regulatory filings as defined in the quality agreement.

7.6 Regulatory Cooperation.

(a) Regulatory Authority. Customer will have the sole authority and responsibility for filing all documents with all regulatory authorities and taking any other actions that may be required for the receipt and/or maintenance of regulatory authority approval for the commercial manufacture of the Product. Regis will assist Customer at Customer's expense, to obtain regulatory authority approval for the commercial manufacture of all Products as quickly as reasonably possible and then subsequently, to maintain any such approval. In addition, at Customer's request Regis shall to a commercially reasonable extent make appropriate personnel available for meetings with Regulatory Authorities related to the manufacture of the Product. Regis shall be responsible for all regulatory filings and regulatory compliance relating to the Regis Facility. In addition, at Customer's expense Regis agrees to reasonably cooperate with Customer (or its designees) with respect to Customer's obligations to submit or report information relevant to Product pursuant to FDA and other Regulatory Authorities or to comply with Applicable Laws relevant to the Production Facility.

(b) Customer Responsibility. Subject to the foregoing, Regis will not assume any responsibility for the accuracy of any application for receipt of an approval by a regulatory authority. Customer is solely responsible for the preparation and filing of the application for approval by the regulatory authority and any relevant costs will be borne by the Customer.

(c) Annual Product Review. Regis shall prepare annual reports and/or product quality reviews (collectively, "Annual Product Reviews") with respect to the Product as detailed in the Quality Agreement.

(d) Inspection by Regulatory Authorities. Customer shall notify Regis if actions taken by Customer could prompt a Regulatory inspection. The terms for notification are defined in the Quality Agreement.

8. SHIPMENTS

Delivery terms shall be [***]. Regis will coordinate the shipping of product using an agreed upon vendor and agreed upon conditions with the Customer. Customer is responsible for all shipping, insurance and related charges. These fees will be invoiced to Customer as a pass-through cost with no mark-up. Title and risk of loss for the Product shall transfer to Customer per [***]. Each shipment of Product shall be accompanied by a certificate of analysis, which will include a signed certification of GMP compliance and such additional documents as may be specified in the Quality Agreement.

9. PRODUCT CLAIMS

9.1 Product Claims. Customer has the right to reject any portion of any shipment of Product that deviates from the Specifications, GMPs or Applicable Laws without invalidating the remainder of the shipment. Customer will inspect the Product upon receipt and will give Regis written notice (a "Deficiency Notice") of all claims for Products that deviate from the Specifications, GMPs or Applicable Laws within [***] after product release. Should Customer fail to give Regis the Deficiency Notice within the applicable period, then the delivery will be deemed to have been accepted by Customer. Subject to Section 6.2, Regis will have no liability for any deviations for which it has not received notice within the applicable period, or any agreed extension. The Deficiency Notice shall state in reasonable detail the reason why the Product is rejected.

Customer also may reject Product delivered hereunder for Latent Defects (as defined below) provided Customer notifies Regis in writing no later than the earlier of: (a) [***] of discovery of a Latent Defect, and (b) [***] from the date of Product's manufacture. If it is confirmed that the cause of the Latent Defect is attributable to Regis, then Regis will replace at no cost to Customer all such latently defective Product with Product that meets the Product Specifications. All other relevant provisions of Section 9.1 will apply to the inspection, testing and release of such replacement Product. Replacement of the latently defective Product shall be Customer's sole remedy under this Agreement. The Parties will consult to confirm the cause of the Latent Defects. In the event of disagreement between the Parties as to the existence or cause of a Latent Defect, the Parties shall refer the dispute to an independent laboratory as set forth in Section 6.2(a). "Latent Defects" shall mean any defects in the Product to meet Product Requirements that existed at the time of delivery to Customer but could not be reasonably detected upon review of records or the initial testing and inspection of the Product, provided that such defects are unrelated to the shipping or storage of the Product after acceptance. Regis shall not be responsible for any Latent Defects that are attributable to the Starting Material.

9.2 Determination of Deficiency. Upon receipt of a Deficiency Notice, Regis will have [***] to advise Customer by notice in writing that it disagrees with the contents of the Deficiency Notice. If Customer and Regis fail to agree within [***] after Regis's notice to Customer as to whether any Product deviates from the Specifications, GMPs or Applicable Laws, then the parties will mutually select an independent laboratory to evaluate Product deviations from the

Specifications, GMPs or applicable laws. This evaluation will be final and binding on the parties. If the evaluation certifies that Product deviates from the Specifications, GMPs or applicable laws, Customer may reject this Product and Regis will be responsible for the costs of the evaluation. If the evaluation does not so certify, then Customer will be deemed to have accepted the relevant Product and Customer will be responsible for the costs of the evaluation.

9.3 Suspension of Payments. If any Product is rejected by Customer, Customer's duty to pay all amounts payable to Regis in respect of the Rejected Product shall be (i) suspended until such time as it is determined by an independent laboratory or consultant that the Products in question were unreasonably rejected by Customer, or (ii) waived and null and void if it is determined by an independent laboratory or consultant that the Rejected Products were reasonably rejected by Customer. If only a portion of an order is rejected, only the duty to pay the amount allocable to such portion shall be suspended or waived, as applicable.

9.4 Regis' Responsibility for Defective Product. If Customer rejects Product and the deviation is determined to have arisen from Regis's failure to manufacture the Product in accordance with the relevant Specifications, GMPs or Applicable Laws, Regis will as soon as reasonably practicable given other commitments of Regis in the Production Facility and at no cost to Customer and at Customer's sole discretion:

(a) manufacture and deliver to Customer sufficient Product to replace the defective Product, or

(b) credit or reimburse (as the case may be) the amount paid by Customer to Regis for the deficient Product (including all shipping cost) if the cause of the nonconforming batch was solely Regis' gross negligence or willful misconduct.

10. RESERVED

11. PRICES, MAINTENANCE FEE, AND PAYMENT TERMS

11.1 The purchase price payable by Customer to Regis for the Product delivered to Customer hereunder as well as the methodology for price adjustment during the Term are set forth in Exhibit 3.

11.2 Beginning with the first anniversary of the Agreement, Regis will invoice Customer for an annual Product Maintenance Fee as set forth in Exhibit 3. This annual Maintenance Fee will be invoiced upon completion of the Annual Product Review each year for the duration of the Agreement. Such fee will include: (i) the Annual Product Review as described in Section 7.8(c); (ii) storage of SM safety stock; and (iii) storage of up to [***] of Product. If it is necessary to store more than two batches of Product to meet Customer's safety stock requirements, storage of additional batches will be invoiced separately as set forth in Exhibit 3. Regis agrees to store up to [***] at any one time.

11.3 Invoices will be sent to Customer when the Product is released by Regis Quality Assurance. Each invoice will, to the extent applicable, identify Customer's purchase order number, Product quantity, unit price, freight charges, and the total amount to be paid by Customer.

11.4 Customer will pay all invoices within [***] of the date of Customer's receipt of undisputed invoice thereof, unless Customer has notified Regis within such 30-day period that it disputes any particular invoiced item(s), which dispute the parties shall attempt to resolve in good faith. Interest on past due accounts will accrue at 2% per month. Regis will provide Customer with [***] notice of its delinquency prior to the addition of interest.

11.5 The Product Price, and any other fees or charges by Regis to Customer pursuant to this Agreement do not include value added, sales, use, consumption, or excise taxes of any taxing authority. The amount of such taxes, if any, will be added on the invoices submitted to Customer by Regis pursuant to this Agreement as a separate line item and Customer shall pay the amount of such taxes to Regis in accordance with the payment provisions of this Agreement.

12. REPRESENTATIONS AND WARRANTIES.

12.1 Authority. Each Party represents and warrants that is has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

12.2 Customer represents and warrants that any Customer Intellectual Property, used by Regis in performing manufacturing services hereunder is Customer's or its Affiliates' unencumbered property, may lawfully be used as directed by Customer and does not infringe any rights of third parties when used by Regis in accordance with this Agreement for providing manufacturing services for Customer hereunder.

12.3 Regis represents and warrants that all Product will be manufactured, tested, stored and released in conformance with the relevant Specifications, GMPs and Applicable Laws.

12.4 Regis represents and warrants that Product, at the time of delivery to Customer, shall not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act.

12.5 Regis represents and warrants that any Regis Intellectual Property used by Regis for manufacturing Product hereunder is Regis's or its Affiliates' unencumbered property, may lawfully be used as directed by Regis and does not infringe any rights of third parties.

12.6 Regis represents and warrants that title to all Product provided to Customer under this Agreement shall pass as provided in this Agreement, free and clear of any security interest, lien or other encumbrance.

12.7 Regis warrants and represents that Regis is not now, nor has Regis ever been, an individual, corporation, partnership, association or entity that has been debarred by a Regulatory Authority, including, but not limited to, pursuant to 21 U.S.C. §335 (a) and any foreign equivalents (a "Debarred Person") or disqualified as a Clinical Investigator by a Regulatory Authority, including, but not limited to, pursuant to 21 C.F.R. §312.70 or §812.119 and their foreign equivalents (a "Disqualified Person"). Regis further warrants and represents that none of Regis's employees or affiliates have ever been debarred or disqualified, nor has any Debarred/Disqualified Person performed or rendered, or will be permitted to perform or render, any services undertaken

pursuant to this Agreement. Regis further warrants and represents that Regis has no knowledge of any circumstances, which may affect the accuracy of the foregoing warranties and representations, including, but not limited to, FDA investigations of, or debarment proceedings against Regis or any other person or entity performing services pursuant to this Agreement. Regis shall immediately notify Customer if it becomes aware of any change in circumstances that would render any of the foregoing representations or warranties untrue or misleading in any material respect during the Term of the Agreement and any extensions thereto.

12.8 Regis represents and warrants to Customer that it has and will maintain during the term of this Agreement all government permits, including without limitation health, safety and environmental permits, necessary for the conduct of the manufacturing services it will perform pursuant to this Agreement.

12.9 Regis represents and warrants that: (i) it has all requisite corporate power and authority for the ownership and operation of its properties and for carrying on of its business as currently conducted or proposed to be conducted for the purpose of this Agreement; (ii) the execution, delivery and performance of this Agreement and the conduct of manufacturing services hereunder will not conflict with or breach any agreement, instrument or understanding, oral or written, to which Regis is a party or by which Regis may be bound, nor, does it violate any applicable law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; or (iii) it has no obligations to any Third Party which (a) will in any way limit or restrict its ability to perform manufacturing services for Customer hereunder or (b) conflict with the rights granted to Customer hereunder.

12.9 Disclaimer of Other Warranties. OTHER THAN THE WARRANTIES SPECIFICALLY SET FORTH IN THIS AGREEMENT, REGIS MAKES NO OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED. REGIS MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCT.

13. REMEDIES AND INDEMNITIES

13.1 Consequential Damages. Notwithstanding any provision hereof to the contrary, under no circumstances whatsoever shall either Party be liable to the other in contract, tort, negligence, breach of statutory duty or otherwise for any lost profits, business interruption, or any indirect, incidental, special, consequential, exemplary, or punitive damages arising out of this Agreement, even if the Party has been advised of the possibility of such damages or liability (it being understood that nothing in this sentence will limit any indemnified Party's right to indemnification for such damages claimed by third parties).

13.2 Limitation of Liability. EXCEPT FOR A PARTY'S INDEMNIFICATION OBLIGATIONS, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, EACH PARTY'S MAXIMUM LIABILITY TO THE OTHER PARTY UNDER THIS AGREEMENT PER CALENDAR YEAR FOR ANY REASON WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ANY LIABILITY ARISING UNDER THIS AGREEMENT OR RESULTING FROM ANY AND ALL BREACHES OF ITS REPRESENTATIONS, WARRANTIES, OR ANY OTHER OBLIGATIONS UNDER THIS AGREEMENT WILL NOT EXCEED [***].

13.3 Regis Indemnity. Regis agrees to defend, indemnify, and hold Customer, its Affiliates and their officers, employees, and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability resulting from (i) a failure by Regis to manufacture the Product in accordance with the Specifications, GMPs, and Applicable Laws, or (ii) a material breach of this Agreement by Regis, including, without limitation, any representations or warranties contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and lability are due to the gross negligence or wrongful act(s) of Customer, its officers, employees, agents, or Affiliates. If a claim occurs, Customer will: (a) promptly notify Regis of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Regis in the defense of the claim; and (d) permit Regis to control the defense and settlement of the claim, all at Regis's cost and expense (provided that no settlement of a claim other than for monetary damages to be paid by Regis shall be made without Customer's prior written consent).

13.4 Customer Indemnity. Customer agrees to defend, indemnify, and hold Regis, its officers, employees, and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favor of third parties (other than Affiliates) resulting from, or relating to any claim of infringement or alleged infringement of any third party rights in the Product, or any portion thereof, or any claim of personal injury or property damage to the extent that the injury or damage is the result of a material breach of this Agreement by Customer, including, without limitation, any representation or warranty contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the gross negligence or wrongful act(s) of Regis, its officers, employees, or agents. If a claim occurs, Regis will: (a) promptly notify Customer of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Customer in the defense of the claim; and (d) permit Customer to control the defense and settlement of the claim, all at Customer's cost and expense.

13.5 Reasonable Allocation of Loss. This Agreement including, without limitation, this Section 13 is reasonable and creates a reasonable allocation of risk for the relative profits the Parties each expect to derive from the Product. Regis assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Product because Customer has developed and holds the marketing approval for the Product, Customer requires Regis to manufacture the Product strictly in accordance with the Specifications, GMPs and applicable laws, and Customer, not Regis, is best positioned to inform and advise potential users about the circumstances and manner of use of the Product.

14. INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER

14.1. Intellectual Property belonging to each of the parties independently from the agreements between them:

(a) all Confidential Information and Intellectual Property owned by or licensed to Regis from third parties, including the Regis Technology prior to the Effective Date or thereafter developed by Regis independently from this Agreement ("Regis Intellectual Property") shall at all times remain the property or in the control of Regis and no rights in or to any such Regis Intellectual Property shall vest in Customer;

(b) all Confidential Information and Intellectual Property owned by or licensed to Customer from third parties prior to the Effective Date or thereafter developed by or on behalf of Customer independently from this Agreement ("Customer Intellectual Property") shall at all times remain the property or in the control of Customer, and no rights in or to any such Customer Intellectual Property shall vest in Regis;

14.2 All Intellectual Property arising from activities under this Agreement, whether it is conceived, generated, made, or reduced to practice, as the case may be, by Regis or Customer, will be the sole and exclusive property of Customer (hereinafter, "Contract Results"), and Regis shall and hereby does assign to Customer all of its right, title and interest in and to any Contract Results and Regis shall co-operate with Customer in seeking applicable patent coverage therefore.

14.3 Regis agrees to disclose all Contract Results promptly to Customer to facilitate Customer seeking protection for such Contract Results, including patent and copyright rights in any and all countries as the owner(s) may determine. Customer may, in its own discretion, file and prosecute in its own name and at its own expense, applications for foreign and United States patents on any Contract Results. Upon the request of Customer, and at Customer's expense, Regis shall (and shall cause its Representatives to) assist in prosecuting such applications and shall execute and deliver any and all instruments necessary to make, file, prosecute and maintain all such patents, patent applications, provisional patent applications, divisions, continuations, continuations-in-part, reissues, extensions, validations or renewals thereof.

14.4 The form and style of batch documents, including, but not limited to batch production records, packaging records, equipment set up control, operating parameters, and data print outs, raw material data, and laboratory notebooks are the exclusive property of Regis, *except for* specific Product-related information contained in those batch documents that is Customer Intellectual Property and/or Customer Confidential Information which shall be the exclusive property of Customer.

14.5 Technology Transfer. Promptly upon Customer's request, but no more than [***] during the Term, Regis shall provide Customer or its designee with reasonable assistance in order to transfer the manufacturing process for Product to Customer or its designee; provided, that Customer may only make such request following (i) a breach of this Agreement by Regis; (ii) receipt by Customer of a notice of non-renewal from Regis pursuant to Section 17.1 below; or (iii) any notice of termination of this Agreement pursuant to Section 17.2 below. Regis shall provide reasonably necessary support, including documents, samples, process-related know-how and other information, to complete the technology transfer, provided that the scope of Regis's technical assistance shall in any event be limited to a maximum of [***] FTE working days. Regis will use commercially reasonable efforts to complete the technology transfer set forth in this Section 14.5 in accordance with a schedule and technology transfer plan, including a budget, mutually agreed upon by the Parties. Except in the event that Customer has terminated this Agreement pursuant to Section 17.2 below, Customer shall reimburse Regis for any reasonable out-of-pocket expenses incurred by Regis in providing such technology transfer.

15. CONFIDENTIALITY

15.1 Confidentiality of information disclosed by one of the parties hereto (the "Disclosing Party") to the other (the "Receiving Party") is governed by Section 15.2.

15.2 All information regarding the Disclosing Party's business in general given or known to the Receiving Party by the Disclosing Party hereunder and the existence and contents of this Agreement are confidential. All information regarding the Product and Customer Intellectual Property shall be considered Customer confidential information and Customer shall be considered the Disclosing Party with regard to any Customer confidential information. During the term of this Agreement and for [***] thereafter, unless any written consent by the Disclosing Party or written agreement between the parties provides otherwise, the Receiving Party must treat such information in strict confidence as it would treat its own proprietary information. The Receiving Party may not divulge such information to any third party except (x) to the extent required to obtain official licenses from local or national authorities, (y) as required by law or regulation or legal or regulatory proceedings; provided, however, that the Receiving Party gives (to the extent legally permissible) prior written notice of such requirement to the Disclosing Party and reasonably cooperates (at the Disclosing Party's sole cost) with the Receiving Party's efforts to limit such disclosure and (z) to the Receiving Party's employees, officers, directors, consultants and professional advisors who need to know such information and who are bound by obligations of confidentiality at least as stringent as those set forth herein. In addition, each Party may disclose confidential information to third parties 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 (A) any such third party agrees to be bound by reasonable obligations of confidentiality and non-use and (B) the Disclosing Party provides prior written consent; provided, that Regis agrees that Customer may disclose such information to its existing lenders or their successors). The Receiving Party must ensure that such information is not used for any purpose other than that set forth in this Agreement except when:

(a) such information is public knowledge or after disclosure hereunder becomes public knowledge through no fault of the Receiving Party

(b) such information can be shown by the Receiving Party to have been in its possession on a non-confidential basis prior to receipt hereunder

(c) such information is received by the Receiving Party from any third party for use or disclosure by the Receiving Party without obligation to the Disclosing Party, or

(d) the Receiving Party can show that such information was developed independently by the Receiving Party or any of its Affiliates without recourse to the information disclosed hereunder.

The burden of proof regarding the existence of any of the above contingencies will lie with the Receiving Party.

15.3 In the context of this section Affiliates will not be considered as third parties provided that they assume the secrecy obligations set forth in this Agreement and are therefore bound to the secrecy obligations of the respective party hereto. Each party shall be liable towards the other party for the compliance of its Affiliates with the secrecy and non-use obligations hereunder.

15.4 Both Parties agree that upon termination or expiration of this Agreement, or, at the other's request, and subject only to any applicable regulatory requirements, it shall (and shall cause its directors, officers, employees, contractors, agents, representatives and advisors to) return to the other Party all parts of the other Party's Confidential Material and return or destroy any copies thereof made by it, its Affiliates and their respective directors, officers, employees, contractors, agents or representatives. However, each Party may retain one (1) copy of the other Party's Confidential Material for archival purposes. Section 14 shall remain binding on the parties during the Term of this Agreement and for a period of [***] after the expiration or termination of this Agreement, regardless of the cause of such expiration or termination or from last disclosure, whichever is longer.

15.5 Each Party acknowledges that disclosure or distribution of the other Party's Confidential Material or use of the other Party's Confidential Material contrary to the terms of this Agreement may cause irreparable harm for which damages at law may not be an adequate remedy, and agrees that the provisions of this Agreement prohibiting disclosure or distribution of the other Party's Confidential Material or use contrary to the provisions hereof may be specifically enforced by a court of competent jurisdiction without the necessity of proving actual damages in addition to any and all other remedies available at law or in equity.

16. FORCE MAJEURE

16.1 Neither Party shall be liable for any damage, loss, cost or expense arising out of or in connection with any breach of this Agreement to the extent such breach is due to force majeure.

16.2 In this Section, force majeure shall mean any and all circumstances beyond the reasonable control of the Party concerned, including, without limitation, acts of God (such as earthquake, flood, storm or lightning), fire, explosion, war, terrorism, riot, civil disturbance, sabotage, accident, epidemic, strike, lockout, slowdown, labour disturbances, lack of or failure of transportation, breakdown of plant or essential equipment or machinery, emergency repair or maintenance, breakdown of public utilities, etc.

16.3 The Party invoking force majeure shall inform the other Party thereof as soon as possible. The Parties shall consult each other in order to minimize the other Party's damage and costs and all other negative effects of the force majeure event on the performance of the Party invoking force majeure.

17. TERM AND TERMINATION

17.1 This Agreement will enter into force on the Effective Date and will remain in force for seven (7) years, unless the Parties agree to terminate earlier or to extend it. Thereafter, this Agreement shall renew for successive three (3) year periods each, unless notice of termination is

given by either Party no later than twenty-four (24) months prior to the expiration of the original term or any renewal period thereof.

17.2 Either Party may terminate this Agreement for material breach by the other Party if the breaching Party has not corrected such material breach within sixty (60) days of receipt of written notice thereof from the non-breaching Party.

17.3 Either Party may terminate this Agreement at any time with immediate effect by written notice to the other if the other Party is or will in the near future be dissolved, liquidated, bankrupt.

17.4 Without limiting any other provisions of this Agreement, if two (2) (a) Late Shipments of Product or (b) Shortages of Supply of Product occur during any two (2) year period, then Customer shall have the right to terminate this Agreement immediately by providing written notice to Regis no later than10 days of receiving notice from Regis of a Shortage of Supply or Late Shipment of Product. For purposes of this section, "Late Shipment" shall mean any shipment of a Regis confirmed Purchase Order that is delivered more than thirty (30) days past the delivery date specified in the applicable Purchase Order (each, a "Late Shipment").

17.5 Except as set forth in this Agreement, each Party will remain liable to the other after expiry or termination for all obligations it incurred prior to such expiry or termination.

17.6 In the event Customer terminates this Agreement because of non-performance or other breach by Regis, Regis will at Regis' expense provide reasonably necessary assistance to assist Customer and its Affiliates in transferring the manufacture of the Product to another facility.

17.7 Sections that by their nature are intended to survive will survive expiry or termination of this Agreement and continue to be enforceable.

18. MISCELLANEOUS

18.1 This Agreement represents the complete and entire understanding between the Parties regarding the subject matter hereof and supersedes all prior negotiations, representations or agreements, either written or oral, regarding this subject matter. This Agreement may be amended only in writing, signed by both Parties.

18.2 In the event any provision of this Agreement is deemed to be void under any law, the remaining provisions of this Agreement shall not be affected and the void provision shall be deemed to have been replaced by such valid and enforceable provision that most closely reflects the original intention of the parties.

18.3 Failure by Regis or Customer to enforce the terms and conditions of the Agreement shall not affect or impair such terms or conditions, or the right of Regis or Customer to avail itself of such remedies as it may have for any breach of such terms or conditions under the provisions of this Agreement, in equity or at law.

18.4 For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

18.5 Nothing in this Agreement shall prevent Regis from engaging in a business or businesses separate and apart from that of Customer.

18.6 The Parties agree that their rights and obligations under this Agreement may not be assigned or otherwise transferred to a third party without the prior written consent of the other Party hereto. Notwithstanding the foregoing, either Party may transfer or assigns its rights and obligations under this Agreement to (x) an affiliate which controls, is controlled by or is under common control with such Party within the meaning of the U.S. federal securities laws or (y) a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise; provided that such assignee or transferee has agreed to be bound by the terms and conditions of this Agreement. Subject to the foregoing, this Agreement inures to the benefit of and is binding upon the Parties, their respective successors in interest by way of merger, acquisition, or otherwise, and their permitted assigns.

19. GOVERNING LAW

This Agreement will be construed and enforced in accordance with the laws of the State of Delaware and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof, without regard to any choice of law principle that would dictate the application of the law of another jurisdiction.

20. NOTICES

20.1 Any communication which is required or permitted hereunder shall be in writing and shall be deemed to have been duly given if delivered made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Regis to:

Regis Technologies, Inc.
8210 Austin Avenue
Morton Grove, IL 60053
Attn: President & CEO

With a copy (which shall not constitute notice) to:

Regis Technologies, Inc.
8210 Austin Avenue
Morton Grove, IL 60053

If to Customer to:

Strongbridge Biopharma plc
900 Northbrook Drive, Suite 200
Trevose, PA 19053
Attention: Peter J. Valentinsson, Senior Vice President Global Technical Operations

With a copy to:
Strongbridge Dublin Limited
c/o Xeris Pharmaceuticals, Inc.
180 N. LaSalle St. Suite 1600

Attn: General Counsel Attn: Legal Department

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate as of on the day and year written.

Strongbridge Dublin Limited	**Regis Technologies, Inc.**
By: /s/ Peter Valentinsson	By: /s/ Louis Glunz IV
Name: Peter Valentinsson	Name: Louis Glunz IV
Title: SVP, Global Technical Operations	Title: President and CEO
Date: 1/26/2022	Date: 1/27/2022

Exhibits:

Exhibit 1: Product Specifications
Exhibit 2: First Forecast covering [***] from the Effective Date
Exhibit 3: Price, Fees and Adjustments
Exhibit 4: Purchase Order Template

COMMERCIAL MANUFACTURING SERVICES AND SUPPLY AGREEMENT

This Commercial Manufacturing Services and Supply Agreement (the "Agreement") is made and entered into as of May 4, 2021 ("Effective Date"), by and between Strongbridge Dublin Limited (a Strongbridge Biopharma PLC Company) a company incorporated under the laws of Ireland, having its registered office at Suite 206, Fitzwilliam Hall, Fitzwilliam Place, Dublin 2, D02 T292, Ireland (hereinafter collectively referred to as "Strongbridge") and Xcelience, LLC, with a principal place of business at [***] ("Lonza"), a wholly-owned subsidiary of Lonza America, Inc. Each of Lonza and Customer may be referred to herein individually as a "Party," and Lonza and Customer may be referred to collectively as the "Parties."

WHEREAS, Customer is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, Lonza possesses the expertise to manufacture commercial pharmaceutical products; and

WHEREAS, Customer wishes to engage Lonza, and Lonza wishes to be engaged by Customer, to manufacture quantities of Product (defined below), pursuant to the terms and subject to the conditions of this Agreement for human pharmaceutical use in the Territory (defined below), and in accordance with cGMP and the Specifications (each as defined below).

NOW THEREFORE, in consideration of the representations, covenants and warranties set forth herein, and for other good and valuable consideration, the Parties agree as follows:

1. DEFINITIONS AND GENERAL MATTERS

1.1 **Defined Terms.** As used in this Agreement, the following words and phrases shall have the meanings set forth below.

- "Actual Delivery Date" has the meaning given in Section 4.6.
- "Affiliate" means any Person who, directly or indirectly through one or more intermediaries, Controls, is Controlled by, or is under common Control with any other Person. For purposes of this definition, "Control" means (a) the direct or indirect legal or beneficial ownership of more than fifty percent (50%) of (i) the ownership interests in a Person or (ii) the outstanding voting rights in a Person or (b) the power to otherwise direct the business activities of a Person.
- "API" means levoketoconazole.
- "Cancellation Fee" has the meaning given in Section 3.6.
- "Claim or Proceeding" means any third party claim, action, suit, proceeding or arbitration, including any governmental authority action or investigation for death, bodily injury or property damage.
- "Commencement Date" means the date of commencement of the Services with respect to a batch of Product.
- "cGMP's" mean all applicable Laws in the Territory relating to manufacturing practices of medicinal products for human use promulgated by any relevant governmental authority, as may be updated, supplemented or amended from time to time and including, without limitation, as set forth in 21 C.F.R. Parts 210 and 211, as amended, and any successor provision thereto.
- "Estimated Delivery Date" means the date Lonza using reasonable commercial efforts estimates that the Product will be released to Customer so the Product may be shipped to the location designated by Customer.

- "Facility" means Lonza's manufacturing facilities located at [***].
- "FDA" means the United States Food and Drug Administration, or any successor organization.
- "Hidden Defect" means those deviations from the Specifications that are not visible or readily identifiable at the Actual Delivery Date.
- "Law" means all applicable treaties, laws, regulations in the Territory including cGMP.
- "Losses" means any and all losses, fines, fees, settlements, payments, obligations, penalties, deficiencies, liabilities, damages, costs and expenses (including reasonable attorneys' fees).
- "Manufacturing" means manufacture and supply to include testing and storage and the procurement, testing and release of components and finished product as per applicable regulatory filing(s).
- "Person" means an individual, partnership, corporation, association, trust, joint venture, or unincorporated organization.
- "PDUFA Date" means the date that the FDA is expected to deliver its decision on the Customer's New Drug Application for the Product.
- "Price" means the price for Product referred to in Section 4.1.
- "Product - Bulk Tablets" means the Recorlev (levoketoconazole) 150 mg tablets in accordance with the Specifications.
- "Product - Britestock" means the Recorlev (levoketoconazole) 150 mg tablets in unlabeled primary packaging in accordance with the Specifications.
- "Product" shall mean both Product - Bulk Tablets and Product - Britestock.
- "Quality Agreement" means the Quality Agreement referred to in Section 8.1.
- "Raw Materials" means all materials used in connection with the manufacture and supply of Product hereunder, other than the API, as specified in the Specifications attached to this Agreement as Exhibit B.
- "Regulatory Approval" means the receipt of all approvals, licenses, registrations or authorizations from the FDA necessary to market and sell the Product in the Territory.
- "Services" means the commercial manufacturing services and related services to be performed by Lonza under this Agreement as required to manufacture and supply Customer with Product as set forth herein, the particulars of which are set out in in the Specifications and each Purchase Order.
- "Specifications" means the release specifications for the manufacture, processing, bulk packaging, testing and testing procedures, shipping, storage and supply of the Product, any Raw Material requirements, analytical procedures and standards of quality control and quality assurance, established by the Parties for the Product. The Specifications are attached to this Agreement as Exhibit B.
- "Territory" means the United States of America, its territories and possessions, the United Kingdom, Canada, the European Union and its member countries and any other countries or jurisdictions that are mutually agreed to by the Parties in writing.

1.2 **Exhibits.** The attached Exhibits are incorporated into and form part of this Agreement:

EXHIBIT A	COMMERCIAL TERMS
EXHIBIT B	SPECIFICATIONS
EXHIBIT C	ENVIRONMENTAL AND HEALTH AND SAFETY INFORMATION
EXHIBIT D	SDS OF MATERIALS PROVIDED BY CUSTOMER

2. TERM; FACILITY; AFFILIATES

2.1 **Term.** The term of this Agreement shall commence on the Effective Date and, subject to the rights of earlier termination contained in this Agreement, shall remain in effect for five (5) years from the Regulatory Approval ("Initial Term"). The Initial Term may thereafter be extended for subsequent years upon the mutual written agreement of the Parties. The Parties will commence good faith renewal discussions no less than [***] prior to the end of the Initial Term or any renewal term with the goal of finalizing the renewal no less than [***] prior to the end of the then current Term (the Initial Term, together with such subsequent periods, the "Term").

2.2 **Facility.** Lonza shall perform all manufacturing activities and all storage activities at the Facility. Lonza may use other facilities for the manufacture and storage of Product provided that (i) such facilities have been approved for such manufacture and storage by all applicable governmental authorities and (ii) Customer written approval is obtained prior to the use of such facilities, such approval not to be unreasonably withheld by Customer.

2.3 **Affiliates.** Lonza may instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement and any particular Purchase Order (defined below in Section 3.2) as mutually agreed to by the Parties in writing, provided, however, that use of any Affiliate that be subject to Customer's prior written consent and Lonza shall remain fully responsible in respect of those obligations. Such Affiliate shall be entitled to submit invoices to Customer for the specific Services performed by such Affiliate under the applicable Purchase Order. Any of said Affiliates so used by Lonza shall be subject to all of the terms and conditions applicable to Lonza under this Agreement and shall be entitled to all rights and protections afforded Lonza under this Agreement.

2.4 **Subcontracting.** Lonza may subcontract Services as described in a standalone statement of work, with Customer's prior written consent. The Parties agree that Lonza may subcontract assays and other testing to qualified third parties with Customer's prior written consent. In each case Lonza shall remain fully responsible to Customer for the performance of its subcontractors in respect of any subcontracted obligations.

3. FORECASTS AND ORDERS

3.1 **Forecasts.** (a) Commencing not less than [***] before the supply is estimated to commence, each month by the [***] , Customer shall submit to Lonza a good faith, estimated [***] rolling forecast of the quantity of Product that Customer expects to order for production commencing with the month following the month in which such forecast is provided ("Forecast"). No later than [***] after receipt of the Forecast, Lonza shall use its reasonable commercial efforts to accept the Forecast, or if despite its reasonable commercial efforts Lonza is unable to accept the Forecast, Lonza shall propose changes to the Forecast to Customer. If Lonza accepts the Forecast as originally proposed, or the Customer accepts the proposed changes from Lonza, then the first [***] of each Forecast shall constitute the binding purchase commitments for its required quantities of Product (the "Binding Forecast"). In order to ensure optimal production planning Customer will use its good faith efforts to reach an accuracy of [***] of the non-binding portion of any Forecast; provided, however, that Customer may update and revise the non-binding portion of any Forecast from time to time at Customer's sole discretion. Lonza shall accept all forecasts as binding provided that (i) they are within [***]of the non-binding forecast; (ii) Lonza has no inability to source the necessary raw materials or equipment necessary to perform the Services; or (iii) Lonza's commitments to the US Department of Defense (the "DoD") due to the DoD's invocation of the Defense Production Act requiring Lonza to prioritize rated contracts for the manufacturing and supply of Covid-19 therapies which

may cause Lonza's commitments to Customer to be delayed due to the fulfilment of the DoD commitment.

(b) Upon Lonza's acceptance of the Forecast, or Customer's acceptance of the proposed changes to the Forecast, the Customer shall issue a purchase order for the Binding Forecast ("Firm Order") as per section 3.2. Customer agrees that any Product under the Binding Forecast is a binding obligation of Customer and Lonza, irrespective of whether a Purchase Order is issued by Customer. Lonza shall notify Customer immediately in writing if at any time Lonza has reason to believe that it will not be able to fill a Firm Order. For the avoidance of doubt, no Forecast shall amend any previous Firm Order.

(c) No later than [***] following Lonza's acceptance of a Forecast, Lonza shall provide written notice to Customer providing an estimated production schedule showing the estimated Commencement Date and the Estimated Delivery Date of each batch consistent with the delivery date in the Forecast.

3.2 **Purchase Orders.** Customer shall submit a purchase order corresponding to the Firm Order ("Purchase Order") no later than [***] from the Estimated Delivery Date of the Product. Each Purchase Order shall specify the quantity of Product ordered, Customer' purchase order number, the Estimated Delivery Date, the invoice address, the shipping address and any further information necessary or reasonably requested by Lonza to facilitate the shipment of Product. In the event that the Actual Delivery Date is later than [***] from the Estimated Delivery Date, then Customer will receive a [***] discount on the delayed batch of Product. In the event that the Actual Delivery Date is later than [***] from the Estimated Delivery Date, then Customer shall have the right to cancel the batch of Product upon written notice to Lonza.

3.3 **Forms and Inconsistencies.** Any term or condition of a Purchase Order, acceptance form used by Lonza, or any other correspondence between the parties that is different from, inconsistent with or contrary to the terms and condition of this Agreement shall be void. All Purchase Orders submitted by Customer shall be deemed to incorporate and be subject to the terms and conditions of this Agreement. Lonza's failure to object to any provisions contained in any communication from Customer shall not be deemed a waiver of the provisions herein.

3.4 **Rescheduling.** Lonza shall have the right to reschedule a Commencement Date of manufacturing of any Product upon reasonable prior written notice to Customer, provided that the rescheduled Commencement Date is no earlier than [***] or no later than [***] from the Commencement Date originally estimated at the time of Lonza's acceptance of the binding Purchase Order. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, manufacture of the Customer's Product may be delayed until an adequate time period is available in the Facility schedule. Any such change requested by Customer may result in a rescheduling fee. Any delay requested by Customer of more than [***] shall be considered a cancellation pursuant to Section 3.6 unless both parties agree to the revised schedule.

3.5 **Cancellation of a Binding Purchase Order.** Customer may cancel a binding Purchase Order upon written notice to Lonza, subject to the payment of a cancellation fee of [***] in the event that the Customer provides written notice of cancellation to Lonza less than or equal to [***] prior to the Commencement Date.

3.6 **Payment of Cancellation Fee.** Any Cancellation Fee shall be payable within [***] following the written notice of cancellation associated with the cancelled batch. The Cancellation Fee includes all costs associated with the cancelled batch, including any Raw Materials.

3.7 **Replacement Project.** Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to secure a new project (but excluding any project then under contract with Lonza) for the manufacturing space, and for the same dates and duration that would have been occupied by Customer, and then, in such case, the Cancellation Fee for each Purchase Order cancelled that is replaced by a new project shall be reduced by an amount equal to [***].

3.8 **Raw Material Safety Stock.** At a time to be mutually agreed to by the Parties in writing following the Effective Date, Supplier agrees that it shall review and discuss a safety stock of selected components in such quantities as mutually agreed to by the Parties (the "Safety Stock"). The Parties agree to use good faith efforts to agree, within [***] of the Effective Date, on the quantities of the Safety Stock that Supplier shall maintain. In the event that this Agreement is terminated for any reason, Company agrees to purchase the Safety Stock, if any, that Supplier cannot return or utilize in its other operations.

4. PRICE; PAYMENT TERMS; TITLE

4.1 **Price.** Customer agrees to pay Lonza for the Product provided hereunder at the Price set forth on Exhibit A hereto.

4.2 **Taxes.** The Price is exclusive of taxes, which taxes shall be for the account of Customer. Taxes that Lonza is required by Law to collect from Customer, e.g., V.A.T., will be separately stated in Lonza's invoice and will be paid by Customer to Lonza.

4.3 **Payment Terms.** Customer will make payment to Lonza in the amount set forth in an invoice within [***] of delivery of such invoice from Lonza. All invoices are strictly net and payment must be made within [***] of date of invoice. Lonza shall issue invoices to Customer for [***] of the Price for Products or Services upon Lonza's acceptance of the Purchase Order, and [***] upon Lonza's Release of Batch or completion of applicable Services, unless otherwise agreed to in a duly executed statement of work. Each shipment shall constitute an independent transaction, and Customer shall pay for the same in accordance with the specified payment terms and without deduction or set-off.

4.4 **Late Payment Interest.** If Customer is in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) one percent (1%) per month or (ii) the maximum rate allowable by applicable Law, interest to accrue on a day to day basis until full payment; and Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services and/or delivery of Product until all overdue amounts have been paid in full including interest for late payments.

4.5 **Price adjustments.**

4.5.1 Commencing with [***] Lonza may adjust the Price by [***]. The new Price reflecting such adjustment shall be effective for any manufacture of Product for which the Commencement Date is on or after the date of Lonza's notice to Customer of the Price adjustment.

4.6 **Shipping Term; Title.** All Product shall be delivered [***]. Title and risk of loss or damage to the Product shall pass to Customer at the time Product is released by Lonza's QA department together with appropriate release documentation and made available to Customer at the Facility (the "Actual Delivery Date"). Lonza shall provide necessary documentation to allow shipment from Lonza's premises to those detailed in the Purchase Order. Customer shall arrange for shipment and take delivery of such Product from the Facility, at Customer's expense, within fifteen (15) days after the Actual Delivery Date of the Product by Lonza or pay applicable storage costs. Lonza shall provide storage on a bill and hold basis for such batch(es) at no charge for up to [***]
; provided that any additional storage beyond [***] will be subject to availability and, if available, will be charged to Customer at [***], and will be subject to a separate bill and hold agreement. Within [***] following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored batch.

4.7 **Credit.** Lonza shall have the right to cancel any Purchase Order accepted by Lonza, or to delay the shipment of the Product ordered therein, if Customer fails to meet payment schedules or other credit or financial requirements established by Lonza. Customer agrees to make available to Lonza such

statements of Customer's financial condition as Lonza may, from time to time, request. Lonza reserves the right at all times, either generally or with respect to any specific Purchase Order, to vary, change or limit the amount or duration of credit to be allowed to Customer.

4.8 **Inspection Readiness, Support, Response Fees and Filing Maintenance Fees.** (a) The following one-time non-creditable, non-refundable fees will be paid by Customer to Lonza in support of significant resources applied to FDA inspection readiness for the Product:

[***]

If additional regulatory inspections are required solely for Customer's Product, then the Parties will negotiate in good faith Lonza's fees for such inspections.

(b) Commencing [***] after Regulatory Approval of Product, if Customer fails to order at least [***] per calendar year then a "Filing Maintenance Fee" of [***] will be invoiced by Lonza to Customer in December of the relevant calendar year. For the avoidance of doubt, if Customer orders at least [***]in the relevant calendar year, then this Filing Maintenance Fee will be waived. [***] will be deemed to have been ordered in a calendar year if it is ordered with an Estimated Delivery Date in such calendar year based upon the lead time set forth in Section 3.2.

5. OBLIGATIONS OF THE CUSTOMER

5.1 **Manufacture and Supply of API.** Customer shall comply with all applicable Laws related to the manufacture of API and the delivery of API to Lonza. Customer shall identify, qualify, purchase and deliver the API to the Facility. Customer shall be responsible for the quality of the API, Quality Assurance and management of API vendor relationship. Customer shall supply Lonza with the quantity of API required to manufacture the Product in the amount specified in Customer's Purchase Order, plus [***] (excluding material for lab testing and retain) ("Loss Allowance") to allow for normal waste and breakage calculated over a [***] period, not less than [***] prior to the Estimated Delivery Date. Delivery shall take place [***]. Lonza shall not be responsible for any failure to deliver or any delivery delay of Product due to (i) the failure of Customer to deliver or cause delivery of API in the time specified in this Section, or (ii) the delivery of defective API, and Customer shall be responsible for all additional costs and expenses arising out of such delay or defect, including, if applicable, any idle Facility capacity costs and any Cancellation Fees if such delay or defect results in Lonza not being able to manufacture Product in the manufacturing slots reserved for Customer at the Facility. In the event of any loss or damage to API while in the possession of Lonza in excess of the Loss Allowance due to Lonza's negligence, Lonza's liability to Customer related to or arising out of such loss shall be limited to amount set forth in Section 7.3.

5.2 **Packaging Commitment.** For a period no less than [***] from the anniversary of the Regulatory Approval, Customer agrees to conduct packaging of the Product at the Facility. After which time, the Customer is only required to purchase Product - Bulk Tablets with no penalty.

5.3 **Health & Safety Data.** (a) Customer has provided to Lonza certain information relating to the API, attached hereto as Exhibit D. To the extent Customer has not provided the information in Exhibit D and to the extent it possesses the information, Customer shall provide to Lonza, prior to the shipment of any API to Lonza hereunder, the environmental, health and safety information described in Exhibit C as it relates to the APL To the extent the information contained in paragraphs 2 and 3 of Exhibit C, has not yet been generated by Customer, tests, analyses and/or research necessary to collect such information and data shall be conducted, at the expense of Customer, by Customer internally or by an outside laboratory retained by Customer. Customer shall properly document all such test results and shall provide such documentation to Lonza prior to the delivery of any API to Lonza. If the data indicates that Lonza cannot safely handle the API without the addition of certain engineering controls or other changes to its facilities and/or equipment, the Parties will discuss cost allocation for required changes.

(b) Customer shall provide to Lonza promptly upon receipt by Customer (i) any information needed to clarify, correct, supplement or amend any of the information described in Exhibit C or provided in Exhibit D and (ii) any other information reasonably related to the environmental, health and safety implications, including employee health and safety, of the handling, manufacture, distribution, use and disposal of the APL Lonza shall not be responsible for any failure to deliver or delivery delay due to Customer's failure to deliver such results or documentation.

5.4 **Compliance with Law; Use and Disposal of Product.** Customer is responsible for (a) the use, labeling, distribution, marketing, promotion, sale and disposal of Product, including compliance with all present and future Laws related to the same; (b) packaging in the case of Product - Bulk Tablets, (b) communicating with any governmental authority concerning the Product, including without limitation with respect to the registration, classification or notification of a new Product or substance, or the use, packaging, labeling, distribution, marketing, promotion, sale or disposal of the same or any adverse events related to the Product (for the avoidance of doubt, Lonza may interact with governmental authorities for the purpose of fulfilling its obligations hereunder); (c) storing and handling Product in appropriate conditions following its delivery; and (d) determining the Specifications for the Product to permit its sale in each country in the world as required. Customer shall conduct all such activities at all times in compliance with applicable Laws. The Parties acknowledge and agree that Lonza has no control, role, or other form of influence in Customer's use, packaging, labeling, distribution, marketing, promotion, sale and disposal of Product, nor does it control or influence any payments or transfers of value that may be made by Customer to health care professionals, health care institutions, or any other customer or third party. Customer is responsible for participation and compliance in all government health care programs such as Medicare and Medicaid, and any rebate liability, mandatory pricing, or reporting obligations resulting therefrom.

5.5 **Additional Obligations.** Without limitation Lonza's indemnification obligations hereunder, Customer shall manage, direct and be responsible for all intellectual property decisions and being responsible for all litigation costs which result solely from the filing of the Products. Customer shall maintain pharmacovigilance infrastructure as required by a distributor of Product. Customer will own and control all regulatory approvals in the Territory (including all associated contents and correspondences) and applications therefore related to the Product and any other marketing authorizations within the Territory.

6. OBLIGATIONS OF LONZA AND CUSTOMER; PROCESS VALIDATION SERVICES

6.1 **Materials.** Lonza shall be responsible for procuring Raw Materials and Components identified in the Specifications other than the APL Lonza will destroy or ship unused API following instructions provided by Customer, consistent with Lonza's environmental, health and safety guidelines. Customer shall pay for the costs of destruction or shipment.

6.2 **Lonza Regulatory Obligations.** Lonza is responsible for (a) manufacturing and supplying the Product in compliance with the Specifications and all applicable Laws, including but not limited to environmental health and safety laws and cGMP, and (b) storing and handling Product, material and components in appropriate conditions before its delivery to Customer in accordance with Section 4.6. Lonza shall obtain and maintain during the Term all regulatory approvals necessary in the jurisdiction in which the Facility is located for Lonza to operate the Facility.

6.3 **Inspections and Audits.** Subject to the terms of the Quality Agreement, Customer and its representatives shall have the right to visit or audit, or request a reputable third party to visit or audit the Facility to verify that the documentation, equipment, facility, testing, manufacturing, procedures, systems and material relating to the Product is maintained in accordance with applicable Laws and that Lonza is performing its obligations hereunder. Customer shall bear Customer costs related to any such audit, visit or inspection. This Section 6.3 is subject in all cases to any such party executing a confidentiality agreement with Lonza, in form and substance reasonably acceptable to Lonza. Lonza shall in good faith, work with Customer to promptly address any issues identified during an audit or inspection, but shall be under no obligation to implement any corrective actions to any observations identified by Customer Subject to the terms of the Quality Agreement and Section 4.8, Lonza will allow full access to any governmental

regulatory inspection and shall promptly inform Customer an inspection has commenced and the results of such inspections to the extent such inspection directly affects Lonza's performance under this Agreement.
Customer shall have the right, subject to any Third Party confidentiality obligations and prior advance notice to Lonza of at least [***], during normal business hours, to examine those technical records made or kept by Lonza that relate to the Product. The documentation to be issued prior to shipment is outlined in the Quality Agreement.

6.4 **Customer Regulatory Obligations.** Customer is responsible for compiling the registration dossiers (with reasonable and necessary assistance from Lonza), filing the marketing applications with the regulatory authorities in the Territory, and maintaining marketing authorizations for the Product and the costs associated with the same. Lonza shall reasonably assist Customer in obtaining and maintaining marketing authorizations for the Product. Customer is responsible for (a) the formulation, use, packaging, labeling, distribution and disposal of Product, including compliance with all Laws related to the same; (b) communicating with any governmental authority concerning the Product (for the avoidance of doubt, Lonza may interact with governmental authorities for the purpose of fulfilling legal obligations); and (c) storing and handling Product in appropriate conditions following its delivery; and (d) determining that the Product is permitted for human use. Customer is responsible for developing all Product labeling, printing the labels, and for labeling content.

6.5 **Adverse Events.** Lonza shall promptly notify and forward to Customer any information concerning any potentially serious or unexpected side effect, injury, toxicity or sensitivity reaction or any unexpected incidence or other adverse experience related to the Product (an "Adverse Experience") reported to it. Customer agrees that it shall be solely responsible to review, analyze and respond to any Adverse Experience. Lonza shall have no obligation with respect to an Adverse Experience other than the obligation to notify Customer.

6.6 **Process Validation; Analytical Validation; Regulatory Support Activities.** The Parties agree that any process validation services, analytical validation services, or regulatory support services are not included in the Price, and shall be subject to separate, standalone statement of works to be negotiated and agreed to by the Parties in good faith.

6.7 Recall. Customer, in its sole responsibility and discretion, shall be entitled to make all decisions with respect to any recall, market withdrawals or other corrective action related to the Product. Lonza shall reasonably cooperate with Customer in connection with any such action. The costs and expenses associated with any such action shall be borne by Customer, provided that Lonza shall bear all such costs and expenses to the extent due to Lonza's breach of its representations and warranties under Section 7.1, up to the value of the Product subject to the recall.

7. REPRESENTATIONS AND WARRANTIES

7.1 **Regarding the Product.** Lonza represents and warrants to Customer that, as of the Actual Delivery Date, the Product released by Lonza has been manufactured (a) in conformity with the Specifications, (b) in accordance with cGMP, and (c) in accordance with the Quality Agreement.

7.2 **Rejection of Product; Disposal of Rejected Shipments.** (a) Customer may reject any Product that does not meet the warranties set forth in Section 7.1 ("Non-Complying Product") by providing written notice of rejection to Lonza within [***] following the Actual Delivery Date; provided that such period for rejection shall in the case of Hidden Defects in the Product be [***] following the Actual Delivery Date. Failure by Customer to provide notice of rejections within the applicable timeframe shall constitute irrevocable acceptance of the Product by Customer.

(b) Lonza shall have the right to examine and test any Product that Customer claims to be a Non-Complying Product and shall notify Customer in writing of the results of such examination.

(c) In the event the Parties cannot agree as to whether or not any shipment of Product is a Non-Complying Product, the Parties shall appoint a third party, a mutually acceptable independent reputable laboratory to complete and report the relevant testing within [***], the findings of which shall be binding on the Parties, absent manifest error. The Parties shall ensure that such independent laboratory is bound to the Parties by obligations of confidentiality no less exacting than those applying between the Parties. Expenses of such laboratory testing shall be borne by the Party whose position is determined to have been in error or, if the laboratory cannot place the fault noticed and complained about, then the Parties shall share equally the expenses of the laboratory.

(d) Customer agrees that Lonza shall have no liability if the Non-Complying Product is due to any action or inaction on the part of Customer, any Affiliate of Customer or any third party under contract with or subject to the control or direction of Customer or any Affiliate of Customer.

7.3 **Remedy for Non-Complying Product.** Customer shall return any shipments of Non-Complying Product (or portions thereof) rejected to Lonza at Lonza's expense. As Lonza's sole liability and Customer' sole remedy with respect to such Non-Complying Product, upon Customer's request, Lonza shall re-perform the Services and replace such rejected Non-Complying Product as soon as reasonably possible with additional API supplied by Customer at Customer's cost but at no additional charge (including any freight charge) to Customer; provided, that, such re-performing of services shall only be done at Lonza's expense in the event Lonza fails to manufacture in accordance with the specifications, GMPs, or follow the project documentation; provided, further, that Lonza shall reimburse Customer for API costs up to [***] in the event Lonza fails to manufacture in accordance with the specifications, GMPs, or follow the project documentation. These provisions shall survive termination or expiration of the Agreement, provided that, subsequent to the termination or expiration of the Agreement, Lonza may, in lieu of replacing any rejected or missing quantities of Product, elect in its sole discretion to reimburse Customer for the amounts paid by Customer to Lonza for such rejected quantities of Non-Complying Product (including any applicable freight charges).

7.4 **Disclaimer of Other Warranties.** EXCEPT AS STATED IN THIS ARTICLE 7 LONZA MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW LONZA SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7.5 Lonza advises, and Customer acknowledges that, the Products resulting from the Services performed under this Agreement may not be used in the production, encapsulation, packaging or marketing of any product which is in violation of any applicable Laws or with any person or entity on any applicable government sanction, restricted party or denial list without a license or otherwise in violation of applicable Laws.

7.6 Customer represents and warrants that the Products will not be made available to any person or entity on any sanction, restricted party or denied party list of the United States of America, Switzerland, the European Union or United Nations without a license or otherwise in violation of applicable Laws.

8. MANUFACTURING STANDARDS; MINIMUM SHELF LIFE

8.1 **Quality Agreement.** The Parties agree to negotiate and update in good faith a mutually acceptable Quality Agreement relating to the manufacture of the Product to be executed and delivered. Specifications and Product conformance shall be set forth in the Quality Agreement. Lonza shall manufacture and supply the Product in accordance with the Quality Agreement as reasonably updated by the Parties from time to time, notably to take into consideration any marketing authorization(s) for the Product. If there are any conflicts between the Quality Agreement and this Agreement, the provisions of this Agreement shall govern and control, with the exception that the Quality Agreement shall control with respect to all matters relating to the quality and disposition of the Product.

8.2 **Modifications in Specifications.** Any changes to the Specifications shall be agreed between the Parties in writing. Costs for amendments to the Specifications (including without limitation any additional production, testing and/or procurement costs) shall be borne by the Customer.

8.3 **Modifications in Materials.** Customer shall notify Lonza of any change related to the API that may affect the validated process including but not limited to supplier changes, process changes, regulatory changes, and environment health safety characteristics. Customer should provide to Lonza a written notification of such change at least [***] before implementation of the change. If the change warrants validation batches, then the costs associated with such change will be borne by the Customer.

8.4 **Minimum Shelf Life.** On the Actual Delivery Date, the Product shall have the following minimum remaining shelf life: (x) in the case which Lonza manufactures, releases, and packages Product - Bradstock, the minimum remaining shelf life shall be [***]; and (y) in the case which Lonza manufactures and releases Product- Bulk Tablets, the minimum remaining shelf life shall be [***].

8.5 Debarment; Excluded Lists. Lonza will not use in connection with the Services in any capacity, the services of any individual or entity (i) debarred or subject to debarment under the Generic Drug Enforcement Act of 1992, amending the Act at 21 USC §335a, or (ii) on any Excluded Lists. Lonza agrees to notify Customer immediately in the event any person providing services to Customer relating to this Agreement is debarred, becomes subject to debarment or is placed on any Excluded List. For purposes of this Section, "Excluded Lists" means (i) the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals/Entities that are excluded from participation in Medicare, Medicaid and all other Federal Health Care Programs, (ii) the Excluded Parties List maintained by the U.S. General Services Administration, and (iii) foreign counterparts of any of the foregoing.

9. INDEMNIFICATION

9.1 **Indemnification of Customer.** Lonza shall indemnify, defend and hold Customer, its Affiliates and their respective officers, directors, employees and agents (each, a "Customer Indemnified Party") harmless from and against any and all Losses suffered, incurred or sustained by any Customer Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from Lonza's: (i) breach of the representation and warranties in this Agreement or (ii) negligence, willful misconduct or violation of Laws in connection with this Agreement; provided however, that Lonza shall have no obligation of indemnity hereunder with respect to any Losses to the extent caused by the negligence or willful misconduct on the part of Customer.

9.2 **Indemnification of Lonza.** Customer shall indemnify, defend and hold Lonza, its Affiliates and their respective directors, officers, employees and agents (each, a "Lonza Indemnified Party") harmless from and against any and all Losses suffered, incurred or sustained by any Lonza Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from Customer's (i) breach of the representation and warranties in this Agreement; (ii) negligence or willful misconduct or violation of Laws in connection with this Agreement; (iii) the use, packaging, labeling, distribution, marketing, promotion, sale and disposal of Product or API; or (iv) resulting from the inherent risk of the Product or API; provided however, that Customer shall have no obligation of indemnity hereunder with respect to any Losses to the extent caused by the negligence or willful misconduct on the part of Lonza or any Third Party performing Services on behalf of Lonza.

Customer shall also indemnify, defend and hold each Lonza Indemnified Party harmless from and against any and all claims, suits, and/or proceedings (including any assertion of an intellectual property right, regardless of whether the assertion has been or will be adjudicated), as well as all damages, losses, liabilities, and expenses (including reasonable attorneys' fees and costs), of whatever nature resulting from, arising out of, or relating to a claim or allegation that the Product, or any part thereof, or any intellectual property, information or material supplied by or on behalf of Customer infringes, misappropriates, or otherwise violates a patent, copyright, trade secret, trademark or other intellectual property right of any third party.

9.3 **Indemnification Procedures.** In the event that any Claim or Proceeding is asserted or imposed against a Party, and such Claim or Proceeding involves a matter which is subject to a claim for indemnification under this Article 9, then such Party (the "Indemnified Party") shall promptly give written notice to the other Party (the "Indemnifying Party") of such Claim or Proceeding. The Indemnifying Party shall assume, at its cost and expense, the defense of such Claim or Proceeding through its legal counsel selected and reasonably acceptable to the Indemnified Party, except that the Indemnified Party may, at its option and expense, select and be represented by separate counsel. The Indemnifying Party shall have control over the Claim or Proceeding, including the right to settle; provided, however, that the Indemnifying Party shall not, absent the prior written consent of the Indemnified Party, consent to the entry of any judgment or enter into any settlement that (1) provides for any relief other than the payment of monetary damages for which the Indemnifying Party shall be solely liable, and (2) where the claimant or plaintiff does not release the Indemnified Party, its Affiliates and their respective directors, officers, employees, agents and representatives, as the case may be, from all liability in respect thereof. In no event shall the Indemnified Party be liable for any claims that are compromised or settled in violation of this Section.

9.4 **Waiver of Certain Losses.** OTHER THAN IN THE EVENT OF GROSS, NEGLIGENCE, WILLFUL MISCONDUCT, WILLFUL BREACH, IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY LOSS OF OPPORTUNITY, LOSS OF PROFITS, LOSS OF ANTICIPATED SALES, OR FOR ANY PUNITIVE, INCIDENT AL, CONSEQUENTIAL, INDIRECT OR SPECIAL LOSSES OR DAMAGES WHETHER OR NOT FORESEEABLE, OR WHETHER OR NOT THE INDEMNIFIED PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OF ANY KIND HOWEVER CAUSED, WHETHER BASED ON CONTRACT, NEGLIGENCE, INDEMNITY OR OTHER THEORY OF LAW, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY PURCHASE ORDER, AS APPLICABLE.

9.5 **Limitation of Liability.** Notwithstanding any other provision in this Agreement or a Purchase Order, as applicable, the total liability, in the aggregate, of Lonza and its Affiliates, to Customer and anyone claiming by or through Customer, for any and all claims, losses, costs, damages or fees, including without limitation, attorneys' fees resulting from or in any way related to this Agreement or a Purchase Order from any cause or causes shall not exceed [***].

9.6 **Insurance.** Each Party shall, during the Term and for [***], obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage in the amount of at least [***] per claim. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

10. CONFIDENTIALITY

10.1 **Non-disclosure and Non-use.** Neither Party shall disclose to any third party nor use for its own purposes (other than those contemplated by this Agreement) any information of the other Party that is not in the public domain and that was disclosed to it by the other Party in connection with this Agreement ("Confidential Information"). For purposes of this Agreement, Confidential Information shall mean all proprietary information, trade secrets, business plans, pharmaceuticals, materials, operations, equipment, processes, methods, strategies and systems, and financial information, prices, materials, building techniques and any drawings, specifications, designs and other information or data, or any fact with respect to any of the foregoing relating to this Agreement. If information is disclosed in written form, the receiving Party's obligations of non-disclosure and non-use shall apply only to information which is, at the time of the disclosure, identified in writing by the disclosing party as being "Confidential." Notwithstanding the above, either Party may disclose Confidential Information to those of its and its Affiliates' directors, officers, employees, agents, consultants, representatives and advisors (collectively, "Agents") and to those approved subcontractors who have a need to know for the purposes of this Agreement. Each Party shall ensure that all of its Agents and subcontractors are bound by confidentiality obligations no less stringent than those stated herein. The receiving Party shall be liable for any failure of any of its Agents to (a) maintain the

confidentiality of the disclosing Party's Confidential Information, or (b) otherwise comply with the terms of this Article 10 to the same extent as the receiving Party is obligated to do so.

10.2 **Exclusion of Confidential Information.** The obligations of confidentiality and non-use set forth in Section 10.1 shall not apply to Confidential Information that: (a) is or becomes part of the public domain without a violation of this Agreement; (b) was already in possession of a receiving Party or its Affiliates at the time of receipt from the disclosing Party, as shown by documentary evidence, without violating an obligation of confidentiality; (c) after the date of this Agreement is received from a third party whose direct or indirect source is not the disclosing Party; or (d) the receiving Party can demonstrate was independently developed by or for the receiving Party or its Affiliates without violating the terms of this Agreement.

10.3 **Information Required by Law.** If the receiving Party is requested to disclose the Confidential Information of the disclosing Party or the substance of this Agreement in connection with a legal or administrative proceeding or otherwise to comply with a requirement under applicable Law, the receiving Party will, to the extent legally permissible, give the disclosing Party prompt written notice of such request so that the disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the disclosing Party seeks a protective order or other remedy, the receiving Party, at the disclosing Party's expense, will cooperate with and assist the disclosing Party in such efforts. If the disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, the receiving Party will disclose only that portion of the Confidential Information which its legal counsel determines it is required by applicable Law to disclose.

10.4 **Confidentiality Period.** All obligations of confidentiality under this Article 10 will terminate [***] after the expiration or termination of this Agreement; provided however that the obligations of confidentiality for Confidential Information identified as a trade secret will survive indefinitely until such trade secret information no longer qualifies as a trade secret.

10.5 **Publicity.** Neither Party shall use or reference in any advertising, sales promotion, press release or other communication, the endorsement, direct or indirect quote, code, drawing, logo, trademark, specification, or picture of the other Party or the other Party's Affiliates without the prior written consent of the other Party. Customer and Lonza agree to coordinate external communications (e.g., a joint press release) regarding the Parties' collaboration.

10.6 **Document Retention.** In case of termination of this Agreement, all technical documents of Customer shall be returned in original form without retaining any copies except for such copies as are required for regulatory purposes. All executed documents of exhibit and commercial batches shall be kept by Lonza as per regulatory requirements and the Quality Agreement and shall be destroyed after the applicable retention period without retaining any copies.

10.7 **Reservation of Rights.** Except as specifically set forth herein, this Agreement does not (i) give either Party any license, right, title, interest in or ownership to any Confidential Information of the other Party; or (ii) grant any license or right under any intellectual property rights.

11. INTELLECTUAL PROPERTY

11.1 This Agreement does not (i) give any of Party any license, right, title, interest in or ownership to any Confidential Information of the other Party; or (ii) grant any license or right under any intellectual property rights.

11.2 All claims, expenses or damages (including attorneys' fees) in connection with any litigation instituted by a third party relating to a claim or claims of infringement of patents against either of the Parties, relating to or arising from the filings and/or the manufacturing, marketing, use or offer to sell

of the Products in the Territory shall be the responsibility of Customer. Lonza shall support Customer with all necessary relevant information required by Customer for intellectual property evaluation and in case of any related legal notice and/or litigation, to the extent of providing supporting data and information related to such legal notice and/or litigation.

11.3 Customer acknowledges that it shall be solely and fully responsible for doing any and all freedom to operate assessments regarding possible infringement of third party intellectual property rights for any and all products and processes for any Product which it makes, has made, uses, sells, offers for sale or imports.

11.4 The marketing of Products shall be carried out by Customer under its own trademark. A Party shall acquire no rights or license on the other Party's trademarks, unless such other Party provides prior written consent.

12. TERMINATION

12.1 **Breach; Insolvency.** If either Party is in material breach of any of its obligations, including its representations, warranties or covenants, under this Agreement, and fails to remedy such breach within [***] of receipt of written notice from the other Party, the non- breaching Party may terminate this Agreement with immediate effect with written notice of termination to the breaching Party, without liability to the other Party and without prejudice of any other rights or remedies; provided however, that if the breaching party is diligently pursuing in good faith the remedy of the breach at the expiration of such [***] cure period, then such [***] cure period shall be extended as reasonably required to effect the cure. Subject to any limitations under applicable Law, either Party shall have the right to terminate this Agreement by giving notice to the other Party in the event that the other Party becomes insolvent or goes into bankruptcy, liquidation or receivership, or is admitted to the benefits of any procedure for the settlement of debts or becomes a party to dissolution proceedings. For purposes of clarity, Lonza shall have the right to terminate this Agreement in the event Customer (i) breaches its payment obligations; (ii) materially delays the manufacture program; or (iii) becomes insolvent.

12.2 **For Convenience.** This Agreement may be terminated by either Party without cause upon [***] prior written notice to the other Party.

12.3 **Consequences of Termination.**

12.3.1 In the event of termination hereunder, except in the event that Customer terminates for Lonza's breach in accordance with Section 12.1 above, (a) Lonza shall be compensated for: (i) Services rendered up to the date of termination, including in respect of any Product in-process; and (ii) all costs incurred through the date of termination and directly related to Firm Orders or Purchase Orders, including Raw Materials costs; and (b) Lonza shall complete all Purchase Orders unless otherwise requested in writing by Customer in which case all Purchase Orders shall be deemed cancelled and Customer shall pay the Cancellation Fee (in accordance with the terms of this Agreement) in respect of such cancelled manufacturing of Product due under Section 3.6, without proration of the final calendar year. In the case of termination by Lonza for Customer's material breach, Cancellation Fees shall be calculated as of the date of written notice of termination.

12.3.2 In the event of termination by Customer for Lonza's material breach in accordance with Section 12.1 above, Lonza shall be compensated for all Product delivered to Customer hereunder and meeting the Specifications.

12.4 **Environmental Effects; Health and Safety.** Lonza reserves the right to terminate immediately this Agreement upon prior written notice to Customer if, for any reason, (a) Lonza determines in good faith that the information provided by Customer pursuant to Section 5.3 is incomplete, inadequate, or inaccurate to protect the environment or the health, safety and well-being of Lonza's employees (or those

of its Affiliate) or (b) Lonza determines in good faith that continued performance of the Services hereunder may adversely affect the environment or the health, safety and well-being of Lonza's employees (or those of its Affiliate).

12.5 **Survival.** Termination or expiration of this agreement shall not relieve either Party of any liabilities, rights or obligations accruing prior to such termination or expiration. In the event of any termination or expiration of this Agreement, the provisions of this Section 12.5, and Sections 4, 5.2, 5.3, 6.1, 7, 9, 10, 15.1, and 15.3 shall survive such termination or expiration, together with any other provision hereof that by its terms survives termination or expiration hereof and any other obligations that have accrued prior to the termination or expiration of this Agreement.

13. NOTICES

13.1 Notices hereunder shall be deemed given as of the date sent. All notices shall be in writing mailed via certified mail, return receipt requested, or a reputable overnight courier, addressed as follows, or to such other address as may be designated from time to time:

if to Lonza:

Xcelience, LLC
[***] Attention: Managing
Director

Copy to:

Lonza, Inc.
[***]Attention: General Counsel, North America

If to Customer: Strongbridge Biopharma plc
900 Northbrook Drive, Suite 200
Trevose, PA 19053
Attention: Peter J. Valentinsson, Senior Vice President Global Technical Operation
Copy to: Stephen Long, Chief Legal Officer

14. FORCE MAJEURE

14.1 If Lonza is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives prompt written notice thereof to Customer specifying the matters constituting Force Majeure together with such evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, Lonza shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. Provided that, if such Force Majeure persists for a period of [***] or more, Customer may terminate this Agreement by delivering written notice to Lonza.

14.2 "Force Majeure" shall be deemed to include any reason or cause beyond Lonza's reasonable control affecting the performance by Lonza of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labor or transportation, at prices and on terms deemed by Lonza to be reasonably practicable, from Lonza's usual sources of supply.

14.3 With regard to Lonza, any such event of Force Majeure affecting services or production at its Affiliates or suppliers shall be regarded as an event of Force Majeure.

15 MISCELLANEOUS

15.1 **Entire Agreements; Amendments; Waivers.** The terms and provisions contained in this Agreement and all Exhibits hereto constitute the entire agreement between the Parties with respect to the commercial terms and conditions related to the commercial supply of Product, superseding all prior and contemporaneous agreements or understandings between the Parties with respect to the commercial terms and conditions related to the Product. In the event of a conflict between the terms of the Agreement, any Exhibit and the Quality Agreement, the terms of this Agreement shall control. Any amendments of this Agreement must be in writing and signed by the Parties. A waiver of any breach or failure to enforce any of the terms or conditions of this Agreement shall in no way affect, limit or waive a Party's rights at any time to enforce strict compliance thereafter with every term or condition of this Agreement.

15.2 **Successors and Assigns.** Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) Lonza may assign this Agreement to (i) any Affiliate of Lonza or (ii) any third party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business related to providing the Services, (b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer, and (c) Customer may assign this Agreement without the consent of Lonza in the event of a sale of all or substantially all of the assets or business to which this Agreement relates, provided that, if the assignee is a party whose primary business is contract manufacturing of pharmaceutical products, such assignment shall require the prior written consent of Lonza, not to be unreasonably withheld, conditioned or delayed. For purposes of this Section 15.2, the terms "assign" and "assignment" shall include, without limitation the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

15.3 **Independent Contractor.** The relationship of the Parties under this Agreement is that of independent contractors and nothing contained herein shall be construed to create a partnership, joint venture or agency relationship between Customer and Lonza, nor shall either Party be authorized to bind the other in any way.

15.4 **Joint Steering Committee; Joint Project Team.** Promptly after execution of this Agreement, the Parties shall establish a steering committee to oversee, review and coordinate the activities of the Parties under this Agreement (the "Joint Steering Committee" or "JSC"). Each Party shall name a mutually agreed upon equal number of representatives for the Joint Steering Committee, each of whom shall be a knowledgeable specialist in an appropriate discipline. The Joint Steering Committee shall meet at least [***]during the Term, or as otherwise mutually agreed by the Parties. The Joint Steering Committee shall appoint a joint project team (the "Joint Project Team" or "JPT") to manage the day-to-day activities under this Agreement. Decisions of the Joint Project Team shall be made by unanimity, with each Party having one vote. In the event that the Joint Project Team does not reach unanimity with respect to a particular matter, and the Joint Project Team is unable to resolve the dispute after endeavoring for [***], or as otherwise mutually agreed by the Parties, to do so, then (i) either Party may, upon written notice, refer such matter to the Joint Steering Committee, for attempted resolution by good faith negotiations within [***], or as otherwise mutually agreed by the Parties, after such written notice, and (ii) if the Joint Steering Committee do not reach resolution on such a matter within [***], or as otherwise mutually agreed by the Parties, after such notice, then either Party may refer such matter to dispute resolution pursuant to Section 15.5, and other matters that are not mutually agreed shall be referred to dispute resolution pursuant to Section 15.5

15.5 **Governing Law; Dispute Resolution.** This Agreement is governed in all respects by the laws of the State of New York, without regard to its conflicts of laws principles. The Parties agree to submit to the exclusive jurisdiction of the courts located in the Southern District of New York. The Parties shall have the right to proceed to a suitable jurisdiction for the purpose of enforcing a judgment, award, or order

(including without limitation seeking specific performance) and injunctive reliefs.

15.6 **Severability.** If any provision of this Agreement is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the purpose of this Agreement.

15.7 **Counterparts; Electronic Signatures.** This Agreement may be executed in one or more counterparts, and by the Parties in separate counterparts, each of which when so executed shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement, to the extent signed and delivered by electronic means, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

15.8 **No Third Party Beneficiaries.** No third party including any employee of a Party shall have or acquire any rights by reason of this Agreement whether by way of statute or otherwise.

15.9 **Miscellaneous.** The division of this Agreement into articles, sections, subsections and exhibits, and the insertion of headings, are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa. Any reference herein to a "day" or "days" shall be references to a calendar day or days. Any period of days specified in this Agreement ending on a Saturday, Sunday or public holiday shall automatically be extended to the first business day in the country of manufacture ending after such Saturday, Sunday or public holiday.

15.10 **Construction.** Each of the Parties agrees that it has read and had the opportunity to review this Agreement with its legal counsel and, accordingly, the rule of construction that any ambiguity contained in this Agreement shall be construed against the drafting Party shall not apply.

IN **WITNESS WHEREOF,** the Parties have executed this Agreement as of the Effective Date.

STRONGBRIDGE BIOPHARMA PLC	**XCELIENCE, LLC**
By: /s/ Richard S. Kollender	By: /s/ Amber Broadbent
Name: Richard S. Kollender	Name: Amber Broadbent
Title: President and CFO	Title: Director, Commercial Development
Date: 5/4/21	Date: 11-May-2021

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. 1 TO
COMMERCIAL MANUFACTURING SERVICES AND SUPPLY AGREEMENT

This Amendment No. 1 ("Amendment") effective as of May 23, 2024 ("Amendment Effective Date") by and between Lonza Tampa, LLC (formerly known as Xcelience, LLC), having an address at [***] ("Lonza") and Strongbridge Dublin Limited , a company incorporated under the laws of Ireland, having its office at Suite 206, Fitzwilliam Hall, Fitzwilliam Place, Dublin 2, D02 T292, Ireland (hereinafter collectively referred to as "Strongbridge" or "Customer").

PRELIMINARY STATEMENT

WHEREAS, Lonza and Strongbridge entered into that certain Commercial Manufacturing Services and Supply Agreement dated effective May 4th, 2021 (the "Agreement"); and

WHEREAS, Lonza and Strongbridge desire to amend the Agreement upon the terms and conditions noted below;

NOW, THEREFORE, in consideration of the premises, the mutual covenants contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Lonza and Strongbridge hereby agree as follows:

1. All references in the Agreement to "Xcelience, LLC" are deleted and hereby replaced with "Lonza Tampa, LLC."

2. The introductory paragraph is deleted in its entirety and replaced with the following:

   "This Commercial Manufacturing Services and Supply Agreement (the 'Agreement') is made and entered into as of May 6th, 2021 ('Effective Date') by and between Strongbridge Dublin Limited, a company incorporated under the laws of Ireland, having an office at Suite 206, Fitzwilliam Hall, Fitzwilliam Place, Dublin 2, D02 T292, Ireland (hereinafter collectively referred to as "Strongbridge" or "Customer") and Lonza Tampa, LLC, with a principal place of business at [***] ('Lonza'). Each of Lonza and Customer may be referred to herein individually as a 'Party,' and Lonza and Customer may be referred to collectively as the 'Parties.'"

3. In Section 13.1 of the Agreement, the notice address for Customer is deleted and replaced with the following:

   "If to Customer:

   Strongbridge Dublin Limited
   c/o Xeris Pharmaceuticals, Inc.
   1375 W Fulton St, Suite 1300, Chicago, IL 60607
   Attention: Legal Department

   Copy to: [***]

Copy to: [***]
Copy to: [***]
Copy to: Legal@xerispharma.com

4. **Exhibit A** of the Agreement is hereby deleted in its entirety and replaced with Exhibit A as attached hereto and incorporated herein by reference.

5. This Amendment supersedes and replaces that certain Amendment No. 1 dated August 25, 2023, by and between Lonza and Xeris Pharmaceuticals, Inc. ("Xeris") ("Voided Amendment") which purported to amend the Agreement without the consent of Strongbridge. For avoidance of doubt, the Voided Amendment shall be void and of no force and effect.

6. The provisions of this Amendment are hereby made a part of the Agreement.

7. Any conflict between the provisions of this Amendment and the Agreement shall be resolved in favor of the provisions of this Amendment.

8. All capitalized terms used in this Amendment and not defined herein shall have the same meanings as given to them in the Agreement.

In order to demonstrate their agreement, the parties have executed and delivered this Amendment as of the Amendment Effective Date.

Agreed and Accepted:

LONZA TAMPA, LLC

By: /s/ Filipe Tomas

Name: Filipe Tomas

Title: Head of Account Management, North America

Agreed and Accepted:

STRONGBRIDGE DUBLIN LIMITED

By: /s/ Ken Johnson

Name: Ken Johnson

Title: Senior Vice President

Acknowledged and Agreed:

Xeris Pharmaceuticals, Inc.

By: /s/ Peter Valentinsson

Name: Peter Valentinsson

Title: SVP, Product Development/Technical Operations

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, John Shannon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Xeris Biopharma Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2024

By: /s/ John Shannon
John Shannon
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Steven M. Pieper, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Xeris Biopharma Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2024

By: /s/ Steven M. Pieper
Steven M. Pieper
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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, John Shannon 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, 2024 (Periodic Report) to which this statement is an exhibit fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

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

Date: August 8, 2024

/s/ John Shannon
John Shannon
Chief Executive Officer and Director
(Principal Executive Officer)

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