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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: 001-34703

Alimera Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-0028718**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
6310 Town Square, Suite 400 Alpharetta, GA	**30005**
(Address of principal executive offices)	**(Zip Code)**

(678) 990-5740
(Registrant's telephone number, including area code)

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, $0.01 par value per share	ALIM	The Nasdaq Stock Market LLC (Nasdaq Global 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 August 2, 2024, there were 54,384,165 shares of the registrant's $0.01 par value Common Stock issued and outstanding.

ALIMERA SCIENCES, INC.
QUARTERLY REPORT ON FORM 10-Q

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND PROJECTIONS

Various statements in this report of Alimera Sciences, Inc. ("we," "our," "Alimera" or the "Company") are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties (some of which are beyond our control) and are based on information currently available to our management. Words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "forecast," "outlook," "contemplates," "predict," "project," "aim," "seek," "target," "likely," "remain," "potential," "continue," "ongoing," "will," "will likely result," "will continue," "would," "should," "could," or the variation or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements.

All written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely on the forward-looking statements we make or that are made on our behalf as predictions of future events. We undertake no obligation and specifically decline any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

We encourage you to read management's discussion and analysis of our financial condition and results of operations and our accompanying unaudited interim condensed consolidated financial statements and notes thereto ("Interim Financial Statements") contained in this Quarterly Report on Form 10-Q and our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023. There can be no assurance that we will in fact achieve the actual results or developments we anticipate or, even if we do substantially realize them, that they will have the expected consequences to, or effects on, us. Therefore, we can give no assurances that we will achieve the outcomes stated in those forward-looking statements, projections and estimates.

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

ALIMERA SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	June 30, 2024	December 31, 2023
	(In thousands, except share and per share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 10,828	$ 12,058
Restricted cash	33	32
Accounts receivable, net	37,079	34,545
Prepaid expenses and other current assets	4,013	3,909
Inventory	3,455	1,879
Total current assets	55,408	52,423
Property and equipment, net	2,278	2,466
Right-of-use assets, net	996	1,124
Intangible assets, net	91,587	97,355
Deferred tax asset	101	104
Warrant asset	7	52
Total assets	$ 150,377	$ 153,524
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,208	$ 8,252
Accrued expenses	5,708	6,192
Accrued licensor payment	3,677	7,275
Finance lease obligations	245	194
Total current liabilities	19,838	21,913
Non-current liabilities:		
Notes payable, net of discount	69,731	64,489
Accrued licensor payments	16,111	15,136
Other non-current liabilities	5,909	5,816
Total liabilities	111,589	107,354
Commitments and contingencies (note 8)		
Stockholders' equity:		
Preferred stock, $.01 par value — 10,000,000 shares authorized at June 30, 2024 and December 31, 2023, none issued	—	—
Common stock, $.01 par value — 150,000,000 shares authorized, 52,387,763 shares issued and outstanding at June 30, 2024 and 52,354,450 shares issued and outstanding at December 31, 2023	524	524
Common stock warrants	4,396	4,396
Additional paid-in capital	464,825	462,446
Accumulated deficit	(428,052)	(418,490)
Accumulated other comprehensive loss	(2,905)	(2,706)
Total stockholders' equity	38,788	46,170
Total liabilities and stockholders' equity	$ 150,377	$ 153,524

See Notes to Unaudited Interim Condensed Consolidated Financial Statements ("Interim Financial Statements")

ALIMERA SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands, except share and per share data)			
Net revenue	$ 27,000	$ 17,538	$ 50,011	$ 31,084
Cost of goods sold, excluding depreciation and amortization	(3,831)	(2,425)	(7,184)	(4,453)
Gross profit	23,169	15,113	42,827	26,631
Operating expenses:				
Research, development and medical affairs expenses	4,263	3,648	8,624	7,812
General and administrative expenses	7,379	4,373	12,811	8,544
Sales and marketing expenses	8,511	6,434	17,593	12,238
Depreciation and amortization	3,093	1,866	6,178	2,547
Total operating expenses	23,246	16,321	45,206	31,141
Loss from operations	(77)	(1,208)	(2,379)	(4,510)
Interest expense and other, net	(3,153)	(1,694)	(6,892)	(3,361)
Unrealized foreign currency loss, net	(125)	(7)	(321)	(20)
Loss on extinguishment of debt	—	(1,079)	—	(1,079)
Change in fair value of common stock warrant	—	(5,911)	—	(5,911)
Change in fair value of warrant asset	1	(105)	(45)	(91)
Net loss before income taxes	(3,354)	(10,004)	(9,637)	(14,972)
Income tax benefit (provision)	43	(25)	75	(25)
Net loss	(3,311)	(10,029)	(9,562)	(14,997)
Preferred stock dividends	—	(669)	—	(683)
Net loss applicable to common stockholders	$ (3,311)	$ (10,698)	$ (9,562)	$ (15,680)
Net loss per share — basic and diluted	$ (0.06)	$ (1.32)	$ (0.18)	$ (2.07)
Weighted average shares outstanding — basic and diluted	54,383,604	8,093,640	54,370,216	7,565,868

See Notes to Interim Financial Statements.

ALIMERA SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands)			
Net loss	$ (3,311)	$ (10,029)	$ (9,562)	$ (14,997)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(51)	—	(199)	172
Total other comprehensive (loss) income	(51)	—	(199)	172
Comprehensive loss	$ (3,362)	$ (10,029)	$ (9,761)	$ (14,825)

See Notes to Interim Financial Statements.

ALIMERA SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Six Months Ended June 30,	
	2024	2023
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (9,562)	$ (14,997)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,178	2,547
Loss on extinguishment of debt	—	1,079
Provision for credit losses	176	1,496
Unrealized foreign currency transaction loss, net	321	20
Amortization of debt discount and deferred financing costs	542	488
Stock-based compensation expense	2,302	442
Change in fair value of warrant asset	45	91
Change in fair value of warrant liability	—	5,911
Changes in assets and liabilities:		
Accounts receivable	(3,028)	(4,355)
Prepaid expenses and other current assets	(59)	(539)
Inventory	(1,588)	559
Accounts payable	4,445	(2,066)
Accrued expenses and other current liabilities	(287)	202
Other non-current liabilities	975	917
Net cash provided by (used in) operating activities	460	(8,205)
Cash flows from investing activities:		
Purchases of property and equipment	(132)	(171)
Purchase of intangible assets	—	(75,272)
Net cash used in investing activities	(132)	(75,443)
Cash flows from financing activities:		
Repurchase of Series A Preferred Stock	—	(938)
Proceeds from issuance of Series B Convertible Preferred Stock	—	78,339
Series B Convertible Preferred Stock issuance costs	—	(509)
Proceeds from issuance of common stock	40	2,404
Proceeds from exercise of stock options	37	—
Repurchase of common stock	—	(314)
Issuance of debt	5,000	22,500
Payment of debt costs	(62)	(4,108)
Payment of accrued licensor obligations	(3,750)	—
Payment of SLR exit fee agreements	(2,425)	—
Payment of finance lease obligations	(188)	(251)
Net cash (used in) provided by financing activities	(1,348)	97,123
Effect of exchange rates on cash and cash equivalents and restricted cash	(209)	28
Net change in cash and cash equivalents and restricted cash	(1,229)	13,503
Cash and cash equivalents and restricted cash — beginning of period	12,090	5,304
Cash and cash equivalents and restricted cash — end of period	$ 10,861	$ 18,807
Supplemental cash flow information:		
Cash paid for interest	$ 3,723	$ 3,136
Cash paid for income taxes	$ 21	$ 21
Supplemental noncash investing and financing activities:		
Note payable end of term payment accrued but unpaid	$ 3,625	$ 3,375

See Notes to Interim Financial Statements.

ALIMERA SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS ' EQUITY (DEFICIT)

(UNAUDITED)

	Common Stock		Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Additional Paid-In Capital	Common Stock Warrants	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
					(In thousands, except share data)						
2023											
Balance, December 31, 2022	6,995,513	$ 70	600,000	$ 19,227	—	$ —	$ 378,238	$ —	$ (415,388)	$ (2,955)	$ (20,808)
Issuance of common stock, net of issuance costs	597,000	6	—	—	—	—	(6)	—	—	—	—
Repurchase of common stock	(200,919)	(2)	—	—	—	—	(312)	—	—	—	(314)
Repurchase of Preferred Stock - Series A	—	—	(600,000)	(19,227)	—	—	—	—	18,289	—	(938)
Issuance of Preferred Stock - Series B	—	—	—	—	12,000	7,714	—	—	—	—	7,714
Preferred stock dividends	—	—	—	—	—	14	—	—	(14)	—	—
Stock-based compensation expense	—	—	—	—	—	—	226	—	—	—	226
Net loss	—	—	—	—	—	—	—	—	(4,968)	—	(4,968)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	172	172
Balance, March 31, 2023	7,391,594	74	—	—	12,000	7,728	378,146	—	(402,081)	(2,783)	(18,916)
Issuance of common stock, net of issuance costs	1,415,133	14	—	—	—	—	34	—	—	—	48
Forfeitures of restricted stock	(3,000)	—	—	—	—	—	—	—	—	—	—
Issuance of Preferred Stock - Series B	—	—	—	—	66,617	66,328	2,355		—	—	68,683
Preferred stock dividends	—	—	—	—	—	669	—		(669)	—	—
Forfeiture of common stock warrants	—	—	—	—	—	—	6,227		—	—	6,227
Stock-based compensation expense	—	—	—	—	—	—	217	—	—	—	217
Net loss	—	—	—	—	—	—	—	—	(10,029)	—	(10,029)
Balance, June 30, 2023	8,803,727	$ 88	—	$ —	78,617	$ 74,725	$ 386,979	$ —	$ (412,779)	$ (2,783)	$ 46,230
2024											
Balance, December 31, 2023	52,354,450	$ 524	—	$ —	—	$ —	$ 462,446	$ 4,396	$ (418,490)	$ (2,706)	$ 46,170
Issuance of common stock, net of issuance costs	7,112	—	—	—	—	—	—	—	—	—	—
Stock option exercises	13,125	—	—	—	—	—	37	—	—	—	37
Stock-based compensation expense	—	—	—	—	—	—	845	—	—	—	845
Net loss	—	—	—	—	—	—	—	—	(6,251)	—	(6,251)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	(148)	(148)
Balance, March 31, 2024	52,374,687	524	—	—	—	—	463,328	4,396	(424,741)	(2,854)	40,653
Issuance of common stock, net of issuance costs	13,826	—	—	—	—	—	40	—	—	—	40
Forfeitures of restricted stock	(750)	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,457	—	—	—	1,457
Net loss	—	—	—	—	—	—	—	—	(3,311)	—	(3,311)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	(51)	(51)
Balance, June 30, 2024	52,387,763	$ 524	—	$ —	—	$ —	$ 464,825	$ 4,396	$ (428,052)	$ (2,905)	$ 38,788

See Notes to Interim Financial Statements.

ALIMERA SCIENCES, INC.

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

1. NATURE OF OPERATIONS

Alimera Sciences, Inc., together with its wholly-owned subsidiaries (the "Company"), is a global pharmaceutical company that specializes in the commercialization and development of ophthalmic retinal pharmaceuticals. The Company was formed on June 4, 2003, under the laws of the State of Delaware.

The Company presently focuses on diseases affecting the retina, because the Company believes these diseases are not well treated with current therapies and affect millions of people globally. The Company's commercialized products are ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg, which has received marketing authorization and reimbursement in the United States ("U.S.") and 24 countries for the treatment of diabetic macular edema ("DME") and YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg, available in the U.S. for the treatment and prevention of non-infectious uveitis affecting the posterior segment of the eye ("NIU-PS").

In the U.S. and certain other countries outside Europe, ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. In 17 countries in Europe, ILUVIEN is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. In addition, ILUVIEN has received marketing authorization in 17 European countries and reimbursement in ten countries for the prevention of relapse in recurrent NIU-PS.

The Company markets ILUVIEN directly in the U.S., Germany, the United Kingdom ("U.K."), Portugal and Ireland. In addition, the Company has entered into various agreements under which distributors are providing or will provide regulatory, reimbursement and sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, Australia, New Zealand and several countries in the Middle East. In addition, the Company has granted an exclusive license to Ocumension Therapeutics ("Ocumension") for the development and commercialization of the Company's 0.19 mg fluocinolone acetonide intravitreal injection in China, East Asia and the Western Pacific. As of June 30, 2024, the Company has recognized sales of ILUVIEN to its international distributors in the Middle East, China, Austria, Belgium, Czech Republic, France, Italy, Luxembourg, Spain, the Netherlands, and certain Nordic countries.

In the U.S., YUTIQ is indicated for the treatment and prevention of chronic NIU-PS of the eye. The Company has the rights to commercialize YUTIQ under a product rights agreement dated May 17, 2023 (the "Product Rights Agreement") with EyePoint Pharmaceuticals, Inc. ("EyePoint Parent") in the entire world, except Europe, the Middle East and Africa, as the Company had previously licensed from EyePoint Pharmaceuticals US, Inc. ("EyePoint") rights in those territories to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent NIU-PS (see Note 4). The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU-PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension.

Agreement and Plan of Merger with ANI Pharmaceuticals, Inc. and ANIP Merger Sub INC.

On June 21, 2024, the Company, entered into an Agreement and Plan of Merger (the "Merger Agreement") with ANI Pharmaceuticals, Inc., a Delaware corporation ("ANI"), and ANIP Merger Sub INC., a Delaware corporation and a wholly owned indirect subsidiary of ANI ("Merger Subsidiary"), providing for the merger of Merger Subsidiary with and into the Company (the "Merger"), with the Company surviving the Merger as a wholly owned indirect subsidiary of ANI (the "Surviving Corporation"). At the effective time of the Merger (the "Effective Time"), each share of common stock, par value $0.01 per share, of the Company (the "Company Common Stock") outstanding immediately prior to the Effective Time (including each Company RSA (as defined below) but excluding any treasury shares or shares owned by ANI, Merger Subsidiary or any other subsidiary of ANI or the Company), shall be canceled and cease to exist and shall be converted into the right to receive (i) $5.50 in cash, without interest (such amount, as may be adjusted in accordance with the Merger Agreement, the "Closing Cash Consideration") and (ii) one contingent value right (a "CVR"), which shall represent the right to receive the Milestone Payments (as defined below) subject to the terms and conditions set forth in the CVR Agreement (as defined below) (the consideration contemplated by (i) and (ii), together, the "Merger Consideration").

Consummation of the Merger is subject to customary closing conditions, including, without limitation, the absence of certain legal impediments, the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and approval by the holders of a majority of the voting power of the outstanding shares of Company Common Stock entitled to vote on the Merger. Consummation of the Merger by ANI and Merger Subsidiary is further subject to satisfaction of customary closing conditions on the part of the Company, including, without limitation, the Company having performed, or complied with, in all material respects its agreements, covenants and other obligations required to be performed or complied with by the Merger Agreement at or prior to the Closing Date, the representations and warranties of the Company being true and correct (subject in certain instances to materiality qualifiers as specified within the respective agreement), and no continuing Company Material Adverse Effect.

Consummation of the Merger by the Company is further subject to satisfaction of customary closing conditions on the part of ANI and the Merger Subsidiary, including, without limitation, ANI and Merger Subsidiary having performed, or complied with, in all material respects all of their respective agreements, covenants and obligations required to be performed or complied with by each of them under the Merger Agreement at or prior to the Closing Date, the representations and warranties of ANI and Merger Subsidiary being true and correct (subject in certain instances to materiality qualifiers as specified within the respective agreement), and the CVR Agreement being in full force and effect.

The Merger Agreement includes covenants requiring the Company not to (i) initiate, solicit or knowingly encourage or facilitate any inquiries or the making of any proposal or offer that constitutes, or would reasonably be expected to lead to, any Acquisition Proposal, (ii) engage in, continue or otherwise participate in any discussions or negotiations regarding, or provide any non-public information or data to any person, in each case relating to, any Acquisition Proposal or any proposal or offer that would reasonably be expected to lead to an Acquisition Proposal, (iii) amend or grant any waiver or release under any standstill or similar agreement with respect to any class of equity securities of the Company or any of the Company Subsidiaries (as defined in the Merger Agreement) (subject to the Company Board's (as defined in the Merger Agreement) ability to exercise its fiduciary duties), (iv) approve any transaction under, or any third party becoming an "interested stockholder" under, Section 203 of the Delaware General Corporation Law, (v) otherwise knowingly facilitate any effort or attempt by any third party (or its potential sources of financing) to make any proposal or offer that constitutes an Acquisition Proposal, (vi) approve, endorse, recommend or execute or enter into any letter of intent, agreement in principle, term sheet, memorandum of understanding, merger agreement, acquisition agreement or other similar contract relating to an Acquisition Proposal or (vii) approve, authorize, agree or publicly announce any intention to do any of the foregoing, with customary exceptions for superior proposals. The Merger Agreement also includes covenants customary for a transaction of this nature regarding the operation of the business of the Company and its subsidiaries between signing of the Merger Agreement and the Effective Time.

The Merger Agreement requires the Company, as promptly as reasonably practicable, and in any event within 25 business days following the date of the Merger Agreement, to prepare and file with the U.S. Securities and Exchange Commission (the "SEC") a proxy statement for the purpose of seeking stockholder approval to the Merger Agreement. To satisfy this requirement, the Company completed a PREM14A filing with the SEC on July 24, 2024.

The Merger Agreement contains certain termination rights for the Company and ANI. Upon termination of the Merger Agreement under specified circumstances, the Company will be required to pay ANI a termination fee of approximately $10.4 million. Among other termination rights, and subject to certain limitations, (i) either the Company or ANI may terminate the Merger Agreement if the Merger is not consummated by December 21, 2024 and (ii) the Company and ANI may mutually agree to terminate the Merger Agreement.

At the Effective Time, outstanding awards of restricted stock with respect to shares of Company Common Stock (each, a "Company RSA"), whether vested or unvested as of immediately prior to the Effective Time, for which the holder thereof made a timely and valid election (an "83(b) Election") under Section 83(b) of the Internal Revenue Code of 1986, as amended, shall be canceled and cease to exist, and shall be converted into the right to receive the Merger Consideration. At the Effective Time, each Company RSA for which the holder thereof did not make a timely and valid 83(b) Election shall be canceled and converted into the right to receive (i) an amount in cash (without interest and subject to deduction for any required withholding as contemplated by the Merger Agreement) equal to: (A) the total number of shares of such Company RSAs multiplied by (B) the Closing Cash Consideration, without any interest thereon, and (ii) CVRs in an amount equal to the total number of shares of such Company RSAs.

At the Effective Time, each stock option granted by the Company to purchase Company Common Stock (each, a "Company Option") that is outstanding and unvested immediately prior to the Effective Time will vest in full, and (i) each Company Option that is then outstanding and unexercised and which has a per share exercise price that is less than the Closing Cash Consideration shall be canceled and converted into the right to receive the sum of an amount in cash (without interest and subject to deduction for any required withholding as contemplated in the Merger Agreement) equal to: (a) the excess, if any, of the Closing Cash Consideration over the exercise price per share of such Company Option; multiplied by the number of shares of Company Common Stock underlying such Company Option and (b) one (1) CVR, (ii) each Company Option that is then outstanding and unexercised, and which has a per share exercise price that equals or exceeds the Closing Cash Consideration, but is less than the Maximum Total Consideration (as defined in the Merger Agreement) (each, an "Eligible Option") shall be canceled and converted into the right to receive a cash payment equal to (a) the excess, if any, of (A) the Total Consideration (as defined in the Merger Agreement) over (B) the per share exercise price of such Eligible Option, multiplied by (b) the total number of shares of Company Common Stock subject to such Eligible Option immediately prior to the Effective Time, and (iii) each Company Option that is then outstanding and unexercised and that has a per share exercise price that is equal or greater than the Maximum Total Consideration shall be canceled with no consideration payable in respect thereof.

At the Effective Time, each Company performance stock unit ("Company PSU") that is then outstanding shall automatically be canceled and converted into the right to receive (i) from the Surviving Corporation an amount of cash equal to the product of (A) the total number of shares of Company Common Stock then underlying such Company PSUs pursuant to the applicable Company PSU grant terms, with, for the avoidance of doubt, all performance metrics deemed achieved at 100%, multiplied by (B) the Closing Cash Consideration, without any interest thereon and (ii) CVRs in an amount equal to the total number of shares of Company Common Stock then underlying such Company PSUs pursuant to the applicable Company PSU grant terms, with, for the avoidance of doubt, all performance metrics deemed achieved at 100%.

At the Effective Time, each Company restricted stock unit ("Company RSU") that is then outstanding shall automatically be canceled and converted into the right to receive (i) from the Surviving Corporation an amount of cash equal to the product of (A) the number of shares of Company Common Stock then underlying such Company RSU multiplied by (B) the Closing Cash Consideration, without any interest thereon and (ii) CVRs in an amount equal to the total number of shares of Company Common Stock then underlying such Company RSUs.

At the Effective Time, each Company warrant ("Company Warrant") that is outstanding as of immediately prior to the Effective Time shall, upon the Effective Time, convert into the right to receive, upon exercise of such Company Warrant, the same Merger Consideration as such holder would have been entitled to receive following the Effective Time if such holder had been, immediately prior to the Effective Time, the holder of the number of shares of Company Common Stock then issuable upon exercise in full of such Company Warrant without regard to any limitations on exercise contained therein.

Voting Agreement

In connection with the execution of the Merger Agreement, ANI and the Company entered into a voting agreement (the "Voting Agreement") with Caligan Partners LP, Caligan Partners Master Fund LP and Caligan Partners CV VI LP (collectively, "Caligan"). Pursuant to the Voting Agreement, Caligan has agreed, among other things, to (i) vote or cause to be voted all of its shares of Company Common Stock in favor of the Merger and the transactions contemplated by the Merger Agreement and (ii) prior to the Expiration Time (as defined in the Voting Agreement) and subject to limited exceptions, not to sell or otherwise transfer any of its shares of Company Common Stock other than with the consent of ANI and the Company. The shares of Company Common Stock owned by Caligan represented approximately 32.1% of the outstanding shares of Company Common Stock as of July 31, 2024.

Contingent Value Rights Agreement

At or immediately prior to the Effective Time, ANI will enter into a contingent value rights agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"), pursuant to which each holder of Company Common Stock, as well as holders of Company Warrants, Company Options, Company PSUs, Company RSAs and Company RSUs, may become entitled to contingent cash payments per CVR (each, a "Milestone Payment"), such payments being contingent upon, and subject to, the achievement of: (i) $140.0 million in net revenue (the "2026 Milestone") on third party sales of ILUVIEN and YUTIQ for ANI's 2026 fiscal year (the "2026 Net Revenue") and/or (ii) $160.0 million in net revenue (the "2027 Milestone" and together with the 2026 Milestone, the "Milestones") on third party sales of ILUVIEN and YUTIQ for ANI's 2027 fiscal year (the "2027 Net Revenue").

When issued, each CVR will entitle the holder (the "Holder") to receive a Milestone Payment upon satisfaction of the applicable Milestones. The Milestone Payment for each CVR will equal the product (rounded to the nearest 1/100 of $0.01) of (i) $0.25 multiplied by a fraction (not exceeding one), the numerator of which is the amount, if any, by which the 2026 Net Revenue exceeds $140.0 million and the denominator of which is $10.0 million (subject to adjustment for the exercise price of Eligible Options) and/or (ii) $0.25 multiplied by a fraction (not exceeding one), the numerator of which is the amount, if any, by which the 2027 Net Revenue exceeds $160.0 million and the denominator of which is $15.0 million (subject to adjustment for the exercise price of Eligible Options).

If a Milestone is attained, the distributions in respect of the CVRs will be made on or prior to the date that is fifteen (15) business days following the filing by ANI of its audited financial statements with the SEC on Form 10-K in respect of the applicable year in which such Milestone has been achieved, and will be subject to a number of deductions, exceptions and limitations, including but not limited to certain taxes.

Under the CVR Agreement, the Rights Agent will have, and Holders of at least 35% of the CVRs then-outstanding have, certain rights to audit and enforcement on behalf of all Holders of the CVRs. ANI will undertake under the terms of the CVR Agreement to use diligent efforts to achieve the Milestones, as such efforts are further described in the CVR Agreement.'

Costs incurred associated with the Merger Agreement totaled $2.2 million for both the three and six months ended June 30, 2024 and are included in general and administrative expenses in our condensed consolidated statement of operations.

2. BASIS OF PRESENTATION

The Company has prepared the accompanying unaudited interim condensed consolidated financial statements and notes thereto ("Interim Financial Statements") in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X of the SEC. Accordingly, these Interim Financial Statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of the Company's management, the accompanying Interim Financial Statements reflect all adjustments, which include normal recurring adjustments, necessary to present fairly the Company's interim financial information.

The accompanying Interim Financial Statements and related notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2023, and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 8, 2024 (the "2023 Form 10-K"). The financial results for any interim period are not necessarily indicative of the expected financial results for the full year.

As of June 30, 2024 and December 31, 2023, the Company had approximately $10.9 million and $12.1 million in cash and cash equivalents, respectively. The Company anticipates its commercial operations will generate sufficient cash flow, combined with the Company's current financial assets, to fund all conditional and unconditional financial obligations for at least the next 12 months.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accounting policies followed for quarterly financial reporting are the same as those disclosed in the Notes to Financial Statements included in the 2023 Form 10-K. Certain of the Company's more significant accounting policies adopted in the current year are as follows:

Acquisition of Intangible Assets

The Company accounts for the acquisition of pharmaceutical product licenses as an asset acquisition in accordance with *Business Combinations (Topic 805) – Accounting for Contract Assets and Contract Liabilities from Contracts with Customers* ("ASC 805"). ASC 805 specifies that if substantially all of the fair value of the gross assets acquired in a transaction are concentrated in a single identifiable asset or group of similar identifiable assets, then the set is not a business and is recorded as an asset acquisition. Under this model, the Company assigns the cost of the transaction to the acquired tangible assets, to the identified intangible assets and liabilities, and to any above or below-market contracts. The purchase price, including the direct amounts paid for the net assets in the transaction and any acquisition costs incurred that relate directly to the acquisition, is assigned based on the relative fair values of the assets acquired and liabilities assumed. The fair value of any identified intangible assets is determined at the acquisition date based on inputs and other factors based on market participants.

Foreign Currency Translation

The financial statements of each of the Company's subsidiaries with a functional currency other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss) in stockholders' equity. Foreign currency transaction gains and losses are included in other (expense) income, net in the results of operations.

Adoption of New Accounting Standards

In June 2022, the Financial Accounting Standards Board ("FASB") issued ASU No. 2022-03, *Fair Value Measurement (Topic 820) – Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. This standard clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. This standard became effective for the Company on January 1, 2024. The adoption of this ASU did not have a material impact on the Company's financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures*. This standard requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker ("CODM") and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss and the title and position of the entity's CODM. The amendments in this update also expand the interim segment disclosure requirements. All disclosure requirements under this standard are also required for public entities with a single reportable segment. This standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and the amendments in this update are required to be applied on a retrospective basis. This standard became effective for the Company on January 1, 2024. The adoption of this ASU did not have a material impact on the Company's financial statements and related disclosures.

Accounting Standards Issued but Not Yet Effective

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* ("ASU 2020-04"). This standard provides optional expedients and exceptions for applying U.S. GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The standard is available until December 31, 2022. In December 2022, the FASB issued ASU No. 2022-06, *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848,* which extended the period of time preparers can utilize the reference rate reform relief guidance in ASU 2020-04. The guidance ensures the relief in ASU 2020-04 covers the period of time during which a significant number of modifications may take place and the ASU defers the sunset date of ASU 2020-04 from December 31, 2022, to December 31, 2024. The Company does not anticipate the adoption of this ASU will have a material impact on its financial statements.

In October 2023, the FASB issued ASU No. 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative* ("ASU 2023-06"). This standard modifies the disclosure or presentation requirements of a variety of topics and aligns requirements with the SEC's existing disclosure requirements. ASU 2023-06 is effective on the date each amendment is removed from Regulation S- X or Regulation S-K with early adoption prohibited. The amendments in ASU 2023-06 will be applied prospectively in the consolidated financial statements. The Company is currently evaluating the timing of its adoption of this standard and the impact on its financial statements.

In December 2023, ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09") requires public business entities to disclose on an annual basis additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate for federal, state, and foreign income taxes. It also requires greater detail about individual reconciling items in the rate reconciliation to the extent the impact of those items exceeds a specified threshold. In addition, ASU 2023-09 requires disclosure pertaining to taxes paid, net of refunds received, to be disaggregated for federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. ASU 2023-09 is effective for the Company for the annual period beginning on January 1, 2025. Early adoption is permitted. ASU 2023-09 should be applied on a prospective basis. However, companies have the option to apply the standard retrospectively. The Company is currently evaluating the potential impact that this new standard will have on its financial statements and related disclosures.

4. REVENUE RECOGNITION

Overview

The Company recognizes revenue when a customer obtains control of the related good or service pursuant to ASC 606, *Revenue from Contracts with Customers*. The amount recognized reflects the consideration the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following steps as outlined in the guidance: (1) identify the contract with the customer, (2) identify the performance obligations within the contract, (3) determine the net sales price ("transaction price"), (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when the entity satisfies a performance obligation. At the inception of a contract, the contract is evaluated to determine if it falls within the scope of ASC 606, followed by the Company's assessment of the goods or services promised within each contract, assessment of whether the promised good or service is distinct and determination of the performance obligations. The Company then recognizes revenue based on the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions related to the performance obligations.

Product Revenue

The Company sells its products to major pharmaceutical distributors, pharmacies, hospitals and wholesalers (collectively, its "Customer(s)"). In addition to distribution agreements with Customers, the Company enters into arrangements with healthcare providers and payors that provide for government-mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products. The Company recognizes revenues from product sales at a point in time when the Customer obtains control, typically upon delivery. The Company accrues fulfillment costs when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Estimates of Variable Consideration

Revenues from product sales are recorded at the transaction price, which includes estimates of variable consideration for reserves related to statutory rebates to State Medicaid and other government agencies; commercial rebates and fees to Managed Care Organizations, Group Purchasing Organizations, distributors, and specialty pharmacies; product returns; sales discounts (including trade discounts); distributor costs; wholesaler chargebacks; and allowances for patient assistance programs relating to the Company's sales of its products.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Management's estimates take into consideration historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, and Customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration included in the net sales price is limited to the amount that is probable not to result in a significant reversal in the amount of the cumulative revenue recognized in a future period. If actual results vary, the Company may adjust these estimates, which could have an effect on earnings in the period of adjustment.

With respect to the Company's international contracts with third-party distributors, certain contracts have elements of variable consideration, and management reviews those contracts on a regular basis and makes estimates of revenue based on historical ordering patterns and known market events and data. The amount of variable consideration included in net sales in each period could vary depending on the terms of these contracts and the probability of reversal in future periods.

Consideration Payable to Customers

Distribution service fees are payments issued to distributors for compliance with various contractually defined inventory management practices or services provided to support patient access to a product. Distribution service fees reserves are based on the terms of each individual contract and are classified within accrued expenses and are recorded as a reduction of revenue.

Product Returns

The Company's policies provide for product returns in the following circumstances: (a) expiration of shelf life on certain products; (b) product damaged while in the Customer's possession; and (c) following product recalls. Generally, returns for expired product are accepted three months before and up to one year after the expiration date of the related product, and the related product is destroyed after it is returned. The Company may, at its option, either refund the sales price paid by the Customer by issuing a credit or exchange of the returned product for replacement inventory. The Company typically does not provide cash refunds. The Company estimates the proportion of recorded revenue that will result in a return by considering relevant factors, including historical returns experience, the estimated level of inventory in the distribution channel, the shelf life of products, and product recalls, if any.

The estimation process for product returns involves, in each case, several interrelating assumptions, which vary for each Customer. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue from product sales in the period the related revenue is recognized, and because this returned product cannot be resold, there is no corresponding asset for product returns. Through the date of the Interim Financial Statements, product returns have been minimal.

Collaboration and License Revenue

The Company enters into agreements in which it licenses certain rights to its products to partner companies that act as distributors. The terms of these agreements may include payment to the Company of one or more of the following: non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions related to the performance obligations.

The Company will recognize sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606. For those milestone payments which are contingent on the occurrence of particular future events, the Company determines that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the expected value method. As such, the Company assesses each milestone to determine the probability of and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, the Company will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

Customer Payment Obligations

The Company receives payments from its Customers based on billing schedules established in each contract, which vary across the Company's locations, but generally range between 30 to 120 days. Occasionally, the Company offers extended payment terms or payment term discounts to certain Customers. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation is that the Customer will pay for the product or services within one year or less of receiving those products or services.

Accounts Receivable, net

Accounts receivable are generated through sales primarily to major pharmaceutical distributors, pharmacies, hospitals and wholesalers. The Company does not require collateral from its customers for accounts receivable. The carrying amount of accounts receivable is reduced by an allowance for expected credit losses that reflects management's best estimate of the amounts that will not be collected. Management considers many factors in assessing the need for an allowance for expected credit losses, including the length of time trade accounts receivable are past due, the customer's ability to pay its obligation, customer types, credit worthiness and the condition of the general economy and the industry as a whole. From time to time, management may adjust its assumptions for anticipated changes in any of those or other factors expected to affect collectability.

The Company writes off accounts receivable when management determines they are uncollectable and credits payments subsequently received on such receivables to bad debt expense in the period received. As of June 30, 2024 and 2023, the Company had $0.2 million reserved for expected credit losses. During the three months ended June 30, 2024 and 2023, the Company reserved $0 and $0.6 million for expected credit losses, respectively.

Allowance for credit losses consisted of the following for the three and six months ended June 30, 2024 and 2023:

	Three Months Ended June 30,	
	2024	2023
	(In thousands)	
Beginning balance	$ 186	$ 185
Provision for credit losses	—	625
Write-off of bad debt	—	(625)
Ending Balance	$ 186	$ 185

	For the Six Months Ended June 30,	
	2024	2023
	(In thousands)	
Beginning balance	$ 1,222	$ —
Provision for credit losses	176	1,496
Write-off of bad debt	(1,212)	(1,311)
Ending Balance	$ 186	$ 185

5. LEASES

The Company evaluates all of its contracts to determine whether it is or contains a lease component under FASB ASC 842 – *Leases* ("ASC 842"). Upon adoption of ASC 842, the Company elected the transition package of three practical expedients permitted within the standard. In accordance with the package of practical expedients, the Company did not reassess initial direct costs, lease determination and classification for existing leases. The Company made an accounting policy election not to recognize right of use assets and liabilities for leases with a term of 12 months or less, or those that do not meet the Company's capitalization threshold, unless the leases include options to renew or purchase the underlying asset that are reasonably certain to be exercised. Lease costs associated with those leases are recognized as incurred. The Company has also chosen the practical expedient that allows it to combine lease and non-lease components as a single lease component.

Lease renewal options are not recognized as part of the lease liability until the Company determines it is reasonably certain it will exercise any applicable renewal options. The Company has determined that it is not reasonably certain it will exercise any applicable renewal options. Accordingly, the Company has not recorded any liability for renewal options in these consolidated financial statements. The useful lives of leased assets as well as leasehold improvements, if any, are limited by the expected lease term.

Operating Leases

The Company's operating lease activities primarily consist of leases for office space in the U.S., the U.K., and Ireland. Most of these leases include options to renew, with renewal terms generally ranging from one to eight years. The exercise of lease renewal options is at the Company's sole discretion. Certain of the Company's operating lease agreements include variable lease costs that are based on common area maintenance and property taxes. The Company expenses these payments as incurred. The Company's operating lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Supplemental balance sheet information as of June 30, 2024 and December 31, 2023 for the Company's operating leases is as follows:

	June 30, 2024	December 31, 2023
	(In thousands)	
Non-current assets:		
Right-of-use assets, net	$ 996	$ 1,124
Total lease assets	$ 996	$ 1,124
Current liabilities:		
Accrued expenses	$ 535	$ 634
Non-current liabilities:		
Other non-current liabilities	1,691	1,826
Total lease liabilities	$ 2,226	$ 2,460

The Company's operating lease cost for the three and six months ended June 30, 2024 was $0.1 million and $0.3 million, respectively, and is included in general and administrative expenses in its condensed consolidated statement of operations. The Company's operating lease cost for the three and six months ended June 30, 2023 was $0.3 million and $0.4 million, respectively, and is included in general and administrative expenses in its condensed consolidated statement of operations.

As of June 30, 2024, a schedule of maturity of lease liabilities under all of the Company's operating leases is as follows:

Years Ending December 31	(In thousands)
2024 (remaining)	$ 319
2025	474
2026	488
2027	503
2028	518
Thereafter	534
Total	2,836
Less amount representing interest	(610)
Present value of minimum lease payments	2,226
Less current portion (as a portion of accrued expenses)	(535)
Non-current portion (as a portion of other non-current liabilities)	$ 1,691

For the three months ended June 30, 2024 and 2023, cash paid for operating leases was $0.2 million and $0.3 million, respectively. For the six months ended June 30, 2024 and 2023, cash paid for operating leases was $0.2 million and $0.4 million, respectively. No right-of-use assets were obtained in connection with operating leases for the three and six months ended June 30, 2024 or 2023.

As of June 30, 2024, the weighted average remaining lease terms of the Company's operating leases was 5.3 years. The weighted average discount rate used to determine the lease liabilities was 9.4%.

Finance Leases

The Company's finance lease activities primarily consist of leases for automobiles. Property and equipment leases are capitalized at the lesser of fair market value or the present value of the minimum lease payments at the inception of the leases using the Company's incremental borrowing rate. The Company's finance lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Supplemental balance sheet information as of June 30, 2024 and December 31, 2023 for the Company's finance leases is as follows:

	June 30, 2024	December 31, 2023
	(In thousands)	
Non-current assets:		
Property and equipment, net	$ 589	$ 554
Total lease assets	$ 589	$ 554
Current liabilities:		
Finance lease obligations	$ 245	$ 194
Non-current liabilities:		
Finance lease obligations - less current portion	244	256
Total lease liabilities	$ 489	$ 450

Depreciation expense associated with property and equipment under finance leases was $ 0.1 million for both the three months ended June 30, 2024 and 2023. Depreciation expense associated with property and equipment under finance leases was approximately $ 0.1 million for both the six months ended June 30, 2024 and 2023. Interest expense associated with finance leases was less than $ 0.1 million for both the three months ended June 30, 2024 and 2023. Interest expense associated with finance leases was less than $ 0.1 million for both the six months ended June 30, 2024 and 2023.

As of June 30, 2024, a schedule of maturity of lease liabilities under finance leases, together with the present value of minimum lease payments, is as follows:

Years Ending December 31	(In thousands)
2024 (remaining)	$ 195
2025	284
2026	182
2027	13
Total	674
Less amount representing interest	(185)
Present value of minimum lease payments	489
Less current portion	(245)
Non-current portion	$ 244

Cash paid for finance leases was $ 0.1 million during both of the three months ended June 30, 2024 and 2023. Cash paid for finance leases was $0.2 million and $ 0.3 million for the six months ended June 30, 2024 and 2023, respectively. The Company acquired $ 0.1 million of property and equipment in exchange for finance leases for both the three months ended June 30, 2024 and 2023. The Company acquired $ 0.2 million and $0.1 million of property and equipment in exchange for finance leases for the six months ended June 30, 2024 and 2023, respectively.

As of June 30, 2024, the weighted average remaining lease terms of the Company's finance leases was 1.3 years. The weighted average discount rate used to determine the finance lease liabilities was 10.2%.

6. INVENTORY

Inventories are stated at the lower of cost or net realizable value with cost determined under the first in, first out ("FIFO") method. Included in inventory costs are component parts, work-in-progress and finished goods. The Company relies on third-party manufacturers for the production of all inventory and does not capitalize any internal costs. The Company periodically reviews inventories for excess, obsolete or expiring inventory and writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value in the period in which the impairment is identified.

As of June 30, 2024 and December 31, 2023, inventory consisted of the following:

	June 30, 2024	December 31, 2023
	(In thousands)	
Component parts (1)	$ 653	$ 688
Work-in-process (2)	308	134
Finished goods	2,494	1,057
Total Inventory	$ 3,455	$ 1,879

(1) Component parts inventory consists of manufactured components of the ILUVIEN applicator.

(2) Work-in-process consists of completed units of ILUVIEN that are undergoing, but have not completed, quality assurance testing as required by U.S. or European Economic Area regulatory authorities.

7. INTANGIBLE ASSETS

ILUVIEN Intangible Asset

As a result of the U.S. Food and Drug Administration's approval of ILUVIEN in September 2014, the Company was required to pay a milestone payment of $25.0 million (the "EyePoint Milestone Payment") to EyePoint in October 2014 (see Note 8).

The gross carrying amount of the ILUVIEN intangible asset is $ 25.0 million, which is being amortized over approximately 13 years from the acquisition date. The amortization expense related to the ILUVIEN intangible asset was approximately $0.5 million for the three months ended June 30, 2024 and 2023. The amortization expense related to the ILUVIEN intangible asset was approximately $ 1.0 million for the six months ended June 30, 2024 and 2023. The net book value of the ILUVIEN intangible asset was $ 6.0 million and $7.0 million as of June 30, 2024 and December 31, 2023, respectively.

The estimated remaining amortization of the ILUVIEN intangible asset as of June 30, 2024, is denoted in the following:

Years Ending December 31	(In thousands)
2024 (remaining)	$ 978
2025	1,940
2026	1,940
2027	1,191
Total	$ 6,049

YUTIQ Intangible Asset

On May 17, 2023, the Company was granted an exclusive and sublicensable right and license, pursuant to the Product Rights Agreement to commercialize YUTIQ for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa (where ILUVIEN is utilized), excluding any rights for the treatment and prevention of chronic NIU-PS of the eye in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint and Ocumension Therapeutics. As a result, the Company paid EyePoint Parent an upfront payment of $75.0 million and has made two quarterly payments to EyePoint totaling approximately $ 3.8 million for the six months ended June 30, 2024 and will make two additional guaranteed payments to EyePoint Parent totaling approximately $ 3.8 million through December 31, 2024. Also, the Company will pay royalties starting in 2025 through 2028 (see Note 8). The present value of the 2024 quarterly payments and the present value of estimated royalties payable to EyePoint Parent for years 2025 to 2028 is included in the cost of the intangible the Company recorded. The estimated royalties will continue to be revalued at each reporting date until they are settled.

As of June 30, 2024, the gross carrying amount of the YUTIQ intangible asset is $ 96.4 million, which is being amortized over 10 years. The net book value of the YUTIQ intangible asset was $85.5 million and $90.3 million as of June 30, 2024 and December 31, 2023, respectively. The amortization expense related to the YUTIQ intangible asset was approximately $2.4 million and $1.2 million for the three months ended June 30, 2024 and 2023. The amortization expense related to the YUTIQ intangible was $4.8 million and $1.2 million for the six months ended June 30, 2024 and 2023.

The estimated remaining amortization of the YUTIQ intangible asset as of June 30, 2024 is as follows (in thousands):

Years Ending December 31	(In thousands)
2024 (remaining)	$ 4,853
2025	9,627
2026	9,627
2027	9,627
2028	9,654
Thereafter	42,150
Total	$ 85,538

8. LICENSE AGREEMENTS

EyePoint Agreements

In February 2005, the Company entered into an agreement with EyePoint for the use of fluocinolone acetonide ("FAc") in EyePoint's proprietary insert technology. This agreement was subsequently amended several times (as amended, the "EyePoint Agreement"). The EyePoint Agreement provides the Company with a worldwide exclusive license to utilize certain underlying technology used in the development and commercialization of ILUVIEN.

On July 10, 2017, the Company and EyePoint entered into a Second Amended and Restated Collaboration Agreement (the "New Collaboration Agreement"), which amended and restated the EyePoint Agreement. The New Collaboration Agreement expanded the license to include uveitis, including NIU-PS, in Europe, the Middle East and Africa and also allows the Company to pursue an indication for NIU-PS for ILUVIEN in those territories. The New Collaboration Agreement converted the Company's obligation to share 20% of its net profits to a royalty payable on global net revenues of ILUVIEN. The Company began paying a 2% royalty on net revenues and other related consideration to EyePoint on July 1, 2017. This royalty amount increased to 6% effective December 12, 2018. Pursuant to the New Collaboration Agreement, the Company was required to pay an additional 2% royalty on global net revenues and other related consideration in excess of $75 million in any year.

On May 17, 2023, the Company entered into a product rights agreement with EyePoint Parent which grants the Company an exclusive and sublicensable right and license under EyePoint Parent's and its affiliates' interest in certain of EyePoint Parent's and its affiliates' intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where the Company already has such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension holds a license from EyePoint Parent. Pursuant to the agreement, the Company paid EyePoint Parent an upfront payment of $75.0 million and will also make four quarterly guaranteed payments to EyePoint Parent totaling $ 7.5 million during 2024. The Company will also pay royalties to EyePoint Parent from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of certain products (including YUTIQ and ILUVIEN) in excess of certain thresholds, beginning at $70.0 million in 2025, increasing annually thereafter. Upon making the quarterly payments in the aggregate amount of $7.5 million in 2024, the licenses and rights granted to the Company will automatically become perpetual and irrevocable. For the quarter ended June 30, 2024, the Company paid the second quarterly payment of $1.9 million. The present value of the 2024 quarterly payments and the present value of estimated royalties payable to EyePoint Parent for years 2025 to 2028 is included in the cost of the intangible the Company recorded. The estimated royalties will continue to be revalued at each reporting date until they are settled.

Concurrently in May 2023, the Company also entered into a commercial supply agreement (the "Supply Agreement") with EyePoint Parent pursuant to which, during the term of the Product Rights Agreement, EyePoint Parent will be responsible for manufacturing and exclusively supplying (subject to certain exceptions) to agreed-upon quantities of YUTIQ necessary for the Company to commercialize YUTIQ in the U.S. at certain cost-plus amounts, subject to adjustments. EyePoint Parent's manufacture and supply of YUTIQ will be exclusive (subject to certain exceptions) until the Company has the ability to manufacture and supply YUTIQ for commercialization in the U.S. The term of the Supply Agreement is for a period of two years through May 2025 and thereafter automatically renews for successive one-year terms unless either party provides notice of non-renewal to the other party within a specified period of time prior to the beginning of the next automatic renewal term, provided that the Supply Agreement automatically terminates upon the successful completion of the transfer of manufacturing for YUTIQ to the Company or its designee. The Supply Agreement also automatically terminates upon termination of the Product Rights Agreement.

The Company's license rights to EyePoint's proprietary delivery device could revert to EyePoint if the Company were to: (i) fail twice to cure its breach of an obligation to make certain payments to EyePoint following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of the EyePoint Agreement within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period; (iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors, appoint or suffer appointment of a receiver or trustee over its property, file a petition under any bankruptcy or insolvency act or have any such petition filed against it and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) notify EyePoint in writing of its decision to abandon its license with respect to a certain product using EyePoint's proprietary insert technology.

In connection with a previous agreement with EyePoint, the Company was entitled to recover commercialization costs that were incurred prior to profitability of ILUVIEN and offset a portion of future payments owed to EyePoint in connection with sales of ILUVIEN with those accumulated commercialization costs, referred to as the "Future Offset." Following the signing of the New Collaboration Agreement, the Company retained the right to recover up to $15.0 million of the Future Offset. In March 2019, pursuant to the New Collaboration Agreement, the Company forgave $ 5.0 million of the Future Offset in connection with the approval of ILUVIEN for NIU-PS in the U.K. As of June 30, 2024 and December 31, 2023, the balance of the Future Offset was approximately $6.4 million and $6.5 million, respectively, which was fully reserved.

SWK Agreements

On December 17, 2020, EyePoint entered into a royalty purchase agreement (the "SWK Agreement") with SWK Funding, LLC ("SWK"). Pursuant to the SWK Agreement, EyePoint sold its interest in royalties that the Company is obligated to pay EyePoint under the New Collaboration Agreement. The Company is not a party to the SWK Agreement.

On June 19, 2024, the Company entered into a letter agreement (the "Letter Agreement") with SWK updating certain terms of the Company's existing New Collaboration Agreement and associated royalty payments. The Letter Agreement modifies the royalty payment that the Company is obligated to pay SWK to 3.125% on net revenues (the "Alternative Royalty") for any FAc product, including ILUVIEN and YUTIQ. In addition, pursuant to the terms of the Letter Agreement, in the case of a Change of Control (as defined in the Letter Agreement), the Company may, at its option, at any time during the six (6) months following the effective date of such Change of Control buy out the entire royalty obligation for the greater of (a) $ 17,250,000 or (b) 4.75 times the aggregate amount of Alternative Royalty paid or payable (x) over the most recently completed four (4) calendar quarters, or (y) if such Option is exercised prior to April 1, 2025, then 3.125% of net revenues for any FAc product over the most recently completed four (4) calendar quarters.

If the Company or SWK were to default under the Letter Agreement, the Company would be required to revert to making royalty payments under the New Collaboration agreement in lieu of the Alternative Royalty.

Royalty Expense

For the three months ended June 30, 2024 and 2023, the Company recognized $0.8 million and $0.5 million of royalty expense, respectively, which is included in cost of goods sold. For the six months ended June 30, 2024 and 2023, the Company recognized $1.7 million and $0.9 million of royalty expense, respectively, which is included in cost of goods sold. As of June 30, 2024 and 2023, approximately $0.8 million and $0.9 million of this royalty expense was included in the Company's accounts payable, respectively.

Ocumension License Agreement

On April 14, 2021, the Company entered into an exclusive license agreement (the "License Agreement") with Ocumension (Hong Kong) Limited ("Ocumension HK"), a wholly owned subsidiary of Ocumension, for the development and commercialization under Ocumension HK's own brand name(s), either directly or through its affiliates or approved third-party sublicensees, of the Company's 190 microgram fluocinolone acetonide intravitreal implant in applicator (the "Product"; currently marketed in the United States, Europe, and the Middle East as ILUVIEN) for the treatment and prevention of eye diseases in humans, other than uveitis, in a specified territory. The territory is defined as the People's Republic of China, including Hong Kong SAR and Macau SAR, region of Taiwan, South Korea, Brunei, Cambodia, East Timor, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam (the "Territory").

The Company received a nonrefundable upfront payment of $10.0 million from Ocumension HK and may in the future receive additional sales-based milestone payments totaling up to $89.0 million upon the achievement by Ocumension HK of certain specified sales milestones during the term of the License Agreement of the Product. The Company's receipt of future milestone payments depends upon whether Ocumension HK is able to successfully complete product development and commercialization in the Territory, which requires, among other things, obtaining necessary regulatory approvals and appropriate reimbursement pricing in the various countries and jurisdictions in the Territory, a process that may take several years.

The term of the License Agreement will continue (a) until the 10th anniversary of the latest first commercial sale of the Product in any country or jurisdiction in the Territory or (b) for as long as Ocumension HK is commercializing the Product in any part of the Territory, whichever is later. The term is subject to the Company's right to partially terminate the License Agreement beginning on the 10th anniversary of the effective date with respect to any country or jurisdiction in the Territory in which Ocumension has not achieved at the time of termination first commercial sale and is not continuing to commercialize the Product. Ocumension will purchase Product from the Company at a fixed transfer price without royalty obligation on future sale (other than milestone payments as described above). Ocumension HK is responsible for all costs of development and commercialization in the Territory.

As of June 30, 2024 and December 31, 2023, the Company had approximately $0.3 and $0.4 million, respectively, of deferred revenue under the Ocumension license agreement that will be recognized over the remaining term of the agreement once Ocumension begins to sell the Product under the License Agreement.

Warrant Subscription Agreement

On April 14, 2021, the Company entered into the warrant agreement with Ocumension pursuant to which Ocumension agreed to issue to the Company 1,000,000 non-transferable warrants granting the Company the right for a period of four years to subscribe to up to an aggregate of 1,000,000 shares of Ocumension stock at the subscription price of HK$23.88 per warrant share (or US$3.07 per warrant share as converted to U.S. Dollars at the exchange rate on April 9, 2021 of 0.12853 U.S. Dollars per HK$), subject to adjustment. (The converted rate is for illustrative purposes only; if the Company exercises the warrants, it will pay the subscription price of HK$23.88 per warrant share in HK$.) The warrants were issued on August 13, 2021, pursuant to the terms of the warrant agreement and expire on April 14, 2025. The warrants are not and will not be listed on any stock exchange. The fair value of the warrants are included on the balance sheet and revalued at each of the Company's reporting dates with fluctuations being booked through the Company's statement of operations.

9. LOAN AGREEMENTS

Loan Agreements with SLR Investment Corp. (formerly Solar Capital Ltd.)

On January 5, 2018, the Company entered into a $40.0 million loan and security agreement with SLR Investment Corp. ("SLR," also formerly known as Solar Capital Ltd.), as Collateral Agent, and the parties signatory thereto from time to time as "Lender(s)," including Solar Capital Ltd. in its capacity as a Lender (the "2018 Loan Agreement") and a related exit fee agreement (the "2018 Exit Fee Agreement").

On December 31, 2019, the Company refinanced the 2018 Loan Agreement by entering into a $45.0 million loan and security agreement (the "2019 Loan Agreement") and a related exit fee agreement (the "2019 Exit Fee Agreement") with SLR, as Agent, and the parties signing the 2019 Loan Agreement from time to time as Lenders, including SLR in its capacity as a Lender. The Company has amended the 2019 Loan Agreement on multiple occasions, which are summarized as follows:

- On February 22, 2022, the Company entered into a Third Amendment to the 2019 Loan Agreement (the "Third Amendment"), which, among other things, amended the provisions relating to the minimum revenue amount that the Company must achieve at the end of each calendar quarter, as calculated on a trailing six-month basis (the "Revenue Covenant").

- On December 7, 2022, the Company entered into a Fourth Amendment to the 2019 Loan Agreement (the "Fourth Amendment"), which, among other things, extended the amortization date from January 1, 2023 to April 1, 2023, and provided that such date might be further extended to July 1, 2023 upon the Company's request and in consultation with the Lenders, in each of the Lenders' sole discretion. The Fourth Amendment also amended the provisions relating to the Revenue Covenant effective with the first calendar quarter in 2023.

- On March 24, 2023, the Company entered into a Fifth Amendment to the 2019 Loan Agreement (the "Fifth Amendment") and a related Fifth Amendment Exit Fee Agreement (the "2023 Exit Fee Agreement"). Pursuant to the Fifth Amendment, the Lenders agreed to, among other things, (i) an additional tranche of $2.5 million to increase the Company's existing term loan facility to $47.5 million, subject to certain closing conditions, (ii) extend availability of the amount of $15.0 million to be funded at the Lender's sole discretion, and (iii) amended the Revenue Covenants to be effective for calendar quarters ending on or after March 31, 2023.

- On May 17, 2023, the Company entered into a Sixth Amendment to the 2019 Loan Agreement, (the "Sixth Amendment"). Pursuant to the Sixth Amendment, the Lenders agreed to, among other things, (i) an increase of the limit of availability from $15.0 million to $20.0 million, and (ii) amended the Revenue Covenants to be effective for calendar quarters ending on or after June 30, 2023. The Company received aggregate gross proceeds of $20.0 million upon execution of the Sixth Amendment.

- On March 6, 2024, Alimera entered into the Seventh Amendment to the 2019 Loan Agreement, (the "Seventh Amendment"). Pursuant to the Seventh Amendment, the Lenders agreed to, among other things, increase the amount available under the facility from $67.5 million to $72.5 million and funded an additional $5.0 million on March 6, 2024.

Interest on the 2019 Loan Agreement prior to the Fifth Amendment was payable at an annual rate the greater of (i) one-month LIBOR or (ii) 1.78%, plus 7.65% per annum. Interest on the 2019 Loan Agreement following the Fifth Amendment is payable at an annual rate equal to 5.15% plus the greater of (i) 4.60% or (ii) one-month SOFR, which will reset monthly. As of June 30, 2024 and December 31, 2023, the interest rate on the 2019 Loan Agreement was approximately 10.48% and 10.50%, respectively. The 2019 Loan Agreement provides for interest only payments until April 30, 2025, which may be extended an additional 12 months if the Company meets certain financial targets by April 20, 2025, followed by monthly payments of principal and interest through the loan maturity date of April 30, 2028. The Company met such financial targets during the year ended December 31, 2023, and provided there are no events of default as defined by the Loan Agreement on or prior to April 20, 2025, the Company anticipates being able to extend the interest only period for an additional 12 months.

The Company is in compliance with the Revenue Covenant, and expects to comply with the remainder of the Revenue Covenant through one year after these Interim Financial Statements are issued.

Exit Fee Agreements

2018 Exit Fee Agreement

Pursuant to the existing 2018 Exit Fee Agreement, the Company is obligated to pay an exit fee of up to $ 2.0 million upon the occurrence of an exit event, which generally means a "change in control" (as defined in the 2018 Exit Fee Agreement) and will survive the termination of the 2019 Loan Agreement and accompanying amendments with a term of 10 years. To the extent that the Company has not already paid the $2.0 million exit fee, the Company is also obligated to pay a fee of $1.0 million on achieving each of the following milestones:

- First, if the Company achieves revenues of $80.0 million or more from the sale of its ILUVIEN product in the ordinary course of business to third-party customers, measured on a trailing 12-month basis during the term of the agreement, tested at the end of each month; and

- Second, if the Company achieves revenues of $100.0 million or more from the sale of its ILUVIEN product in the ordinary course of business to third party customers, measured in the same manner.

2019 Exit Fee Agreement

Pursuant to the existing 2019 Exit Fee Agreement, the Company is obligated to pay an exit fee of up to a $ 0.7 million upon the occurrence of an exit event, which generally means a "change in control" (as defined in the 2019 Exit Fee Agreement) and will survive the termination of the 2019 Loan Agreement and accompanying amendments with a term of 10 years. To the extent that the Company has not already paid the $0.7 million exit fee, the Company is obligated to pay a fee of $0.3 million on achieving each of the following milestones:

- First, if the Company achieves revenues of $75.0 million or more from the sale of its ILUVIEN product in the ordinary course of business to third-party customers, measured on a trailing 12-month basis during the term of the agreement, tested at the end of each month; and

- Second, if the Company achieves revenues of $95.0 million or more from the sale of its ILUVIEN product in the ordinary course of business to third party customers, measured in the same manner.

2023 Exit Fee Agreement

Pursuant to the existing 2023 Exit Fee Agreement, the Company is obligated to pay 1.5% of the aggregate principal amount funded under the 2019 Loan Agreement and accompanying amendments (principal amount currently is $72.5 million) as an exit fee upon the occurrence of an exit event, which generally means a change in control, and will survive the termination of the 2019 Loan Agreement and accompanying amendments and has a term of 10 years. To the extent that the Company has not already paid the 1.5% (currently $1.1 million) of the aggregate principal amount funded under the 2019 Loan Agreement and accompanying amendments, the Company is obligated to pay a fee of 1.5% of the aggregate principal amount funded under the 2019 Loan Agreement and accompanying amendments upon achieving the following milestone:

- If the Company achieves revenues of $82.5 million or more from the sale of its ILUVIEN product in the ordinary course of business to third-party customers, measured on a trailing 12-month basis during the term of the agreement, tested at the end of each month.

On May 17, 2023, the Company amended the revenue criteria for all three exit fee agreements to include the sales of YUTIQ in the ordinary course of business to third-party customers. The exit fees payable pursuant to the Company's existing exit fee agreements will not exceed $3.8 million in total.

During the fourth quarter of 2023, the Company met one revenue milestone under the 2018 Exit Fee Agreement and one revenue milestone under the 2019 Exit Fee Agreement. Accordingly, the Company recognized $ 1.3 million of interest expense during the fourth quarter of 2023. During the first quarter of 2024, the Company met the revenue milestone under the 2023 Exit Fee Agreement and recognized $ 1.1 million of interest expense. During the second quarter of 2024, the Company met one revenue milestone under the 2019 Exit Fee Agreement and recognized $ 0.3 million of interest expense. As of June 30, 2024, there was $0.3 million in exit fees included in accounts payable. As of June 30, 2024, one revenue milestone relating to the 2018 Exit Fee Agreement, totaling $1.0 million, remained untriggered.

Modification of Debt

The Company capitalized approximately $2.6 million of deferred financing costs in connection with the Fifth and Sixth Amendments during 2023. In connection with the Seventh Amendment, the Company capitalized less than $0.1 million of deferred financing costs.

Extinguishment of Debt

In accordance with the guidance in ASC Subtopic 470-50, *Debt – Modifications and Extinguishments*, the Company entered into and accounted for the Sixth Amendment as an extinguishment of debt. The Company recognized a loss on extinguishment of $1.1 million in connection with the Sixth Amendment.

Fair Value of Debt

The weighted average interest rates of the Company's notes payable approximate the rate at which the Company could obtain alternative financing. Therefore, the carrying amount of the notes approximated their fair value at June 30, 2024 and December 31, 2023.

10. EARNINGS (LOSS) PER SHARE

The Company follows ASC 260, *Earnings Per Share* ("ASC 260"), which requires the reporting of both basic and diluted earnings per share ("EPS"). Because the Company's preferred stockholders participate in dividends equally with common stockholders (if the Company were to declare and pay dividends), the Company uses the two-class method to calculate EPS. However, the Company's preferred stockholders are not contractually obligated to share in losses. The Company's preferred stock for Series A and Series B were eliminated in 2023 (see Note 11).

Basic net loss per share is calculated by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock units and Employee Stock Purchase Plan ("ESPP") shares are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented as a result of the Company's net loss.

The following common stock equivalents were excluded from the computation of diluted net loss per share for the three and six months ended June 30, 2024 and 2023, respectively, because their inclusion would have had anti-dilutive effect:

	June 30,	
	2024	2023
Series B convertible preferred stock	—	45,272,874
Common stock warrants	1,600,000	1,600,000
Stock options	3,275,893	1,217,045
Restricted stock units ("RSUs")	869,638	—
Performance stock units ("PSUs")	900,000	—
Total	6,645,531	48,089,919

11. STOCKHOLDERS' EQUITY

Series A Convertible Preferred Stock

In October 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of Series A Convertible Preferred Stock ("Series A Preferred Stock") and warrants (which expired on October 1, 2017) to purchase 300,000 shares of Series A Preferred Stock for gross proceeds of $40.0 million prior to the payment of approximately $ 0.6 million of related issuance costs. In 2014, 400,000 shares of Series A Preferred Stock were converted into common stock. In 2023, the Company repurchased the remaining 600,000 shares of Series A Preferred Stock. Following such repurchase, the Company filed a certificate of elimination of the Series A Preferred Stock with the Secretary of State of the State of Delaware. The authorized shares of Series A Preferred Stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series.

Series B Convertible Preferred Stock

In March 2023, the Company issued and sold an aggregate of 12,000 shares of Series B Convertible Preferred Stock at a purchase price of $ 1,000 per share and warrants to purchase common stock for aggregate gross proceeds of $12.0 million. In May 2023, the Company issued and sold an additional aggregate of 67,000 shares of Series B Convertible Preferred Stock at a purchase price of $ 1,000 per share and warrants to purchase common stock for aggregate gross proceeds of $67.0 million. On August 1, 2023, the Company amended the Certificate of Designation of Series B Convertible Preferred Stock to allow for the issuance of pre-funded warrants ("Pre-Funded Warrants") to certain holders of Series B Preferred Stock. Prior to such amendment, the Certificate of Designation provided that the Series B Preferred Stock (including any accrued but unpaid dividends) would automatically convert at the then-applicable conversion price (the "Mandatory Conversion") in full into the Company's common stock following stockholder approval. Stockholder approval was received at the Company's 2023 annual meeting of stockholders held on August 1, 2023, and the Company designated August 15, 2023, as the date for the Mandatory Conversion of the Series B Convertible Preferred Stock into its common stock and Pre-Funded Warrants to purchase common stock. In connection with the Mandatory Conversion, the Company issued 43,617,114 shares of common stock and Pre-Funded Warrants exercisable for 2,000,000 shares of common stock at an exercise price of $ 0.01 per share to the holders of the Series B Convertible Preferred Stock. Following the Mandatory Conversion, no shares of the Series B Convertible Preferred Stock remain outstanding. The authorized shares of Series B Preferred Stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series.

In August 2024, the Pre-Funded Warrants were exercised by the holder on a cashless basis, resulting in the issuance of 1,996,402 shares of common stock, and no Pre-Funded Warrants remaining outstanding.

Common and Preferred Stock

The Company's authorized capital stock consists of (a) 150,000,000 shares of common stock, par value $ 0.01 per share; and (b) 10,000,000 shares of preferred stock, par value $0.01 per share. At June 30, 2024 and December 31, 2023, there were 52,387,763 and 52,354,450 shares of common stock issued and outstanding, respectively. At June 30, 2024 and December 31, 2023, there were no shares of preferred stock issued and outstanding.

12. STOCK-BASED COMPENSATION

2023 Equity Incentive Plan

On August 1, 2023, the Company's stockholders approved the 2023 Equity Incentive Plan (the "2023 Plan"), which replaced the 2019 Omnibus Incentive Plan (the "2019 Plan"). The 2023 Plan has a share reserve equal to the sum of (a) 3,231,755 shares of common stock, (b) shares that are subject to awards granted under the 2019 Plan that are outstanding on or after August 1, 2023 (the "Effective Date") and that are subsequently forfeited, cancelled, expire or lapse unexercised or unsettled or are reacquired by the Company, (c) the number of shares reserved under the 2019 Plan that are not issued or subject to outstanding awards under the 2019 Plan on the Effective Date, and (d) the increase in shares described in the next sentence. On the first anniversary of the Effective Date, the number of shares of common stock that may be issued under the 2023 Plan will increase by a number of shares equal to 6% of the number of outstanding shares of common stock. Under the 2023 Plan, the Compensation Committee of the Company's board of directors is authorized to grant equity-based incentive awards that include stock options, restricted stock units ("RSUs"), shares of restricted stock ("RSS") and performance-based restricted stock units ("PSUs") to officers, directors, employees and contractors. Equity-based awards are also outstanding under the Company's 2019 and 2010 equity incentive plans, although no new awards can be granted under either plan. The Company's equity incentive plans permit the issuance of various types of awards including but not limited to stock options, restricted stock, RSUs and PSUs.

2024 Equity Inducement Plan

On February 8, 2024, upon recommendation of the Compensation Committee of the Board of Directors of the Company, they approved and adopted the 2024 Equity Inducement Plan (the "2024 Equity Inducement Plan"), and subject to the adjustment provisions of the 2024 Equity Inducement Plan, reserved 800,000 shares of the Company's common stock, par value $ 0.01 per share, for issuance of equity awards under the 2024 Equity Inducement Plan. The 2024 Equity Inducement Plan was approved and adopted without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. The 2024 Equity Inducement Plan provides for grants of non-statutory stock options, RSUs, PSUs, stock appreciation rights, and restricted shares (each, an "Inducement Award"). In addition, the Compensation Committee of the Board of Directors also approved various forms of stock-based awards. The terms and conditions of the 2024 Equity Inducement Plan are intended to comply with the Nasdaq inducement award rules. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, the only persons eligible to receive grants of Inducement Awards are individuals who were not previously employees or directors of the Company (or following a bona fide period of non-employment), as an inducement material to the individuals' entry into employment with the Company.

An aggregate 440,814 and 142,511 shares of the Company's common stock were available for issuance of new awards granted under the Company's equity incentive plans as of June 30, 2024 and December 31, 2023, respectively.

Stock Options

Options granted to employees typically become exercisable over a four-year vesting period and have a ten-year contractual term. Initial options granted to directors typically vest over a four-year period and have a ten-year contractual term. Annual option grants to directors typically vest in full on the date of the Company's next annual meeting of shareholders and have a ten-year contractual term.

During the three months ended June 30, 2024 and 2023, the Company recorded compensation expense related to stock options of approximately $0.5 million and $0.1 million, respectively. During the six months ended June 30, 2024 and 2023, the Company recorded compensation expense related to stock options of approximately $1.0 million and $0.3 million, respectively. As of June 30, 2024, the total unrecognized compensation cost related to non-vested stock options granted was $4.5 million and is expected to be recognized over a weighted average period of 3.16 years.

The following table presents a summary of stock option activity for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,			
	2024		2023	
	Options	Weighted Average Exercise Price ($)	Options	Weighted Average Exercise Price ($)
Options outstanding at beginning of period	3,239,384	7.38	1,216,953	18.03
Grants	64,000	3.00	17,321	2.55
Forfeitures and expirations	(27,491)	12.80	(17,229)	45.18
Exercises	—	—	—	—
Options outstanding at period end	3,275,893	7.25	1,217,045	17.43
Options exercisable at period end	1,245,003	13.51	893,401	22.07
Weighted average per share fair value of options granted during the period	$ 2.19		$ 1.77	

The following table presents a summary of stock option activity for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,			
	2024		2023	
	Options	Weighted Average Exercise Price ($)	Options	Weighted Average Exercise Price ($)
Options outstanding at beginning of period	3,194,574	7.42	1,175,339	19.03
Grants	163,500	3.72	117,723	2.70
Forfeitures and expirations	(69,056)	7.55	(76,017)	19.41
Exercises	(13,125)	2.82	—	—
Options outstanding at period end	3,275,893	7.25	1,217,045	17.43
Options exercisable at period end	1,245,003	13.51	893,401	22.07
Weighted average per share fair value of options granted during the period	$ 2.60		$ 1.86	

The following table provides additional information related to outstanding stock options as of June 30, 2024:

	Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value ($) (In thousands)
Outstanding	3,275,893	7.25	7.25	5,600
Exercisable	1,245,003	13.51	5.88	1,206
Outstanding, vested and expected to vest	2,826,910	7.86	7.76	4,617

The following table provides additional information related to outstanding stock options as of December 31, 2023:

	Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value ($) (In thousands)
Outstanding	3,194,574	7.42	8.35	2,460
Exercisable	993,037	16.34	5.40	258
Outstanding, vested and expected to vest	2,887,226	7.84	8.20	2,164

Shares outstanding, vested and expected to vest in the table above do not reflect any accelerated vesting of unvested stock options that may result from the ANI Merger Agreement.

As of June 30, 2024, 110,179 shares remain available for grant under the 2023 Plan. As of June 30, 2024, 311,500 shares remain available for grant under the 2024 Equity Inducement Plan.

Restricted Stock and Restricted Stock Units

The following table presents a summary of restricted stock and RSUs activity for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,			
	2024		2023	
	Shares	Weighted Average Grant Date Fair Value ($)	Shares	Weighted Average Grant Date Fair Value ($)
Restricted stock and RSUs outstanding at beginning of period	1,281,120	2.66	685,176	1.67
Grants	—	—	—	—
Vested restricted stock and RSUs	—	—	—	—
Forfeitures	(750)	1.35	(3,000)	1.35
Restricted stock and RSUs outstanding at period end	1,280,370	2.67	682,176	1.67

The following table presents a summary of restricted stock and RSUs activity for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,			
	2024		2023	
	Shares	Weighted Average Grant Date Fair Value ($)	Shares	Weighted Average Grant Date Fair Value ($)
Restricted stock and RSUs outstanding at beginning of period	1,217,076	2.35	73,594	4.98
Grants	223,300	3.77	632,050	1.39
Vested restricted stock and RSUs	(159,256)	1.82	(20,468)	4.98
Forfeitures	(750)	1.35	(3,000)	1.35
Restricted stock and RSUs outstanding at period end	1,280,370	2.67	682,176	1.67

Employee stock-based compensation expense related to restricted stock and RSUs recognized in accordance with ASC 718, *Compensation - Stock Compensation* ("ASC 718") was $0.3 million and approximately $0.1 million for the three months ended June 30, 2024 and 2023. Employee stock-based compensation expense related to restricted stock and RSUs recognized in accordance with ASC 718, *Compensation - Stock Compensation* ("ASC 718") was $0.6 million and $0.1 million for the six months ended June 30, 2024 and 2023.

As of June 30, 2024, the total unrecognized compensation cost related to restricted stock and RSUs was $ 3.0 million and is expected to be recognized over a weighted average period of 3.16 years.

Performance-based restricted stock units

During the fourth quarter of 2023, the Company began granting performance-based PSUs that will settle in stock. PSUs awarded to employees have a three-year performance period and vest equally upon the achievement of annual performance measures established at the date of grant. Participants may ultimately earn between zero and 100% of the number of PSUs granted based on the degree of achievement of the performance metrics. If zero PSUs vest in a given year because the annual performance metric was not achieved, such PSUs will not be eligible to vest in a later year for the participant.

The following table summarizes the PSUs activity for three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,			
	2024		2023	
	Shares	Weighted Average Grant Date Fair Value ($)	Shares	Weighted Average Grant Date Fair Value ($)
PSUs outstanding at beginning of period	900,000	3.23	—	—
Grants	—	—	—	—
Vested	—	—	—	—
Forfeitures	—	—	—	—
Restricted stock and RSUs outstanding at period end	900,000	3.23	—	—

The following table summarizes the PSUs activity for six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,			
	2024		2023	
	Shares	Weighted Average Grant Date Fair Value ($)	Shares	Weighted Average Grant Date Fair Value ($)
PSUs outstanding at beginning of period	625,000	2.99	—	—
Grants	275,000	3.77	—	—
Vested	—	—	—	—
Forfeitures	—	—	—	—
Restricted stock and RSUs outstanding at period end	900,000	3.23	—	—

The Company recognized $0.9 million in compensation costs related to the PSUs during the three and six months ended June 30, 2024, as performance conditions were expected and probable to be achieved as of June 30, 2024. The Company recognized no compensation costs related to the PSUs during the three and six months ended June 30, 2023. As of June 30, 2024, there was approximately $2.0 million of total unrecognized compensation cost related to outstanding PSUs that could be recognized over a weighted average period of 2.64 years if the PSUs vest.

In July 2024, 299,999 PSUs vested in accordance with the performance conditions outlined in the PSU agreements. Per the PSU agreements, the vested PSUs will be settled in the form of common stock as soon as practicable on or following the end of each measurement year within the performance period.

Employee Stock Purchase Plan

During the three months ended June 30, 2024 and 2023, the Company recorded compensation expense related to its employee stock purchase plan of less than $0.1 million for each period. For both the six months ended June 30, 2024 and 2023, the Company recorded compensation expense related to its employee stock purchase plan of less than $0.1 million for each period.

13. INCOME TAXES

In accordance with ASC 740, *Income Taxes,* the Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of its assets and liabilities at the enacted tax rates in effect for the year in which the differences are expected to reverse. Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. Due to uncertainties with respect to the realization of U.S. deferred tax assets due to the history of operating losses, a valuation allowance has been established against the entire net U.S. deferred tax asset balance. The valuation allowance is based on management's estimates of taxable income in the jurisdictions in which the Company operates and the period over which deferred tax assets will be recoverable. If actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company's financial position and results of operations.

At the end of each interim period, the Company makes its best estimate of the effective tax rate expected to be applicable for the full fiscal year. This estimate reflects, among other items, the Company's best estimate of operating results and foreign currency exchange rates.

The Company also applies the provisions for income taxes related to, among other things, accounting for uncertain tax positions and disclosure requirements. There has been no change to the Company's policy that recognizes potential interest and penalties related to uncertain tax positions. The Company conducts business globally and, as a result, files income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. In the normal course of business, the Company is subject to examination by taxing authorities throughout the world.

For the three and six months ended June 30, 2024, the Company has recorded a tax benefit for both periods of less than $ 0.1 million. The effective tax rate for the period differs from the statutory tax rate for the period primarily due to the effects of valuation allowances on net operating losses and on other deferred tax assets.

As of December 31, 2023, the Company had federal NOL carry-forwards of approximately $ 146.8 million and state NOL carry-forwards of approximately $106.8 million, subject to further limitation based upon the final results of the Company's analyses of Internal Revenue Code Sections 382 and 383. These NOLs are available to reduce future income unless otherwise taxable. If not utilized, the federal NOL carry-forwards will expire at various dates between 2029 and 2037, the Company's federal NOL created in 2018 and onward will carry forward indefinitely and the state NOL carry-forwards will expire at various dates between 2023 and 2043.

Sections 382 and 383 of the Internal Revenue Code limit the annual use of NOL carry-forwards and tax credit carry-forwards, respectively, following an ownership change. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 ("Section 382") (or comparable provisions of state law) if certain changes in ownership were to occur. The Company periodically evaluates its NOL carry-forwards and whether certain changes in ownership have occurred that would limit the Company's ability to utilize a portion of its NOL carry-forwards. If it is determined that significant ownership changes have occurred since the Company generated its NOL carry-forwards, the Company may be subject to annual limitations on the use of these NOL carry-forwards under Section 382 (or comparable provisions of state law). The Company has determined that Section 382 changes in ownership occurred in late 2015 and in 2023. As a result of these changes in ownerships, the Company estimated that substantially all of its federal and state NOL carry-forwards and tax credits generated prior to the 2023 change in ownership will be subject to Section 382 limitations and may not be fully utilized in the future. The Company is currently in the process of evaluating the Section 382 impact to determine if a write-off is necessary. The reduction to the Company's NOL deferred tax asset due to the annual Section 382 limitation and the NOL carryforward period would result in an offsetting reduction in valuation allowance recorded against the NOL deferred tax asset.

Effective January 1, 2022, for U.S. tax purposes research and development costs, including software development costs, are required to be capitalized and will be deductible over five years for costs incurred domestically and over fifteen years for costs incurred in a foreign country. Additionally, the first year of amortization requires that amortization begin with the midpoint of the taxable year.

As of December 31, 2023 and 2022, the Company's U.K. subsidiary is in a net deferred tax asset position primarily due to the step up in tax basis for intangible assets created by the transfer of intellectual property from the Netherlands to the U.K. Based upon the expected pattern of reversal of deferred taxes, it is not more likely than not that these deferred tax assets will be realized. As such, a full valuation allowance is placed against the net deferred tax assets of the U.K. subsidiary. The Company's Irish subsidiary has a deferred tax asset for net operating loss carryforwards. The Company utilized $1.1 million of this carryforward as of December 31, 2023. The Company expects the remaining net operating loss carryforward to be fully realizable in the future based upon the Company's control of the transfer pricing arrangements. A valuation allowance is not recorded on the deferred tax assets of the Ireland subsidiary. Deferred tax considerations for all other foreign entities are immaterial to the financial statements.

The Company anticipates that its foreign subsidiaries will be profitable and have earnings in the future. Once the foreign subsidiaries have earnings, the Company intends to indefinitely reinvest in its foreign subsidiaries all undistributed earnings and original investments in such subsidiaries. As a result, the Company does not expect to record deferred tax liabilities in the future related to excesses of book over tax basis in the stock of its foreign subsidiaries in accordance with ASC 740-30-25.

14. SEGMENT INFORMATION

The Company's operations are managed as three operating segments: U.S., International and Operating Cost. The Company determined that each of these operating segments represented a reportable segment. In monitoring performance, aligning strategies and allocating resources, the Company's CODM manages and evaluates our U.S., International and Operating Cost segments based on segment income or loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. Therefore, the Company classifies within Other (a) the non-cash expenses included in research, development and medical affairs expenses; general and administrative expenses; and sales and marketing expenses; and (b) depreciation and amortization.

The Company's U.S. and International segments represent the sales and marketing, general and administrative and research and development activities dedicated to the respective geographies. The Operating Cost segment primarily represents the general and administrative and research and development activities not specifically associated with the U.S. or International segments and includes expenses such as executive management; information technology administration and support; legal; compliance; clinical studies; and business development.

Each of the Company's U.S., International and Operating Cost segments is separately managed and is evaluated primarily upon segment income or loss from operations. Other is presented to reconcile to the Company's consolidated totals. The Company does not report balance sheet information by segment because the Company's CODM does not review that information. The Company allocates certain operating expenses among its reporting segments based on activity-based costing methods. These activity-based costing methods require the Company to make estimates that affect the amount of each expense category that is attributed to each segment. Changes in these estimates will directly affect the amount of expense allocated to each segment and therefore the operating profit of each reporting segment.

During the three months ended June 30, 2024 and 2023, two customers within the U.S. segment that are large pharmaceutical distributors accounted for 65% and 68% of the Company's consolidated product revenues, respectively. During the six months ended June 30, 2024 and 2023, two customers within the U.S. segment that are large pharmaceutical distributors accounted for 64% and 63% of the Company's consolidated product revenues, respectively. These same two customers within the U.S. segment accounted for approximately 70% of the Company's consolidated accounts receivable at June 30, 2024 and at December 31, 2023. Internationally, our distributors produced approximately 64% and 41% of our international product revenues during the three months ended June 30, 2024 and 2023, respectively. Internationally, our distributors produced approximately 58% and 44% of our international product revenues during the six months ended June 30, 2024 and 2023, respectively.

The following table presents a summary of the Company's reporting segments for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30, 2024				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
Net revenue	$ 17,558	$ 9,442	$ —	$ —	$ 27,000
Cost of goods sold, excluding depreciation and amortization	(1,925)	(1,906)			(3,831)
Gross profit	15,633	7,536	—	—	23,169
Operating expenses:					
Research, development and medical affairs expenses	1,347	737	2,137	42	4,263
General and administrative expenses	341	625	5,263	1,150	7,379
Sales and marketing expenses	5,942	1,828	474	267	8,511
Depreciation and amortization	—	—	—	3,093	3,093
Total operating expenses	7,630	3,190	7,874	4,552	23,246
Segment income (loss) from operations	8,003	4,346	(7,874)	(4,552)	(77)
Other income and expenses, net	—	—	—	(3,277)	(3,277)
Net loss before taxes					$ (3,354)

	Three Months Ended June 30, 2023				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
Net revenue	$ 11,876	$ 5,662	$ —	$ —	$ 17,538
Cost of goods sold, excluding depreciation and amortization	(1,290)	(1,135)	—	—	(2,425)
Gross profit	10,586	4,527	—	—	15,113
Operating expenses:					
Research, development and medical affairs expenses	1,748	842	1,033	25	3,648
General and administrative expenses	1,101	510	2,619	143	4,373
Sales and marketing expenses	4,781	1,379	225	49	6,434
Depreciation and amortization	—	—	—	1,866	1,866
Total operating expenses	7,630	2,731	3,877	2,083	16,321
Segment income (loss) from operations	2,956	1,796	(3,877)	(2,083)	(1,208)
Other income and expenses, net	—	—	—	(8,796)	(8,796)
Net loss before taxes					$ (10,004)

The following table presents a summary of the Company's reporting segments for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30, 2024				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
Net revenue	$ 32,110	$ 17,901	$ —	$ —	$ 50,011
Cost of goods sold, excluding depreciation and amortization	(3,349)	(3,835)	—	—	(7,184)
Gross profit	28,761	14,066	—	—	42,827
Operating expenses:					
Research, development and medical affairs expenses	2,647	1,421	4,462	94	8,624
General and administrative expenses	909	1,186	8,920	1,796	12,811
Sales and marketing expenses	12,895	3,377	908	413	17,593
Depreciation and amortization	—	—	—	6,178	6,178
Total operating expenses	16,451	5,984	14,290	8,481	45,206
Segment income (loss) from operations	12,310	8,082	(14,290)	(8,481)	(2,379)
Other income and expenses, net	—	—	—	(7,258)	(7,258)
Net loss before taxes					$ (9,637)

	Six Months Ended June 30, 2023				
	U.S.	International	Operating Cost	Other	Consolidated
			(In thousands)		
Net revenue	$ 19,456	$ 11,628	$ —	$ —	$ 31,084
Cost of goods sold, excluding depreciation and amortization	(2,195)	(2,258)	—	—	(4,453)
Gross profit	17,261	9,370	—	—	26,631
Operating expenses:					
Research, development and medical affairs expenses	2,910	1,589	3,266	47	7,812
General and administrative expenses	2,205	1,227	4,814	298	8,544
Sales and marketing expenses	9,056	2,794	291	97	12,238
Depreciation and amortization	—	—	—	2,547	2,547
Total operating expenses	14,171	5,610	8,371	2,989	31,141
Segment income (loss) from operations	3,090	3,760	(8,371)	(2,989)	(4,510)
Other income and expenses, net	—	—	—	(10,462)	(10,462)
Net loss before taxes					$ (14,972)

15. FAIR VALUE

The Company applies FASB ASC 820, *Fair Value Measurements* ("ASC 820"), in determining the fair value of certain assets and liabilities. ASC 820 defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

- Level 1 – Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 – Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Pursuant to the Company's warrant agreement with Ocumension, the Company has the right to exercise the warrants at its option, which are considered to be derivative instruments and classified as non-current warrant assets. The Company uses the Black-Scholes pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Changes in the fair value during each reporting period are reported in the consolidated statement of operations.

There have been no changes to the valuation methods during the three months ended June 30, 2024 or 2023.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents and current assets and liabilities approximate their fair value because of their short maturities. The weighted average interest rate of the Company's notes payable approximates the rate at which the Company could obtain alternative financing; therefore, the carrying amount of the note approximates the fair value.

The following fair value table presents information about certain of the Company's assets measured at fair value on a recurring basis:

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Warrant asset (1)	$ —	$ 7	$ —	$ 7
Assets measured at fair value	$ —	$ 7	$ —	$ 7

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Warrant asset (1)	$ —	$ 52	$ —	$ 52
Assets measured at fair value	$ —	$ 52	$ —	$ 52

(1) The Company uses the Black-Scholes pricing model and assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Changes in this value each reporting period are reported in the condensed consolidated statement of operations.

16. SUBSEQUENT EVENTS

On July 17, 2024, the Company entered into a Manufacturing Services Agreement (the "New Siegfried Agreement") with Alliance Medical Products, Inc. d.b.a. Siegfried Irvine ("Siegfried") that supersedes and replaces the First Amended and Restated Commercial Contract Manufacturing Agreement, dated as of February 5, 2016, between the Company and Siegfried. Pursuant to the terms of the New Siegfried Agreement, Siegfried will be responsible for manufacturing and supplying to Alimera agreed-upon quantities of ILUVIEN at certain cost-plus amounts, subject to adjustments set forth in the New Siegfried Agreement. Siegfried has agreed that during the term of the New Siegfried Agreement, it will not manufacture for any other customer any product competitive with ILUVIEN (meaning any other drug-eluting eye implant for the treatment of diabetic macular edema or uveitis). The term of the New Siegfried Agreement is for a period of five (5) years and shall thereafter automatically renew for successive two (2) year terms unless either party provides notice of non-renewal to the other party within a specified period of time prior to the beginning of the next automatic renewal term.

The New Siegfried Agreement contains customary representations and warranties. The assertions embodied in the representations and warrants were made solely for purposes of the transaction contemplated therein and may be subject to important qualifications and limitations. Moreover, the representations and warranties may be subject to a contractual standard of materiality that may be different from what may be viewed as material to stockholders or may have been used for purposes of allocating risk between the Company and Siegfried rather than establishing matters as facts. For the foregoing reasons, no person should rely on such representations and warranties as statements of factual information at the time they were made or otherwise.

In July 2024, 299,999 PSUs vested in accordance with the performance conditions outlined in the PSU agreements. Per the PSU agreement, the vested PSUs will be settled in the form of common stock as soon as practicable on or following the end of each measurement year within the performance period.

In August 2024, the Pre-Funded Warrants were exercised by the holder on a cashless basis, resulting in the issuance of 1,996,402 shares of common stock, and no Pre-Funded Warrants remaining outstanding.

ITEM 2. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion and analysis should be read in conjunction with our unaudited interim condensed consolidated financial statements and the related notes ("Interim Financial Statements") that appear elsewhere in this quarterly report on Form 10-Q. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those described in Part I, Item 1A, "Risk Factors" and elsewhere in the 2023 Form 10-K. For further information regarding forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements and Projections" immediately after the index to this report above.

Overview

Alimera Sciences, Inc., and its subsidiaries ("we," "our," "us," "Alimera" or the "Company"), is a global pharmaceutical company that specializes in the commercialization and development of prescription ophthalmic retinal pharmaceuticals. We are committed to improving the retinal health of patients through long term treatment of chronic retinal diseases. We believe these diseases are not well treated with current therapies and affect millions of people globally. Our vision is to be the place in retina and our mission is to be invaluable to patients, physicians and partners concerned with retinal health and maintaining better vision longer.

The term "ILUVIEN®" and "YUTIQ®" are our registered trademarks. All other trademarks, trade names and service marks appearing in these Interim Financial Statements are the property of their respective owners.

Agreement and Plan of Merger with ANI Pharmaceuticals, Inc. and ANIP Merger Sub INC.

On June 21, 2024, the Company, entered into an Agreement and Plan of Merger (the "Merger Agreement") with ANI Pharmaceuticals, Inc., a Delaware corporation ("ANI"), and ANIP Merger Sub INC., a Delaware corporation and a wholly owned indirect subsidiary of ANI ("Merger Subsidiary"), providing for the merger of Merger Subsidiary with and into the Company (the "Merger"), with the Company surviving the Merger as a wholly owned indirect subsidiary of ANI (the "Surviving Corporation"). At the effective time of the Merger (the "Effective Time"), each share of common stock, par value $0.01 per share, of the Company (the "Company Common Stock") outstanding immediately prior to the Effective Time (including each Company RSA (as defined below) but excluding any treasury shares or shares owned by ANI, Merger Subsidiary or any other subsidiary of ANI or the Company), shall be canceled and cease to exist and shall be converted into the right to receive (i) $5.50 in cash, without interest (such amount, as may be adjusted in accordance with the Merger Agreement, the "Closing Cash Consideration") and (ii) one contingent value right (a "CVR"), which shall represent the right to receive the Milestone Payments (as defined below) subject to the terms and conditions set forth in the CVR Agreement (as defined below) (the consideration contemplated by (i) and (ii), together, the "Merger Consideration").

Consummation of the Merger is subject to customary closing conditions, including, without limitation, the absence of certain legal impediments, the expiration or termination of the required waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and approval by the holders of a majority of the voting power of the outstanding shares of Company Common Stock entitled to vote on the Merger. Consummation of the Merger by ANI and Merger Subsidiary is further subject to satisfaction of customary closing conditions on the part of the Company, including, without limitation, the Company having performed, or complied with, in all material respects its agreements, covenants and other obligations required to be performed or complied with by the Merger Agreement at or prior to the Closing Date, the representations and warranties of the Company being true and correct (subject in certain instances to materiality qualifiers as specified within the respective agreement), and no continuing Company Material Adverse Effect.

Consummation of the Merger by the Company is further subject to satisfaction of customary closing conditions on the part of ANI and the Merger Subsidiary, including, without limitation, ANI and Merger Subsidiary having performed, or complied with, in all material respects all of their respective agreements, covenants and obligations required to be performed or complied with by each of them under the Merger Agreement at or prior to the Closing Date, the representations and warranties of ANI and Merger Subsidiary being true and correct (subject in certain instances to materiality qualifiers as specified within the respective agreement), and the CVR Agreement being in full force and effect.

The Merger Agreement includes covenants requiring the Company not to (i) initiate, solicit or knowingly encourage or facilitate any inquiries or the making of any proposal or offer that constitutes, or would reasonably be expected to lead to, any Acquisition Proposal, (ii) engage in, continue or otherwise participate in any discussions or negotiations regarding, or provide any non-public information or data to any person, in each case relating to, any Acquisition Proposal or any proposal or offer that would reasonably be expected to lead to an Acquisition Proposal, (iii) amend or grant any waiver or release under any standstill or similar agreement with respect to any class of equity securities of the Company or any of the Company Subsidiaries (as defined in the Merger Agreement) (subject to the Company Board's (as defined in the Merger Agreement) ability to exercise its fiduciary duties), (iv) approve any transaction under, or any third party becoming an "interested stockholder" under, Section 203 of the Delaware General Corporation Law, (v) otherwise knowingly facilitate any effort or attempt by any third party (or its potential sources of financing) to make any proposal or offer that constitutes an Acquisition Proposal, (vi) approve, endorse, recommend or execute or enter into any letter of intent, agreement in principle, term sheet, memorandum of understanding, merger agreement, acquisition agreement or other similar contract relating to an Acquisition Proposal or (vii) approve, authorize, agree or publicly announce any intention to do any of the foregoing, with customary exceptions for superior proposals. The Merger Agreement also includes covenants customary for a transaction of this nature regarding the operation of the business of the Company and its subsidiaries between signing of the Merger Agreement and the Effective Time.

The Merger Agreement requires the Company, as promptly as reasonably practicable, and in any event within 25 business days following the date of the Merger Agreement, to prepare and file with the U.S. Securities and Exchange Commission (the "SEC") a proxy statement for the purpose of seeking stockholder approval to the Merger Agreement. To satisfy this requirement, the Company completed a PREM14A filing with the SEC on July 24, 2024.

The Merger Agreement contains certain termination rights for the Company and ANI. Upon termination of the Merger Agreement under specified circumstances, the Company will be required to pay ANI a termination fee of approximately $10.4 million. Among other termination rights, and subject to certain limitations, (i) either the Company or ANI may terminate the Merger Agreement if the Merger is not consummated by December 21, 2024 and (ii) the Company and ANI may mutually agree to terminate the Merger Agreement.

At the Effective Time, outstanding awards of restricted stock with respect to shares of Company Common Stock (each, a "Company RSA"), whether vested or unvested as of immediately prior to the Effective Time, for which the holder thereof made a timely and valid election (an "83(b) Election") under Section 83(b) of the Internal Revenue Code of 1986, as amended, shall be canceled and cease to exist, and shall be converted into the right to receive the Merger Consideration. At the Effective Time, each Company RSA for which the holder thereof did not make a timely and valid 83(b) Election shall be canceled and converted into the right to receive (i) an amount in cash (without interest and subject to deduction for any required withholding as contemplated by the Merger Agreement) equal to: (A) the total number of shares of such Company RSAs multiplied by (B) the Closing Cash Consideration, without any interest thereon, and (ii) CVRs in an amount equal to the total number of shares of such Company RSAs.

At the Effective Time, each stock option granted by the Company to purchase Company Common Stock (each, a "Company Option") that is outstanding and unvested immediately prior to the Effective Time will vest in full, and (i) each Company Option that is then outstanding and unexercised and which has a per share exercise price that is less than the Closing Cash Consideration shall be canceled and converted into the right to receive the sum of an amount in cash (without interest and subject to deduction for any required withholding as contemplated in the Merger Agreement) equal to: (a) the excess, if any, of the Closing Cash Consideration over the exercise price per share of such Company Option; multiplied by the number of shares of Company Common Stock underlying such Company Option and (b) one (1) CVR, (ii) each Company Option that is then outstanding and unexercised, and which has a per share exercise price that equals or exceeds the Closing Cash Consideration, but is less than the Maximum Total Consideration (as defined in the Merger Agreement) (each, an "Eligible Option") shall be canceled and converted into the right to receive a cash payment equal to (a) the excess, if any, of (A) the Total Consideration (as defined in the Merger Agreement) over (B) the per share exercise price of such Eligible Option, multiplied by (b) the total number of shares of Company Common Stock subject to such Eligible Option immediately prior to the Effective Time, and (iii) each Company Option that is then outstanding and unexercised and that has a per share exercise price that is equal or greater than the Maximum Total Consideration shall be canceled with no consideration payable in respect thereof.

At the Effective Time, each Company performance stock unit ("Company PSU") that is then outstanding shall automatically be canceled and converted into the right to receive (i) from the Surviving Corporation an amount of cash equal to the product of (A) the total number of shares of Company Common Stock then underlying such Company PSUs pursuant to the applicable Company PSU grant terms, with, for the avoidance of doubt, all performance metrics deemed achieved at 100%, multiplied by (B) the Closing Cash Consideration, without any interest thereon and (ii) CVRs in an amount equal to the total number of shares of Company Common Stock then underlying such Company PSUs pursuant to the applicable Company PSU grant terms, with, for the avoidance of doubt, all performance metrics deemed achieved at 100%.

At the Effective Time, each Company restricted stock unit ("Company RSU") that is then outstanding shall automatically be canceled and converted into the right to receive (i) from the Surviving Corporation an amount of cash equal to the product of (A) the number of shares of Company Common Stock then underlying such Company RSU multiplied by (B) the Closing Cash Consideration, without any interest thereon and (ii) CVRs in an amount equal to the total number of shares of Company Common Stock then underlying such Company RSUs.

At the Effective Time, each Company warrant ("Company Warrant") that is outstanding as of immediately prior to the Effective Time shall, upon the Effective Time, convert into the right to receive, upon exercise of such Company Warrant, the same Merger Consideration as such holder would have been entitled to receive following the Effective Time if such holder had been, immediately prior to the Effective Time, the holder of the number of shares of Company Common Stock then issuable upon exercise in full of such Company Warrant without regard to any limitations on exercise contained therein.

Voting Agreement

In connection with the execution of the Merger Agreement, ANI and the Company entered into a voting agreement (the "Voting Agreement") with Caligan Partners LP, Caligan Partners Master Fund LP and Caligan Partners CV VI LP (collectively, "Caligan"). Pursuant to the Voting Agreement, Caligan has agreed, among other things, to (i) vote or cause to be voted all of its shares of Company Common Stock in favor of the Merger and the transactions contemplated by the Merger Agreement and (ii) prior to the Expiration Time (as defined in the Voting Agreement) and subject to limited exceptions, not to sell or otherwise transfer any of its shares of Company Common Stock other than with the consent of ANI and the Company. The shares of Company Common Stock owned by Caligan represented approximately 32.1% of the outstanding shares of Company Common Stock as of July 31, 2024.

Contingent Value Rights Agreement

At or immediately prior to the Effective Time, ANI will enter into a contingent value rights agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"), pursuant to which each holder of Company Common Stock, as well as holders of Company Warrants, Company Options, Company PSUs, Company RSAs and Company RSUs, may become entitled to contingent cash payments per CVR (each, a "Milestone Payment"), such payments being contingent upon, and subject to, the achievement of: (i) $140.0 million in net revenue (the "2026 Milestone") on third party sales of ILUVIEN and YUTIQ for ANI's 2026 fiscal year (the "2026 Net Revenue") and/or (ii) $160.0 million in net revenue (the "2027 Milestone" and together with the 2026 Milestone, the "Milestones") on third party sales of ILUVIEN and YUTIQ for ANI's 2027 fiscal year (the "2027 Net Revenue").

When issued, each CVR will entitle the holder (the "Holder") to receive a Milestone Payment upon satisfaction of the applicable Milestones. The Milestone Payment for each CVR will equal the product (rounded to the nearest 1/100 of $0.01) of (i) $0.25 multiplied by a fraction (not exceeding one), the numerator of which is the amount, if any, by which the 2026 Net Revenue exceeds $140.0 million and the denominator of which is $10.0 million (subject to adjustment for the exercise price of Eligible Options) and/or (ii) $0.25 multiplied by a fraction (not exceeding one), the numerator of which is the amount, if any, by which the 2027 Net Revenue exceeds $160.0 million and the denominator of which is $15.0 million (subject to adjustment for the exercise price of Eligible Options).

If a Milestone is attained, the distributions in respect of the CVRs will be made on or prior to the date that is fifteen (15) business days following the filing by ANI of its audited financial statements with the SEC on Form 10-K in respect of the applicable year in which such Milestone has been achieved, and will be subject to a number of deductions, exceptions and limitations, including but not limited to certain taxes.

Under the CVR Agreement, the Rights Agent will have, and Holders of at least 35% of the CVRs then-outstanding have, certain rights to audit and enforcement on behalf of all Holders of the CVRs. ANI will undertake under the terms of the CVR Agreement to use diligent efforts to achieve the Milestones, as such efforts are further described in the CVR Agreement.

Costs incurred associated with the Merger Agreement totaled $2.2 million for both the three and six months ended June 30, 2024 and are included in general and administrative expenses in our condensed consolidated statement of operations.

ILUVIEN and YUTIQ

At Alimera, we internally developed and commercialized ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg, in the United States ("U.S.") and internationally for the treatment of diabetic macular edema ("DME"), and certain international markets for chronic non-infectious uveitis affecting the posterior segment of the eye ("NIU-PS"), both are leading causes of severe vision loss and blindness. DME is a disease of the retina that affects individuals with Type 1 or Type 2 diabetes. ILUVIEN is sold to treat DME only in the U.S. In certain European and Middle Eastern countries, ILUVIEN is approved and commercialized to treat DME and to prevent relapse in recurrent NIU-PS, an inflammatory disease of the uveal tract, which is comprised of the iris, ciliary body and choroid. We also have rights to commercialize ILUVIEN for NIU-PS in Africa and parts of Asia. In May 2023, we acquired exclusive commercialization rights to YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg, from EyePoint Pharmaceuticals, Inc. ("EyePoint Parent") for the treatment of chronic NIU-PS. Alimera sells YUTIQ to treat chronic NIU-PS only in the U.S.

ILUVIEN and YUTIQ are both intravitreal implants that are inserted into the back of the patient's eye in non-surgical procedures employing devices with 25-gauge needles, which allow for self-sealing wounds. "Intravitreal" refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. The implants, which are non-bioerodible, provide consistent delivery as a result of their constant surface area, permitting elution of FAc to the vitreous. We call this CONTINUOUS MICRODOSING™. This delivery mechanism provides lower daily and aggregate exposure to corticosteroids than any other intraocular dosage forms currently available, which we believe mitigates the typical risks associated with corticosteroid therapy. CONTINUOUS MICRODOSING delivery makes ILUVIEN and YUTIQ the only approved drug therapies for DME and NIU-PS that can deliver consistent daily therapeutic levels of corticosteroid and reduce the recurrence of DME and uveitis for up to three years. Other therapies that physicians currently use to treat DME, such as anti-VEGF treatments and other corticosteroids, are acute (short-acting) therapies that provide a higher initial daily dose but then rapidly decline, requiring frequent reinjection by the physician to maintain an effective dose or reestablish the therapeutic effect after the disease has recurred.

FAc is a non-proprietary corticosteroid and the active compound in ILUVIEN and YUTIQ. We at Alimera believe that corticosteroids provide the best option in the treatment of DME and NIU-PS because they reduce the inflammatory aspects of both diseases. ILUVIEN and YUTIQ deliver continuous daily sub-microgram levels of FAc in in vivo release kinetic studies for up to 36 months. ILUVIEN and YUTIQ are the only single injection therapies available to treat retinal diseases consistently every day for up to three years, which may allow patients to see better, longer, with fewer injections.

Chronic inflammation results in a loss of integrity of retinal blood vessels, which begin to leak fluid into extracellular spaces. The buildup of fluid and other blood constituents leads to macular swelling (i.e. edema) and causes visual disturbances due to mechanical stress put upon retinal cells. To compensate for the damaged blood vessels, the body begins to upregulate production of vascular endothelial growth factor ("VEGF"), which promotes the generation of new blood vessels. However, these new blood vessels also lack structural integrity and add to the problem rather than solving it. This process, called neovascularization, has been well characterized in DME as well as other retinal diseases.

The primary way to combat the process of neovascularization is to inhibit the growth of new blood vessels by preventing downstream VEGF signaling via anti-VEGF agents. However, the inflammatory process is early and central to DME pathogenesis, often preceding the vascular changes that lead to symptoms perceived by the patient. Chronic hyperglycemia present in the diabetic state leads to upregulation of many inflammatory cytokines, including, but not limited to, VEGF. Early and complete control of this inflammatory cascade is essential to maintain vascular integrity and thus prevent macular edema. This is evident in the results from a Diabetic Retinopathy Clinical Research Network study showed that 32-65% of patients treated with anti-VEGF monotherapy on a monthly basis for six months had persistent macular edema, despite this aggressive treatment regimen.

Comprehensive control over the various inflammatory factors promoting macular edema is rarely achieved by focusing on only one vasogenic cytokine. This has been demonstrated throughout multiple studies, first establishing an understanding of the broad spectrum of inflammatory control steroids exert, and another demonstrating significant reductions in vitreous levels of multiple inflammatory cytokines after six months of ILUVIEN therapy. Further, a growing body of literature has identified particular biomarkers that predict better outcomes to early corticosteroid therapy, including intraretinal cysts, subretinal fluid, disorganization of inner retinal layers, and hyper-reflective foci on optical coherence tomography images. As the benefits of steroids become more widely understood and appreciated, more efforts are being put into identifying patients most likely to experience optimal therapeutic outcomes with this drug class.

NIU-PS is by definition an inflammatory disease and is almost always managed with some form of local or systemic steroid. In controlled studies, treatment of recurrent NIU-PS with a local, low-dose, long-acting steroid (such as YUTIQ) extended time between recurrence of symptoms, led to improved visual acuity, and fewer adjuvant therapies compared to sham-treated eyes. Though the etiologies differ between DME and NIU-PS, the resulting edema originating from excessive inflammatory factors is similar and responds well to corticosteroid therapy.

Corticosteroids, including FAc, have demonstrated a range of pharmacological actions, including inhibition of inflammation and neurodegeneration, as well as promoting cellular processes that protect the integrity of the blood-retinal barrier. These pharmacological actions have the potential to treat various ocular conditions, including DME and NIU-PS. FAc is highly lipophilic and therefore effectively penetrates retinal tissue and allows FAc to achieve a therapeutic effect at a low dose. Despite providing clinically significant anatomic and visual benefits, steroids are often relegated to second line therapy (particularly in DME) due to drug-class specific side effects of potential increases in intraocular pressure ("IOP") and accelerated cataract development. To mitigate these side effects, ILUVIEN and YUTIQ are designed to deliver significantly lower daily exposure than any other available corticosteroid dosage form while maintaining a therapeutic effect. Further, adherence to the U.S. label requiring a steroid challenge prior to utilizing ILUVIEN has been shown to reduce the risk of uncontrolled IOP responses. Additionally, as demonstrated with real-world evidence, the side effects of ILUVIEN and YUTIQ are consistent with and predictable following the use of shorter duration or acute corticosteroid therapies, increasing the physician's ability to manage those side effects.

Disease Overview and Market Opportunity

Diabetes and Diabetic Retinopathy

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood glucose. Hyperglycemia, also called raised blood glucose or raised blood sugar, is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, especially the nerves and blood vessels. Diabetes mellitus is a disease of inadequate control of blood glucose levels. Diabetes mellitus, with its systemic and ophthalmic complications, represents a global public health threat. The International Diabetes Federation ("IDF") estimated prevalence of diabetes worldwide in 2021 increased to 537 million people and is expected to increase to 783 million people by 2045.

All patients with diabetes are at risk of developing some form of diabetic retinopathy, an ophthalmic complication of diabetes with symptoms including the swelling and leakage of blood vessels within the retina or the abnormal growth of new blood vessels on the surface of the retina. According to the CDC Vision Health Initiative, diabetic retinopathy causes approximately 12,000 to 24,000 new cases of blindness in the U.S. each year; making diabetes the leading cause of new cases of blindness in adults aged 20 to 70. Diabetic retinopathy can be divided into either non-proliferative or proliferative retinopathy. Non-proliferative retinopathy develops first and causes increased capillary permeability, micro aneurysms, hemorrhages, exudates (when fluid leaks out of blood vessels into nearby vessels), macular ischemia (lack of adequate blood supply) and macular edema (thickening of the retina caused by fluid leakage from capillaries). Proliferative retinopathy is an advanced stage of diabetic retinopathy that, in addition to characteristics of non-proliferative retinopathy, results in the growth of new blood vessels. These new blood vessels are abnormal and fragile, growing along the retina and along the surface of the clear vitreous gel that fills the inside of the eye. By themselves, these blood vessels do not cause symptoms or vision loss. However, these blood vessels have thin, fragile walls that are prone to leakage and hemorrhage.

When the blood vessel leakage of diabetic retinopathy leads to the build-up of fluid, or edema, in a region of the retina called the macula, the condition is called DME. This area of the eye is important for the sharp, straight-ahead vision that is used for reading, recognizing faces, and driving. DME is the most common cause of vision loss among people with diabetic retinopathy and about 30% of people with diabetic retinopathy will develop DME. It is more likely to occur as diabetic retinopathy worsens, although it may occur at any stage of the disease. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. There are an estimated 750,000 people with DME in the U.S., according to the National Eye Institute's 2019 update.

Studies have shown that DME is a multifactorial disease underpinned by inflammatory cytokine activity in the eye. Of the currently approved pharmacotherapies used to treat DME, only corticosteroids, including FAc found in the ILUVIEN implant, affect multiple cytokines.

As the incidence of diabetes continues to increase worldwide, the incidence of DME and other complications is predicted to rise as well. Most patients who suffer from diabetes do not meet glycemic (glucose or blood sugar) targets, resulting in hyperglycemia (elevated levels of glucose in the blood). This, in turn, leads to the development of micro-vascular complications, which manifest in the eye as diabetic retinopathy, as well as elevated cytokines that break down the blood-retina barrier, leading to macular edema in many diabetic retinopathy patients.

Uveitis

Uveitis means inflammation of the uveal tract, which is a layer of tissue located between the outer layer (cornea and sclera) and the inner layer (retina) of the eye. The front portion (anterior) of the uveal tract contains the iris, and the back portion (posterior) of the uveal tract contains the choroid and the stroma of the ciliary body. Inflammation of the uvea encompasses approximately 30 inflammatory disorders characterized by intraocular inflammation, a major cause of visual loss in people of working age in both developed and developing countries. It can affect people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. According to the classification scheme recommended by the International Uveitis Study Group, the disease can be classified on the basis of anatomic locations: anterior, intermediate, posterior or pan uveitis. Uveitis can be caused by a number of factors such as infection (infectious uveitis) or other autoimmune diseases or conditions. Non-infectious uveitis is a persistent and recurrent disease that can adversely affect the retina. Additionally, it commonly affects vision, more so than anterior uveitis, and macular edema is the most common mechanism of visual loss, affecting 44% patients with posterior uveitis.

There are two forms of uveitis:

- infectious uveitis (bacterial, viral, fungal or parasitic), which is treated with an appropriate antimicrobial drug as well as corticosteroids and cycloplegics; and
- non-infectious uveitis (“NIU”), where corticosteroids are used to reduce inflammation and prevent adhesions in the eye.

Chronic NIU-PS of the eye is an inflammatory disease that afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. This disease affects between 60,000 to 100,000 people each year in the U.S. and causes approximately 30,000 new cases of blindness every year. The standard of care treatment for this disease typically involves the use of short-acting corticosteroids to reduce uveitis flares followed by additional treatments of sustained release, lower dose steroids to minimize the risk of further flares.

Our NEW DAY Study

We believe that ILUVIEN continues to be underutilized in the treatment of DME and should be used much earlier in patients suffering from DME. Our prior clinical data sets demonstrate the ability of ILUVIEN to control the underlying disease process and reduce the recurrence of edema for up to three years, rather than treating recurrent chronic edema with short-term therapies. With the NEW DAY Study, we intend to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME by comparing ILUVIEN to the current standard of care, anti-VEGF therapy.

In July 2020, we announced the initiation of our NEW DAY clinical trial, a multicenter, single masked, randomized and controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over using the current standard of care of repeat anti-VEGF injections. The NEW DAY Study was fully enrolled with 300 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. The planned treatment period in the study is 18 months. Once the treatment period is concluded, patients will be given the option to participate in an open label extension study for up to 42 months. We expect to share the study data in 2025.

The primary outcome measure for the NEW DAY Study is the mean number of supplemental aflibercept injections needed during the trial between treatment groups. Key secondary endpoints include mean best corrected visual acuity (“BCVA”) score over time up to 18 months, time to first supplemental treatment, retinal thickness amplitude on optical coherence tomography (“OCT”), and diabetic retinopathy scores. In addition, the trial will collect patient-reported outcome measures to evaluate the effect on patients’ quality of life and level of functioning. Exploratory endpoints will include neuronal functional measures and OCT imaging measures of retinal nerve layer thickness.

Our SYNCHRONICITY Study

The SYNCHRONICITY Study is a multicenter, open label study evaluating YUTIQ in chronic inflammation. The Synchronicity Study currently has enrolled 110 patient eyes in approximately 25 sites around the U.S. Patients who meet the entry criteria receive YUTIQ as an intravitreal injection in the designated study eye. The treatment period is 36 months, with data capture for this study being the first 24 months of YUTIQ drug treatment.

The primary outcome measure for the SYNCHRONICITY Study is the mean change from baseline in BCVA letter score in the study eye measured by ETDRS (Early Treatment Diabetic Retinopathy Study) at Month 6 and the mean change from baseline central subfield thickness at Month 6. Key secondary endpoints include time to recurrence of non-infectious inflammation in the study eye, presence of vascular leakage at Months 1, 3, 6, 12, 18 and 24, proportion of subjects with resolution of macular edema at Months 1, 3, 6, 12, 18 and 24, mean change from baseline in BCVA letter score at Day 14 and at Months 1, 3, 12, 18 and 24, and mean change from baseline in CST at Months 1, 3, 12, 18 and 24.

ILUVIEN for Other Diseases of the Eye

ILUVIEN is currently being studied in a DRCR Retina Network study entitled “A Randomized Clinical Trial Evaluating Intravitreal Faricimab (6.0 mg) Injections or Fluocinolone Acetonide (0.19 mg) Intravitreal Implants vs Observation for Prevention of Visual Acuity Loss due to Radiation Retinopathy.” The study is planned to include 600 participants with primary choroidal melanoma receiving treatment with plaque brachytherapy, and in March 2024 the first patient was randomized. The study will assess development of macular edema and associated long-term visual acuity effects of consistent and continuous release of corticosteroid or repeated injections of anti-VEGF initiated near the time of radiation therapy compared to observation until macular edema develops in patients at risk for radiation retinopathy. Radiation retinopathy (“RR”) is a common complication after Iodine-125 plaque brachytherapy for choroidal melanoma. Although the initial radiation insult is immediate, clinical onset of RR is not seen until many months later and RR frequently progresses over time to profound vision loss. When utilized as baseline therapy, we believe ILUVIEN’s CONTINUOUS MICRODOSING delivery may prevent, delay or reduce the occurrence of the complication of radiation retinopathy and consequent vision loss when used in patients treated with plaque brachytherapy.

Although we, as a company, are not actively conducting clinical trials for other new indications, we believe that ILUVIEN has the potential to address other ophthalmic diseases such as retinal vein occlusion (“RVO”), non-proliferative diabetic retinopathy (“NPDR”), dry age-related macular degeneration (“dry AMD”) and wet age-related macular degeneration (“wet AMD”), and we are evaluating opportunities for further clinical trials.

Where We Market ILUVIEN to Treat Diabetic Macular Edema ("DME")

ILUVIEN has received marketing authorization for the use of ILUVIEN to treat DME for the indications and is reimbursed and marketed as shown in the following table:

Indication for the Treatment of DME	Territories Where ILUVIEN Has Received Marketing Authorization to Treat DME	Territories Where ILUVIEN Has Received Reimbursement Approval to Treat DME	Territories Where ILUVIEN is Currently Available to Treat DME
Treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure	U.S., Australia, Hong Kong, Bahrain, Kuwait, Lebanon and the United Arab Emirates	U.S., Kuwait, Lebanon and the United Arab Emirates	U.S., Bahrain, Kuwait, Lebanon and the United Arab Emirates
Treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies	The United Kingdom ("U.K."), Germany, France, Italy, Spain, Portugal, Ireland, Austria, Belgium, Denmark, Norway, Finland, Sweden, Poland, the Czech Republic, the Netherlands and Luxembourg	The U.K., Germany, France, Italy, Spain, Portugal, Ireland, Luxembourg and the Netherlands	The U.K., Belgium, the Czech Republic, Germany, France, Italy, Spain, Portugal, Ireland, Austria, Luxembourg, Denmark, Norway, Finland, Sweden and the Netherlands

Where We Market ILUVIEN and YUTIQ to Treat Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye ("NIU-PS")

YUTIQ has received marketing authorization to treat NIU-PS and is reimbursed and marketed by us in the U.S. ILUVIEN has received marketing authorization to treat NIU-PS and is reimbursed and marketed as shown in the following table:

Indication for the Treatment of NIU-PS	Territories Where ILUVIEN Has Received Marketing Authorization to Treat NIU-PS	Territories Where ILUVIEN Has Received Reimbursement Approval to Treat NIU-PS	Territories Where ILUVIEN is Currently Marketed to Treat NIU-PS
The prevention of relapse in recurrent NIU-PS	The U.K., Germany, France, Spain, Portugal, Ireland, Italy, Austria, Belgium, Denmark, Norway, Finland, Sweden, Poland, the Czech Republic, the Netherlands, Luxembourg and the United Arab Emirates	The U.K., Germany, Ireland, Italy, France, Portugal, Spain, the Czech Republic, Luxembourg and the Netherlands	The U.K., Germany, France, Spain, Portugal, Ireland, Italy, Austria, Belgium, Denmark, Norway, Finland, Sweden, the Czech Republic, the Netherlands, Luxembourg and the United Arab Emirates

Where We Sell ILUVIEN Direct

We commercially market ILUVIEN directly in the U.S., Germany, the U.K., Portugal and Ireland.

Where We Sell ILUVIEN Through Distributors

We have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement or sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, Australia, New Zealand, China and several countries in the Western Pacific and several countries in the Middle East. As of June 30, 2024 and December 31, 2023, we have recognized net product revenue from our international distributors in the Middle East, China, Austria, Belgium, the Czech Republic, France, Italy, Luxembourg, Spain, the Netherlands and certain Nordic countries.

Sources of Revenues

Our sales personnel focus on physician offices, clinics, pharmacies and hospitals in the U.S. and in European countries where we seek to persuade end users to purchase our products. In our promotional efforts, we focus on three main areas to generate demand for our products. The first is to gain access for ILUVIEN or YUTIQ, as appropriate, on formularies and contracts, and through national and local health care authorities to achieve a reasonable price in the countries in which we intend to commercialize. Second is to educate physicians on the efficacy and safety of ILUVIEN and YUTIQ through direct promotion, advocacy building and indirect marketing activities. Third is to enable patients and caregivers in markets where it is permitted to become more educated on their disease and the possible treatments.

Our revenues for the three months ended June 30, 2024 and 2023 were generated from product sales primarily in the U.S., Germany, Spain, Portugal, France and the U.K. In the U.S., two large pharmaceutical distributors accounted for 65% and 68% of our consolidated product revenues for the three months ended June 30, 2024 and 2023, respectively. These U.S.-based distributors purchase ILUVIEN and YUTIQ from us, maintain inventories of ILUVIEN and YUTIQ and sell on to physician offices, pharmacies and hospitals. Internationally, in countries where we sell direct, our customers are hospitals, clinics and pharmacies. We sometimes refer to physician offices, pharmacies, hospitals and clinics as end users. Internationally, in countries where we sell to distributors, these distributors purchase ILUVIEN from us and maintain inventories of ILUVIEN that they sell to their customers.

Transactions with Ocumension Therapeutics ("Ocumension")

On April 14, 2021, we entered into an exclusive license agreement (the "License Agreement") with Ocumension (Hong Kong) Limited, a wholly owned subsidiary of Ocumension Therapeutics ("Ocumension"), for the development and commercialization under Ocumension's own distinct trademark, of our 190 microgram FAc intravitreal implant (the "Product," which is currently marketed elsewhere as ILUVIEN) for the treatment and prevention of eye diseases in humans, other than uveitis, in the People's Republic of China, including Hong Kong SAR and Macau SAR, region of Taiwan, South Korea, Brunei, Cambodia, East Timor, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.

We received a nonrefundable upfront payment of $10.0 million from Ocumension and may in the future receive additional sales-based milestone payments totaling up to $89.0 million upon the achievement by Ocumension of certain specified sales milestones during the term of the License Agreement. Our receipt of future milestone payments depends upon whether Ocumension is able to successfully complete product development and commercialization in the covered territory, which requires, among other things, obtaining necessary regulatory approvals and appropriate reimbursement pricing, which may take several years.

The term of the license will continue until the later of (a) the 10th anniversary of the first commercial sale of the Product in Ocumension's licensed territory or (b) as long as Ocumension is commercializing the Product in its licensed territory. The term is subject to our right to partially terminate the License Agreement beginning on the 10th anniversary of the License Agreement with respect to any country or jurisdiction in which Ocumension has not achieved a commercial sale at such time and is not continuing to commercialize the Product. Ocumension is responsible for all costs of development and commercialization in the licensed territory.

In April 2021, the Company entered into the warrant agreement with Ocumension pursuant to which Ocumension agreed to issue to the Company 1,000,000 non-transferable warrants granting the Company the right for a period of four years to subscribe to up to an aggregate of 1,000,000 shares of Ocumension stock at the subscription price of HK$23.88 per warrant share (or US$3.07 per warrant share as converted to U.S. Dollars at the exchange rate on April 9, 2021 of 0.12853 U.S. Dollars per HK$), subject to adjustment. The warrants were issued on August 13, 2021, pursuant to the terms of the warrant agreement. The warrants are not and will not be listed on any stock exchange. These warrants are revalued at each of the Company's reporting dates with fluctuations being booked to the Company's statement of operations.

For more information about the Ocumension transaction, see Note 8 in the Interim Financial Statements.

Agreements with EyePoint Parent and EyePoint

In February 2005, we entered into a license agreement with the predecessor entity to EyePoint Pharmaceuticals US, Inc. ("EyePoint") in which we received a worldwide license from EyePoint for the use of steroids, including FAc, in EyePoint's proprietary insert technology for the treatment of all ocular diseases in humans other than uveitis. In July 2017, we amended and restated our license agreement with EyePoint (the "New Collaboration Agreement"), to add a license from EyePoint for the use of steroids, including FAc, in EyePoint's proprietary insert technology for the treatment of uveitis in Europe, the Middle East and Africa.

The New Collaboration Agreement converted our previous profit share obligation to a royalty payable on global net revenues of ILUVIEN of 6% for net revenues and other related consideration up to $75.0 million annually and 8% for net revenues and other related consideration in excess of $75.0 million on an annual basis. The New Collaboration Agreement included a right to offset $15.0 million of future royalty payments (the "Future Offset"), which reduces royalties that would otherwise be owed to EyePoint from 6% to 5.2% for net revenues and other related consideration up to $75.0 million annually and from 8% to 6.8% for net revenues and other related consideration in excess of $75.0 million on an annual basis until the future offset is recovered. As of June 30, 2024, the remaining value of the Future Offset is $6.4 million. For further discussion on royalties, see the "SWK Agreements" section below.

On May 17, 2023, we entered into a product rights agreement (the "Product Rights Agreement") with EyePoint Parent which grants Alimera an exclusive and sublicensable right and license to certain intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where we already have such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Myanmar (Burma), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension holds a license from EyePoint Parent. Pursuant to the agreement, we paid EyePoint Parent an upfront payment of $75.0 million and will also make four quarterly guaranteed payments to EyePoint Parent totaling $7.5 million during 2024. We will also pay royalties to EyePoint Parent from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of YUTIQ and ILUVIEN, in excess of certain thresholds, beginning at $70.0 million in 2025, increasing annually thereafter. Upon completing the $7.5 million in payments, the licenses and rights granted to Alimera will automatically become perpetual and irrevocable.

We also entered into a commercial supply agreement (the "Supply Agreement") with EyePoint Parent pursuant to which, during the term of the Product Rights Agreement, EyePoint Parent will be responsible for manufacturing and exclusively supplying (subject to certain exceptions) to us agreed-upon quantities of YUTIQ necessary for us to commercialize YUTIQ in the U.S. at certain cost-plus amounts, subject to adjustments. EyePoint Parent's manufacture and supply to us of YUTIQ will be exclusive (subject to certain exceptions) until we have the right and ability to manufacture and supply YUTIQ for commercialization in the U.S. The term of the Supply Agreement is for a period of two years through May 2025 and thereafter automatically renews for successive one-year terms unless either party provides notice of non-renewal to the other party within a specified period of time prior to the beginning of the next automatic renewal term, provided that the Supply Agreement automatically terminates upon the successful completion of the transfer of manufacturing for YUTIQ to us or our designee. The Supply Agreement also automatically terminates upon termination of the Product Rights Agreement.

For more information about our agreements with EyePoint Parent and EyePoint, including how we calculate the royalty percentages we are required to pay, see Note 8 in the Interim Financial Statements.

SWK Agreements

On December 17, 2020, EyePoint entered into a royalty purchase agreement (the "SWK Agreement") with SWK Funding, LLC ("SWK"). Pursuant to the SWK Agreement, EyePoint sold its interest in royalties that we are obligated to pay EyePoint under the New Collaboration Agreement. We are not a party to the SWK Agreement.

On June 19, 2024, we entered into a letter agreement (the "Letter Agreement") with SWK updating certain terms of our existing New Collaboration Agreement and associated royalty payments. The Letter Agreement modifies the royalty payment that we are obligated to pay SWK to 3.125% on net revenues (the "Alternative Royalty") for any FAc product, including ILUVIEN and YUTIQ. In addition, pursuant to the terms of the Letter Agreement, in the case of a Change of Control (as defined in the Letter Agreement), we may, at our option, at any time during the six (6) months following the effective date of such Change of Control buy out the entire royalty obligation for the greater of (a) $17,250,000 or (b) 4.75 times the aggregate amount of Alternative Royalty paid or payable (x) over the most recently completed four (4) calendar quarters, or (y) if such Option is exercised prior to April 1, 2025, then 3.125% of net revenues for any FAc product over the most recently completed four (4) calendar quarters.

If we or SWK were to default under the Letter Agreement, we would be required to revert to making royalty payments under the New Collaboration agreement in lieu of the Alternative Royalty.

Consolidated Results of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands, except share and per share data)			
Net revenue	$ 27,000	$ 17,538	$ 50,011	$ 31,084
Cost of goods sold, excluding depreciation and amortization	(3,831)	(2,425)	(7,184)	(4,453)
Gross profit	23,169	15,113	42,827	26,631
Operating expenses:				
Research, development and medical affairs expenses	4,263	3,648	8,624	7,812
General and administrative expenses	7,379	4,373	12,811	8,544
Sales and marketing expenses	8,511	6,434	17,593	12,238
Depreciation and amortization	3,093	1,866	6,178	2,547
Total operating expenses	23,246	16,321	45,206	31,141
Loss from operations	(77)	(1,208)	(2,379)	(4,510)
Interest expense and other, net	(3,153)	(1,694)	(6,892)	(3,361)
Unrealized foreign currency gain, net	(125)	(7)	(321)	(20)
Loss on extinguishment of debt	—	(1,079)	—	(1,079)
Change in fair value of common stock warrant	—	(5,911)	—	(5,911)
Change in fair value of warrant asset	1	(105)	(45)	(91)
Net loss before income taxes	(3,354)	(10,004)	(9,637)	(14,972)
Income tax benefit (provision)	43	(25)	75	(25)
Net loss	(3,311)	(10,029)	(9,562)	(14,997)
Preferred stock dividends	—	(669)	—	(683)
Net loss applicable to common stockholders	$ (3,311)	$ (10,698)	$ (9,562)	$ (15,680)
Net loss per share — basic and diluted	$ (0.06)	$ (1.32)	$ (0.18)	$ (2.07)
Weighted average shares outstanding — basic and diluted	54,383,604	8,093,640	54,370,216	7,565,868

Revenue

We generate revenue primarily from sales of ILUVIEN and YUTIQ, our two products. In addition to generating revenue from product sales, we seek to generate revenue from other sources such as upfront fees, milestone payments in connection with collaborative or strategic relationships, and royalties resulting from the licensing of ILUVIEN or any future product candidates and other intellectual property. Revenue from our international distributors fluctuates depending on the timing of the shipment of ILUVIEN to the distributors and the distributors' sales of ILUVIEN to their customers.

Net revenue increased by $9.5 million, or 54%, to $27.0 million for the three months ended June 30, 2024, compared to $17.5 million for the three months ended June 30, 2023 driven by the addition of YUTIQ in the U.S. segment, as well as increased unit sales volumes of ILUVIEN in the International segment of our business.

Net revenue increased by $18.9 million, or 61%, to $50.0 million for the six months ended June 30, 2024, compared to $31.1 million for the six months ended June 30, 2023 driven by the addition of YUTIQ in the U.S. segment, as well as increased unit sales volumes of ILUVIEN in the International segment of our business.

Cost of Goods Sold, Excluding Depreciation and Amortization, and Gross Profit

Gross profit is affected by cost of goods sold, which includes costs of manufactured goods sold and royalty payments to EyePoint under the New Collaboration Agreement. Additionally, cost of goods sold by our international distributors fluctuates depending on the revenue share attributable to the respective contract.

Cost of goods sold, excluding depreciation and amortization, increased by $1.4 million, or 58%, to $3.8 million for the three months ended June 30, 2024, compared to $2.4 million for the three months ended June 30, 2023. The increase was primarily related to our increased product sales.

Cost of goods sold, excluding depreciation and amortization, increased by $2.7 million, or 60%, to $7.2 million for the six months ended June 30, 2024, compared to $4.5 million for the six months ended June 30, 2023. The increase was primarily related to our increased product sales.

Gross profit increased by $8.1 million, or 54%, to $23.2 million for the three months ended June 30, 2024, compared to $15.1 million for the three months ended June 30, 2023. Increases were due to the addition of YUTIQ in May 2023 to the U.S. segment, as well as increased unit sales volumes of ILUVIEN in the International segment of our business. For both periods ended June 30, 2024 and 2023, gross margin was 86%.

Gross profit increased by $16.2 million, or 61%, to $42.8 million for the six months ended June 30, 2024, compared to $26.6 million for the six months ended June 30, 2023. The increases were due to the addition of YUTIQ in May 2023 to the U.S. segment, as well as increased unit sales volumes of ILUVIEN in the International segment of our business. For both periods ended June 30, 2024 and 2023, gross margin was 86%.

Research, Development and Medical Affairs Expenses

Currently, our research, development and medical affairs expenses are primarily focused on activities that support ILUVIEN and YUTIQ. These expenses include salaries and related expenses for research and development and medical affairs personnel, expenses related to clinical trials including our NEW DAY, SYNCHRONICITY and CALM studies. Our research, development and medical affairs expenses also include costs related to symposia development for physician education, and costs related to compliance with U.S. Food and Drug Administration, European Economic Area or other regulatory requirements. We expense both internal and external research and development costs as they are incurred.

Research, development and medical affairs expenses increased by $0.6 million, or 17%, to $4.3 million for the three months ended June 30, 2024, compared to $3.6 million for the three months ended June 30, 2023. The increase was primarily attributable to increases of $0.3 million in consultant costs, $0.1 million in clinical study costs, $0.1 million in personnel costs, $0.1 million in clinical study costs, $0.1 million in registration costs for ILUVIEN under the Prescription Drug User Fee Act, some of which are directly related to the acquisition of YUTIQ and offset by a decrease of $0.2 million in applicator design costs.

Research, development and medical affairs expenses increased by $0.8 million, or 10%, to $8.6 million for the six months ended June 30, 2024, compared to $7.8 million for the six months ended June 30, 2023. The increase was primarily attributable to increases of $0.4 million in consultant costs, $0.3 million in personnel costs, $0.2 million in registration costs for ILUVIEN under the Prescription Drug User Fee Act, $0.1 million in safety and quality costs, some of which are directly related to the acquisition of YUTIQ, partially offset by decreases of $0.1 million in clinical study costs and $0.3 million in applicator design costs.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and administrative functions, including finance, accounting, legal, information technology, and human resources. Other significant costs include facilities costs and professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents and managing license agreements. We expect to continue to incur significant costs to comply with the corporate governance, internal control and similar requirements applicable to public companies.

General and administrative expenses increased by $3.0 million, or 68%, to $7.4 million for the three months ended June 30, 2024, compared to $4.4 million for the three months ended June 30, 2023. The increase was primarily attributable to an increase of $2.0 million in professional fees relating to the ANI Merger Agreement, $0.4 million in personnel costs and $1.0 million in stock-based compensation. These increases are offset by a $0.6 million reduction in bad debt expenses.

General and administrative expenses increased by $4.3 million, or 51%, to $12.8 million for the six months ended June 30, 2024, compared to $8.5 million for the six months ended June 30, 2023. The increase was primarily attributable to an increase of $2.1 million in professional fees relating to the ANI Merger Agreement, $1.1 million personnel costs, $1.5 million in stock-based compensation and $0.5 million in logistics fees. These increases are offset by a $1.3 million reduction in bad debt expenses.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation for employees for commercial promotion of ILUVIEN and YUTIQ, including the assessment of the commercial opportunity, development of market awareness, pursuit of reimbursement approval, and commercialization generally, including launch plans in new markets. Other costs include third-party service fees, professional fees associated with developing plans for ILUVIEN and YUTIQ or any future products or product candidates and maintaining public relations.

Sales and marketing expenses increased by $2.1 million, or 33%, to $8.5 million for the three months ended June 30, 2024, compared to $6.4 million for the three months ended June 30, 2023. The increase was primarily attributable to an increase of $1.3 million in personnel costs, $0.5 million in marketing costs, including an overall increase in costs to market YUTIQ, attend conventions, and costs associated with increasing customer engagement, and $0.2 million in stock-based compensation.

Sales and marketing expenses increased by $5.4 million, or 44%, to $17.6 million for the six months ended June 30, 2024, compared to $12.2 million for the six months ended June 30, 2023. The increase was primarily attributable to an increase of $3.0 million in personnel costs, $1.2 million in marketing costs, including an overall increase in costs to market YUTIQ, attend conventions, and costs associated with increasing customer engagement, and $0.2 million in stock-based compensation.

Operating Expenses

As a result of the increases and decreases in various expenses described above, total operating expenses increased by $6.9 million, or 42%, to $23.2 million for the three months ended June 30, 2024, compared to $16.3 million for the three months ended June 30, 2023. The increase was primarily attributable to $2.2 million in general and administrative expenses related to the merger agreement with ANI Pharmaceuticals Inc., $1.8 million of additional sales and marketing expenses driven by expansion of our commercial infrastructure to support selling two products in the U.S., $1.2 million in additional amortization expense attributable to the YUTIQ acquisition in May 2023, and $1.2 million in additional stock-based compensation expense, as described above.

As a result of the increases and decreases in various expenses described above, total operating expenses increased by $14.1 million, or 45%, to $45.2 million for the six months ended June 30, 2024, compared to $31.1 million for the six months ended June 30, 2023. The increase was primarily attributable to increases of $0.8 million in research and development expenses, $3.6 million in depreciation and amortization, $5.4 million in sales and marketing expenses, and $4.3 million in general and administrative expenses, as described above.

Interest Expense and Other, Net

Interest expense and other, net increased by $1.5 million, or 88%, to $3.2 million for the three months ended June 30, 2024, compared to $1.7 million for the three months ended June 30, 2023. This increase is primarily related to the triggering of $0.3 million in exit fees as required under our loan agreements, as well as increased interest on additional borrowings under our credit facility.

Interest expense and other, net increased by $3.5 million, or 103%, to $6.9 million for the six months ended June 30, 2024, compared to $3.4 million for the six months ended June 30, 2023. This increase is primarily related to the triggering of $1.4 million in exit fees as required under our loan agreements, as well as increased interest on additional borrowings under our credit facility.

Basic and Diluted Net Loss Applicable to Common Stockholders per Share of Common Stock

We follow FASB Accounting Standards Codification ("ASC") *Earnings Per Share* ("ASC 260"), which requires the reporting of both basic and diluted earnings per share. As of June 30, 2023, because our preferred stockholders could participate in dividends equally with common stockholders (if we were to declare and pay dividends), we use the two-class method to calculate EPS. However, our preferred stockholders were not contractually obligated to share in losses. As of June 30, 2024, we no longer have any series of preferred stock outstanding.

Basic EPS is computed by dividing net (loss) income available to stockholders by the weighted average number of shares outstanding for the period. Diluted EPS is calculated in accordance with ASC 260 by adjusting weighted average shares outstanding for the dilutive effect of common stock options and warrants we have issued. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, because the effect would be anti-dilutive.

Common stock equivalent securities that would potentially dilute basic EPS in the future but were not included in the computation of diluted EPS because they were either classified as participating and do not share in losses or would have been anti-dilutive. Those securities were approximately 6.6 million for the three and six months ended June 30, 2024, and 48.1 million for the three and six months ended June 30, 2023.

Results of Operations – Segment Review

The following selected unaudited financial and operating data are derived from our Interim Financial Statements. The results and discussions that follow reflect how executive management monitors the performance of our reporting segments.

Our U.S. and International segments represent the sales and marketing, general and administrative and research and development activities dedicated to the respective geographies. The Operating Cost segment primarily represents the general and administrative and research and development activities not specifically associated with the U.S. or International segments and includes expenses such as executive management; information technology administration and support; legal; compliance; clinical studies; and business development. In monitoring performance, aligning strategies and allocating resources, our chief operating decision maker ("CODM"), manages and evaluates our U.S., International and Operating Cost segments based on segment income or loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. Therefore, we classify within Other (a) the non-cash expenses included in research, development and medical affairs expenses; general and administrative expenses; and sales and marketing expenses; and (b) depreciation and amortization.

Each of our U.S., International and Operating Cost segments is separately managed and is evaluated primarily upon segment income or loss from operations. Other is presented to reconcile to our consolidated totals. For that reconciliation, please see Note 14 of the accompanying Interim Financial Statements. We do not report balance sheet information by segment because our CODM does not review that information. We allocate certain operating expenses among our reporting segments based on activity-based costing methods. These activity-based costing methods require us to make estimates that affect the amount of each expense category that is attributed to each segment. Changes in these estimates will directly affect the amount of expense allocated to each segment and therefore the operating profit of each reporting segment.

U.S. Segment Results

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands)			
Net revenue	$ 17,558	$ 11,876	$ 32,110	$ 19,456
Cost of goods sold, excluding depreciation and amortization	(1,925)	(1,290)	(3,349)	(2,195)
Gross profit	15,633	10,586	28,761	17,261
Operating expenses:				
Research, development and medical affairs expenses	1,347	1,748	2,647	2,910
General and administrative expenses	341	1,101	909	2,205
Sales and marketing expenses	5,942	4,781	12,895	9,056
Total operating expenses	7,630	7,630	16,451	14,171
Segment income from operations	$ 8,003	$ 2,956	$ 12,310	$ 3,090

U.S. Segment – three months ended June 30, 2024 compared to the three months ended June 30, 2023

Net revenue. Net revenue increased by $5.7 million, or 48%, to $17.6 million for the three months ended June 30, 2024, compared to $11.9 million for the three months ended June 30, 2023. The increase was primarily driven by net revenue from YUTIQ, which was acquired in May 2023.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization, increased by $0.6 million, or 46%, to $1.9 million for the three months ended June 30, 2024, compared to approximately $1.3 million for the three months ended June 30, 2023. The increase was primarily attributable to our increased product sales led by the YUTIQ acquisition in May 2023.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by $0.4 million, or 24%, to $1.3 million for the three months ended June 30, 2024, compared to $1.7 million for the three months ended June 30, 2023. The decrease was primarily attributable to a decrease of $0.2 million in personnel costs.

General and administrative expenses. General and administrative expenses decreased by $0.8 million, or 73%, to $0.3 million for the three months ended June 30, 2024, compared to $1.1 million for the three months ended June 30, 2023. The decrease was primarily attributable to a $0.6 million decrease in bad debt expense and a $0.3 million decrease in insurance costs.

Sales and marketing expenses. Sales and marketing expenses increased by $1.1 million, or 23%, to $5.9 million for the three months ended June 30, 2024, compared to $4.8 million for the three months ended June 30, 2023. The increase was primarily attributable to an increase of $0.9 million in personnel costs and $0.2 million in marketing costs, including costs to attend conventions, costs associated with customer engagement, and costs to market YUTIQ.

U.S. Segment – six months ended June 30, 2024 compared to the six months ended June 30, 2023

Net revenue. Net revenue increased by approximately $12.6 million, or 65%, to $32.1 million for the six months ended June 30, 2024, compared to $19.5 million for the six months ended June 30, 2023. The increase was primarily driven by net revenue from YUTIQ, which was acquired in May 2023.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization, increased by $1.1 million, or 50%, to $3.3 million for the six months ended June 30, 2024, compared to $2.2 million for the six months ended June 30, 2023. The increase was primarily attributable to our increased product sales led by the YUTIQ acquisition in May 2023.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by $0.3 million, or 10%, to $2.6 million for the six months ended June 30, 2024, compared to $2.9 million for the six months ended June 30, 2023. The decrease was primarily attributable to a decrease of $0.3 million in clinical study costs offset in part by an increase of $0.2 million in registration costs primarily related to YUTIQ under the Prescription Drug User Fee Act.

General and administrative expenses. General and administrative expenses decreased by $1.3 million, or 59%, to $0.9 million for the six months ended June 30, 2024, compared to $2.2 million for the six months ended June 30, 2023. The decrease was primarily attributable to a $1.1 million decrease in bad debt expense, a $0.2 million decrease in personnel costs, and a $0.5 million decrease in insurance costs, partially offset by a $0.3 million increase in logistics costs.

Sales and marketing expenses. Sales and marketing expenses increased by $3.8 million, or 42%, to $12.9 million for the six months ended June 30, 2024, compared to $9.1 million for the six months ended June 30, 2023. The increase was primarily attributable to an increase of $2.4 million in personnel costs and $1.4 million in marketing costs, including costs to attend conventions, costs associated with customer engagement, and costs to market YUTIQ.

International Segment Results

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands)			
Net revenue	$ 9,442	$ 5,662	$ 17,901	$ 11,628
Cost of goods sold, excluding depreciation and amortization	(1,906)	(1,135)	(3,835)	(2,258)
Gross profit	7,536	4,527	14,066	9,370
Operating expenses:				
Research, development and medical affairs expenses	737	842	1,421	1,589
General and administrative expenses	625	510	1,186	1,227
Sales and marketing expenses	1,828	1,379	3,377	2,794
Total operating expenses	3,190	2,731	5,984	5,610
Segment income from operations	$ 4,346	$ 1,796	$ 8,082	$ 3,760

International Segment - three months ended June 30, 2024 compared to the three months ended June 30, 2023

Net revenue. Net revenue increased by $3.7 million, or 65%, to $9.4 million for the three months ended June 30, 2024 compared to $5.7 million for the three months ended June 30, 2023. The increase in international net revenue was driven both by increased stocking of our international distributors and growth in end user demand.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by $0.8 million, or 73% to $1.9 million for the three months ended June 30, 2024, compared to $1.1 million for the three months ended June 30, 2023. The increase was primarily attributable to increased product sales.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by $0.1 million, or 13%, to $0.7 million for the three months ended June 30, 2024, compared to $0.8 million for the three months ended June 30, 2023.

General and administrative expenses. General and administrative expenses increased by approximately $0.1 million or 20%, to $0.6 million for the three months ended June 30, 2024, compared to $0.5 million for the three months ended June 30, 2023. The increase was primarily attributable to increases of $0.1 million in personnel costs and $0.1 million in insurance costs.

Sales and marketing expenses. Sales and marketing expenses increased by $0.4 million, or 29%, to $1.8 million for the three months ended June 30, 2024, compared to $1.4 million for the three months ended June 30, 2023. The increase was primarily attributable to a $0.2 million increase in marketing costs and a $0.1 million increase in personnel costs.

International Segment - six months ended June 30, 2024 compared to the six months ended June 30, 2023

Net revenue. Net revenue increased by $6.3 million, or 54%, to $17.9 million for the six months ended June 30, 2024 compared to $11.6 million for the six months ended June 30, 2023. The increase was primarily due to significant demand gains in both the direct and distributor markets.

Cost of goods sold, excluding depreciation and amortization. Cost of goods sold, excluding depreciation and amortization increased by $1.6 million, or 73% to $3.8 million for the six months ended June 30, 2024, compared to $2.2 million for the six months ended June 30, 2023. The increase was primarily attributable to increased product sales.

Research, development and medical affairs expenses. Research, development and medical affairs expenses decreased by $0.2 million, or 13%, to $1.4 million for the six months ended June 30, 2024, compared to $1.6 million for the six months ended June 30, 2023. The decrease was primarily related to a decrease of $0.2 million in consultant costs.

General and administrative expenses. General and administrative expenses remained unchanged for the six months ended June 30, 2024, as compared to the six months ended June 30, 2023 at $1.2 million.

Sales and marketing expenses. Sales and marketing expenses increased by $0.6 million, or 21%, to $3.4 million for the six months ended June 30, 2024, compared to $2.8 million for the six months ended June 30, 2023. The increase was primarily attributable to increases of $0.2 million in marketing costs, $0.2 million in personnel costs and $0.1 million in consultant costs.

Operating Cost Segment Results

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands)			
Operating expenses:				
Research, development and medical affairs expenses	$ 2,137	$ 1,033	$ 4,462	$ 3,266
General and administrative expenses	5,263	2,619	8,920	4,814
Sales and marketing expenses	474	225	908	291
Total operating expenses	7,874	3,877	14,290	8,371
Segment loss from operations	$ (7,874)	$ (3,877)	$ (14,290)	$ (8,371)

Operating Cost Segment - three months ended June 30, 2024 compared to the three months ended June 30, 2023

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by $1.1 million, or 110%, to $2.1 million for the three months ended June 30, 2024, compared to $1.0 million for the three months ended June 30, 2023. The increase was primarily attributable to increases of $0.4 million in consultant costs, $0.1 million in clinical study costs and $0.1 million in safety and quality related costs, partially offset by a decrease of $0.2 million in applicator design costs.

General and administrative expenses. General and administrative expenses increased by $2.7 million, or 104%, to $5.3 million for the three months ended June 30, 2024, compared to $2.6 million for the three months ended June 30, 2023. The increase was primarily attributable to increases of $2.0 million in professional fees relating to $2.2 million in ANI Merger Agreement costs, $0.4 million in personnel costs and $0.3 million in insurance costs.

Sales and marketing expenses. Sales and marketing expenses increased by $0.3 million, or 150%, to $0.5 million for the three months ended June 30, 2024, compared to $0.2 million for the three months ended June 30, 2023. The increase was primarily attributable to an increase in personnel costs.

Operating Cost Segment - six months ended June 30, 2024 compared to the six months ended June 30, 2023

Research, development and medical affairs expenses. Research, development and medical affairs expenses increased by $1.2 million, or 36%, to $4.5 million for the six months ended June 30, 2024, compared to $3.3 million for the six months ended June 30, 2023. The increase was primarily attributable to increases of $0.7 million in personnel costs, $0.5 million in consultant costs, $0.2 million in clinical study costs and $0.1 million in safety and quality related costs. These increases were partially offset by a decrease of $0.3 million in applicator re-design costs.

General and administrative expenses. General and administrative expenses increased by $4.1 million, or 85%, to $8.9 million for the six months ended June 30, 2024, compared to $4.8 million for the six months ended June 30, 2023. The increase was primarily attributable to increases of $2.1 million in professional fees relating to $2.2 million in ANI Merger Agreement costs, $1.0 million in personnel costs, $0.6 million in insurance costs, and $0.1 million in office costs.

Sales and marketing expenses. Sales and marketing expenses increased by $0.6 million, or 200%, to $0.9 million for the six months ended June 30, 2024, compared to $0.3 million for the six months ended June 30, 2023. The increase was primarily attributable to an increase in personnel costs.

Other

In monitoring performance, aligning strategies and allocating resources, our CODM manages and evaluates our U.S., International and Operating Cost segments based on segment income or loss from operations adjusted for certain non-cash items, such as stock-based compensation expense and depreciation and amortization. Therefore, we classify within Other: the non-cash expenses included in research, development and medical affairs expenses, general and administrative expenses, sales and marketing expenses; and depreciation and amortization. Other is presented to reconcile to our consolidated totals.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands)			
Operating expenses:				
Research, development and medical affairs expenses	$ 42	$ 25	$ 94	$ 47
General and administrative expenses	1,150	143	1,796	298
Sales and marketing expenses	267	49	413	97
Depreciation and amortization	3,093	1,866	6,178	2,547
Total operating expenses	4,552	2,083	8,481	2,989
Segment loss from operations	$ (4,552)	$ (2,083)	$ (8,481)	$ (2,989)

Operating expenses. Operating expenses in Other increased by $2.5 million, or 119%, to $4.6 million for the three months ended June 30, 2024, compared to $2.1 million for the three months ended June 30, 2023. The increase was primarily attributable to an increase of $1.2 million in depreciation and amortization expenses, as described below, and an increase of $1.0 million in general administrative expenses relating to stock compensation expenses.

Operating expenses. Operating expenses in Other increased by $5.5 million, or 183%, to $8.5 million for the six months ended June 30, 2024, compared to $3.0 million for the six months ended June 30, 2023. The increase was primarily attributable to an increase of $3.6 million in depreciation and amortization expenses, as described below, and an increase of $1.5 million in general administrative expenses relating to stock compensation expenses.

Depreciation and amortization. Depreciation and amortization increased by $1.2 million, or 63%, to $3.1 million for the three months ended June 30, 2024, compared to $1.9 million for the three months ended June 30, 2023. The increase was primarily attributable to amortization of the YUTIQ intangible asset which was acquired in May 2023.

Depreciation and amortization. Depreciation and amortization increased by $3.6 million, or 138%, to $6.2 million for the six months ended June 30, 2024, compared to $2.6 million for the six months ended June 30, 2023. The increase was primarily attributable to amortization of the YUTIQ intangible asset which was acquired in May 2023.

Liquidity and Capital Resources

Overview

Since inception, we have incurred recurring losses, negative cash flow from operations and have accumulated a deficit in stockholders' equity of $428.1 million as of June 30, 2024.

Current Cash Position

As of June 30, 2024, we had $10.9 million in cash, cash equivalents and restricted cash. Cash and cash equivalents include highly liquid investments that are readily convertible into cash and have a maturity of 90 days or less when purchased. Generally, cash, cash equivalents and restricted cash held at financial institutions are in excess of federally insured limits.

We believe our commercial operations will generate sufficient cash flow, combined with our current financial assets, to fund all conditional and unconditional financial obligations through consummation of the Merger Agreement and for at least the next 12 months. However, if the Merger is not consummated, and we may need to raise alternative or additional financing to fund our operations and support growth. The source, timing, and availability of any future financing will depend upon market conditions and other factors that may be outside of our control. Funding may not be available when needed, at all, or on terms acceptable to us. If we were to raise additional funds by issuing equity securities, substantial dilution to existing stockholders could result, and the terms of any new equity securities may have a preference over our common stock. If we were to attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining those agreements, or in receiving milestone or royalty payments under them. If we were to attempt to raise additional funds through debt financing, we would be required to obtain permission or participation of SLR Investment Corp., which we might not be able to obtain.

Sources and Uses of Cash for the six months ended June 30, 2024 compared to the six months ended June 30, 2023

Operating Activities

For the six months ended June 30, 2024, net cash provided by operating activities was $0.5 million, which primarily consisted of $9.6 million of net loss, offset by non-cash adjustments: 1) depreciation and amortization of $6.2 million; 2) share-based compensation expense of $2.3 million; 3) amortization of debt discount and deferred financing costs of $0.5 million and 4) provision for credit losses of $0.2 million. A cash increase of $0.5 million from the management of working capital was driven primarily by accounts payable and other non-current liabilities and offset by accrued expenses and other current liabilities, accounts receivable, prepaid expenses and other current assets and inventory.

For the six months ended June 30, 2023, net cash used in operating activities was $8.2 million. The cash used in our operations was impacted by our net loss of $15.0 million, a net increase of $2.9 million in accounts receivable, and a net decrease of $1.9 million in accounts payable, accrued expenses and other current liabilities. Cash used in operations for the six months ended June 30, 2023 was offset by $2.5 million of non-cash depreciation and amortization, a $1.1 million loss on the extinguishment of debt associated with the Sixth Amendment (as defined below) to the 2019 Loan Agreement (as defined below), an increase in long-term liabilities of $0.9 million, a decrease of $0.6 million in inventory, $0.5 million of non-cash interest expense associated with the amortization of our debt discount and deferred financing costs, and $0.4 million of non-cash stock-based compensation expense.

Investing Activities

For the six months ended June 30, 2024, net cash used in investing activities was $0.1 million. Cash used was related to the acquisition of property and equipment.

For the six months ended June 30, 2023, net cash used in investing activities was $75.4 million, which was primarily due to the acquisition of intangible assets in May 2023.

Financing Activities

For the six months ended June 30, 2024, net cash used in financing activities was $1.3 million, which primarily consisted of a $3.8 million payment of accrued licensor obligations, $2.4 million in SLR exit fee agreement payments, $0.1 million in debt issuance costs and $0.2 million in finance lease obligations. Cash used in financing activities was offset by $5.0 million in gross proceeds in connection with the closing of the Seventh Amendment to the 2019 Loan Agreement (described further below).

For the six months ended June 30, 2023, net cash provided by financing activities was $97.1 million, which was primarily due to the $78.3 million in proceeds from the closings of our Series B Preferred Stock financings, $22.5 million received in connection with the Fifth and Sixth Amendments (each, as defined below) to the 2019 Loan Agreement, and $2.4 million received in connection with common stock issuances. The cash provided was partially offset by $4.1 million of debt issuance costs, $0.9 million in the repurchase of Series A Preferred Stock, $0.5 million in preferred stock issuance costs and the $0.3 million in repurchases of common stock.

Indebtedness

Loans from SLR Investment Corp. (“SLR”)

In December 2019, we refinanced our previously outstanding debt facility by entering into a $45.0 million loan and security agreement (the “2019 Loan Agreement”) with SLR, as Agent, and the parties signing the loan agreement from time to time as Lenders, including SLR in its capacity as a Lender (collectively, the “Lender(s)”). The 2019 Loan Agreement has been amended on multiple occasions.

On February 22, 2022, we entered into a Third Amendment to the 2019 Loan Agreement (the “Third Amendment”), which among other things:

(a) specified the minimum revenue amount, calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2022, that we must achieve for each such period (the “Third Revenue Covenant”);

(b) consented to maintaining a lower minimum revenue amount under the Third Revenue Covenant for the trailing six-month period ended December 31, 2021 than previously required under the 2019 Loan Agreement (and waived any event of default that may have occurred or may be deemed to have occurred as a result of our lower revenue amount for that period); and

(c) required that the Third Revenue Covenant be tested at June 30, 2023 and at the last day of each quarter thereafter, with the minimum revenue amount equal to a percentage of our projected revenues in accordance with an annual plan we must submit to the Collateral Agent by January 15 of such year, such plan to be thereafter approved by our Board of Directors (the “Board”) and the Collateral Agent in its sole discretion no later than February 28 of such year.

On December 7, 2022, we entered into a Fourth Amendment to the 2019 Loan Agreement (the "Fourth Amendment"), which among other things:

(a) extended the amortization date from January 1, 2023 to April 1, 2023, provided that such date could be further extended to July 1, 2023 upon our request and in consultation with the Lenders, in each of the Lenders' sole discretion;

(b) specified the minimum revenue amount, calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2023, that we must achieve for each such period (the "Fourth Revenue Covenant"); and

(c) required that the Fourth Revenue Covenant be tested at June 30, 2024 and at the last day of each quarter thereafter, with the minimum revenue amount equal to a percentage of our projected revenues in accordance with an annual plan submitted to the Collateral Agent by January 15th of such year, such plan to be thereafter approved by the Board and the Collateral Agent in its sole discretion no later than February 28 of such year.

On March 24, 2023, we entered into a Fifth Amendment to the 2019 Loan Agreement (the "Fifth Amendment"), which among other things:

(a) added an additional tranche of $2.5 million to increase the existing term loan facility to $47.5 million, subject to certain closing conditions;

(b) extended availability of $15.0 million to be funded at the Lender's sole discretion;

(c) specified an annual interest rate equal to 5.15% plus the greater of (i) 4.60% and (ii) one-month SOFR, which will reset monthly;

(d) extended the maturity date to April 30, 2028 and the interest-only period to April 30, 2025, which may be extended an additional 12 months if the Company meets certain financial targets by April 20, 2025; and

(e) specified the minimum revenue amount, calculated on a trailing six-month basis beginning with the six month period ended September 30, 2023, and tested at the end of each calendar quarter, that the Company must achieve for each such period.

On May 17, 2023, we entered into a Sixth Amendment to the 2019 Loan Agreement (the "Sixth Amendment"), which among other things:

(a) increased the availability to be funded at the Lender's sole discretion from $15.0 million to $20.0 million;

(b) the Lender funded the $20.0 million of availability;

(c) specified the minimum revenue amount calculated on a trailing six-month basis and tested at the end of each calendar quarter in 2023 and 2024, that we must achieve for each such period.

On March 6, 2024, we entered into the Seventh Amendment to the 2019 Loan Agreement, (the "Seventh Amendment"), which among other things:

(a) added an additional tranche of $5.0 million to increase the existing term loan facility to $72.5 million;

(b) the Lender funded the $5.0 million increase to the existing term loan facility;

(c) reaffirmed the maturity date of the 2019 Loan Agreement as April 30, 2028, and the interest-only period remains in effect through April 30, 2025. The interest-only period may be extended an additional 12 months if Alimera meets certain financial targets by April 20, 2025.

We currently have no additional borrowing capacity under this facility, and the 2019 Loan Agreement generally prohibits any additional debt unless we obtain the prior consent of the Lenders.

Since January 2022, the Federal Reserve has raised interest rates eleven times to try and combat the effects of inflation. In 2024, the Federal Reserve has commented that interest rate reductions are expected in 2024, however, interest rate reductions may not incur unless the effects of inflation start to recede. An increase in SOFR would increase our interest costs. Significant increases in our interest costs could materially and adversely affect our results of operations and our ability to pay amounts due under the 2019 Loan Agreement, including various amendments, and any increase in the interest we pay would reduce our cash available for working capital, acquisitions, and other uses.

We have maintained compliance with our revenue covenant throughout 2023 and 2024, including at the last measurement date, which was June 30, 2024. We expect to comply with the revenue covenant for the remaining measurement date in 2024. If we fail to comply with the revenue covenant and the lenders do not provide consent and waiver, acceleration of the maturity of the loan is one of the remedies available to the lenders. If the lenders accelerate the maturity of the loan, we would be forced to find alternative financing or enter into an alternative agreement with the lenders. We cannot be sure that alternative financing will be available when needed or that, if available, the alternative financing could be obtained on terms that are not significantly detrimental to us or our stockholders.

Series A Convertible Preferred Stock and Elimination

In October 2012, the Company closed its preferred stock financing in which it sold units consisting of 1,000,000 shares of Series A Convertible Preferred Stock ("Series A Preferred Stock") and warrants (which expired on October 1, 2017) to purchase 300,000 shares of Series A Preferred Stock for gross proceeds of $40.0 million prior to the payment of approximately $0.6 million of related issuance costs. In 2014, 400,000 shares of Series A Preferred Stock were converted into common stock. In 2023, the Company repurchased the remaining 600,000 shares of Series A Preferred Stock. Following such repurchase, the Company filed a certificate of elimination of the Series A Preferred Stock with the Secretary of State of the State of Delaware. The authorized shares of Series A Preferred Stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series.

Series B Preferred Stock Financings and Elimination

In March 2023, we issued and sold an aggregate of 12,000 shares of Series B Convertible Preferred Stock at a per-share purchase price of $1,000 and warrants to purchase common stock for aggregate gross proceeds of $12.0 million. In May 2023, we issued and sold an aggregate of 67,000 shares of Series B Convertible Preferred Stock at a per-share purchase price of $1,000 and warrants to purchase common stock for aggregate gross proceeds of $67.0 million. On August 1, 2023, we amended the Certificate of Designation of Series B Convertible Preferred Stock to allow for the issuance of Pre-Funded Warrants. Stockholder approval was received at our 2023 annual meeting of stockholders held on August 1, 2023, and we designated August 15, 2023 as the date for Mandatory Conversion of the Series B Convertible Preferred Stock into our common stock and Pre-Funded Warrants to purchase common stock. In connection with the Mandatory Conversion, we issued 43,617,114 shares of common stock and Pre-Funded Warrants exercisable for 2,000,000 shares of common stock to the holders of the Series B Convertible Preferred Stock. Following the Mandatory Conversion, no shares of the Series B Convertible Preferred Stock remain outstanding.

In August 2024, the holder of the Pre-Funded Warrants notified the Company of the option to exercise the Pre-Funded Warrants via a cashless exercise. This resulted in the issuance of 1,996,402 shares of common stock and the Pre-Funded Warrants are no longer outstanding.

Common and Preferred Stock

The Company's authorized capital stock consists of (a) 150,000,000 shares of common stock, par value $0.01 per share; and (b) 10,000,000 shares of preferred stock, par value $0.01 per share. At June 30, 2024 and December 31, 2023, there were 52,387,763 and 52,354,450 shares of common stock issued and outstanding.

Contractual Obligations and Commitments

The NEW DAY Study. In January 2020, we began entering into agreements with contract research organizations ("CROs") and physician clinics in connection with a multicenter, single masked, randomized and controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over the current standard of care of repeat anti-VEGF injections (the "NEW DAY Study"). The NEW DAY Study has enrolled approximately 300 treatment-naïve, or almost naïve, DME patients in approximately 40 sites around the U.S. For the three months ended June 30, 2024 and 2023, we incurred approximately $0.6 million and $1.4 million, respectively, of expense associated with the NEW DAY Study. For the six months ended June 30, 2024 and 2023, we incurred approximately $1.6 million and $2.8 million, respectively, of expense associated with the NEW DAY Study. In connection with the NEW DAY Study, we expect to incur additional expenses of $1.5 million for the remainder of 2024, and less than $1.0 million in 2025.

Manufacturing Services Agreement with Alliance. In February 2016, we and Alliance Medical Products Inc., a Siegfried Company ("Alliance"), a third-party manufacturer, amended and restated the parties' existing agreement for the manufacture of the ILUVIEN implant, the assembly of the ILUVIEN applicator and the packaging of the completed ILUVIEN commercial product. Under the amended and restated Alliance agreement, its term was extended by five years, at which point the agreement became automatically renewable for successive one-year periods unless either party delivers notice of non-renewal to the other party at least 12 months before the end of the term or any renewal term. We are responsible for supplying the ILUVIEN applicator and the active pharmaceutical ingredient, and we must order at least 80% of the ILUVIEN units required in the covered territories from Alliance.

The Company entered into, as of July 17, 2024, a Manufacturing Services Agreement (the "New Alliance Agreement") with Alliance that supersedes and replaces the First Amended and Restated Commercial Contract Manufacturing Agreement, dated as of February 2016, between the Company and Alliance. Pursuant to the terms of the New Alliance Agreement, Alliance will be responsible for manufacturing and supplying to Alimera agreed-upon quantities of ILUVIEN at certain cost-plus amounts, subject to adjustments set forth in the New Alliance Agreement. Alliance has agreed that during the term of the New Alliance Agreement, it will not manufacture for any other customer any product competitive with ILUVIEN (meaning any other drug-eluting eye implant for the treatment of diabetic macular edema or uveitis). The term of the New Alliance Agreement is for a period of five (5) years and shall thereafter automatically renew for successive two (2) year terms unless either party provides notice of non-renewal to the other party within a specified period of time prior to the beginning of the next automatic renewal term. The New Alliance Agreement contains customary representations and warranties. The assertions embodied in the representations and warrants were made solely for purposes of the transaction contemplated therein and may be subject to important qualifications and limitations. Moreover, the representations and warranties may be subject to a contractual standard of materiality that may be different from what may be viewed as material to stockholders or may have been used for purposes of allocating risk between the Company and Alliance rather than establishing matters as facts. For the foregoing reasons, no person should rely on such representations and warranties as statements of factual information at the time they were made or otherwise.

Manufacturing Services Agreement with Cadence. On October 30, 2020, we entered into a Manufacturing Services Agreement (the "Cadence Agreement") with Cadence, Inc., for the manufacture of certain component parts of the ILUVIEN applicator (the "components") at its facility near Pittsburgh, Pennsylvania. Under the Cadence Agreement, we will pay certain per-unit prices based on regularly scheduled shipments of a minimum number of components. The initial term of the Cadence Agreement expires on October 30, 2025. After the expiration of the initial term, the Cadence Agreement will automatically renew for separate, successive one-year terms unless either party provides written notice to the other party that it does not intend to renew the Cadence Agreement at least 24 months before the end of the term. The Cadence Agreement may be terminated by either party under certain circumstances. We have transferred the manufacturing of component parts of the ILUVIEN inserter to Cadence from our prior manufacturer and have spent cash resources to purchase new equipment, to update clean room facilities and to assist in the regulatory approval process. In connection with the Cadence Agreement, we expect to be invoiced less than $1.0 million for the remainder of 2024.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established to facilitate off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of SEC Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance and the performance of our subsidiaries.

Impact of Recent Accounting Pronouncements

See Note 3 in the Interim Financial Statements for a description of recent accounting pronouncements, including the expected dates of adoption and expected effects on results of operations and financial condition, if known.

Foreign Exchange

Our international operations are subject to certain opportunities and risks, including currency fluctuations and governmental actions. The impact of fluctuations in foreign currency exchange rates decreased our net product revenue for the six months ended June 30, 2024 by approximately $0.1 million.

Non-GAAP Financial Measure

We provide all information required in accordance with U.S. GAAP, but we believe that evaluating our ongoing operating results may be difficult if limited to reviewing only U.S. GAAP financial measures. In an effort to provide investors with additional information regarding our results, we also provide non-GAAP information that management believes is useful to investors. We discuss net income (loss) performance measures that are, for comparison purposes, adjusted to eliminate items or results stemming from discrete events. We do this because management uses these measures in evaluating our underlying performance on a consistent basis across periods. We also believe non-GAAP measures are frequently used by securities analysts, investors and other interested parties in the evaluation of our ongoing performance.

See the table below entitled “Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA.” U.S. GAAP net loss is the most directly comparable U.S. GAAP financial measure to adjusted EBITDA.

This non-GAAP financial measure, as presented, may not be comparable to a similarly titled measure reported by other companies because not all companies adjust revenue for currency fluctuations in an identical manner. Therefore, this non-GAAP financial measure is not necessarily an accurate measure of comparison between companies.

The presentation of this non-GAAP financial measure is not intended to be considered in isolation or as a substitute for guidance prepared in accordance with U.S. GAAP. The principal limitation of this non-GAAP financial measure is that it excludes significant elements required by U.S. GAAP to be recorded in Alimera’s financial statements. In addition, this non-GAAP financial measure is subject to inherent limitations because it reflects the exercise of judgment by management in determining it.

Reconciliation of U.S. GAAP Net Loss to Non-GAAP Adjusted EBITDA (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands)			
U.S. GAAP net loss	$ (3,311)	$ (10,029)	$ (9,562)	$ (14,997)
Adjustments to U.S. GAAP net loss:				
Interest expense and other, net	3,153	1,694	6,892	3,361
Expenses incurred with Merger Agreement	2,226	—	2,226	—
Income tax (benefit) provision	(43)	25	(75)	25
Depreciation and amortization	3,093	1,866	6,178	2,547
Stock-based compensation	1,457	217	2,302	442
Foreign currency exchange losses	125	7	321	20
Extinguishment of debt	—	1,079	—	1,079
Change in fair value of warrant asset	(1)	105	45	91
Change in fair value of common stock warrant	—	5,911	—	5,911
Severance expenses	15	—	191	—
Non-GAAP adjusted EBITDA	$ 6,714	$ 875	$ 8,518	$ (1,521)

ITEM 3. *Quantitative and Qualitative Disclosures About Market Risk*

Because we are allowed to comply with the disclosure obligations applicable to a “smaller reporting company,” as defined by Rule 12b-2 of the Exchange Act, with respect to this Quarterly Report on Form 10-Q, we are not required to provide the information required by this Item.

ITEM 4. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, we evaluated the effectiveness of the design and operation of our "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2024.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the three months ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

PART II. OTHER INFORMATION

ITEM 1. *Legal Proceedings*

From time to time, we may become subject to legal proceedings, claims, and litigation arising in the ordinary course of business. We currently are not a party to any threatened or pending material litigation and do not have contingency reserves established for any litigation liabilities. However, third parties might allege that we are infringing their patent rights or that we are otherwise violating their intellectual property rights, including trade names and trademarks. Such third parties may resort to litigation. We accrue contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

ITEM 1A. *Risk Factors*

In the 2023 Form 10-K, we identify under Item 1A of Part I important factors that could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report on Form 10-Q. However, the risks described in the 2023 Form 10-K are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations. There have been no material changes in our risk factors since the filing of the 2023 Form 10-K, other than the addition of the risk factors below marked with an asterisk (*) and the restatement of the risk factor below marked with two asterisks (**).

Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business.*

Economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control. In recent years, the United States and other significant markets have experienced cyclical downturns and worldwide economic conditions remain uncertain, particularly as a result of increased inflationary and recessionary pressures, and related market and macroeconomic responses including interest rate increases. Furthermore, sustained uncertainty about, or worsening of, geopolitical tensions, including further escalation of war between Russia and Ukraine, further escalation of trade tensions between the U.S. and China, escalation of tensions between China and Taiwan, further escalation in the conflict between Israel and Hamas, as well as further escalation of tensions between Israel and various countries in the Middle East and North Africa, could result in a global economic slowdown or increased market volatility, increased cyber-attacks, supply chain disruptions or increases in costs necessary to manufacture our products, and a deterioration in political and trade relationships worldwide. Any changes related to these and other factors could adversely affect our business, both in the U.S. and internationally.

Economic uncertainty and associated macroeconomic conditions, including geopolitical tensions, escalating inflation, supply chain issues and the availability and cost of credit and government stimulus programs in the U.S. and other countries have contributed, and may continue to contribute, to increased market volatility or market declines, and make it extremely difficult for our partners, suppliers, and us to accurately forecast and plan future business activities. Sales of our products will depend, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations in the U.S., Germany, Portugal, Ireland, the U.K. and other countries. Negative trends in the general economy in any of the jurisdictions in which we may do business may cause these organizations to be unable to satisfy their reimbursement obligations or to delay payment. In addition, health authorities in some jurisdictions may reduce reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

We may not complete the pending Merger with ANI and Merger Subsidiary within the timeframe anticipated, or at all, which could have a material adverse effect on our business, financial condition or results of operations, as well as negatively impact our share price.*

On June 21, 2024, we entered into a Merger Agreement with ANI and Merger Subsidiary. The Merger Agreement provides that, upon the terms and subject to the conditions set forth therein and in accordance with the General Corporation Law of the State of Delaware.

The Merger Agreement includes covenants requiring the Company not to (i) initiate, solicit or knowingly encourage or facilitate any inquiries or the making of any proposal or offer that constitutes, or would reasonably be expected to lead to, any Acquisition Proposal, (ii) engage in, continue or otherwise participate in any discussions or negotiations regarding, or provide any non-public information or data to any person, in each case relating to, any Acquisition Proposal or any proposal or offer that would reasonably be expected to lead to an Acquisition Proposal, (iii) amend or grant any waiver or release under any standstill or similar agreement with respect to any class of equity securities of the Company or any of the Company Subsidiaries (as defined in the Merger Agreement) (subject to the Company Board's (as defined in the Merger Agreement) ability to exercise its fiduciary duties), (iv) approve any transaction under, or any third party becoming an "interested stockholder" under, Section 203 of the Delaware General Corporation Law, (v) otherwise knowingly facilitate any effort or attempt by any third party (or its potential sources of financing) to make any proposal or offer that constitutes an Acquisition Proposal, (vi) approve, endorse, recommend or execute or enter into any letter of intent, agreement in principle, term sheet, memorandum of understanding, merger agreement, acquisition agreement or other similar contract relating to an Acquisition Proposal or (vii) approve, authorize, agree or publicly announce any intention to do any of the foregoing, with customary exceptions for superior proposals. The Merger Agreement also includes covenants customary for a transaction of this nature regarding the operation of the business of the Company and its subsidiaries between signing of the Merger Agreement and the Effective Time.

Failure to complete the merger within the timeframe anticipated could adversely affect our business and the market price of our shares in a number of ways, including:

- The price of our common stock may decline to the extent that current market prices of our common stock reflect assumptions that the Merger will be completed on a timely basis.
- We could be required to pay ANI and Merger Subsidiary a termination fee of approximately $10.4 million if the Merger Agreement is terminated under specific circumstances described in the Merger Agreement.
- The failure to complete the merger may result in negative publicity and negatively affect our relationship with our stockholders, employees, customers, suppliers and lenders.
- If the Merger is not completed, the time and resources committed by our management team could have been devoted to pursuing other opportunities.
- We have incurred, and will continue to incur, significant expenses for professional services in connection with the merger for which we will have received little or no benefit if the merger is not completed.

The announcement and pendency of the Merger could materially adversely affect our business, financial condition or results of operations, as well as negatively impact our share price.*

Our efforts to complete the Merger could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our business, financial condition or results of operations, or the price of our common stock. Uncertainty as to whether the Merger will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following consummation of the merger. A substantial amount of our management's and employees' attention is being directed toward the completion of the transaction and thus is being diverted from our day-to-day operations. Uncertainty as to our future also could adversely affect our business and our relationship with collaborators, strategic partners, suppliers, existing or prospective customers or regulators. For example, collaborators, suppliers, existing or prospective customers and other counterparties may defer decisions concerning us, or seek to change existing business relationships with us, whether pursuant to the terms of their existing agreements with us or otherwise. Changes to or termination of existing business relationships could materially adversely affect our financial condition and results of operations, as well as negatively impact our share price. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction, changes to the terms of the transaction or termination of the Merger Agreement.

In certain instances, the Merger Agreement requires us to pay a termination fee, which could require us to use available cash that would have otherwise been available for general corporate purposes and other uses.*

The Merger Agreement contains certain termination rights for us, ANI and Merger Subsidiary. Subject to certain limitations, we or ANI and Merger Subsidiary may terminate the Merger Agreement if (i) the merger is not closed by December 21, 2024, or (ii) either we or ANI and Merger Subsidiary may terminate the Merger Agreement upon mutual agreement. Upon termination of the Merger Agreement, the Company, under specified circumstances and conditions set forth in the Merger Agreement, will be required to pay ANI and Merger Subsidiary a termination fee equal to $10.4 million.

Additionally, if the Merger Agreement is terminated under such circumstances, the termination fee we would be required to pay under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes and other uses. Further, a failed transaction may result in negative publicity and a negative impression of us in the investment community. For these and other reasons, termination of the Merger Agreement could materially and adversely affect our business, results of operations and financial condition, which in turn would materially and adversely affect the price of our common stock.

We have incurred, and will continue to incur, direct and indirect costs as a result of the pending Merger .*

We have incurred, and will continue to incur, significant costs and expenses, including legal, accounting and other advisory fees and other transaction costs, in connection with the pending Merger. We will be required to pay a substantial portion of these costs and expenses whether or not the Merger is completed. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses.

We may be targets of securities class action and derivative lawsuits that could result in substantial costs and may delay or prevent the merger from being completed.*

Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. The outcome of litigation is uncertain and we may not be successful in defending against future claims brought against us even if they are without merit. Regardless of the outcome of any lawsuits brought against us, such lawsuits could delay or prevent the merger, divert the attention of our management and employees from our day-to-day business, result in substantial costs and otherwise adversely affect us financially. A potential adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. Additionally, if a plaintiff is successful in obtaining an injunction prohibiting completion of the merger, that injunction may delay or prevent the merger from being completed, or from being completed within the anticipated timeframe, which may adversely affect our business, financial condition or results of operations.

Our executive officers and directors may have interests in the proposed Merger that are different from, or in addition to, those of our stockholders generally.*

Our executive officers and directors may have interests in the proposed Merger that are different from the interests of our stockholders generally, including, among others, the acceleration of the vesting of equity awards and receipt of change in control or other severance payments in connection with the proposed Merger, continued indemnification and insurance and potentially continued service to the combined company. These interests, among others, may influence, or appear to influence, our executive officers and directors and cause them to view the merger differently from how our stockholders generally may view it.

Additional information regarding our executive officers and directors and their interests in the proposed merger are included in the proxy statement relating to the proposed merger, filed with the SEC.

If the Merger occurs, our stockholders will not be able to participate in any further upside to our business.*

If the Merger is consummated, our stockholders will receive the right to receive an amount in cash equal to $5.50 per Share, without interest. Upon completion of the Merger, ANI and the Rights Agent will enter into the CVR Agreement, pursuant to which holders of CVRs will receive up to $0.50 in milestone payments for certain milestone goals achieved in fiscal year 2026 and fiscal year 2027. Our shareholders will not receive any equity interests in the Surviving Corporation.

The manufacture and packaging of pharmaceutical products such as ILUVIEN and YUTIQ are subject to the requirements of the FDA and similar foreign regulatory entities. If we or our third-party manufacturers fail to satisfy these requirements, our commercialization and regulatory approval efforts may be materially harmed.**

The FDA and similar foreign regulatory agencies regulate the manufacture and packaging of pharmaceutical products such as ILUVIEN and YUTIQ, which must be conducted in accordance with the FDA's current good manufacturing practice (cGMP) and comparable requirements of foreign regulatory agencies. Only a limited number of manufacturers that operate under these cGMP regulations are both capable of manufacturing our current products and willing to do so. If we or our third-party manufacturers fail to comply with applicable regulations, requirements or guidelines, the regulatory agencies could refuse to grant marketing approval of our current products or any future products or product candidates and could impose sanctions on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. Failure of our manufacturers to maintain compliance could interrupt the production of our current products, resulting in delays and additional costs that could significantly and adversely affect our business. For instance, on July 12, 2024, EyePoint Parent, our supplier of YUTIQ, received a warning letter (the "Warning Letter") from the FDA alleging violations of cGMP requirements in connection with a February 2024 FDA inspection at EyePoint's Watertown, Massachusetts facility and an associated February 2024 Form FDA-483 specifically related to the manufacturing of YUTIQ. The Warning Letter requires EyePoint to implement certain corrective and preventive actions, and if EyePoint is unable to remediate the findings to the FDA's satisfaction, our supply of YUTIQ may be adversely affected. Any significant delays in the manufacture of our current products or issues with the quality of the product could materially harm our business and prospects.

Changes in certain aspects of the manufacturing process or procedures require prior FDA review or approval of the manufacturing process and procedures in accordance with the FDA's cGMP regulations. There are comparable foreign requirements as well. This review may be costly and time-consuming and could delay or prevent the launch of a product. If we elect or are required to manufacture products at another facility, we will transfer the manufacturing to a registered medical device manufacturing company to seek to ensure that the new facility and the manufacturing process comply with cGMP and comparable foreign regulations. Any such new facility would also be subject to inspection. In addition, we would be required to demonstrate by physical and chemical methods, which may be costly and time-consuming, that the product made at any new facility is equivalent to the product made at the former facility. The FDA or a foreign regulatory agency may require clinical testing to prove equivalency of the product manufactured at any new facility compared to the old facility, which would result in additional costs and delay.

Further, we are required to complete testing on both the active pharmaceutical ingredient and on the finished product in the packaging that we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, our manufacturers are required to consistently produce our product in commercial quantities and of specified quality in a reproducible manner and document their ability to do so. This requirement is referred to as process validation. The FDA and similar foreign regulatory agencies may also implement new standards or change their interpretation and enforcement of existing standards and requirements for the manufacture, packaging or testing of products at any time.

ITEM 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***

None.

ITEM 3. ***Defaults Upon Senior Securities***

None.

ITEM 4. ***Mine Safety Disclosures***

Not applicable.

ITEM 5. ***Other Information***

Not applicable.

ITEM 6. EXHIBITS

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated June 21, 2024, by and among ANI Pharmaceuticals, Inc., ANIP Merger Sub INC. and Alimera Sciences, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K, as filed June 24, 2024, and incorporated herein by reference).
3.1	Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-K, as filed on March 2, 2020, and incorporated herein by reference).
3.2	Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on March 27, 2023, and incorporated herein by reference).
3.3	Certificate of Amendment to Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on May 18, 2023, and incorporated herein by reference).
3.4	Certificate of Amendment to Certificate of Designation of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, and incorporated herein by reference).
3.5	Certificate of Elimination of Series B Convertible Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, as filed on August 15, 2023, and incorporated herein by reference).
3.6	Amended and Restated Bylaws of the Registrant, as amended (filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, as filed on March 2, 2020 and incorporated herein by reference).
4.1	Form of Pre-Funded Warrant (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, and incorporated herein by reference).
10.1	Chairman Emeritus Agreement, dated as of August 1, 2023, by and between Alimera Sciences, Inc. and C. Daniel Myers (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, and incorporated herein by reference).
10.2	Alimera Sciences, Inc. 2023 Equity Incentive Plan and forms of award agreements thereunder (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on August 2, 2023, and incorporated herein by reference).
10.3	Alimera Sciences, Inc. 2024 Equity Inducement Plan as Adopted on February 8, 2024 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed February 9, 2024, and incorporated herein by reference)
10.4	Seventh Amendment to Loan and Security Agreement, dated as of March 6, 2024, by and among Alimera Sciences, Inc., SLR Investment Corp., as Collateral Agent, and the parties signatory thereto as Lenders, including SLR in its capacity as a Lender (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, as filed on May 14, 2024, and incorporated herein by reference).
10.6*	Letter Agreement, dated as of June 19, 2024, by and between Alimera Sciences, Inc. and SWK Funding LLC.
10.7*	Manufacturing Services Agreement, dated as of July 17, 2024, by and between Alimera Sciences, Inc. and Alliance Medical Products, Inc. d.b.a. Siegfried Irvine.
31.1*	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Loss, (iv) Condensed Consolidated Statements of Cash Flows, (v) Condensed Consolidated Statements of Changes in Stockholders' Deficit and (vi) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101).

* Filed herewith
** Furnished herewith

The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Alimera Sciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

ALIMERA SCIENCES, INC.

August 7, 2024

By: /s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 10.6

June 19, 2024

SWK Funding LLC
c/o SWK Holdings Corporation
14755 Preston Road, Suite 105
Dallas, Texas 75254
Attention: Joe D. Staggs

Re: Alternative Royalty Payment

Dear Jody:

This letter agreement (this "Letter Agreement") is entered into as of the date set forth above by and between Alimera Sciences, Inc., a Delaware corporation with its principal place of business at 6310 Town Square, Suite 400, Alpharetta, GA 30005 ("Alimera"), and SWK Funding LLC, a Delaware limited liability company ("SWK Funding"). Alimera and SWK Funding are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

Reference is made to that certain Royalty Purchase Agreement, dated as of December 17, 2020 (as amended from time to time, the "Royalty Purchase Agreement"), by and among SWK Funding, on the one hand, and EyePoint Pharmaceuticals US, Inc. (f/k/a pSivida US. Inc.) ("EyePoint US") and EyePoint Pharmaceuticals, Inc. ("EyePoint"), on the other hand. Capitalized terms used but not otherwise defined in this Letter Agreement shall have the meanings ascribed to them in the Royalty Purchase Agreement.

WHEREAS, EyePoint US and Alimera entered into that certain Second Amended and Restated Collaboration Agreement, dated as of July 10, 2017 (as amended from time to time, the "Collaboration Agreement"), pursuant to which, *inter alia*, EyePoint US granted Alimera certain rights and covenants to enable Alimera to develop, manufacture and commercialize certain products, including ILUVIEN® ("ILUVIEN"), as more fully set forth therein;

WHEREAS, SWK Funding, EyePoint US and EyePoint entered into the Royalty Purchase Agreement pursuant to which, *inter alia*, SWK Funding purchased from EyePoint US, and EyePoint US conveyed to SWK Funding, all rights, title and interests in and to the Purchased Receivables;

WHEREAS, the Purchased Receivables consist solely of the Royalties (as defined in the Collaboration Agreement) payable by Alimera to EyePoint US under the Collaboration Agreement (the "Purchased Receivables");

WHEREAS, as of the date set forth above, Alimera has been making payments of Royalties (as defined in the Collaboration Agreement), and provided all reporting related thereto, directly to SWK Funding pursuant to a Notice and Acknowledgement, dated December 8, 2020, sent from EyePoint to Alimera, instructing the same;

WHEREAS, Eyepoint and Alimera entered into that certain Product Rights Agreement, dated as of May 17, 2023 (as amended from time to time, the "Product Rights Agreement"), pursuant to which, *inter alia*, Eyepoint granted Alimera certain rights and covenants to enable Alimera to develop, manufacture and commercialize YUTIQ® ("YUTIQ"), as more fully set forth therein; and

WHEREAS, SWK Funding and Alimera desire to enter into this Letter Agreement to, *inter alia*, agree to an alternative calculation of the royalties payable to SWK in lieu of the Purchased Receivables, all as more fully set forth herein;

NOW THEREFORE, in consideration of the premises and of the mutual covenants contained in this Letter Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. **Defined Terms**. Except as otherwise expressly set forth in this Letter Agreement, the following terms shall have the respective meanings set forth below, irrespective of any similar term or definition set forth in the Royalty Purchase Agreement, Collaboration Agreement or Product Rights Agreement:

    a. "Acquiring Entity" means a Third Party that acquires a Party (and is therefore deemed to be an Affiliate of such Party) through a Change of Control, together with any Affiliates of such Third Party existing immediately prior to the consummation of the Change of Control. For clarity, an "Acquiring Entity" of a Party shall exclude (i) the Party and all of its Affiliates existing immediately prior to the consummation of the Change of Control, and (ii) any Person that becomes an Affiliate of such Third Party following the consummation of the Change of Control, and not as a result of the Change of Control.

    b. "Alternative Royalty" means a royalty payable by Alimera to SWK Funding, on a calendar quarter basis, in an amount equal to 3.125% of FAc Net Sales for such calendar quarter.

    c. "Change of Control" means, with respect to a Party, (i) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (ii) except in the case of a bona fide equity financing in which a Party issues new shares of its capital stock, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (iii) the sale or other transfer to a Third Party of all or substantially all of such Party's assets to which this Agreement relates. For clarity, the sale or other transfer to a Third Party all or substantially all of Alimera's rights to FAc Products would constitute a Change of Control of Alimera.

    d. "FAc Net Sales" means, the aggregate Net Sales by Alimera or its Affiliates of all FAc Products.

e. "FAc Product" means a drug delivery device owned or controlled by Alimera or any of its Affiliates that has a core within a polymer layer that delivers a corticosteroid by implantation, injection, or other direct delivery method to the posterior portion of the eye, excluding any such drug delivery device that is owned or controlled by, and the subject of ongoing material development or commercialization activities taken by or on behalf of, a previously unaffiliated Acquiring Entity or any of its Affiliates existing immediately prior to the consummation of a Change of Control of Alimera or any of its Affiliates. For clarity, (i) YUTIQ® 0.18mg, and (ii) ILUVIEN® 0.19 mg, are each a FAc Product.

f. "Gross Revenues" means, for any period, on an accrual basis (i) for any arm's length transaction in which FAc Products are sold separately by Alimera or its Affiliates to a Third Party, the gross invoice price for FAc Products in such transactions, and (ii) for all other transactions (i.e., other than those described in subsection (i)) in which FAc Products are sold, used or otherwise disposed of by Alimera or its Affiliates (including in barter or similar transactions, or transactions that are not at arm's length to a Third Party, or transactions in which FAc Products are not sold separately, but not including the provision of FAc Products intended for use solely as samples, including, without limitation, as free clinical trial materials), the total imputed sales price for FAc Products in such transactions, using as the imputed sales price the weighted average gross invoice price for FAc Products under subsection (i) during the preceding calendar quarter for the applicable indication and country or, if there have been no Gross Revenues under subsection (i) in the preceding quarter, using a reasonable imputed price to be determined at the time by the Parties. For purposes of this definition, "sold separately" means sold, solely for monetary consideration, on a stand-alone basis (i.e., with a selling price independent of any other product) for not less than arm's length value.

g. "Net Sales" shall mean, with regard to a FAc Product, on an accrual basis, for any period, Gross Revenues less reasonable and customary deductions in accordance with GAAP applied on a consistent basis, however, as points of clarity, (i) the costs associated with administering any contractual and governmental rebates or co-pay assistance program shall be excluded as a deduction from Gross Revenues, and (ii) in all instances in which Alimera or its Affiliates invoices a Sublicensee or distributor separately for the fully burdened cost of a FAc Product (other than amounts specifically identified on such invoice, and invoiced at cost or less, for a FAc Product to be used as samples or for clinical trials), such amounts are to be included as a component of Gross Revenues and Net Sales upon which the Alternative Royalty is calculated.

h. "Sublicensee" means any Third Party, including a co-promotion or co-marketing partner, to whom Alimera or any of its Affiliates grants a sublicense of the licenses and rights granted by EyePoint US or EyePoint under the Collaboration Agreement or the Product Rights Agreement, respectively, to sell or offer to sell a FAc Product.

i. "Third Party" means any Person other than a Party or an Affiliate of such Party.

2. **Alternative Royalty Agreement**. Upon the terms and subject to the conditions of this Agreement, with respect to sales of Products made in the second (2nd) calendar quarter of 2024 (i.e. commencing April 1, 2024) and continuing during the term of this Agreement, on a quarterly basis, Alimera agrees to pay SWK Funding the Alternative Royalty and SWK Funding agrees to accept such Alternative Royalty payment in lieu of such quarter's Purchased Receivables payment which would otherwise have been payable pursuant to the Collaboration Agreement. On a quarterly basis, SWK Funding, upon receipt of the Alternative Royalty payment, will and does hereby release its right to the quarterly Purchased Receivables payment payable under the Collaboration Agreement.

3. **Additional Terms**.

a. Existing Agreements. The Parties agree that: (i) the Collaboration Agreement, Product Rights Agreement and Royalty Purchase Agreement (collectively, the "Existing Agreements") are all in full force and effect. Except as explicitly set forth herein, this Letter Agreement shall not alter or affect the Existing Agreements or any provisions therein, (ii) all payments of the Alternative Royalty shall continue to be made in connection with and pursuant to the Collaboration Agreement and the license of intellectual property rights set forth therein, and (iii) the consideration for giving up the higher royalty rate of the Purchased Receivables for the lower royalty rate of the Alternative Royalty is the payment of such lower rate on a broader base of sale as defined as FAc Net Sales herein.

b. Payment Terms. Alimera shall pay the Alternative Royalty within sixty (60) calendar days after the end of each calendar quarter. All payments shall be made in U.S. dollars. If any currency conversion is required in connection with the calculation of Net Sales, such conversion shall be made in accordance with GAAP.

c. Reports; Records; Audits. SWK Funding shall continue to have all of the rights and obligations granted and assigned under the Collaboration Agreement as assigned to SWK Funding pursuant to the Royalty Purchase Agreement, including, but not limited to, the reporting, record-keeping and auditing provisions of the Collaboration Agreement; *provided, however*, that such reporting shall include the Alternative Royalty calculation and backup information.

4. **Alternative Royalty Buy-Out**.

a. Option Payment. In the event that a Change of Control occurs with respect to Alimera during the Term, then at any time during the six (6) months following the effective date of such Change of Control (such period, the "Option Term"), Alimera (or its successor) may buy-out the Alternative Royalty payable or to be payable under this Letter Agreement by payment to SWK Funding of an amount equal to the greater of (i) $17,250,000 and (ii) 4.75 times the aggregate amount of the Alternative Royalty paid or payable pursuant to Section 2 of this Letter Agreement (x) over the most recently completed four (4) calendar quarters, or (y) if such Option is exercised prior to April 1, 2025, then 3.125% of the FAc Net Sales over the most recently completed four (4) calendar quarters (such greater amount of (i) and (ii), the "Option Payment"). Such Option Payment amount shall be paid to SWK Funding prior to the expiration of the Option Term. Any Alternative Royalty from completed calendar quarters that have not been paid prior to the payment of the Option Payment shall still remain due and payable and shall be paid concurrently with the Option Payment.

b. Effect of Option Payment. Effective upon payment of the Option Payment: (i) Alimera shall have no further obligation to make, and SWK Funding shall have no further right to receive, any payments under this Letter Agreement or the Royalty Purchase Agreement; and (ii) SWK Funding shall and hereby does, effective upon payment of the Option Payment, assign to Alimera, and Alimera shall and hereby does assume from SWK Funding, the Royalty Purchase Agreement in its entirety.

5. **Representations, Warranties and Covenants**.

   a. SWK Funding. SWK Funding represents and warrants that: (i) it has not been in material breach of, or material default under, the Royalty Purchase Agreement at any time during the term of the Royalty Purchase Agreement; (ii) it is not in material breach of, or material default under, the Royalty Purchase Agreement as of the date of this Letter Agreement; and (iii) it has not, at any time, received from EyePoint or EyePoint US any written notice alleging that SWK Funding is in breach of, or default under, the Royalty Purchase Agreement. SWK Funding hereby covenants that: (1) it shall not amend, modify or supplement the Royalty Purchase Agreement; (2) it shall not terminate the Royalty Purchase Agreement; and (3) it shall not enforce, or require or request that EyePoint or EyePoint US to enforce, any provision of the Collaboration Agreement or rights granted to SWK Funding under the Royalty Purchase Agreement to the extent related to the payment of the Purchased Royalties for which Alimera has paid the Alternative Royalty to SWK Funding.

   b. Alimera. Alimera represents and warrants that: (i) it has not been in material breach of, or material default under, the Collaboration Agreement or the Product Rights Agreement at any time during the term of the Royalty Purchase Agreement; (ii) it is not in material breach of, or material default under, the Collaboration Agreement or the Product Rights Agreement as of the date of this Letter Agreement; and (iii) it has not, at any time, received from EyePoint or EyePoint US any written notice alleging that Alimera is in breach of, or default under, the Collaboration Agreement or the Product Rights Agreement.

6. **Term; Survival**.

   a. This Letter Agreement shall be effective as of the date set forth above and shall, unless earlier terminated upon mutual written agreement of the Parties, continue in full force and effect unless and until the earliest of (i) expiration or earlier termination of the Collaboration Agreement, (ii) expiration or earlier termination of the Royalty Purchase Agreement, (iii) the termination of this Letter Agreement by SWK Funding upon the material breach by Alimera of its obligation to make a required payment of the Alternative Royalty under Section 3(ii) of this Letter Agreement if Alimera does not cure such nonpayment within ten (10) business days after receiving written notice from SWK Funding of such material breach, and (iv) assignment of the Royalty Purchase Agreement in full from SWK Funding to Alimera following payment of the Option Payment pursuant to Section 4.

   b. Upon expiration or termination of this Letter Agreement, the following provisions shall survive: Articles 1, 7 and Section 2 (last sentence with respect to Purchased Receivables for the calendar quarter(s) SWK Funding previously received Alternative Royalty payments), Section 4(b) (upon termination under Section 6(a)(iv)), and this Section 6(b).

7. **Miscellaneous**.

   a. Confidentiality. Neither Party may disclose this Letter Agreement, the substance contained herein or its existence to any person or entity (including EyePoint, EyePoint US, their Affiliates and their respective officers, directors, employees, consultants and agents) without the other Party's prior written consent except (i) as required by applicable laws and/or regulations, and/or (ii) to its advisors, current and prospective investors, lenders, underwriters, and/or acquirers, in each case under a commercially reasonable obligation of confidentiality. Notwithstanding the above, the Parties recognize that each of the Parties are subject to public company reporting requirements.

   b. Further Assurances. Each Party shall, as and when requested by the other Party, do all acts and execute all documents as may be reasonably necessary to give effect to the provisions of this Agreement.

   c. Headings. The captions to the Sections and subsections hereof are not a part of this Letter Agreement but are for convenience only and shall not be deemed to limit or otherwise affect the construction thereof.

   d. Notices. Except where expressly provided otherwise in this Letter Agreement, whenever it is provided in this Letter Agreement that notice, demand, request, consent or other communication shall be given to or served upon any Party by the other Party, any such notice demand, request, consent or other communication shall be in writing and personally delivered, sent by certified or registered mail, return receipt requested, by overnight delivery service with confirmation of delivery or by electronic (notices and other communications sent to an e-mail address shall also be sent by overnight delivery service or personal delivery) to the following address or addresses, or such other address or addresses as may be designated from time to time by a Party in accordance with this Section 8(d):

If to Alimera:	Alimera Sciences, Inc. 6310 Town Square, Suite 400 Alpharetta, GA 30005 Attention: General Counsel Email: Chris.Visick@alimerasciences.com
With a copy to:	DLA Piper LLP (US) 51 John F. Kennedy Parkway, Suite 120 Short Hills, New Jersey 07078 Attention: Andrew P. Gilbert Email: andrew.gilbert@us.dlapiper.com
If to Purchaser:	SWK Funding LLC c/o SWK Holdings Corporation 5956 Sherry Lane, Suite 650 Dallas, Texas 75225 Attn: Joe D. Staggs jstaggs@swkhold.com
With a copy to:	Holland & Knight LLP 1722 Routh Street, Suite 1500 Dallas, Texas 75201 Attn: Ryan Magee and Paul Smith ryan.magee@hklaw.com and paul.smith@hklaw.com

   Notice in each of the above cases shall be deemed effective for all purposes (i) upon hand delivery if hand delivered, (ii) three (3) business days after posting in the United States Mail if sent by certified mail, or (iii) on the day of confirmed delivery by overnight delivery service, facsimile or email (return receipt requested).

   e. Expenses. All fees, costs and expenses (including any legal fees) incurred by the Parties in connection with the preparation and negotiation of, and entry into, this Letter Agreement and to consummate the transactions contemplated hereby shall be paid by the Party incurring such expenses.

f. Assignment. Neither this Letter Agreement nor any of a Party's rights, interests or obligations hereunder may be assigned, delegated or otherwise transferred, in whole or in part, by operation of law or otherwise by a Party without the prior written consent of the other Party, and any such purported assignment, delegation or transfer without such consent shall be void *ab initio* and of no effect; provided, however, that (i) Alimera may, without the prior written consent of SWK Funding, assign this Letter Agreement to any person or entity to which Alimera assigns, and such person or entity assumes, the Collaboration Agreement, and (ii) SWK Funding may, without the prior written consent of Alimera, assign this Letter Agreement to (A) any person or entity to which SWK Funding assigns, and such person or entity assumes, the Royalty Purchase Agreement, or (B) any lender as collateral for a loan provided that the Royalty Purchase Agreement is also collateral for such loan to such lender.

g. Successors and Assigns. This Letter Agreement shall be binding upon, inure to the benefit of and be enforceable by, the Parties and, subject to the provisions of Section 7(f), their respective successors and assigns.

h. Amendment and Waiver.

    i. This Letter Agreement may be amended, modified or supplemented, or any provision hereof waived, only in a writing signed by Alimera and SWK Funding.

    ii. No failure or delay on the part of either Party in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing between the Parties shall be effective to amend, modify, supplement or waive any provision of this Letter Agreement.

i. Entire Agreement. This Letter Agreement, together with the Collaboration Agreement and Royalty Purchase Agreement (as necessary to give effect to any of the terms of this Letter Agreement), sets forth the entire agreement and understanding between the Parties as to the subject matter hereof. All express or implied agreements, arrangements, representations and understandings as to the subject matter hereof, whether oral or written, heretofore made are superseded by this Letter Agreement.

j. Independent Contractors. The Parties recognize and agree that each is operating as an independent contractor and not as a partner, joint venturer, agent or fiduciary of the other.

k. No Third Party Beneficiaries. This Letter Agreement is for the sole benefit of Alimera and SWK Funding and, subject to Section 7(f), their successors and assigns, and nothing herein expressed or implied shall give or be construed to give to any person or entity, other than the Parties and such successors and assigns, any legal or equitable rights hereunder.

l. Governing Law. THIS LETTER AGREEMENT SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO CONFLICT OF LAWS PRINCIPLES THEREOF (OTHER THAN SECTIONS 5-1401 AND 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS LAW).

m. Jurisdiction; Venue; Service of Process; Waiver of Jury Trial . Each Party irrevocably submits to the exclusive jurisdiction of (i) the United States District Court for the Southern District of New York, and (ii) the Supreme Court of the State of New York, New York County, for the purposes of any suit, action or other proceeding arising out of this Letter Agreement or any transaction contemplated hereby. Each Party agrees to commence any action, suit or other proceeding relating hereto in the courts of United States District Court for the Southern District of New York or, if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York located in New York County. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or other proceeding arising out of this Letter Agreement and the transactions contemplated hereby in (A) the United States District Court for the Southern District of New York, or (B) the Supreme Court of the State of New York, New York County, and hereby further irrevocably and unconditionally waives, and shall not assert by way of motion, defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper, or that this Letter Agreement and the transactions contemplated hereby and thereby may not be enforced in or by any of the above-named courts. EACH OF ALIMERA AND SWK FUNDING HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, THE RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM FILED BY EITHER PARTY, WHETHER IN CONTRACT, TORT OR OTHERWISE, RELATING DIRECTLY OR INDIRECTLY TO THIS LETTER AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREIN.

n. Equitable Remedies. The Parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy, would occur in the event that the Parties do not perform their respective obligations under the provisions of this Letter Agreement in accordance with their specific terms or otherwise breach such provisions. It is accordingly agreed that the Parties shall be entitled to seek an injunction or injunctions, specific performance and other equitable relief to prevent breaches of this Letter Agreement and to enforce specifically the terms and provisions of this Letter Agreement. Each of the Parties agrees that it shall not oppose the granting of an injunction, specific performance and other equitable relief when expressly available pursuant to the terms of this Letter Agreement on the basis that the other Party has an adequate remedy at law or an award of specific performance is not an appropriate remedy for any reason at law or equity.

o. Other Damages. In the event of the breach by either Party of this Letter Agreement, the non-breaching Party shall be entitled to seek monetary damages. Nothing in this Letter Agreement shall affect either Party's right to seek damages under the Collaboration Agreement, provided that SWK Funding shall not be entitled to seek damages (i) to the extent related to the Purchased Royalties for which Alimera has paid the Alternative Royalty to SWK Funding pursuant to this Letter Agreement or (ii) in the event that Alimera has made payment of the Option Payment.

p. Severability. If any term or provision of this Letter Agreement is held to be invalid, illegal or unenforceable by a court or other governmental entity of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Letter Agreement, which shall remain in full force and effect, and the Parties shall replace such term or provision with a new term or provision permitted by applicable law and having an economic effect as close as possible to the invalid, illegal or unenforceable term or provision. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

q. Counterparts. This Letter Agreement may be executed in any number of counterparts and by the Parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Copies of executed counterparts transmitted by email with PDF attachment shall be considered original executed counterparts.

[*Rest of page left intentionally blank.*]

Sincerely yours,

ALIMERA SCIENCES, INC.

By:____/s/ Richard S. Eiswirth, Jr._____
Name: Richard S. Eiswirth, Jr.
Title: Chief Executive Officer

The foregoing is hereby agreed to and accepted by:

SWK FUNDING LLC

By: SWK Holdings Corporation,
its sole Manager

By: ____/s/ Joe D. Staggs_____
Name: Joe D. Staggs
Title: President and Chief Executive Officer

Exhibit 10.7
Portions of this document have been redacted as marked with [***]

Manufacturing Services Agreement

Custom Drug Product

This Manufacturing Services Agreement (**Agreement**) is entered into as of July 17, 2024 (the **Effective Date**) between

Alliance Medical Products, Inc., 9342 Jeronimo Rd, Irvine, CA 92618, USA

(**Siegfried**)

and

Alimera Sciences, Inc., 6310 Town Square, Suite 400, Alpharetta, GA 30005, USA

(**Customer**)

(each a **Party**, together the **Parties**).

Preamble

A. Customer engages in the business of research, development and commercialization of pharmaceutical products;

B. Siegfried has substantial expertise in manufacturing medical products;

C. Siegfried and Customer are each currently party to a First Amended and Restated Commercial Contract Manufacturing Agreement dated as of February 5, 2016 (the "2016 Agreement"); and

D. Customer and Siegfried desire to enter into this Agreement to supersede and replace the 2016 Agreement to provide the terms and conditions upon which Siegfried shall continue to perform certain manufacturing services for Customer.

Now, therefore, the Parties agree as follows:

1. Definitions

Unless otherwise defined in this Agreement, each of the capitalized terms used in this Agreement (other than the headings of the sections) shall have the meanings indicated below. Such meanings shall apply equally to all forms of such terms, including singular and plural forms, unless otherwise clearly indicated.

1.1 **Affiliate** shall mean with respect to any Party any person or entity controlling, controlled by, or under common control with such Party at any time during the term of this Agreement. For purposes of this definition, the term control shall mean the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting stock, by contract or otherwise, including, in the case of a corporation or limited liability company, through the direct or indirect ownership of at least fifty percent (50%) of the outstanding voting equity.

1.2 **Batch** shall mean a specific quantity of Product that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture as defined by the applicable Batch record.

1.3 **Business Day** shall mean a day (not being a Saturday or Sunday) on which banks are open for business in Irvine, California.

1.4 **cGMP Regulations** shall have the meaning as set forth in the Quality Agreement.

1.5 **Change** shall mean any change to the Specifications, Master Batch Record, Raw Materials, Customer Supplied Materials, Mandatory Vendor, or the Facility, or any other change referred to in the change control procedure set forth in the Quality Agreement, such Change being either (i) a Required Change (as defined in Section 14.1), (ii) a Customer Change (as defined in Section 14.3), or (iii) a Siegfried Change (as defined in Section 14.4).

1.6 **Confidential Information** shall mean any information of whatever kind, and all tangible and intangible embodiments and oral disclosures thereof of any kind whatsoever, which has been or will be disclosed or otherwise made accessible by one Party (Disclosing Party) to the other Party (Receiving Party) in connection with this Agreement, and which is confidential or proprietary to the Disclosing Party or an Affiliate thereof, including, without limitation, any and all information pertaining to this Agreement, the Product or the Manufacturing Services and other non-public information which relates to the business of either Party, including business plans, strategies, operations, pricing, policies, procedures, techniques, accounts, marketing plans, financial plans and status, and personnel of either Party, *provided that* such information was designated in writing as *"Confidential"* or *"Proprietary"* information at the time of the initial disclosure or by confirmation in writing to the Receiving Party within one (1) month of the initial disclosure; and further provided, that such information shall be subject to the obligations set forth herein and constitute Confidential Information, even if not identified as confidential, if the Receiving Party knows, or in the exercise of reasonable business judgment should know, such information to be confidential to the Disclosing Party.

1.7 **Customer Supplied Materials** shall mean the active pharmaceutical ingredients and other materials that are to be provided by or on behalf of Customer (directly or through Customer's relevant vendor) to Siegfried for the performance of the Manufacturing Services under this Agreement, as set forth in Annex B.

1.8 **Effective Date** shall have the meaning set forth on the front page of this Agreement.

1.9 **EMA** shall mean the European Medicines Agency or any successors to its responsibilities with respect to pharmaceutical products.

1.10 **Entitled Person** shall have the meaning set forth in 18.2.

1.11 **Facility** shall mean Siegfried's facility where the Manufacturing is performed Alliance Medical Products, Inc., 9342, 9292, and/or 9272 Jeronimo Rd, Irvine, CA 92618. Additional Siegfried facilities may be added upon written agreement between the Parties.

1.12 **FDA** shall mean the US Food and Drug Administration or any successors to its responsibilities with respect to pharmaceutical products.

1.13 **Force Majeure Event** shall have the meaning set forth in 20.3.

1.14 **Forecast** shall have the meaning as set out in 4.1.

1.15 **Hidden Defects** shall mean any failure of a Product to conform to the Specifications that is not discoverable upon reasonable physical inspection or standard testing upon receipt of the Product.

1.16 **Improvement** shall mean any result, data, documentation, invention, improvement, modification, adaptation, enhancement, or other improvement to or for any part of the Product, which is conceived, derived, reduced to practice, made or developed by Siegfried in its performance of the Manufacturing Services under this Agreement.

1.17 **Independent Improvement** shall mean an Improvement which is severable from Customer's Intellectual Property and which is not uniquely applicable to the Product.

1.18 **Initial Term** shall have the meaning set forth in 19.1.

1.19 **Intellectual Property** shall mean all inventions, patent applications, patents, registered or unregistered design rights, copyrights, database rights, trademarks, trade names, know-how, trade secrets and other industrial or intellectual property and the rights relating thereto of whatever kind.

1.20 **Mandatory Vendor** shall mean any vendor (other than Siegfried) that is registered in the Marketing Authorization or any other regulatory documentation of Customer or as set forth in the Quality Agreement or Annex B.

1.21 **Manufacture / Manufacturing Services** shall mean all operations performed by or on behalf of Siegfried in the receipt of Raw Materials and the production, including without limitation sterilization, packaging, labeling, handling, warehousing, quality control testing, and stability testing of Product(s).

1.22 **Marketing Authorization** shall mean any of the following: (a) a New Drug Application (NDA) filed with the FDA, (b) an Abbreviated New Drug Application (ANDA) filed with the FDA or (c) any other similar or equivalent regulatory filing with any Regulatory Authority seeking authorization and approval to manufacture, package, ship, and sell the Product that will be used to treat humans; and (d) all supplements and amendments that may be filed with respect to the foregoing.

1.23 **Master Batch Record** shall mean the master production batch record approved by Customer for specifying the Manufacture of the Product(s).

1.24 **Party, Parties** shall mean either Customer or Siegfried, or both, as the context may require.

1.25 **Person in Plant** shall mean an employee, contractor, or consultant of the Customer and designated by Customer located at the Facility.

1.26 **Product** shall mean the good to be Manufactured by Siegfried as defined in Annex A and Annex B.

1.27 **Quality Agreement** shall mean the Quality/Technical Agreement for the contract manufacture of medicinal products between Siegfried and Customer signed in March 2021. The terms of the Quality Agreement shall be incorporated by reference into this Agreement.

1.28 **Raw Materials** shall mean all excipients, packaging materials and other raw materials, excluding any Customer Supplied Materials, which are necessary to Manufacture the Product, including but not limited to those set forth in Annex B.

1.29 **Regulatory Authority** shall mean any of the FDA, the European Medicines Agency, and any similar or equivalent competent regulatory authority from any other country outside the US and the European Union.

1.30 **Specifications** shall mean the detailed description of technical requirements that the Product has to conform to, as further defined in the Quality Agreement.

2. Manufacture of Product

2.1 **Manufacturing.** Subject to the terms and conditions set forth in the Agreement and any related statements of work, Siegfried shall Manufacture the Product for the Customer at the Facility and Customer shall purchase such Product from Siegfried. Customer shall have the right to designate a Person in Plant who shall be entitled, upon advance notice to and approval from Siegfried, to observe, and provide general support and feedback to Customer with respect to, Product Manufacturing. The Person in the Plant shall coordinate his or her on-site presence with Siegfried to occur at reasonable times and for appropriate purposes. The Person in Plant will take all necessary precautions and follow Siegfried's directions to avoid disruption to Siegfried operations and to comply with Facility safety, security, and confidentiality policies.

2.2 **Manufacturing standards.** Siegfried shall conduct all Manufacturing Services in compliance with this Agreement, the Quality Agreement, the Master Batch Record, cGMP Regulations and all laws, rules and regulations applicable to the Manufacturing of the Product at the place of the Facility.

2.3 **[Intentionally Omitted.]**

2.4 **Quality Agreement.** The Parties have entered into the Quality Agreement which is incorporated herein by reference, as same may be amended from time to time by written agreement between the Parties.

2.5 **Volume requirement.** Customer agrees to purchase from Siegfried and Siegfried agrees to Manufacture and supply to the Customer the volume of Product as set forth in Annex A.

2.6 **Information.** During the term of this Agreement, Customer shall provide to Siegfried all information available to Customer or in its possession which may be required for the due performance by Siegfried of its Manufacturing Services or other obligations under this Agreement, including but not limited to any existing or new information on Product safety, efficacy or quality and/or regulatory requirements relating thereto.

3. Product Schedules and Affiliates

3.1 **Product Schedules.** During the term of this Agreement, Siegfried and Customer shall enter into a Product Schedule (see Annex A) for each Product, each of which is incorporated into and made part of this Agreement upon execution.

3.2 **Affiliates.** If an Affiliate of Customer desires to purchase a Product under this Agreement, such Affiliate may obtain the Product by entering into a Product Schedule executed by Siegfried, Customer and the applicable Customer Affiliate. If an Affiliate of Siegfried desires to provide Product, such Affiliate may do so by entering into a Product Schedule executed by Customer, Siegfried, and the applicable Siegfried Affiliate. Customer shall not unreasonably withhold its consent to Siegfried's wish to Manufacture the Product at a Siegfried Affiliate provided that Customer shall have the opportunity to review and approve in advance a detailed Manufacturing Services qualification plan and provided further that all changes are authorized and approved in writing by the Customer in advance of the change per Section 14 of this Manufacturing Services Agreement and the Quality Agreement. Siegfried shall bear all costs of any Manufacturing Services setup or transfer initiated by Siegfried or an Affiliate. The Parties agree to discuss in good faith potential sharing of transfer expenses when the relocation of manufacturing activities is reasonably expected to provide benefits to both Parties.

4. Forecast and Ordering

4.1 **Forecast.** On the Effective Date and by the 15 th calendar day of each calendar month thereafter, Customer shall submit an eighteen (18)-month rolling forecast, broken down on a monthly basis, covering Customer's anticipated requirements of Product as set forth in Annex A (**Forecast**). The first four (4) months of each Forecast shall be binding on both Parties; the remaining non-binding fourteen (14) month part of each Forecast shall be for information and planning purposes only and shall be non-binding for both Parties. The foregoing notwithstanding, upon qualification of a second, additional manufacturing line for Product the Parties agree to extending the binding portion of each Forecast to six (6) months.

4.2 **Information**. In the event, Siegfried anticipates any difficulties with regard to the Manufacture of the Product according to the non-binding Forecast, Siegfried shall inform Customer in writing within no more than fourteen (14) days after receipt of a Forecast and the Parties shall discuss and, as appropriate, agree on a revised Forecast in good faith.

4.3 **Orders.** Customer shall submit firm written Orders (by email (pdf) or letter) to Siegfried for the binding period of the Forecast and may submit firm written Orders for the non-binding period of the Forecast, giving Siegfried a lead time, i.e. time period between receipt of the Order and delivery date, as set forth in the Annex A (**Lead Time**). Each Order shall specify (i) the Product ordered, (ii) the quantity ordered (iii) the Price pursuant to Annex A and (iv) the required delivery date in accordance with the respective Lead Time.

4.4 **Exceeding Orders**. Customer may submit and Siegfried shall confirm Orders, which exceed the binding forecast volume by up to twenty-five percent (25%). Orders exceeding the binding forecast by more than twenty-five percent (25%) of the corresponding binding Forecast shall be discussed between the Parties in good faith. The order quantity for Orders of Customer is restricted to full batches as set forth in Annex A.

4.5 **Order Confirmation.** Each Order that meets all of criteria (i)-(iii) below shall be binding on Siegfried, and Siegfried shall send Customer a written confirmation within ten (10) Business Days from the date of the receipt of the Order from Customer. Siegfried shall be bound by and confirm any Order, which

(i) complies with the Lead Time of the relevant Product;

(ii) is consistent with the minimum order quantities listed in Annex A;

(iii) does not deviate by more than twenty-five percent (25%) from the latest binding Forecast of the Product for the relevant month.

Each response confirming an Order shall either confirm the requested delivery date and quantities set forth in the Order or propose reasonable alternative delivery dates. Both Parties agree to find within five (5) Business Days after the receipt of the Confirmation by Siegfried, a mutually acceptable date of delivery, which will become binding. Failure by Siegfried to confirm in writing an Order that satisfies the foregoing criteria (i) – (iii) shall not relieve Siegfried from its obligation to fill the Order according to its terms.

5. Raw Materials and Customer Supplied Materials

5.1 **Raw Materials.** Siegfried shall timely order sufficient quantities of Raw Materials to enable Siegfried to Manufacture and deliver Product in line with the 12-month rolling forecast. Customer acknowledges that Siegfried will rely on the accuracy of Customer's Forecasts in planning its acquisitions of Raw Materials. Thus, Siegfried has the right to use the Forecast for planning and buying Raw Materials reasonably ahead sufficient for covering the Forecast for the Product needs of Customer (especially with respect to long lead-time items). Customer shall be responsible for the cost of Raw Material reasonably purchased to be used in the Manufacture of Product that is not Manufactured because Customer fails to submit Orders according to the Forecasts and which Siegfried cannot reasonably use for the Manufacture of the Product under future Orders or third-party products. Any material bought for the submitted Forecasts, which Siegfried is not able to use for Manufacturing of Product or other products because of Customer's failure to submit Orders in line with the Forecast, will be sold to Customer upon Siegfried's request at a price equal to Siegfried's purchase price from supplier plus a handling fee of [***]%.

5.2 **Customer Supplied Material** Customer shall supply all Customer Supplied Material in sufficient quantity and good quality as necessary to enable Siegfried to Manufacture Product in accordance with Customer's Forecast and Orders, at Customer's cost and expense. Any import duties, taxes or other fees due to Governmental Authorities regarding Customer Supplied Materials shall be paid by Customer (DDP Incoterms 2020).

i) Unless otherwise ordered by Siegfried in writing, Customer shall supply Customer Supplied Materials to Siegfried no later than the requested delivery date as set forth in the order issued by Siegfried requesting the delivery of Customer Supplied Material. Customer shall compensate Siegfried for any loss or damage (including idle capacity) incurred in connection with late delivery or delivery of non-conforming Customer Supplied Materials. In the event of a Delay in Customer supplied materials, Siegfried will have 10 days upon actual delivery to Siegfried's site to recalculate the new confirmed delivery date of all impacted Customer orders.

ii) Siegfried shall use all reasonable and appropriate precautions in handling and storing Customer Supplied Materials and inform Customer promptly in writing of any damage occurring to Customer Supplied Materials in Siegfried's possession and any adverse effects experienced by persons handling Customer Supplied Materials.

iii) Any Customer Supplied Materials shall be used by Siegfried solely for the purpose of conducting the Manufacture of Products and shall not be transferred to any third party unless otherwise approved by Customer, including without limitation pursuant to Section 5.1. Customer shall retain all right, title and interest in and to all Customer Supplied Material delivered to Siegfried and shall insure the Consigned Materials against loss and damage. Siegfried shall be liable for any loss of or damage to Customer Supplied Material after delivery to Siegfried if such loss or damage was caused by Siegfried's willful misconduct or gross negligence in handling, storing or processing Customer Supplied Materials.

iv) Siegfried shall inspect any Raw Material and Customer Supplied Material in accordance with the Quality Agreement.

v) Subject to Section 5.1, any delivered Customer Supplied Material which Siegfried is not able to use for Manufacturing of Product or other products prior to its expiration date, will, at Customer's request, either be returned to Customer or destroyed by Siegfried, with all associated packing, transportation, destruction and other costs and expenses to be borne by Customer in either case.

6. Mandatory Vendor

6.1 **Mandatory Vendor.** Siegfried shall purchase the relevant Raw Material only from a Mandatory Vendor. Siegfried shall promptly inform Customer of any acts or omissions of any Mandatory Vendor impacting the due and timely delivery of the Product, including without limitation, any supply shortage, supply failure (including, but not limited to, any supply of defective Raw Material or service) or late supply of Raw Material or late performance of service by such a Mandatory Vendor (each a **Mandatory Vendor Failure**), and the Parties shall confer and use commercially reasonable efforts to have any such Mandatory Vendor Failure promptly cured.

6.2 **Change of Mandatory Vendor.** Either Party may suggest, upon reasonable prior written notice to the other Party, to change or add a Mandatory Vendor and the Parties shall promptly confer in good faith if and how to proceed, including, without limitation, with respect to qualification costs and possible adjustment to Price.

7. Delivery

7.1 **Delivery.** The Product shall be delivered from Siegfried to Customer on the date confirmed in the Order confirmation (see section 4.5 above) according to the Incoterm as set forth in Annex A. Customer assumes all responsibilities and liability arising out of the transport, storage, handling and use of the Product after delivery by Siegfried to Customer.

7.2 **Acceptance of delivery**. Customer shall accept deliveries of +/- 15% (fifteen percent) of an Order. Customer shall pay solely for the Products actually delivered by Siegfried. The Parties will agree in good faith how to manage both excess Product (Product that is more than 15% above the Ordered quantity) and short Product (Product that is more than 15% below the Ordered quantity), including, for example, through allocation to later Orders, increases or decreases to existing or future Orders, or other alternatives, provided, however, that Customer's acceptance of short Product resulting from Siegfried's negligence or other fault shall not affect Customer's right to pursue any other remedy available to it, whether under this Agreement or otherwise, for Siegfried's failure to fulfill a binding Order that cannot reasonably be resolved through increased deliveries in later orders or similar measures or for Siegfried to otherwise meet its obligations under this Agreement or the Quality Agreement.

7.3 **Late pick up.** In the event the Customer does not pick up the Products on the date confirmed in the Order confirmation or any later agreed date, the risk and rewards of ownership in the Product shall pass to Customer on the originally confirmed pick-up date as per the applicable Incoterm except in the event the pick-up delay has resulted from Siegfried's actions or inactions, in which case title will transfer upon actual pick-up. Siegfried shall store the Products that are not picked up on the date confirmed in the Order confirmation in its warehouse on behalf of Customer against a reasonable storage fee and shall have the right to invoice such Products to Customer upon delivery. For Products that have been stored on behalf of Customer for a period of no less than one (1) month after the last scheduled delivery date, Siegfried shall have the right to procure shipment of the Product on behalf of Customer at reasonable rates and have the Product shipped to Customer, at Customer's costs and expenses. In the event Customer is unable to pick up Product on the confirmed or any later agreed delivery date because of Siegfried's failure to have the Product available for Customer's courier, Siegfried shall bear all additional costs of storage, provided that Customer organizes substitute pick up in reasonable time (within two (2) weeks from the date Siegfried informs Customer in writing that the Product is available for pick up).

7.4 **Information on delay.** Siegfried shall promptly notify Customer in writing of any anticipated delay or of any circumstance(s) rendering it unable to deliver the Product in accordance with the confirmed delivery date(s) and the estimated duration of such delay/circumstance(s). Upon such written notice, the Parties will work together to agree upon a revised delivery schedule.

7.5 **Delay.** If delay under Section 7.4 is due to a negligent act or omission of Siegfried, Siegfried, at its cost and expense, shall use all commercially reasonable efforts to deliver the delayed Product within a reasonable after time. The Price for Product whose delivery is delayed beyond [***] days shall be reduced by [***] percent, with an additional [***] percent reduction each additional [***] days thereafter, up to a maximum of a [***]% Price reduction. In the event Customer desires early delivery of Product, the Parties agree to discuss in good faith appropriate financial incentives for Siegfried to make such early delivery.

7.6 **Product Price and Invoicing**

7.7 **Price.** The purchase price for the Product (**Price**) shall be as set forth in Annex A attached hereto.

7.8 **Price increase**. In each calendar year, Siegfried shall have the right to increase the Price based on the annual average percentage increase of the Producer Price Index: Pharmaceutical and Medicine Manufacturing for the previous calendar year (as published by the U.S. Bureau of Labor Statistics).

7.9 **Invoicing**. Invoices shall be issued by Siegfried upon Siegfried Quality release and delivery of the executed batch record to the Customer (see section 7.3). Customer shall pay such invoices to Siegfried within [***] calendar days after the date of such invoice, it being understood that the invoiced amount shall be on Siegfried's bank account on the due date at the latest.

7.10 **Interest**. In case any sum is not paid within [***] after becoming due, then Customer shall pay interest at the [***] per month or at the maximum annual interest rate permitted by law, whichever is lower, on the amount of the late sum (from original due date until the late sum is paid).

7.11 **Payment delay.** If Customer's credit rating demonstrably and materially deteriorates during the term of the Agreement, giving Siegfried reasonable grounds to assume that Customer will not honor the terms of payment, Siegfried has the right to demand an advance payment, security deposit or other financial security by Customer.

7.12 **Outstanding Amounts.** The expiration or termination of this Agreement shall not relieve Customer of its obligation to pay any outstanding amounts due to Siegfried.

7.13 **[Intentionally omitted.]**

7.14 **Product examination.** Upon receipt of the Product, Customer shall examine the Product within thirty (30) Business Days in order to determine compliance with the Specifications. If the Product delivered does not comply with the Specifications, Customer shall notify Siegfried in writing thereof. If Customer does not notify within thirty-five (35) Business Days after receipt of the Product by Customer, the Product shall be deemed accepted, provided that Customer retains the right to reject the Product at a later time, for a period of one (1) year after delivery in case of Hidden Defects, in which case Customer shall notify Siegfried in writing within fifteen (15) Business Days of discovering the existence of a Hidden Defect.

7.15 **Claim by Customer**. Any claims by Customer that a delivered Product does not meet Specifications shall specify in reasonable detail the nature and basis for the claim and cite Siegfried's relevant batch numbers or other information to enable specific identification of the Product involved. Siegfried shall review any written claim made by Customer regarding the quality of the Product and provide Customer with the results of such review. Subject to Section 9.3, if such review and testing by Siegfried confirms that the identified Product did not meet the Specifications, Customer shall have the right to reject such Product and the Parties shall proceed according to Section 9.5.

7.16 **Testing laboratory**. If the Parties fail to agree as to whether a delivered quantity of Product is a non-conforming Product, the Parties shall have the batch in dispute further tested and analyzed by an independent testing laboratory selected by agreement between the Parties. The decision of the independent testing laboratory shall be deemed final. Should the laboratory's testing determine that the delivered Product are non-conforming Product, then (i) Siegfried shall bear all costs for the independent laboratory testing, (ii) Customer shall have the right to reject such non-conforming Product, and (iii) the Parties shall proceed according to Section 9.5. However, if said quantity of Product is determined by the independent laboratory to conform to the Specifications, then Customer shall bear all costs of the independent laboratory and compensate Siegfried for the rejected Products, the replacement delivery (if any), and the transportation costs as set out in this Agreement.

7.17 **Disposal of non-conforming Product**. Customer shall, at Siegfried's expense and written direction, dispose of the Product not conforming to the Specifications or deliver it to such destination as Siegfried shall specify in writing, provided that such directions are in compliance with applicable environmental laws and regulations. Customer shall not use or dispose of any Product that does not, or of which Customer claims that it does not, conform to the Specifications without Siegfried's prior written consent.

7.18 **Non-conforming Product.** If a Product is a non-conforming Product due to a negligent act or omission of Siegfried, Siegfried shall within a reasonable period use all commercially reasonable efforts to replace the rejected Product with Product that conforms with the Specifications and, in the case of Siegfried's gross negligence or willful misconduct, shall reimburse Customer for all Customer Supplied Materials used in Manufacturing the non-conforming Product. Except in the case of Siegfried's gross negligence or willful misconduct, such replacement delivery, shall be the only remedy available to Customer in case of delivery of Non-Conforming Product. For the avoidance of doubt, Siegfried shall not be liable against the Customer for a non-conforming Product if the non-conformity results from the failure of the Customer Supplied Material to meet Specifications or a Mandatory Vendor Failure.

8. Equipment; Manufacturing Footprint

8.1 Siegfried agrees to ensure all calibration and normal operating maintenance on, cleaning of, repair to and replacement of customer-owned and customer-dedicated equipment used, directly or indirectly, to Manufacture Products, are performed as and when necessary, provided that within thirty (30) days after receipt of appropriate documentation from Siegfried (including, without limitation, an invoice), Customer shall reimburse Siegfried for any reasonable expense of, repair or replacement with respect to customer-owned or customer-dedicated equipment only to the extent that such need for repair or replacement does not arise from gross negligence or willful misconduct on the part of Siegfried. The Parties agree to conduct a semi-annual review of performed maintenance and the maintenance schedule as well as a review of the adequacy and condition of the equipment used to Manufacture Product.

8.2 Equipment obtained or used by Siegfried to manufacture Product shall be the property of Customer to the extent the purchase of such equipment was made or reimbursed by Customer. As between the Parties, a Party who identifies a piece of equipment as suitable for use in Product manufacturing shall be responsible for the manufacturing performance of such equipment, and a Party ordering equipment shall be responsible for ensuring that the equipment meets the specifications set forth in the order.

8.3 Siegfried will maintain and not reduce the physical space dedicated to Product manufacturing without the prior written approval of Customer, such approval not to be unreasonably withheld.

9. Safety Stock and Inventory

9.1 Siegfried shall at all times have sufficient inventory of Raw Materials available to Manufacture the binding part of the forecast plus Raw Materials for the Manufacture of two extra batches of Products at any given time. Siegfried shall ensure to manage this safety stock on a rolling basis first-expire, first-out basis; Customer agrees to purchase such Raw Materials, including the Raw Materials for the additional two safety stock batches, upon expiration of the Agreement.

9.2 Siegfried shall provide Customer with a monthly reconciliation sheet with an inventory overview of Customer Supplied Material and Raw Material.

9.3 Customer shall pay Siegfried an annual handling fee for the safety stock of the two extra batches of Raw Material inventory in the amount of fifteen percent (15%) of the worth of such safety stock.

10. Audits and Recalls

10.1 **Audit by Customer.** During the term of this Agreement, Customer has the right to carry out compliance and cGMP Regulations audits on the Facility, as set forth in the Quality Agreement. Any additional audit day not foreseen in the Quality Agreement will be charged [***] per audit day (except for-cause audits). Access shall be granted during normal business hours only and upon three (3) months prior written notice. Limit on number of auditors (2) and number of days (2) for pre-planned audit. If in either party's reasonable opinion, additional auditors or days are needed, the parties will discuss in good faith any increase in auditors or days.

10.2 **Siegfried's policies**. While carrying out the audit on the Facility, Customer shall comply with all of Siegfried's policies regarding safety, health, data protection, confidentiality and the like which Siegfried, in its sole discretion, deems relevant.

10.3 **Audit by Regulatory Authority**. Siegfried shall permit any Regulatory Authority to inspect the buildings, equipment and records on the Facility (at their request).

10.4 **Adverse reaction**. Each Party shall notify the other Party promptly of any serious or unexpected adverse reaction from the use of the Product, which is reported to it or of which it becomes aware otherwise, as set forth in the Quality Agreement.

10.5 **Recall**. In the event either Party believes that any Batch of Product Manufactured by Siegfried is subject of a field alert, recall, market withdrawal or correction (**Recall**), whether threatened or actual, such Party shall notify the other Party as set forth in the Quality Agreement and the Parties shall confer and consult with each other on how best to proceed. The Parties acknowledge and agree that the ultimate decision on conducting a Recall shall always be with the holder of the marketing authorization for the Product.

10.6 **Consequences of Recall**. If a Recall of any batch of Product Manufactured by Siegfried is due to Siegfried's negligent act or omission, Siegfried shall reimburse Customer for all of Customer's reasonable, actual and documented costs and expenses directly related to the Recall, if any. For any Recall affecting unreleased Product that is not due to Siegfried's negligent act or omission, Customer shall reimburse Siegfried for all reasonable, actual and documented costs and expenses incurred by Siegfried that are directly related to the Recall. Customer will have no responsibility for any Siegfried costs or expenses relating to any Recall affecting Product that is due to Siegfried's negligent act or omission.

11. Regulatory Affairs

11.1 **Regulatory Filings**. Customer shall be responsible for all regulatory filings in connection with the Product. All information, documents and updates with regard to the Manufacture of Product which are in the possession of Siegfried and required by any Regulatory Authority shall, as reasonably requested by Customer in connection with a submission for such regulatory filings, be provided by Siegfried to Customer, at Customer's costs.

11.2 **Assistance by Siegfried**. Siegfried shall further provide Customer, at Customer's costs and expenses, with reasonable assistance in preparing or reviewing the regulatory filing or formulating responses to any questions and/or inquiries (e.g. deficiency letters) with respect to the above submissions.

11.3 **Review by Siegfried**. Customer shall provide, and Siegfried shall review, at Customer's cost, any regulatory filings related to Siegfried's key obligations hereunder before any application or modification of a Marketing Authorization are submitted to the relevant Regulatory Authorities. Customer shall consider Siegfried's comments thereto in good faith.

11.4 **Marketing authorization**. Siegfried will support Customer efforts to obtain and maintain Marketing Authorization approvals for a reasonable fee after Customer review and approval. This may include Pre-Approval or Routine Inspections and providing data and information for applications and Annual Reporting. Siegfried will comply and maintain cGMP and Health Authority requirements.

12. Manufacturing Changes

12.1 **Changes**. All Changes shall be handled in accordance with the relevant provisions set forth in the Quality Agreement. In the event of a Change, regardless of whether it is a Required Change, a Customer Change or a Siegfried Change, Siegfried shall provide to Customer (i) a calculation of the Change costs, (ii) if applicable, a new Price for the Product, (iii) the timing for implementation (iv) as well as the amount and discard cost of any Raw Material obsolete because of the Change (**Change Documentation**).

12.2 **Required Change.** In the event that either Party becomes aware and notifies the other Party that any Change is mandated by Applicable Laws and Regulations (including, without limitation cGMP Regulations) or by a competent Regulatory Authority (**Required Change**), Siegfried shall provide Customer the Change Documentation. Siegfried shall, if feasible, implement such Required Change and

(i) if the Required Change relates exclusively to the Product, the Customer shall bear all costs relating to the Required Change;

(ii) if the Required Change relates to, or will be used for, the Products and other products manufactured by Siegfried at the Facility, Customer and Siegfried shall discuss and agree on a pro-rated allocation of any costs in relation to the Required Change in good faith; or

(iii) if the Required Change applies generally to the operation of the Facility, all costs relating to the Required Change shall be borne by Siegfried.

(iv) Customer shall reimburse Siegfried for the Raw Materials rendered obsolete due to the Required Change and Customer shall notify Siegfried whether such obsolete Raw Material shall be delivered to Customer or destroyed on behalf of Customer, both at Customer's costs and expenses.

(v) if applicable, Customer shall pay the new Price for the Product as set forth in the Change Documentation.

12.3 **Customer Change.** In the event Customer wishes to effect a Change, which is not a Required Change (**Customer Change**), Customer shall advise Siegfried in writing of such Customer Change as set forth in the Quality Agreement. Siegfried shall provide the Change Documentation to Customer. In case Customer approves the Change Documentation, Manufacturer shall implement such Customer Change and

(i) Customer shall bear all costs with regard to such Customer Change.

(ii) Customer shall reimburse Siegfried for the Raw Materials rendered obsolete due to the Customer Change and Customer shall notify Siegfried whether such obsolete Raw Material shall be delivered to Customer or destroyed on behalf of Customer, both at Customer's costs and expenses.

(iii) if applicable, Customer shall pay the new Price for the Product as set forth in the Change Documentation.

12.4 **Siegfried Change.** In the event Siegfried wishes to effect a Change, which is not a Required Change (**Siegfried Change**), Siegfried shall advise Customer in writing of such Siegfried Change as set forth in the Quality Agreement. If Customer does not notify Siegfried in writing to refrain from implementation within thirty (30) days after the date of Siegfried's request, then Siegfried shall be free to implement such Siegfried Change. Both Parties shall negotiate in good faith the (a) the allocation of the costs relating to the Siegfried Change, (b) the new Price applicable after the Siegfried Change has been implemented, (c) the timing for implementation (d) as well as an estimated amount of any Raw Material rendered obsolete as a result of the Siegfried Change and respective costs to be allocated. In allocating the costs, the Parties should consider whether such Siegfried Change is beneficial to either or both Parties.

13. Intellectual Property

13.1 **Intellectual Property**. Unless otherwise required by law or specified in writing, the results of the Manufacturing Services performed pursuant to and during the term of this Agreement, including, but not limited to, any Intellectual Property arising out of any Improvements (other than an Independent Improvement) shall be the property of Customer and all rights, title and interest therein shall be vested in Customer. Siegfried shall provide reasonable assistance with, but have no responsibility for, prosecuting, maintaining and enforcing any patents or other Intellectual Property that Customer obtains pursuant to this Agreement.

13.2 **Assignment by Siegfried**. Siegfried assigns to Customer all title and interest it may have in any Intellectual Property Right(s) arising out of any Improvements (other than Independent Improvements); provided, that Customer shall grant a non-exclusive, worldwide, irrevocable, royalty-free, sub-licensable license to Siegfried for the use of such Improvements for manufacture of Products. Customer shall have the sole right to file and seek protection for any Intellectual Property Right(s) arising out of any Improvements (other than an Independent Improvement). To the extent that Customer deems it reasonable to seek protection, Customer shall bear the costs (including, but not limited to attorney's fees) and the responsibility associated with developing, applying for, and maintaining such protection. In the event Customer decides to file and prosecute patent applications on any Improvement (other than an Independent Improvement), Siegfried shall provide Customer with reasonable assistance to obtain and defend such patents at Customer's costs and expenses, including executing any necessary or desirable document to confirm or accomplish the assignment of Intellectual Property Rights described in this paragraph.

13.3 **Independent Improvements**. All rights related to any Independent Improvements shall be the sole property of Siegfried. Siegfried hereby grants Customer a non-exclusive, worldwide, irrevocable, royalty-free license to use such Independent Improvement for the purpose of selling and commercializing any Products Manufactured under this Agreement.

13.4 **Infringement of Intellectual Property**. In the event of patent infringement or regulatory litigation or other legal proceedings, threatened in writing or actual, involving the Product, Siegfried shall have the right to suspend further supply of the Product to the extent this is required by a court order or arbitral award or order (whether interim or final) or deemed necessary or advisable by Siegfried to prevent or limit actual or possible damages, liability or injury. Such suspension shall be deemed a temporary suspension of Siegfried's Manufacturing and supply obligations under this Agreement; provided, that if such suspension continues for more than one hundred an eighty (180) days, the Parties shall jointly attempt in good faith to modify this Agreement to resolve the situation but if they are unable to do so within the following thirty (30) Business Days either Party may terminate this Agreement by notice to the other Party. The Parties will reasonably cooperate in removing, if possible, any impediment to Manufacturing under this Section 15.4, including designing new processes or workarounds to avoid the impediment or obtaining a license on reasonable terms to permit Manufacturing.

14. Representations and Warranties

14.1 **Representations of each Party**. Each Party represents and warrants to the other Party that (i) it has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein; (ii) this Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; and (iii) is not and will not be under any obligation or restriction, including, without limitation, pursuant to its charter document(s) or by-laws, which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement.

14.2 **Representations of Siegfried**. Siegfried represents and warrants that

(i) the Products have been Manufactured in compliance with cGMP Regulations,

(ii) the Products are, upon delivery to Customer, in conformity with the Specifications of such Product,

(iii) in the Manufacture of the Product, none of the Intellectual Property used by Siegfried in its processes or procedures (and other than those under Customer responsibility as set forth in 16.3), infringe or misappropriate or will infringe or misappropriate the Intellectual Property of any third party.

14.3 **Representations of Customer**. Customer represents and warrants that

(i) the Customer Supplied Material is free of defects upon delivery to Siegfried,

(ii) none of the Intellectual Property, processes, procedures, substances or materials of Customer, including any samples and Customer Supplied Materials supplied by or on behalf of Customer and used by Siegfried in the Manufacture of Product infringe or misappropriate or will infringe or misappropriate the Intellectual Property of any third party.

14.4 EXCEPT AS STATED IN 16 OF THIS AGREEMENT, SIEGFRIED MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, MATERIALS OR SERVICES AND DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. EXCEPT FOR CASES OF WILLFUL MISCONDUCT OR GROSS NEGLIGENCE, SIEGFRIED'S LIABILITY UNDER THIS AGREEMENT SHALL BE STRICTLY LIMITED TO THE REMEDIES PROVIDED FOR UNDER THIS AGREEMENT.

15. Indemnity and Liability

15.1 **Indemnification by Siegfried**. Siegfried shall indemnify, defend and hold Customer harmless against all losses arising out of or in connection with third-party claims, suits, actions, demands or judgments to the extent resulting from the negligent (i) breach of representations under this Agreement or (ii) breach of any of Siegfried's obligations under this Agreement, except to the extent Customer is obligated to indemnify Siegfried under Section 17.2 below.

15.2 **Indemnification by Customer**. Customer shall indemnify, defend and hold Siegfried harmless against all losses, arising out of or in connection with third-party claims, suits, actions, demands or judgments to the extent resulting from the negligent (i) breach of representations under this Agreement, (ii) breach of any of Customer's obligations, (iii) the handling, use, distribution of the Product after delivery to Customer, (iv) the death of or injury to any person or any damage to property, resulting from side effects, characteristics or defects of the Product; except to the extent Siegfried is obligated to indemnify Customer under Section 17.1 above.

15.3 **Indemnification procedure**. With respect to any indemnification obligation under this Agreement, the following conditions shall be applicable:

(a) the Party seeking to be indemnified shall notify the indemnifying Party promptly in writing of any claim which may give rise to an obligation on the part of the indemnifying Party hereunder;

(b) the indemnifying Party shall be allowed to timely take the sole control of the defense of any such action and claim, including all negotiations for the settlement, or compromise of such claim or action at its sole expense;

(c) the Party to be indemnified shall, at the expense of the indemnifying Party, render reasonable assistance, information, co-operation and authority to permit the indemnifying Party to defend such action; and

(d) no settlement or compromise shall be binding on a Party hereto without its prior written consent.

15.4 **Limitation of Liability**. Neither Party shall be liable to the other for incidental, indirect (except with respect to the indemnification against claims of third parties under Sections 17.1 or 17.2), or consequential damages of the other Party or any third party, including but not limited to claims based on lost profits, loss of time or loss of business opportunity suffered or incurred as a result of this Agreement, regardless of whether the liable Party was informed in advance of the possibility of such damages and whether such loss or damage may be based upon principles of contract, warranty, negligence or other tort, breach of any statutory duty, principles of indemnity or contribution, the failure of any limited or exclusive remedy to achieve its essential purpose, or otherwise.

15.5 **Liability cap**. To the extent permitted by applicable law, Siegfried's maximum indemnity and liability under this Agreement shall be limited to the Price of the relevant batch of Product giving rise to the dispute, except for cases of willful misconduct or gross negligence.

15.6 **Insurance**. Before the commencement of any Manufacturing Services under this Agreement, Siegfried and Customer shall each obtain and carry in full force and effect adequate commercial, general liability insurance as is common in the industry, including product liability insurance. Such insurance shall be written by a reputable insurance company and shall be endorsed to include liability coverage for Product used. Both Parties shall provide each other on request with a copy of certificates of insurance evidencing the same. The foregoing notwithstanding, each party agrees to maintain in effect at least the following types and amounts of insurance:

Commercial General Liability	$[***] per occurrence
Contractual Liability	$[***] per occurrence
Product Liability	$[***] per occurrence
Annual Aggregate	$[***]

16. Confidentiality

16.1 **Confidentiality**. Each Receiving Party agrees to retain in strict confidence any Confidential Information of the Disclosing Party (or its Affiliate), whether disclosed prior to, or after the Effective Date or the date of prior secrecy agreements and not to use any such Confidential Information for any purpose except pursuant to, and in order to carry out, the terms and objectives of this Agreement, nor to disclose, divulge or otherwise communicate any such Confidential Information to any third party.

16.2 **Entitled Person**. The Receiving Party may disclose Confidential Information of the Disclosing Party to its (or its Affiliate's) officers, directors, employees, agents, consultants, subcontractors or representatives (each an **Entitled Person**), who, in each case, (i) need to know such information for purposes of the implementation and performance by the Receiving Party of this Agreement, (ii) will use the Information only for such limited purposes and (iii) are subject to confidentiality restrictions covering the Confidential Information that are at least as stringent at those contained herein.

16.3 **Exceptions to confidentiality**. The provisions of this Section 18 shall not apply to any Confidential Information disclosed hereunder which

(a) was independently developed or known by the Receiving Party prior to its disclosure to the Receiving Party by the Disclosing Party, as evidenced by written records; or

(b) was before or after the date of such disclosure in the public domain or lawfully disclosed to the Receiving Party by an independent, unaffiliated third party rightfully in possession of the Confidential Information and not under any confidentiality obligation towards the Disclosing Party with regard to such Confidential Information; or

(c) is required to be disclosed by the Receiving Party to the officials of a Regulatory Authority or to comply with applicable laws, to defend or prosecute litigation, or to comply with governmental laws or regulations, judicial orders or valid subpoenas, provided that the Receiving Party provides the Disclosing Party with prior written notice of such intended disclosure and takes reasonable and lawful actions, at Disclosing Party's expense, to avoid and/or minimize the degree of such disclosure.

The burden of proof of the foregoing exceptions shall lie with the Receiving Party. Unless required by law, the Receiving Party in the foregoing circumstances shall not disclose that the same Confidential Information was also acquired from the Disclosing Party.

16.4 **Irreparable Harm**. The Parties acknowledge that any breach of this Section 18 may cause the other Party irreparable harm, and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this Section 18 without the necessity of posting bond, in addition to whatever remedies such Party may otherwise be entitled to at law or in equity.

16.5 **Use of Confidential Information**. All terms of this Section 18 are subject to Customer's and Siegfried's rights under Section 9. Notwithstanding anything herein to the contrary, should Siegfried be granted a license for the use of an Improvement pursuant to 15.2 herein, the Parties agree that mere use alone by Siegfried or an Affiliate pursuant to the license granted shall not be a violation of any term or condition contained in this Article.

16.6 **Return of Confidential Information**. Upon termination or expiration of this Agreement, each Party shall, upon the other Party's request, immediately destroy or deliver to the other (and cause any of its employees, agents or Entitled Persons, consultants to so deliver), at such Party's expense, all Confidential Information of the other Party, including without limitation any and all copies, duplications, summaries and/or notes thereof or derived thereof, regardless of the format, and all remaining samples of Product or Materials, provided however, that both Parties may keep original documents, copies and samples as required by law, for archival purposes or stored on their back up devices.

17. Term and Termination

17.1 **Initial Term**. This Agreement shall become effective on the Effective Date and, unless earlier terminated in accordance with this Agreement, shall continue in full force and effect for an initial period of five (5) years after the Effective Date (hereinafter **Initial Term**).

17.2 **Renewal of Initial Term**. This Agreement shall automatically renew for consecutive two (2) year periods each, unless one of the Parties notifies the other of its election not to renew this Agreement at least twenty-four (24) months prior to the end of the Initial Period or any renewal period then in effect, in which case this Agreement shall terminate upon the expiration of such term.

17.3 **Termination for material breach**. Each Party may terminate this Agreement (i) for material breach by the other Party, (ii) upon one hundred twenty (120) days written notice to the other Party specifying the nature of such material breach and (iii) if such breach has not been substantially cured within such one hundred twenty (120) days period.

17.4 **Termination for cause**. Either Party may terminate this Agreement immediately, but not later than six (6) months after becoming aware of such event, by providing written notice to the other Party:

(a) upon the liquidation or dissolution of the other Party, or the commencement of insolvency procedures or any proceeding under any bankruptcy, insolvency or moratorium law, or any other law or laws for the relief of debtors which proceeding is not dismissed within sixty (60) days, or the appointment of any receiver, trustee or assignee to take possession of the properties of the other Party, or

(b) the cessation of all or substantially all of the other Party's business operations.

17.5 **Survival**. Neither the expiration nor the termination of this Agreement shall relieve the Parties of their obligations incurred prior to such expiration or termination. All provisions that, by their express or implied terms, are meant to survive termination of this Agreement shall continue irrespective of such termination.

18. Miscellaneous

18.1*No set-off.* Neither Party shall be entitled to set off any of its rights or obligations under this Agreement against the rights or obligations of another Party without having first obtained the prior written consent of that other Party.

18.2*Subcontractor.* Siegfried shall be entitled to engage subcontractors for conducting portions of the Manufacturing Services with the prior written consent of Customer, such consent not to be unreasonably withheld. Siegfried shall Manufacture all Product(s) at the authorized/licensed Facility or authorized/licensed subcontractors (i.e. Gamma Sterilization Provider). Changes in manufacturing location or changes to subcontractors must be approved in writing by the Customer and in advance of the change as provided in Section 14 of this Agreement and in the Quality Agreement. Siegfried shall be responsible for all work performed by Siegfried's authorized subcontractor as if performed by itself and further, that the use of said subcontractor is in compliance with the Quality Agreement.

18.3*Force Majeure.* A Party shall be excused from performing its obligations under this Agreement (other than obligations of payment) to the extent that its performance is delayed or prevented by any cause beyond such Party's control, including, but not limited to, supplier failure, fire, explosion, weather, disease (including epidemic and pandemic), war, terrorist act, insurrection, civil strike, riots, government action power failure or energy or Raw Material shortages (each, a **Force Majeure Event**). Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event. Any deadline or time for performance specified in this Agreement that falls due during or subsequent to the occurrence of any of the Force Majeure Event shall be automatically extended for a period of time equal to the period of such Force Majeure Event. The prevented Party shall immediately notify the other Party if, by reason of any Force Majeure Event, the prevented Party is unable to meet any deadline or time for performance specified in this Agreement. In the event that such Force Majeure Event cannot be removed or overcome within one-hundred and eighty (180) days (or such other period as the Parties jointly shall determine) from the date the Party affected first became affected, then either Party may at any time after the expiration of such period, by written notice to the other Party, either (i) suspend this Agreement for as long as such Force Majeure Event continues to exist, or (ii) terminate this Agreement with immediate effect.

18.4*Precedence of Agreement*. Unless expressly agreed otherwise in writing, the terms outlined in this Agreement shall prevail over any inconsistent terms and conditions outlined in any Order and any general terms and conditions of a Party, and such terms and conditions are hereby expressly excluded. In case of discrepancies between this Agreement and an Annex hereto, the provisions of this Agreement shall prevail; provided, however, that in case of discrepancies between this Agreement and the Quality Agreement regarding (i) the delineation of responsibilities pursuant to cGMP Regulations, (ii) the Specifications or (iii) the Manufacturing procedure, the Quality Agreement shall be decisive.

18.5*No Assignment.* This Agreement is binding upon and shall inure to the benefit of the Parties hereto and their successors and permitted assigns. This Agreement and any rights or obligations hereunder, other than claims to payment, may be assigned or delegated only (i) with the consent of the other Party, not to be unreasonably withheld, conditioned or delayed or (ii) to the successor to all or substantially all of the business of a Party (whether by merger, consolidation, asset transfer or similar transaction) to which this Agreement relates. Any other assignment or delegation by either Party without the prior written consent of the other Party is void.

18.6*No waiver.* The failure by either Party at any time to enforce any of the terms, provisions or conditions of this Agreement or to exercise any right hereunder shall not constitute or be construed to constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same.

18.7*Independent Parties.* Nothing in this Agreement shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. Neither Party shall be responsible for the acts or omissions of the other Party, and neither Party shall have authority to speak for, represent or obligate the other Party in any way without prior written consent of the other Party.

18.8*Entire Agreement.* This Agreement contains the full understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties.

18.9*Severability.* If any portion of this Agreement is held invalid by a court of competent jurisdiction, such portion shall be deemed to be of no force and effect and this Agreement shall be construed as if such portion had not been included herein, provided however, if the deletion of such provision materially impairs the commercial value of this Agreement to either Party, the Parties shall attempt to renegotiate such provision in good faith. The fact that any provision of this Agreement shall be prohibited or unenforceable in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the Parties to this Agreement waive any provision of law that renders any provision of this Agreement prohibited or unenforceable in any respect.

18.10*Notices.* Any notice required under this Agreement shall be effective upon delivery and only if in writing and delivered (i) in person, (ii) by a recognized courier service, (iii) by registered mail or (iv) by e-mail (pdf) confirmed by registered mail within five (5) Business Days. Any notice is to be addressed to the applicable address set forth below.

if to Siegfried:
Alliance Medical Products, Inc.
Attention: Troy Gardner Vice President & General Manager
e-mail: [***]

with a copy to:
Siegfried AG
Legal Department
Untere Bruehlstrasse 4,4800 Zofingen, Switzerland
e-mail: [***]

if to Customer:
Alimera Sciences, Inc.
Attention: Chief Operating Officer
6310 Town Square, Suite 400
Alpharetta, GA 30005
e-mail: [***]

Either Party may change the above addresses, but no such change shall have any effect until the other Party has been properly notified with written notice of the change of the address.

18.11 *Compliance with Laws.* Each Party shall comply with all applicable laws, statutes, rules and regulations governing its performance of the terms of this Agreement, including, but not limited to, those relating to health, safety and the environment, fair labor practices, unlawful discrimination, debarment, anti-corruption and anti-bribery laws.

18.12 *Hardship*. If unexpected or unpredictable changes in technical, legal, or economic factors occur during the term of the Agreement external to the will of the Parties and have a seriously detrimental long-term impact on the general economic balance of the Agreement or the ability of one or both Parties to perform the Agreement, the Parties agree to undertake in good faith reasonable efforts to discuss a possible amicable resolution or possible amendment to this Agreement in light of the change in circumstances, provided, however, that neither Party shall have any obligation to amend this Agreement or to waive or modify any of its rights under this Agreement

18.13 *Counterparts*. This Agreement may be executed in two (2) or more counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute one and the same instrument. This Agreement and any future amendments may be signed by electronic signature (e.g., using DocuSign), whereby the Parties acknowledge its validity and binding force.

18.14 *Cumulative Remedies*. No remedy referred to in this Agreement is intended to be exclusive unless expressly so stated but shall be cumulative and in addition to every other remedy referred to in this Agreement or otherwise available at law or equity.

18.15 *Further Assurances*. Each Party agrees to execute such other papers, agreements, documents, instruments, and the like as may be necessary or desirable to effect the purposes of this Agreement and carry out its provisions.

18.16 *Headings; Attachments*. The headings assigned to the articles and sections of this Agreement are for convenience only and shall not limit the scope and applicability of the articles and sections. Each and every attachment to this Agreement is hereby incorporated herein by reference and made a part hereof.

18.17 *Publicity*. This Agreement is Confidential Information of the Parties and shall not be disclosed except as provided herein. The Parties agree to make no public announcement of this Agreement or their relationship without the express permission of the other Party, except that each Party may make such disclosures as are required by law, including the securities laws of the United States.

18.18 *Independent Contractors*. The Parties shall at all times act as and be deemed independent contractors. Nothing in this Agreement shall be construed to render any employee, officer, director of one Party the employee, officer or director of the other or to create any joint venture, agency, or partnership.

19. Applicable Law and Dispute Resolution

19.1 **Applicable law**. This Agreement shall be governed by the laws of the State of California without regard to its conflict of laws provisions. Application of the UN-Convention regarding Contracts on the International Sale of Goods (Vienna Convention) is excluded.

19.2 **Jurisdiction**. The Parties agree that venue for any action arising out or related to this Agreement shall lie in the competent federal courts located in Orange County, California.

List of Annexes

Annex A	Products Schedule Form
Annex B	Customer Supplied Material and Mandatory Vendors

Alliance Medical Products, Inc.

/s/ Troy Gardner

……
Troy Gardner
Vice President & General Manager

/s/ Kevin O'Brien

……
Kevin O'Brien
Vice President, Drug Products North America

Alimera Sciences, Inc.

/s/ Richard S. Eiswirth Jr

……
Richard S. Eiswirth, Jr
President and Chief Executive Officer

Annex A

Product Schedule – ILUVIEN®

[***]

Annex B

Customer Supplied Material and Mandatory Vendors

[***]

EXHIBIT 31.1

CERTIFICATION

I, Richard S. Eiswirth, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Alimera Sciences, 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(s) 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(s) 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 7, 2024

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Elliot Maltz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Alimera Sciences, 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(s) 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(s) 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 7, 2024

/s/ Elliot Maltz
Elliot Maltz
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

Certification

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Alimera Sciences, Inc. (the Company), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 7, 2024

/s/ Richard S. Eiswirth, Jr.
Richard S. Eiswirth, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2024

/s/ Elliot Maltz
Elliot Maltz
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.