UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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, 2025

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 **001-15771**

ABEONA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**83-0221517**
(State or Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)

6555 Carnegie Avenue, 4th Floor
Cleveland, OH 44103
(Address of principal executive offices, zip code)

(646) 813-4701
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	ABEO	Nasdaq Capital 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 ☐
Non-accelerated filer ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting 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 ☒

The number of shares outstanding of the registrant's common stock as of August 8, 2025 was 51,278,539 shares.

ABEONA THERAPEUTICS INC.
Form 10-Q
For the Quarter Ended June 30, 2025

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (including information incorporated by reference) contains statements that express management's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as "expects," "anticipates," "intends," "plans," "believes," "could," "would," "seeks," "estimates," and variations of such words and similar expressions, and the negatives thereof, are intended to identify such forward-looking statements. Such "forward-looking statements" speak only as of the date made and are not guarantees of future performance and involve certain risks, uncertainties, estimates, and assumptions by management that are difficult to predict. Various factors, some of which are beyond the Company's control, could cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In addition, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of this report, except as may otherwise be required by the federal securities laws.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in forward-looking statements due to a number of factors. These statements include statements about: our ability to successfully generate commercial sales of ZEVASKYN™ and generate future revenue; our plans to continue development of AAV-based gene therapies designed to treat ophthalmic diseases; the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals; our pipeline of product candidates; our dependence upon our third-party customers and vendors and their compliance with regulatory bodies; our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing; our intellectual property position and our ability to obtain, maintain and enforce intellectual property protection and exclusivity for our proprietary assets; our estimates regarding the size of the potential markets for ZEVASKYN™ and our product candidates, the strength of our commercialization strategies and our ability to serve and supply those markets; and future economic conditions or performance.

Important factors that could affect performance and cause results to differ materially from management's expectations are described in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as updated from time to time in the Company's SEC filings, including this Quarterly Report on Form 10-Q. These factors include: our ability to maintain existing and obtain additional regulatory approvals of ZEVASKYN™ and any future product candidates; our ability to successfully commercialize and market ZEVASKYN™ and any future product candidates, if approved, and the timing of any commercialization and marketing efforts; our ability to access our existing at-the-market sale agreement; our ability to access additional financial resources and/or our financial flexibility to reduce operating expenses if required; our ability to obtain additional equity funding from current or new stockholders; the potential impacts of global healthcare emergencies, such as pandemics, on our business, operations, and financial condition; the potential impact of unpredicted changes in the structure and/or administration of the United States government or its agencies; our ability to out-license technology and/or other assets, deferring and/or eliminating planned expenditures, restructuring operations and/or reducing headcount, and sales of assets; the dilutive effect that raising additional funds by selling additional equity securities would have on the relative equity ownership of our existing investors, including under our existing at-the-market sale agreement; the outcome of any interactions with the FDA or other regulatory agencies relating to any of our products or product candidates; our ability to continue to secure and maintain regulatory designations for our product candidates; our ability to develop manufacturing capabilities compliant with current good manufacturing practices for our product candidates; our ability to manufacture cell and gene therapy products and produce an adequate product supply to support clinical trials and potentially future commercialization; the rate and degree of market acceptance of our product candidates for any indication once approved; and our ability to meet our obligations contained in license agreements to which we are party.

This Quarterly Report on Form 10-Q includes our trademarks, trade names and service marks, such as "ZEVASKYN™" and "AIM™," which are protected under applicable intellectual property laws and are the property of Abeona Therapeutics Inc. or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this report appear without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
($ in thousands, except share and per share amounts)
(Unaudited)

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 163,535	$ 23,357
Short-term investments	61,983	74,363
Restricted cash	338	338
Inventory	2,686	—
Other receivables	1,630	1,652
Prepaid expenses and other current assets	2,090	1,143
Total current assets	232,262	100,853
Property and equipment, net	9,489	4,430
Operating lease right-of-use assets	4,144	3,552
Other assets	338	96
Total assets	$ 246,233	$ 108,931
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,337	$ 3,441
Accrued expenses	5,495	6,333
Current portion of long-term debt	5,556	5,926
Current portion of operating lease liability	537	823
Accrued taxes	15,512	—
Other current liabilities	80	64
Total current liabilities	34,517	16,587
Long-term operating lease liabilities	3,978	3,262
Long-term debt	14,005	13,037
Warrant liabilities	30,157	32,014
Total liabilities	82,657	64,900
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 51,248,032 and 45,644,091 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	512	457
Additional paid-in capital	879,563	856,824
Accumulated deficit	(716,454)	(813,258)
Accumulated other comprehensive (income) loss	(45)	8
Total stockholders' equity	163,576	44,031
Total liabilities and stockholders' equity	$ 246,233	$ 108,931

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
($ in thousands, except share and per share amounts)
(Unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2025	2024	2025	2024
Revenues:				
License and other revenues	$ 400	$ —	$ 400	$ —
Expenses:				
Royalties	100	—	100	—
Research and development	5,943	9,218	15,884	16,425
Selling, general and administrative	17,149	8,646	26,935	15,769
Total expenses	23,192	17,864	42,919	32,194
Loss from operations	(22,792)	(17,864)	(42,519)	(32,194)
Interest income	1,027	1,191	2,337	2,034
Interest expense	(957)	(1,072)	(1,955)	(2,024)
Change in fair value of warrant and derivative liabilities	(5,388)	24,927	1,857	7,626
Gain from sale of priority review voucher, net	152,366	—	152,366	—
Other income	89	224	230	386
Income (loss) before income taxes	124,345	7,406	112,316	(24,172)
Income tax expense	15,512	—	15,512	—
Net income (loss)	$ 108,833	$ 7,406	$ 96,804	$ (24,172)
Basic income (loss) per common share	$ 2.07	$ 0.19	$ 1.89	$ (0.72)
Dilutive income (loss) per common share	$ 1.71	$ (0.26)	$ 1.47	$ (0.72)
Weighted average number of common shares outstanding:				
Basic	52,524,510	40,010,481	51,159,240	33,662,908
Dilutive	66,640,620	51,226,715	65,111,330	33,662,908
Other comprehensive income (loss):				
Change in unrealized gains related to available-for-sale debt securities	22	50	(53)	(68)
Comprehensive income (loss)	$ 108,855	$ 7,456	$ 96,751	$ (24,240)

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
($ in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at March 31, 2024	27,550,693	$ 276	$ 772,129	$ (781,102)	$ (184)	$ (8,881)
Stock-based compensation expense	—	—	1,323	—	—	1,323
Cancellation of common stock in connection with restricted share awards, net of issuances and shares settled for tax withholding settlement	(186,796)	(2)	(313)	—	—	(315)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	1,013,061	10	3,495	—	—	3,505
Issuance of common stock in connection with underwritten offering, net of offering costs	12,285,056	123	70,030	—	—	70,153
Issuance of common stock upon exercise of pre-funded warrants, net of shares settled	999,979	10	(10)	—	—	—
Net income	—	—	—	7,406	—	7,406
Other comprehensive income	—	—	—	—	50	50
Balance at June 30, 2024	41,661,993	$ 417	$ 846,654	$ (773,696)	$ (134)	$ 73,241

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2023	26,523,878	$ 265	$ 764,151	$ (749,524)	$ (66)	$ 14,826
Stock-based compensation expense	—	—	2,869	—	—	2,869
Cancellation of common stock in connection with restricted share awards, net of issuances and shares settled for tax withholding settlement	(49,296)	—	(329)	—	—	(329)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	1,902,376	19	9,943	—	—	9,962
Issuance of common stock in connection with underwritten offering, net of offering costs	12,285,056	123	70,030	—	—	70,153
Issuance of common stock upon exercise of pre-funded warrants, net of shares settled	999,979	10	(10)	—	—	—
Net loss	—	—	—	(24,172)	—	(24,172)
Other comprehensive loss	—	—	—	—	(68)	(68)
Balance at June 30, 2024	41,661,993	$ 417	$ 846,654	$ (773,696)	$ (134)	$ 73,241

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity (Deficit), Continued
($ in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at March 31, 2025	48,953,171	$ 490	$ 866,260	$ (825,287)	$ (67)	$ 41,396
Stock-based compensation expense	—	—	2,830	—	—	2,830
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	96,255	—	(6)	—	—	(6)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	2,198,606	22	10,479	—	—	10,501
Net income	—	—	—	108,833	—	108,833
Other comprehensive income	—	—	—	—	22	22
Balance at June 30, 2025	51,248,032	$ 512	$ 879,563	$ (716,454)	$ (45)	$ 163,576

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2024	45,644,091	$ 457	$ 856,824	$ (813,258)	$ 8	$ 44,031
Stock-based compensation expense	—	—	5,531	—	—	5,531
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	2,093,052	20	(57)	—	—	(37)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	3,510,889	35	17,265	—	—	17,300
Net income	—	—	—	96,804	—	96,804
Other comprehensive loss	—	—	—	—	(53)	(53)
Balance at June 30, 2025	51,248,032	$ 512	$ 879,563	$ (716,454)	$ (45)	$ 163,576

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
($ in thousands)
(Unaudited)

	For the six months ended June 30,	
	2025	**2024**
Cash flows from operating activities:		
Net income (loss)	$ 96,804	$ (24,172)
Adjustments to reconcile net income (loss) to cash used in operating activities:		
Depreciation and amortization	1,078	978
Stock-based compensation expense	5,531	2,869
Change in fair value of warrant and derivative liabilities	(1,857)	(7,626)
Accretion and interest on short-term investments	290	(66)
Amortization of right-of-use lease assets	505	431
Non-cash interest	598	735
Gain on disposal of property and equipment	—	(2)
Gain from sale of priority review voucher	(152,366)	—
Change in operating assets and liabilities:		
Inventory	(2,686)	—
Other receivables	22	804
Prepaid expenses and other current assets	(947)	(639)
Other assets	(242)	177
Accounts payable and accrued expenses	1,301	(121)
Accrued taxes	15,512	—
Lease liabilities	(667)	(590)
Other current liabilities	(62)	—
Net cash used in operating activities	(37,186)	(27,222)
Cash flows from investing activities:		
Proceeds from sale of priority review voucher, net of transaction costs of $2.6 million	152,366	—
Capital expenditures	(4,302)	(1,436)
Proceeds from disposal of property and equipment	—	18
Purchases of short-term investments	(68,499)	(89,890)
Proceeds from maturities of short-term investments	80,536	39,359
Net cash provided by (used in) investing activities	160,101	(51,949)
Cash flows from financing activities:		
Proceeds from ATM sales of common stock, net of issuance costs	17,300	9,962
Payments related to net settlement of restricted share awards	(37)	(28)
Proceeds from underwritten sales of common stock, net of issuance costs	—	70,153
Proceeds from issuance of long-term debt	—	20,000
Payment of debt issuance costs	—	(963)
Net cash provided by financing activities	17,263	99,124
Net increase in cash, cash equivalents and restricted cash	140,178	19,953
Cash, cash equivalents and restricted cash at beginning of period	23,695	14,811
Cash, cash equivalents and restricted cash at end of period	$ 163,873	$ 34,764
Supplemental cash flow information:		
Cash and cash equivalents	$ 163,535	$ 34,426
Restricted cash	338	338
Total cash, cash equivalents and restricted cash	$ 163,873	$ 34,764
Supplemental non-cash flow information:		
Right-of-use asset obtained in exchange for new operating lease liabilities	$ 1,097	$ —
Derivative and warrant additions associated with loan and security agreement	$ —	$ 1,042
Changes in accrued property and equipment	$ 1,364	$ —
Cash paid for interest	$ 1,358	$ 1,290
Cash paid for taxes	$ —	$ 7

The accompanying notes are an integral part of these unaudited condensed consolidated statements.

NOTE 1 – NATURE OF OPERATIONS

Background

Abeona Therapeutics Inc. (together with the Company's subsidiaries, "Abeona" or the "Company"), a Delaware corporation, is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. On April 28, 2025, the U.S. Food and Drug Administration ("FDA") approved ZEVASKYN™ (prademagene zamikeracel) gene-modified cellular sheets, also known as pz-cel, as the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa ("RDEB"), a serious and debilitating genetic skin disease. The Company's development portfolio also features adeno-associated virus ("AAV")-based gene therapies designed to treat ophthalmic diseases with high unmet need using novel AIM™ capsids.

Liquidity

As a biopharmaceutical organization, the Company has devoted substantially all of its resources since inception to research and development activities for ZEVASKYN™ and other product candidates, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, and providing general and administrative support for these operations.

As a result, the Company has incurred significant operating losses and negative cash flows from operations, other than the current quarter with the gain on sale of its Priority Review Voucher ("PRV"), since its inception. The Company anticipates such losses and negative cash flows will continue until ZEVASKYN™ can provide sufficient revenue for the Company to be profitable and generate positive cash flows. Through June 30, 2025, the Company has relied primarily on its sale of equity securities, its gain on the sale of its PRV, and strategic collaboration arrangements to finance its operations. The Company expects that its capital resources will be sufficient to fund its on-going operations for the next 12 months from the issuance date of these unaudited condensed consolidated financial statements. The Company may need to raise additional capital to fully implement its business plans through the issuance of equity, borrowings, or strategic alliances with partner companies. However, if such financing is not available at adequate levels, the Company would need to reevaluate its operating plans.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 other than those identified below.

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made. These unaudited interim condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The December 31, 2024 condensed consolidated balance sheet was derived from the audited statements but does not include all disclosures required by U.S. GAAP.

Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 20, 2025.

Use of Estimates

The preparation of unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reported period. The Company's significant estimates include, but are not limited to, fair value of warrant and derivative liabilities, the incremental borrowing rate related to the Company's operating leases and stock-based compensation. Due to the uncertainty inherent in such estimates, actual results could differ from these estimates and assumptions.

Inventory

The Company capitalizes inventory costs associated with products when future economic benefit is expected to be realized. These costs consist of raw materials, manufacturing-related costs, personnel costs, facility costs, and other indirect overhead costs. Prior to receiving FDA approval for ZEVASKYN™ in April 2025, the Company expensed costs related to inventory for clinical and pre-commercial purposes directly to research and development expense. Following the FDA's approval of ZEVASKYN™, the Company began capitalizing inventory related to commercialized products held for sale, in-process of production for sale, and raw materials to be used in the manufacturing of inventory.

The Company values its inventory at the lower-of-cost and net realizable value, on a first-in, first-out basis. The Company adjusts the net realizable value of any excess, obsolete or unsalable inventory in the period in which they are identified. Such impairment charges, should they occur, are recorded within cost of product revenue. For the three and six months ended June 30, 2025 there were no inventory write-downs. Inventory as of June 30, 2025 consisted of raw materials.

Other receivables

Other receivables include employee retention credits, sublease rent receivables and other miscellaneous receivables that are expected to be collected within the next twelve months. As of June 30, 2025 and December 31, 2024, the Company had employee retention credits receivables of $1.6 million.

Credit Losses

The Company reviews its available-for-sale investments for credit losses on a collective basis by major security type and in line with the Company's investment policy. As of June 30, 2025, the Company's available-for-sale investments were in securities that are issued by the U.S. treasury and U.S. federal agencies, are highly rated, and have a history of zero credit losses. The Company reviews the credit quality of its accounts receivables by monitoring the aging of its accounts receivable, the history of write-offs for uncollectible accounts, and the credit quality of its significant customers, the current economic environment/macroeconomic trends, supportable forecasts, and other relevant factors. The Company's accounts receivable are with customers that do not have a history of uncollectibility or a history of significantly aged accounts receivables. As of June 30, 2025, the Company did not recognize a credit loss allowance for its investments or accounts receivable.

Segments

The Company determines and presents operating segments based on the information that is internally provided to the Company's chief operating decision maker ("CODM"), its Chief Executive Officer, in accordance with ASC 280, *Segment Reporting*. The Company has determined that it operates in a single business segment, which is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. Refer to Note 12 – Segment Information for further information related to the Company's segment.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) attributable to common shareholders by the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares of common stock includes the weighted average effect of outstanding pre-funded warrants for the purchase of shares of common stock for which the remaining unfunded exercise price is $0.0001 or less per share. Diluted net income (loss) per share is computed based on the weighted average number of shares of common stock plus the effect of dilutive potential commons shares outstanding during the period using the treasury stock method and if-converted method. Dilutive potential securities result from outstanding restricted stock, stock options, stock purchase warrants and conversion features in the Company's loan agreement. When the Company has a net loss during the period, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.

A reconciliation of the numerators and the denominators of the basic and diluted net income (loss) per share computations are as follows (in thousands, except per share amounts):

	For the three months ended June 30,		For the six months ended June 30,	
	2025	2024	2025	2024
Numerator:				
Net income (loss) used for basic net income (loss) per share	$ 108,833	$ 7,406	$ 96,804	$ (24,172)
Effect of dilutive securities:				
Fair value adjustments for warrant and derivative liabilities	4,834	(20,854)	(1,180)	—
Numerator for dilutive net income (loss) per share - net income available for common shareholders' after the effect of dilutive securities	$ 113,667	$ (13,448)	$ 95,624	$ (24,172)
Denominator:				
Weighted average number of common shares outstanding - basic	52,524,510	40,010,481	51,159,240	33,662,908
Effect of dilutive shares:				
Shares of common stock issuable upon exercise of stock options	176,173	178,931	176,273	—
Shares of common stock underlying restricted stock	5,126,127	2,293,570	4,962,006	—
Shares of common stock issuable upon exercise of warrants	8,199,559	8,165,236	8,199,560	—
Shares of common stock issuable upon exercise of conversion feature of loan agreement	614,251	578,497	614,251	—
Dilutive potential common shares	14,116,110	11,216,234	13,952,090	—
Denominator for dilutive net income (loss) per share - adjusted weighted average shares used in computing net income (loss) per share - dilutive	66,640,620	51,226,715	65,111,330	33,662,908
Earnings per share:				
Basic income (loss) per common share	$ 2.07	$ 0.19	$ 1.89	$ (0.72)
Dilutive income (loss) per common share	$ 1.71	$ (0.26)	$ 1.47	$ (0.72)

The following table sets forth the potential securities that could potentially dilute basic loss per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the three months ended June 30,		For the six months ended June 30,	
	2025	2024	2025	2024
Shares of common stock issuable upon exercise of stock options	—	—	—	178,859
Shares of common stock underlying restricted stock	—	—	—	1,647,666
Shares of common stock issuable upon exercise of conversion feature of loan agreement	—	—	—	614,251
Shares of common stock issuable upon exercise of warrants	1,788,000	1,788,000	1,788,000	9,987,560
Total	1,788,000	1,788,000	1,788,000	12,428,336

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*. ASU 2023-09 is intended to enhance the transparency and decision usefulness of income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The standard is effective for annual reporting periods beginning after December 15, 2024, with early adoption permitted. The requirements of this ASU are disclosure related and will not have an impact on the Company's financial condition, results of operations, or cash flows. The Company adopted ASU 2023-09 effective January 1, 2025. Since ASU 2023-09 addresses only disclosures, the adoption of ASU 2023-09 did not have a significant impact on the Company's interim condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): *Disaggregation of Income Statement Expenses*. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

NOTE 3 – SHORT-TERM INVESTMENTS

The following table provides a summary of the short-term investments (in thousands):

	June 30, 2025			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 35,592	—	(37)	$ 35,555
U.S. federal agency securities	16,436	—	(27)	16,409
Certificates of deposit	10,000	19	—	10,019
Total available-for-sale, short-term investments	$ 62,028	19	(64)	$ 61,983

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 23,990	—	(22)	$ 23,968
U.S. federal agency securities	40,365	10	—	40,375
Certificates of deposit	10,000	20	—	10,020
Total available-for-sale, short-term investments	$ 74,355	30	(22)	$ 74,363

As of June 30, 2025, the available-for-sale securities classified as short-term investments mature in one year or less. The Company carries its available-for-sale securities at fair value in the condensed consolidated balance sheets. Unrealized losses on available-for-sale securities as of June 30, 2025, were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. None of the short-term investments have been in a continuous unrealized loss position for more than 12 months. Accordingly, no other-than-temporary impairment was recorded for the three and six months ended June 30, 2025.

There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments for the three and six months ended June 30, 2025 or 2024.

NOTE 4 – PROPERTY AND EQUIPMENT, NET

Property and equipment are stated at cost and depreciated or amortized using the straight-line method based on useful lives as follows (in thousands):

	Useful lives (years)	June 30, 2025	December 31, 2024
Laboratory equipment	5	$ 9,598	$ 8,868
Furniture, software and office equipment	3 to 5	2,236	1,113
Leasehold improvements	Shorter of remaining lease term or useful life	8,913	8,805
Construction-in-progress		4,800	624
Subtotal		25,547	19,410
Less: accumulated depreciation		(16,058)	(14,980)
Total property and equipment, net		$ 9,489	$ 4,430

Construction-in-progress relates to leasehold improvements for the Company's new office space as well as for conversion of existing office space into additional manufacturing space to increase ZEVASKYN™ manufacturing capacity.

Depreciation and amortization on property and equipment was $0.6 million and $0.5 million for the three months ended June 30, 2025 and 2024, respectively and $1.1 million and $1.0 million for the six months ended June 30, 2025 and 2024, respectively. The Company capitalized into inventory $0.1 million relating to depreciation associated with manufacturing equipment and production facilities for the three and six months ended June 30, 2025. The capitalized costs associated are added to inventory and will be expensed through cost of sales product in the condensed consolidated statement of operations and comprehensive income (loss) upon our first commercial sale of ZEVASKYN™

NOTE 5 – FAIR VALUE MEASUREMENTS

The Company calculates the fair value of the Company's assets and liabilities that qualify as financial instruments and includes additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of other receivables, prepaid expenses and other current assets, other assets, accounts payable, accrued taxes and accrued expenses approximate their carrying amounts due to the relatively short maturity of these instruments. The estimated fair value of the Loan Agreement as of June 30, 2025 and December 31, 2024, was $21.9 million and $24.7 million, respectively. Both observable and unobservable inputs were used to determine the fair value of long-term debt, which was classified within the Level 3 category.

U.S. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

The following table provides a summary of financial assets measured at fair value on a recurring and non-recurring basis (in thousands):

Description	Fair Value at June 30, 2025	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market funds	$ 157,115	$ 157,115	$ —	$ —
Money market deposit account	5,177	5,177	—	—
Short-term investments				
U.S. treasury securities	35,555	35,555	—	—
U.S. federal agency securities	16,409	—	16,409	—
Certificates of deposit	10,019	—	10,019	—
Total assets measured at fair value	$ 224,275	$ 197,847	$ 26,428	$ —
Liabilities				
Warrant liabilities	$ 30,157	$ —	$ —	$ 30,157
Total liabilities measured at fair value	$ 30,157	$ —	$ —	$ 30,157

Description	Fair Value at December 31, 2024	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market funds	$ 17,627	$ 17,627	$ —	$ —
Money market deposit account	5,109	5,109	—	—
Short-term investments				
U.S. treasury securities	23,968	23,968	—	—
U.S. federal agency securities	40,375	—	40,375	—
Certificates of deposit	10,020	—	10,020	—
Total assets measured at fair value	$ 97,099	$ 46,704	$ 50,395	$ —
Liabilities				
Warrant liabilities	$ 32,014	$ —	$ —	$ 32,014
Total liabilities measured at fair value	$ 32,014	$ —	$ —	$ 32,014

Warrant Liabilities

As of June 30, 2025 and December 31, 2024, the Company had the following outstanding warrant liabilities:

	June 30, 2025	December 31, 2024
Warrants issued as part of the 2021 public offering, expiration date December 2026, exercise price of $9.75 per share	1,788,000	1,788,000
Warrants issued as part of the 2022 Private Placement Offering, expiration date November 2027, exercise price $4.75 per share	7,609,879	7,609,879
Warrants issued as part of the 2024 Loan Agreement, expiration date January 2029, exercise price $4.07 per share	589,681	589,681

The common stock warrants related to the 2021 Public Offering and the 2022 Private Placement are not indexed to the Company's own stock and therefore have been classified as liabilities at their estimated fair value. The common stock warrants issued in connection with the Loan Agreement issuance were determined to be liability classified under ASC 815 as the common stock warrants were not considered indexed to the Company's stock. In January 2024, as part of the Loan Agreement, see Note 8, the Company issued warrants to purchase $2.4 million worth of shares of the Company's stock which have an exercise price of $4.07 per share and the shares issuable was calculated at 589,681 shares. Changes in the estimated fair value of the warrant liabilities is recorded as changes in fair value of warrant liabilities in the condensed consolidated statement of operations and comprehensive income (loss).

The following table provides a summary of the activity on the warrant liabilities (in thousands):

Warrant liabilities as of December 31, 2024	$ 32,014
Gain recognized in earnings from change in fair value	(1,857)
Warrant liabilities as of June 30, 2025	$ 30,157

The warrant liabilities are valued using significant inputs not observable in the market. Accordingly, the warrant liability is measured at fair value on a recurring basis using unobservable inputs and are classified as Level 3 inputs within the fair value hierarchy. Fair value measurements categorized within Level 3 are sensitive to changes in the assumptions or methodology used to determine fair value and such changes could result in a significant increase or decrease in the fair value. The Company's valuation of the common stock warrants utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates to value the common stock warrants. The Company assessed these assumptions and estimates at the end of each reporting period.

The following table outlines the key inputs for the Black-Scholes option-pricing model:

	June 30, 2025	December 31, 2024
Common share price	$ 5.68	$ 5.57
Expected term (years)	1.46 – 3.53	1.96 – 4.02
Risk-free interest rate (%)	3.63% – 3.77%	4.16% – 4.24%
Volatility (%)	87.61% - 100.00%	92.64% - 100.00%
Expected dividend yield (%)	0%	0%

NOTE 6 – ACCRUED EXPENSES

The following table provides a summary of the components of accrued expenses (in thousands):

	June 30, 2025	December 31, 2024
Accrued employee compensation	$ 3,095	$ 4,392
Accrued contracted services and other	2,400	1,941
Total accrued expenses	$ 5,495	$ 6,333

NOTE 7 – LEASES

The Company leases space under operating leases for administrative, manufacturing and laboratory facilities in Cleveland, Ohio. The Company also leases office space in New York, New York, which the Company sublets. The lease for the office space in New York, New York will terminate in September of 2025, which is the end of the lease term. The Company also leases certain office equipment under operating leases, which have a non-cancelable lease term of less than one year and the Company has elected the practical expedient to exclude these short-term leases from the Company's right-of-use assets and lease liabilities.

During 2024, the Company signed a lease for 16,566 square feet of office space at 6700 Euclid Avenue, Cleveland, Ohio. Pursuant to the lease agreement, the lease term began on January 1, 2025 with an initial term through December 30, 2030. Annual lease payments during the term of the lease are approximately $0.3 million. The total lease payments over the duration of the lease term are approximately $1.5 million. The additional space at the 6700 Euclid Avenue facility will allow the Company to convert office space at the 6555 Carnegie Avenue facility into additional manufacturing space to increase ZEVASKYN™ manufacturing capacity. The impact of this lease agreement was to increase the Company's operating right-of-use lease assets and operating lease liabilities by $1.0 million on January 1, 2025.

The Company has entered into two sublease agreements with unrelated third parties to occupy the Company's administrative offices in New York. The sublease agreements terminate in September of 2025 at the same time the Company's lease terminates. The Company expects to receive $0.1 million in future sublease income through September 2025 from the two subleases noted above.

The following table provides a summary of the Company's operating lease liabilities (in thousands):

	June 30, 2025	December 31, 2024
Current operating lease liability	$ 537	$ 823
Non-current operating lease liability	3,978	3,262
Total operating lease liability	$ 4,515	$ 4,085

Lease costs and rent are reflected in general and administrative expenses and research and development expenses in the condensed consolidated statements of operations and comprehensive income (loss), as determined by the underlying activities.

The following table provides a summary of the components of lease costs and rent (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2025	2024	2025	2024
Operating lease cost	$ 380	$ 328	$ 752	$ 662
Variable lease cost	79	122	195	196
Short-term lease cost	11	11	19	34
Total operating lease costs	$ 470	$ 461	$ 966	$ 892

Cash paid for amounts included in the measurement of operating lease liabilities was $0.3 million for the three months ended June 30, 2025 and 2024, respectively and $0.7 million and $0.6 million for the six months ended June 30, 2025 and 2024, respectively.

Future minimum lease payments and obligations, which do not include short-term leases, related to the Company's operating lease liabilities as of June 30, 2025 were as follows (in thousands):

Future minimum lease payments and obligations	Operating Leases
2025, remainder	$ —
2026	1,102
2027	1,146
2028	1,172
2029	1,199
Thereafter	1,225
Total undiscounted operating lease payments	5,844
Less: imputed interest	1,329
Present value of operating lease liabilities	$ 4,515

The weighted-average remaining term of the Company's operating leases was 62 months, and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 8.1% as of June 30, 2025.

The Company received sublease income, which is recorded in other income on the condensed consolidated statement of operations and comprehensive income (loss), of $0.1 million during the three months ended June 30, 2025 and 2024 and $0.3 million during the six months ended June 30, 2025 and 2024, respectively.

Future cash receipts from the Company's sublease agreements as of June 30, 2025 are as follows (in thousands):

Future cash receipts	Operating Subleases
2025, remainder	$ 140
Total future cash receipts	$ 140

NOTE 8 – DEBT

The following table provides a summary of the Company's debt, net of debt issuance costs and discounts (in thousands):

	June 30, 2025	December 31, 2024
Loan Agreement Principal	$ 20,000	$ 20,000
Accreted final payment fee	544	354
Unamortized debt issuance costs and discounts	(983)	(1,391)
Total long-term debt	19,561	18,963
Less: current maturities	5,556	5,926
Long-term debt, net of current maturities	$ 14,005	$ 13,037

Loan and Security Agreement

On January 8, 2024 (the "Closing Date"), the Company entered into a Loan and Security Agreement, as supplemented by a Supplement, dated as of January 8, 2024 (collectively, the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P., a Delaware limited partnership, as administrative agent and collateral agent ("Avenue" and the "Agent") and Avenue Venture Opportunities Fund II, L.P., a Delaware limited partnership ("Avenue 2" and, together with Avenue, the "Lenders"). The Loan Agreement provides for senior secured term loans (the "Loans") in an aggregate principal amount up to $50 million, with (i) a committed tranche of $20 million advanced on the Closing Date ("Tranche 1"), (ii) a committed tranche of up to $10 million which may be advanced upon the request of the Company between June 30, 2024 and September 30, 2024, subject to the Company obtaining FDA approval of ZEVASKYN™ in RDEB, with the issuance of a Priority Review Voucher ("Tranche 2"), and (iii) a discretionary tranche of up to $20 million which may be advanced between March 31, 2025 and March 31, 2026 (the "Discretionary Tranche") provided at the discretion of the Lenders. The Loans are due and payable on July 1, 2027. As of September 30, 2024, the Tranche 2 was no longer available as the Company did not meet the Tranche 2 criteria.

The loan principal is repayable in equal monthly installments beginning on February 1, 2026. On April 28, 2025, with the FDA approval of ZEVASKYN™ and in accordance with the Loan Agreement, the start date of the loan principal monthly installments was extended from May 1, 2025 to February 1, 2026. The Loans bear interest at a rate per annum (subject to increase during an event of default) equal to the greater of (i) the prime rate, as published by the Wall Street Journal from time to time, plus 5.00% and (ii) 13.50%. The stated interest rate and effective interest rate as of June 30, 2025 was 13.50% and 19.86%, respectively.

The Company may, subject to certain parameters, voluntarily prepay the Loans, in whole, at any time. If prepayment occurs after January 8, 2025 and on or before the January 8, 2026, the Company is required to pay a fee equal to 2.00% of the principal amount of the Loans; if prepayment occurs after the January 8, 2026, the Company is required to pay a fee equal to 1.00% of the principal amount of the Loans. A final payment fee of 5.00% of the principal amount of the funded Tranche 1, Tranche 2 Loans and Discretionary Tranche Loans is also due upon maturity on July 1, 2027 or any earlier date of prepayment.

The Company's obligations under the Loan Agreement are secured by a pledge of substantially all of the Company's assets. Pursuant to the Loan Agreement, the Company is subject to a financial covenant requiring the Company to maintain at all times $5 million in unrestricted cash. The Loan Agreement also contains affirmative and negative covenants customary for financings of this type that, among other things, limit the ability of the Company and its subsidiaries to (i) incur additional debt, guarantees or liens; (ii) pay dividends; (iii) enter into certain change of control transactions; (iv) sell, transfer, lease, license, or otherwise dispose of certain assets; (v) make certain investments or loans; and (vi) engage in certain transactions with related persons, in each case, subject to certain exceptions. The Loan Agreement also includes events of default customary for financings of this type, in certain cases subject to customary periods to cure, following which the Agent may accelerate all amounts outstanding under the Loans.

Pursuant to the Supplement to the Loan and Security Agreement, Avenue also has the right to convert up to $3 million of the outstanding principal of the Loans into shares of Company common stock (the "Conversion Right") at a price per share equal to 120% of the exercise price of the Warrants (further discussed below) at any time while the Loans are outstanding, subject to certain terms and conditions, including ownership limitations. The Conversion Right required bifurcation as certain adjustments to the conversion price were not indexed to the Company's own stock and therefore the Conversion Right was recorded as a derivative liability. On January 8, 2024, the Conversion Right was recorded at the closing date fair value of $0.8 million which was based on a Monte Carlo simulation model. The derivative liability is remeasured at each reporting period with the change in fair value recorded to change in fair value of warrants and derivative liabilities in the condensed consolidated statement of operations until the derivative is exercised, expired, reclassified, or otherwise settled. On September 30, 2024, pursuant to the Loan Agreement, the conversion price was fixed at $4.88 and is considered indexed to the Company's own stock. On September 30, 2024, the Conversion Right no longer met the criteria of a derivative liability and the derivative liability of $1.1 million was reclassified to equity.

In addition, subject to applicable law and specified provisions set forth in the Supplement to the Loan and Security Agreement and solely to the extent permitted under applicable stock exchange rules without requiring stockholder approval, the Lenders may participate in certain equity financing transactions of the Company in an aggregate amount of up to $1 million on the same terms, conditions and pricing offered by the Company to other investors participating in such financing transactions (such right, the "Participation Right"). The Participation Right automatically terminates upon the earliest of (i) July 1, 2027, (ii) such time that the Lenders have purchased $1 million of the Company's equity securities in the aggregate pursuant to the Participation Right, and (iii) the repayment in full of all of the obligations under the Loan Agreement.

On the Closing Date and pursuant to the funding of Tranche 1 of the Loan Agreement, the Company issued to each of Avenue and Avenue 2 (collectively, the "Warrant Holders") warrants to purchase up to $480,000 and $1,920,000 of Company common stock, respectively which is more fully described in Note 9 – Equity below.

The future payment obligations of the principal are as follows as of June 30, 2025 (in thousands):

2025, remainder	$	—
2026		12,222
2027		7,778
Total principal	$	20,000

NOTE 9 – EQUITY

Preferred Stock

The aggregate number of authorized shares of the Company's preferred stock is 2,000,000 shares with a par value of one cent ($0.01). There is no preferred stock outstanding as of June 30, 2025 and December 31, 2024.

Common Stock and Warrants

Public Offerings

On December 21, 2021, the Company closed an underwritten public offering of 1,788,000 shares of common stock at a public offering price of $9.75 per share and stock purchase warrants to purchase 1,788,000 shares of common stock at an exercise price of $9.75. The net proceeds to the Company were $16.0 million, after deducting $1.5 million of underwriting discounts and commissions and offering expenses payable by the Company. The net proceeds were allocated to the warrant liability as noted below with the remainder of $7.0 million recorded in common stock and additional paid-in capital. In the event of certain fundamental transactions involving the Company, the holders of the stock purchase warrants may require the Company to make a payment based on a Black-Scholes valuation, using specific inputs that are not considered indexed to the Company's stock in accordance with ASC 815, *Derivatives and Hed*ging ("ASC 815"). Therefore, the Company accounted for the stock purchase warrants as liabilities, which were recorded at the closing date fair value of $9.0 million which was based on a Black-Scholes option pricing model. The remainder of the proceeds were allocated to common stock issued and recorded as a component of equity.

As of June 30, 2025, there were 1,788,000 stock purchase warrants outstanding related to this public offering. These stock purchase warrants expire on December 21, 2026. During such time as each warrant is outstanding, the holder of the warrant is entitled to participate in any dividends or other distribution of assets to holders of shares of common stock. There was no warrant activity during the three and six months ended June 30, 2025, other than the change in fair value of the warrants for the stock purchase warrants issued as part of this public offering.

On May 7, 2024, the Company sold 12,285,056 shares of its common stock and, in lieu of common stock, pre-funded warrants to purchase 6,142,656 shares of its common stock (the "2024 Pre-Funded Warrants"), for an aggregate purchase price of $75.0 million gross, or $70.2 million net of related costs. The offering price for each share of common stock was $4.07, and the offering price for the 2024 Pre-Funded Warrants was $4.0699, which represents the per share offering price for the Company's common stock less a $0.0001 per share exercise price for each 2024 Pre-Funded Warrant. The 2024 Pre-Funded Warrants are immediately exercisable at a nominal exercise price of $0.0001 per share and may be exercised at any time until the pre-funded warrants are exercised in full. On June 24, 2024, 700,000 of the 2024 Pre-Funded Warrants were exercised and on December 2, 2024, 1,228,531 of the 2024 Pre-Funded Warrants were exercised, leaving 4,214,125 2024 Pre-Funded Warrants outstanding as of June 30, 2025. The 2024 Pre-Funded Warrants are classified as equity in accordance with ASC 815, *Derivatives and Hedging*, given the prefunded warrants are indexed to the Company's own shares of common stock and meet the requirements to be classified in equity. The 2024 Pre-Funded warrants were recorded at their relative fair value at issuance in the stockholders' equity section of the consolidated balance sheet and the 2024 Pre-Funded Warrants are considered outstanding shares in the basic and diluted earnings per share calculation for the three and six months ended June 30, 2025 given their nominal exercise price.

Open Market Sale Agreement

On August 17, 2018, the Company entered into an open market sale agreement (as amended, the "ATM Agreement") with Jefferies LLC ("Jefferies") pursuant to which, the Company may sell from time to time, through Jefferies, shares of its common stock for an aggregate sales price of up to $75.0 million. Any sales of shares pursuant to this agreement are made under the Company's effective "shelf" registration statement on Form S-3 that is on file with and has been declared effective by the SEC.

The Company sold 2,198,606 and 1,013,061 shares of its common stock under the ATM Agreement during the three months ended June 30, 2025 and 2024, respectively, resulting in net proceeds of $10.5 million and $3.5 million during the three months ended June 30, 2025 and 2024, respectively. The Company sold 3,510,889 and 1,902,376 shares of its common stock under the ATM Agreement during the six months ended June 30, 2025 and 2024, respectively, resulting in net proceeds of $17.3 million and $10.0 million during the six months ended June 30, 2025 and 2024, respectively.

Private Placement Offerings

On November 3, 2022, the Company sold 7,065,946 shares of its common stock, and in lieu of shares of common stock, pre-funded warrants exercisable for 543,933 shares of common stock and accompanying warrants to purchase 7,609,879 shares of its common stock to a group of new and existing institutional investors in a private placement. The offering price for each share of common stock and accompanying warrant was $4.60, and the offering price for each pre-funded warrant and accompanying warrant was $4.59, which equaled the offering price per share of the common stock and accompanying warrant, less the $0.01 per share exercise price of each pre-funded warrant. Each accompanying warrant represents the right to purchase one share of the Company's common stock at an exercise price of $4.75 per share of common stock. The pre-funded warrants were exercised in December 2022 and converted to 543,933 shares of commons stock. Total shares sold and converted during the year ended December 31, 2022 were 7,609,879 for an aggregate purchase price of $35.0 million gross, or $32.6 million net of related costs of $1.5 million which was expensed to general and administrative expenses and $0.9 million which was recorded as a reduction to additional paid-in-capital. The net proceeds were allocated to the warrant liability as noted below with the remainder of $12.9 million and $0.1 million recorded in additional paid-in capital and common stock, respectively.

In the event of certain fundamental transactions involving the Company, the holders of the stock purchase warrants may require the Company to make a payment based on a Black-Scholes valuation, using specific inputs that are not considered indexed to the Company's stock in accordance with ASC 815. Therefore, the Company is accounting for the stock purchase warrants as liabilities. On November 3, 2022, the stock purchase warrants were recorded at the closing date fair value of $22.0 million which was based on a Black-Scholes option pricing model. The remainder of the proceeds were allocated to common stock issued and recorded as a component of equity.

As of June 30, 2025, there were 7,609,879 warrants outstanding related to this private placement offering. The warrants expire on November 3, 2027. During such time as each warrant is outstanding, the holder of the warrant is entitled to participate in any dividends or other distribution of assets to holders of shares of common stock. There was no warrant activity during the three and six months ended June 30, 2025, other than the change in fair value of the warrants related to warrants issued as part of this private placement offering.

Direct Placement Offering

On July 6, 2023, the Company sold 3,284,407 shares of its common stock, and in lieu of shares of common stock, pre-funded warrants exercisable for 2,919,140 shares of common stock (the "2023 Pre-Funded Warrants"), to a group of existing institutional investors for an aggregate purchase price of $25.0 million gross, or $23.0 million net of related costs. The offering price for each share of common stock was $4.03, and the offering price for the 2023 Pre-Funded Warrants was $4.0299, which represents the per share offering price for the Company's common stock less a $0.0001 per share exercise price for each such 2023 Pre-Funded Warrant. The 2023 Pre-Funded Warrants are immediately exercisable at a nominal exercise price of $0.0001 per share, may be exercised at any time and do not have an expiration date. On May 9, 2024, 300,000 of the 2023 Pre-Funded Warrants were exercised, leaving 2,619,140 2023 Pre-Funded Warrants outstanding as of June 30, 2025. The 2023 Pre-Funded Warrants are classified as equity in accordance with ASC 815, *Derivatives and Hedging*, given the 2023 Pre-Funded Warrants are indexed to the Company's own shares of common stock and meet the requirements to be classified in equity. The 2023 Pre-Funded Warrants were recorded at their relative fair value at issuance in the stockholders' equity section of the consolidated balance sheet and the 2023 Pre-Funded Warrants are considered outstanding shares in the basic and diluted earnings per share calculation for the three and six months ended June 30, 2025 given their nominal exercise price.

Common Stock Warrants related to the Loan and Security Agreement

On January 8, 2024, in connection with entering into the Loan and Security Agreement, the Company issued to the Warrant Holders warrants to purchase up to $0.5 million and $1.9 million worth of shares, respectively, of Company common stock (collectively, the "January Warrants"). The Warrants expire on January 8, 2029 and upon issuance, had an exercise price per share equal to the lesser of (i) $4.75 and (ii) the price per share of the Company's next bona fide round of equity financing before September 30, 2024 in which the Company sells or issues shares of its common stock, excluding certain excluded issuances as defined in the Supplement. In connection with the underwritten common stock offering consummated on May 7, 2024, and pursuant to the term of the January Warrants, the exercise price of the January Warrants was reduced to $4.07 per share for 589,681 shares. In addition, upon a change of control where the per share price of the Company common stock is less than or equal to two times that of the exercise price, the Warrant Holders would be entitled to receive the shares of common stock underlying the January Warrants without payment of the exercise price. On January 8, 2024, the January Warrants did not include an explicit share limit and the number of shares issuable under the warrant agreements were variable based on the exercise price and therefore the January Warrants were liability classified based on a Black-Scholes valuation in accordance with ASC 815 and were recorded at the closing date fair value of $0.2 million which was based on a Black-Scholes option pricing model. On September 30, 2024, per the terms of the January Warrants, the exercise price and the number of shares issuable became set at $4.07 per share and 589,681 shares, respectively.

The Warrant Holders may exercise the January Warrants at any time, or from time to time up to and including January 8, 2029, by making a cash payment equal to the exercise price multiplied by the quantity of shares. The Warrant Holders may also exercise the January Warrants on a cashless basis by receiving a net number of shares calculated pursuant to the formula set forth in the January Warrants. The January Warrants are subject to anti-dilution adjustments for stock dividends, stock splits, and reverse stock splits.

NOTE 10 – STOCK-BASED COMPENSATION

Prior to May 17, 2023, the Company had previously granted stock options and stock awards under the Abeona Therapeutics Inc. 2015 Equity Incentive Plan (the "2015 Incentive Plan"). As of May 17, 2023, no further grants can be made under the 2015 Incentive Plan. The Company now grants stock options and stock awards under the Abeona Therapeutics Inc. 2023 Equity Incentive Plan (the "2023 Incentive Plan") which was approved by stockholders on May 17, 2023. On April 24, 2024, stockholders approved an amendment to the 2023 Incentive Plan to increase the shares authorized for issuance from 1,700,000 shares to 3,200,000 shares. On December 20, 2024, stockholders approved an additional increase in the shares authorized for issuance under the 2023 Incentive Plan from 3,200,000 shares to 8,400,000 shares. As of June 30, 2025, there were 3,142,949 shares available to be granted under the 2023 Incentive Plan. In addition, in 2023, the Company's board of directors approved various restricted stock awards granted to certain new hires as inducement grants. On October 10, 2023, the Company's board of directors approved the Abeona Therapeutics Inc. 2023 Employment Inducement Equity Incentive Plan (the "Inducement Plan"). As of June 30, 2025, there were 462,853 shares available to be granted under the Inducement Plan.

The following table summarizes stock-based compensation expense (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2025	2024	2025	2024
Research and development	$ 232	$ 224	$ 902	$ 570
Selling, general and administrative	2,598	1,099	4,629	2,299
Total stock-based compensation expense	$ 2,830	$ 1,323	$ 5,531	$ 2,869

Stock Options

The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option-pricing model. The Company then recognizes the grant date fair value of each option as compensation expense ratably using the straight-line attribution method over the service period (generally the vesting period). The Black-Scholes model incorporates the following assumptions:

- Expected volatility – the Company estimates the volatility of the share price at the date of grant using a "look-back" period which coincides with the expected term, defined below. The Company believes using a "look-back" period which coincides with the expected term is the most appropriate measure for determining expected volatility.
- Expected term – the Company estimates the expected term using the "simplified" method, as outlined in SEC Staff Accounting Bulletin No. 107, "Share-Based Payment."
- Risk-free interest rate – the Company estimates the risk-free interest rate using the U.S. Treasury yield curve for periods equal to the expected term of the options in effect at the time of grant.
- Dividends – the Company uses an expected dividend yield of zero because the Company has not declared nor paid a cash dividend, nor are there any plans to declare a dividend.

The Company did not grant any stock options in the three and six months ended June 30, 2025 and 2024.

The Company accounts for forfeitures as they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise.

The following table summarizes stock option activity during the six months ended June 30, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	176,587	$ 38.64	5.83	$ 6
Granted	—	$ —	—	$ —
Cancelled/forfeited	(439)	$ 16.49	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at June 30, 2025	176,148	$ 38.70	5.35	$ 6
Exercisable	172,830	$ 39.11	5.32	$ 5
Unvested	3,318	$ 17.33	6.50	$ 1

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of June 30, 2025, the total compensation cost related to non-vested option awards not yet recognized was approximately $39,000 with a weighted average remaining vesting period of 0.3 years.

Restricted Stock

The following table summarizes restricted stock award activity during the six months ended June 30, 2025:

	Number of Awards	Weighted Average Grant Date Fair Value Per Unit
Outstanding at December 31, 2024	3,320,811	$ 4.60
Granted	2,139,328	$ 5.29
Cancelled/forfeited	(44,525)	$ 5.10
Vested	(500,780)	$ 4.72
Outstanding at June 30, 2025	4,914,834	$ 4.88

As of June 30, 2025, there was $17.7 million of total unrecognized compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted average vesting period of 2.1 years. The total fair value of restricted stock awards that vested during the six months ended June 30, 2025 and 2024 was $2.4 million and $3.9 million, respectively.

NOTE 11 – LICENSE/SUPPLIER AGREEMENT

License Agreement Relating to Recessive Dystrophic Epidermolysis Bullosa (RDEB)

In 2016, the Company entered into two licensing agreements between the Company and The Board of Trustees of Leland Stanford Junior University ("Stanford") to develop EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)) and EB-201 (AAV DJ COL7A1) and to license the invention "Gene Therapy for Recessive Dystrophic EB using Genetically Corrected Autologous Keratinocytes." Under the terms of the licensing agreements, the Company paid an upfront of licensing fees in cash and is subject to annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. As of June 30, 2025, the Company paid the remaining milestone payments of $0.3 million which became due upon FDA approval of ZEVASKYN™ on April 28, 2025 and is included in selling, general and administrative costs in the condensed consolidated statement of operations and comprehensive income (loss).

License Agreement Relating to Novel AAV Capsids ("AIM™ capsids")

In 2016, the Company licensed an international patent family from The University of North Carolina at Chapel Hill ("UNC") covering novel AAV capsids ("AIM™ capsids") that may potentially be used to deliver a wide variety of therapeutic transgenes to human cells to treat genetic diseases. Under the terms of the licensing agreements, the Company paid an upfront licensing fee in cash and is subject to on-going patent expenses incurred in relation to the patents licensed under this agreement and annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. As of June 30, 2025, as a result of exercise of the option to license certain of the Company's AAV capsids, the Company paid $0.1 million to UNC for as a royalty payment under this agreement.

License Agreement Relating to CLN1 Disease

In 2016, the Company licensed from UNC rights to two patent families directed to treating CLN1 disease (also known as infantile Batten disease). Under the terms of the licensing agreements, the Company paid an upfront of licensing fees in cash and is subject to on-going patent expenses incurred in relation to the patents licensed under this agreement and annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. The Company subsequently sublicensed the license to Taysha Gene Therapies ("Taysha"), see detail of the sublicense agreement below. As part of the agreement with UNC, the Company is obligated to pay to UNC a percentage of any sublicense revenue that the Company receives under the agreement. The Company recognizes any payments under this agreement as royalties in the consolidated statement of operations and comprehensive income (loss). During the three and six months ended June 30, 2025 and 2024, no milestone or royalty payments under this agreement have been made.

License Agreement Relating to Rett Syndrome

In 2019, the Company licensed rights to one patent family from UNC and two patent families from The University Court of the University of Edinburgh ("U. Edinburgh") and The University Court of the University of Glasgow ("U. Glasgow") relating to gene therapy for the treatment of Rett Syndrome. Under the terms of the licensing agreements, the Company paid an upfront of licensing fees in cash and is subject to on-going patent expenses incurred in relation to the patents licensed under this agreement and annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. The Company subsequently sublicensed the license to Taysha, see detail of the sublicense agreement below. As part of the agreement with UNC, the Company is obligated to pay to UNC and U. Edinburgh a percentage of any sublicense revenue that the Company receives under the agreement. The Company recognizes any payments under this agreement as royalties in the consolidated statement of operations and comprehensive income (loss). During the three and six months ended June 30, 2025 and 2024, no milestone or royalty payments under this agreement have been made.

License Agreement Relating to AAV Capsids

In 2024, the Company entered into a license agreement with a third party for certain of the Company's AAV capsids. This agreement had an option to exercise before the terms of the agreement were activated. In June 2025, the third party exercised its option as per the agreement with a payment of $0.4 million included as license and other revenues in the statement of operations and comprehensive income (loss).

The Company assessed the nature of the promised license to determine whether the license has significant stand-alone functionality and evaluated whether such functionality can be retained without ongoing activities by the Company and determined that the license has significant stand-alone functionality. Furthermore, the Company has no ongoing activities associated with the license to support or maintain the license's utility. Based on this, the Company determined that the pattern of transfer of control of the license to the third party was at a point in time.

The transaction price of the contract includes (i) $0.4 million of fixed consideration, (ii) up to $24.0 million of variable consideration in the form of event-based milestone payments, (iii) up to $45.0 million of variable consideration in the form of sales-based milestone payments, and (iv) low single-digit royalty-based payments based on net sales. The Company is obligated to pay a portion of milestone payments and royalties on net sales received from the third party to UNC. The event-based milestone payments are based on certain development and regulatory events occurring. The Company evaluated whether the milestone conditions have been achieved and if it is probable that a significant cumulative revenue reversal would not occur before recognizing the associated revenue. The Company determined that these milestone payments are not within the Company's control or the licensee's control, such as regulatory approvals, and are not considered probable of being achieved until those approvals are received. Accordingly, the Company has fully constrained the $24.0 million in event-based milestone payments until such time that it is probable that a significant cumulative revenue reversal would not occur. The sales-based milestone payments and other royalty-based payments are based on a level of sales for which the license is deemed to be the predominant item to which the royalties relate. The Company will recognize revenue for these payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales-based or royalty revenue resulting from this licensing arrangement.

Under this arrangement, the Company recognized $0.4 million in revenue during the three and six months ended June 30, 2025 and no revenue for the three and six months ended June 30, 2024. As of June 30, 2025 and December 31, 2024, the Company does not have any contract assets or contract liabilities as a result of this transaction.

Sublicense and Inventory Purchase Agreements Relating to CLN1 Disease

In August 2020, the Company entered into sublicense and inventory purchase agreements with Taysha relating to a potential gene therapy for CLN1 disease. Under the sublicense agreement, Taysha received worldwide exclusive rights to intellectual property and know-how relating to the research, development, and manufacture of the potential gene therapy, which the Company had referred to as ABO-202. Under the inventory purchase agreement, the Company sold to Taysha certain inventory and other items related to ABO-202. The Company assessed the nature of the promised license to determine whether the license has significant stand-alone functionality and evaluated whether such functionality can be retained without ongoing activities by the Company and determined that the license has significant stand-alone functionality. Furthermore, the Company has no ongoing activities associated with the license to support or maintain the license's utility. Based on this, the Company determined that the pattern of transfer of control of the license to Taysha was at a point in time.

The transaction price of the contract includes (i) $7.0 million of fixed consideration, (ii) up to $26.0 million of variable consideration in the form of event-based milestone payments, (iii) up to $30.0 million of variable consideration in the form of sales-based milestone payments, and (iv) high single-digit royalty-based payments based on net sales. The Company is obligated to pay a portion of milestone payments and royalties on net sales received from Taysha to UNC. The event-based milestone payments are based on certain development and regulatory events occurring. At inception, the Company evaluated whether the milestone conditions had been achieved and if it was probable that a significant cumulative revenue reversal would not occur before recognizing the associated revenue and determined that these milestone payments were not within the Company's control or the licensee's control, such as regulatory approvals, and were not considered probable of being achieved until those approvals were received. Accordingly, at inception, the Company fully constrained the $26.0 million of event-based milestone payments until such time that it is probable that significant cumulative revenue reversal would not occur. The sales-based milestone payments and other royalty-based payments are based on a level of sales for which the license is deemed to be the predominant item to which the royalties relate. The Company will recognize revenue for these payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales-based or royalty revenue resulting from this licensing arrangement.

Under this arrangement, the Company has not recognized any revenue during the three and six months ended June 30, 2025 and 2024, respectively, based on event-based-milestone payments. The Company has no contract assets or liabilities as of June 30, 2025 and December 31, 2024 as a result of this transaction.

Sublicense Agreement Relating to Rett Syndrome

In October 2020, the Company entered into a sublicense agreement with Taysha for a gene therapy for Rett syndrome, including intellectual property related to MECP2 gene constructs and regulation of their expression. The agreement grants Taysha worldwide exclusive rights to intellectual property developed by scientists at UNC, U. Edinburgh and the Company, and the Company's know-how relating to the research, development, and manufacture of the gene therapy for Rett syndrome and MECP2 gene constructs and regulation of their expression.

The Company assessed the nature of the promised license to determine whether the license has significant stand-alone functionality and evaluated whether such functionality can be retained without ongoing activities by the Company and determined that the license has significant stand-alone functionality. Furthermore, the Company has no ongoing activities associated with the license to support or maintain the license's utility. Based on this, the Company determined that the pattern of transfer of control of the license to Taysha was at a point in time.

The transaction price of the contract includes (i) $3.0 million of fixed consideration, (ii) up to $26.5 million of variable consideration in the form of event-based milestone payments, (iii) up to $30.0 million of variable consideration in the form of sales-based milestone payments, and (iv) high single-digit royalty-based payments based on net sales. The Company is obligated to pay a portion of milestone payments and royalties on net sales received from Taysha to UNC and U. Edinburgh. The event-based milestone payments are based on certain development and regulatory events occurring. The Company evaluated whether the milestone conditions have been achieved and if it is probable that a significant cumulative revenue reversal would not occur before recognizing the associated revenue. The Company determined that these milestone payments are not within the Company's control or the licensee's control, such as regulatory approvals, and are not considered probable of being achieved until those approvals are received. Accordingly, the Company fully constrained the $26.5 million in event-based milestone payments until such time that it is probable that a significant cumulative revenue reversal would not occur. The sales-based milestone payments and other royalty-based payments are based on a level of sales for which the license is deemed to be the predominant item to which the royalties relate. The Company will recognize revenue for these payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales-based or royalty revenue resulting from this licensing arrangement.

Under this arrangement, the Company recognized no revenue during the three and six months ended June 30, 2025 and 2024. As of June 30, 2025 and December 31, 2024, the Company does not have any contract assets or contract liabilities as a result of this transaction.

Ultragenyx License Agreement

On May 16, 2022, the Company and Ultragenyx Pharmaceutical Inc. ("Ultragenyx") entered into an exclusive license agreement (the "License Agreement") for AAV gene therapy, ABO-102, for the treatment of Sanfilippo syndrome type A (MPS IIIA). Under the License Agreement, Ultragenyx assumed responsibility for the ABO-102 program from the Company, with the exclusive right to develop, manufacture, and commercialize ABO-102 worldwide. Also pursuant to the License Agreement, following regulatory approval, the Company is eligible to receive tiered royalties from mid-single-digit up to 10% on net sales and up to $30.0 million in commercial milestone payments. Both forms of consideration comprise the transaction price to which the Company expects to be entitled in exchange for transferring the related intellectual property and certain, contractually-specified, transition services to Ultragenyx. The sales-based royalty and milestone payments are subject to the royalty recognition constraint. As such, these fees are not recognized as revenue until the later of: (a) the occurrence of the subsequent sale, and (b) the performance obligation to which they relate has been satisfied. As of June 30, 2025 and December 31, 2024, the Company does not have any contract assets or contract liabilities as a result of this transaction.

NOTE 12 – SEGMENT INFORMATION

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the Chief Operating Decision Maker ("CODM"), or decision making group, in deciding how to allocate resources in assessing performance. The Company is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases and has one reportable segment. The Company's CODM is the chief executive officer.

The accounting policies of the clinical-stage biopharmaceutical segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the commercial-stage biopharmaceutical segment based on net income (loss), which is reported on the consolidated statements of operations and comprehensive income (loss) as consolidated net income (loss). The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. Expenditures for additions to long-lived assets, which include purchases of property and equipment, are included in total consolidated assets reviewed by the chief operating decision maker and are reported on the consolidated statements of cash flows.

To date, the Company has not generated any product revenue. The Company will continue to incur significant expenses and operating losses until ZEVASKYN™ can provide sufficient revenue for the Company to be profitable. As such, the CODM uses cash forecast models in deciding how to invest into the commercial-stage biopharmaceutical segment. Such cash forecast models are reviewed to make decisions about allocating resources and assessing the entity-wide operating results and performance. Net income (loss) is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used to make decisions about allocating resources, assessing the performance of the segment and in establishing management's compensation, along with cash forecast models.

The table below summarizes the significant expense categories regularly reviewed by the CODM:

	For the three months ended June 30,		For the six months ended June 30,	
	2025	2024	2025	2024
License and other revenues	$ 400	$ —	$ 400	$ —
Research and development costs				
Salaries & related costs	$ 2,235	$ 4,441	$ 6,916	$ 7,996
Non-cash stock-based compensation	232	224	902	570
Other research and development costs (a)	3,476	4,553	8,066	7,859
Total research and development costs	$ 5,943	$ 9,218	$ 15,884	$ 16,425
Selling, general and administrative costs				
Salaries & related costs	$ 4,670	$ 3,434	$ 8,323	$ 5,696
Non-cash stock-based compensation	2,598	1,099	4,629	2,299
Pre-commercial preparation costs	2,290	1,460	3,497	2,811
Regulatory and production costs	4,855	—	4,855	—
Other selling, general and administrative costs (b)	2,736	2,653	5,631	4,963
Total selling, general and administrative costs	$ 17,149	$ 8,646	$ 26,935	$ 15,769
Other segment items (c)	(131,525)	(25,270)	(139,223)	(8,022)
Net income (loss)	$ 108,833	$ 7,406	$ 96,804	$ (24,172)

(a) Other research and development expenses include, but are not limited to preclinical lab supplies, preclinical and development costs, clinical trial costs, preclinical manufacturing and manufacturing facility costs, costs associated with preclinical regulatory approvals, preclinical depreciation on lab supplies and manufacturing facilities, and preclinical consultant-related expenses.

(b) Other general and administrative expenses primarily consist of office facility costs, public reporting company related costs, professional fees (e.g., legal expenses) and other general operating expenses not otherwise included in research and development expenses.

(c) Other segment items includes royalties, interest income, interest expense, change in fair value of warrant and derivative liabilities, gain on sale of priority review voucher, other income and income tax expense.

NOTE 13 – INCOME TAXES

The Company recorded a current income tax expense of $15.5 million for the three and six months ended June 30, 2025. The Company did not record an income tax expense for the three and six months ended June 30, 2024 as it generated sufficient tax losses, after consideration of discrete items, during each of the periods. The current income tax expense for the three and six months ended June 30, 2025 was driven by pre-tax income from the gain on sale of priority review voucher, resulting in $14.6 million of federal income tax expense and $0.9 million of state income tax expense.

As previously disclosed, the Company's ability to utilize its net operating loss ("NOL") carryforwards are subject to limitation under Section 382 of the Internal Revenue Code of 1986, as amended. Per Section 382, a change in ownership greater than 50% within a three-year period results in annual limitations on the utilization of NOL carryforwards. The Company is currently in the process of determining if a Section 382 change has occurred and to what extent the use of its NOL carryforwards may be limited. Preliminary results indicate that the Company has experienced multiple ownership changes and may have a material limitation on the use of its NOL carryforwards. The Company expects to complete its Section 382 analysis by December 31, 2025.

On July 4, 2025, the President signed the One Big Beautiful Bill Act into law. The legislation includes several changes to federal tax law that generally allow for more favorable deductibility of certain business expenses beginning in 2025, including the restoration of immediate expensing of domestic R&D expenditures, reinstatement of 100% bonus depreciation, and more favorable rules for determining the limitation on business interest expense.

These changes were not reflected in the Company's income tax provision for the period ended June 30, 2025, as the legislation was enacted after the balance sheet date. The Company is currently evaluating the impact of the One Big Beautiful Bill Act on future periods; however, the Company expects that the favorable changes from the new law will significantly reduce current tax due for 2025. The Company is also evaluating the impact of the legislation on its state income tax position, recognizing that certain states may follow different legislative processes or decouple from federal provisions.

NOTE 14 – SALE OF NONFINANCIAL ASSETS

On May 9, 2025, the Company entered into a definitive asset purchase agreement that transferred the rights to a PRV awarded to the Company following the FDA approval of ZEVASKYN™. The PRV sale was subject to customary closing conditions and was completed in June 2025 following the expiration of applicable U.S. antitrust requirements. The Company accounted for this transaction under ASC Topic 610-20, *Gains and Losses from the Derecognition of Nonfinancial Assets* ("ASC 610-20"). The Company received the gross proceeds of $155.0 million during the three months ended June 30, 2025 and recognized a gain, net of transaction costs of $2.6 million, from sale of priority review voucher of $152.4 million on the Company's condensed consolidated statement of operations and comprehensive income (loss) as it did not have a carrying value at the time of sale.

NOTE 15 – SUBSEQUENT EVENTS

On July 18, 2025, the Company entered into an amendment (the "Amendment") to the Loan Agreement that reduces the interest rate for senior secured term loan owed under the Loan Agreement from 13.5% to a fixed rate of 11.75% per annum. In connection with the Amendment, the Company issued the lenders warrants to purchase up to an aggregate of 16,474 shares of Company common stock (collectively, the "July 2025 Avenue Warrants"). The July 2025 Avenue Warrants expire on July 18, 2030 and have an exercise price per share equal to $6.07.

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

You should read the following discussion and analysis together with our unaudited condensed consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024 (the "Annual Report"). This discussion and analysis contains forward-looking statements, which involve risks and uncertainties. As a result of many factors, such as those described under "Forward-Looking Statements," "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

OVERVIEW

Abeona is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. On April 28, 2025, the U.S. Food and Drug Administration ("FDA") approved ZEVASKYN™ (prademagene zamikeracel) gene-modified cellular sheets, also known as pz-cel, as the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa ("RDEB"), a serious and debilitating genetic skin disease. There is no cure for RDEB, and ZEVASKYN™ is the only FDA-approved product to treat RDEB wounds with a single application.

In connection with the FDA approval of ZEVASKYN™, Abeona received a Rare Pediatric Disease Priority Review Voucher ("PRV"). ZEVASKYN™ has been granted Orphan Drug and Rare Pediatric Disease designations by the FDA and Orphan Drug Designation by the European Medicines Agency ("EMA"). On May 9, 2025, we entered into a definitive asset purchase agreement to sell our PRV for gross proceeds of $155.0 million. The transaction closed on June 27, 2025 and we received $155.0 million in gross proceeds from the sale of the PRV.

We established a current Good Manufacturing Practices ("cGMP") commercial facility in Cleveland, Ohio for manufacturing ZEVASKYN™ drug product to support our commercial launch. ZEVASKYN™ will be made available beginning in the third quarter of 2025 through ZEVASKYN™ Qualified Treatment Centers ("QTCs"). The QTCs are well-recognized epidermolysis bullosa treatment centers with cell and gene therapy experience, situated across the U.S. to ensure patients nationwide have access to this important treatment. On May 14, 2025, Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") was activated as the first QTC for ZEVASKYN™. Lurie Children's has completed QTC start-up activities enabling it to begin patient identification for scheduling of ZEVASKYN™ treatment. Treatments are expected to begin in the third quarter of 2025.

Our development portfolio also features adeno-associated virus ("AAV") based gene therapies designed to treat ophthalmic diseases with high unmet need using novel AIM™ capsids. Abeona's novel, next-generation AAV capsids are being evaluated to improve tropism profiles for a variety of devastating diseases.

Preclinical Pipeline

Our preclinical programs are investigating the use of novel AAV capsids in AAV-based therapies for serious genetic eye diseases, including ABO-504 for Stargardt disease, ABO-503 for X-linked retinoschisis ("XLRS") and ABO-505 for autosomal dominant optic atrophy ("ADOA"). We completed pre-Investigational New Drug Application ("pre-IND") meetings with the FDA regarding the preclinical development plans and regulatory requirements to support first-in-human trials.

Recent Updates

In June 2025, a third-party exercised its option for $0.4 million to license certain of our AAV capsids. This worldwide, non-exclusive license is pursuant to the agreement between Abeona and the third party, announced in July 2024, to evaluate the therapeutic potential of AAV204.

On July 15, 2025, we announced the activation of the newest QTC for ZEVASKYN™ at Lucile Packard Children's Hospital Stanford. As a result, RDEB patients will be able to access ZEVASKYN™ at both Lucile Packard Children's Hospital Stanford and Lurie Children's Hospital of Chicago.

RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2025 and June 30, 2024

	For the three months ended June 30,		Change	
($ in thousands)	**2025**	**2024**	**$**	**%**
Revenues:				
License and other revenues	$ 400	$ —	$ 400	100%
Expenses:				
Royalties	100	—	100	100%
Research and development	5,943	9,218	(3,275)	(36)%
Selling, general and administrative	17,149	8,646	8,503	98%
Total expenses	23,192	17,864	5,328	30%
Loss from operations	(22,792)	(17,864)	(4,928)	28%
Interest income	1,027	1,191	(164)	(14)%
Interest expense	(957)	(1,072)	115	(11)%
Change in fair value of warrant and derivative liabilities	(5,388)	24,927	(30,315)	(122)%
Gain from sale of priority review voucher, net	152,366	—	152,366	100%
Other income	89	224	(135)	(60)%
Income before income taxes	124,345	7,406	116,939	1,579%
Income tax expense	15,512	—	15,512	100%
Net income	$ 108,833	$ 7,406	$ 101,427	1,370%

License and other revenues

License and other revenues for the three months ended June 30, 2025 was $0.4 million as compared to nil for the same period of 2024. The revenue in 2025 of $0.4 million consists of revenue resulting from a third party exercising its option to license certain of our AAV capsids.

Royalties

Total royalty expense for the three months ended June 30, 2025 was $0.1 million as compared to nil for the same period of 2024. The increase in expense was due to royalties owed to the University of North Carolina at Chapel Hill resulting from the milestones due from the exercise of an option by a third party to license certain of our AAV capsids.

Research and development

Research and development expenses include, but are not limited to, payroll and personnel expense, preclinical lab supplies, preclinical and development costs, clinical trial costs, preclinical manufacturing and manufacturing facility costs, costs associated with regulatory approvals, preclinical depreciation on lab supplies and manufacturing facilities, and preclinical consultant-related expenses.

Total research and development spending for the three months ended June 30, 2025 was $5.9 million, as compared to $9.2 million for the same period of 2024, a decrease of $3.3 million. The reduction in expenses was primarily due to $1.4 million of costs capitalized into inventory and $4.9 million of costs such as engineering runs and other production costs that are no longer considered research and development due to FDA approval of ZEVASKYN™ in April of 2025. Excluding this, total costs would have increased by $3.0 million due to $1.7 million increase in salaries and non-cash stock-based compensation costs due to increased headcount related to scale up of manufacturing capacity in preparation for the planned launch of ZEVASKYN™ and $1.3 million in pre-clinical development work.

We expect our research and development activities to continue as we work towards advancing other product candidates towards potential regulatory approval, reflecting costs associated with the following:

- employee and consultant-related expenses;
- preclinical and developmental costs;
- clinical trial costs;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with regulatory approvals.

Selling, general and administrative

Selling, general and administrative expenses primarily consist of payroll and personnel costs, office facility costs, public reporting company related costs, professional fees (e.g., legal expenses), selling and other costs for planned commercial launch and other general operating expenses not otherwise included in research and development expenses.

Total selling, general and administrative expenses were $17.1 million for the three months ended June 30, 2025, as compared to $8.6 million for the same period of 2024, an increase of $8.5 million. The increase in expenses was primarily due to approximately $4.9 million of costs such as engineering runs and other production costs that are no longer considered research and development due to FDA approval in April of 2025. Excluding these costs, the increase in expenses of $3.7 million was primarily due to:

- increased salary and related costs of $1.2 million;
- increased non-cash stock-based compensation of $1.0 million; and
- increased other costs such as professional fees, rent, and recruiting of $1.5 million.

Interest income

Interest income was $1.0 million for the three months ended June 30, 2025, as compared to $1.2 million in the same period of 2024. The decrease resulted from lower earnings on short-term investments driven by decreased average short-term investment balances.

Interest expense

Interest expense was $1.0 million for the three months ended June 30, 2025 compared to $1.1 million in the same period of 2024. Interest expense is due to the credit facility entered into by the Company in January 2024.

Change in fair value of warrant and derivative liabilities

The change in fair value of warrant liabilities was a loss of $5.4 million for the three months ended June 30, 2025. We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. The loss in the fair value of warrant liabilities was primarily due to the increase in our stock price year over year and a shorter term of the outstanding warrants.

The change in fair value of warrant and derivative liabilities was a gain of $24.9 million for the three months ended June 30, 2024. We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. In addition, the conversion feature in our loan agreement is required to be classified as a liability and valued at fair market value at each reporting period. The gain in the fair value of warrant and derivative liabilities was primarily due to the decrease in our stock price over the year and a reduced term of each of the warrants and derivative liabilities.

Gain from sale of priority review voucher, net

In May 2025, we sold our PRV awarded to us following the FDA approval of ZEVASKYN™. We received gross proceeds of $155.0 million during the three months ended June 30, 2025 and recognized a gain the PRV sale of $152.4 million, net of transaction costs of $2.6 million, as it did not have a carrying value at the time of sale.

Other income

Other income was $0.1 million for the three months ended June 30, 2025, as compared to $0.2 million in the same period of 2024. Other income includes sublease income, which had a minor reduction period over period.

Income tax expense

We recorded a current income tax expense of $15.5 million for the three months ended June 30, 2025. We did not record an income tax expense for the three months ended June 30, 2024 as we generated sufficient tax losses, after consideration of discrete items. The current income tax expense for the three months ended June 30, 2025 was driven by pre-tax income from the gain on sale of the PRV, resulting in $14.6 million of federal income tax expense and $0.9 million of state income tax expense. We are currently evaluating the impact of the One Big Beautiful Bill Act on future periods; however, we expect that the favorable changes from the new law will significantly reduce current tax due for 2025. The legislation includes several changes to federal tax law that generally allow for more favorable deductibility of certain business expenses beginning in 2025, including the restoration of immediate expensing of domestic R&D expenditures, reinstatement of 100% bonus depreciation, and more favorable rules for determining the limitation on business interest expense.

Comparison of Six Months Ended June 30, 2025 and June 30, 2024

	For the six months ended June 30,		Change	
($ in thousands)	**2025**	**2024**	**$**	**%**
Revenues:				
License and other revenues	$ 400	$ —	$ 400	100%
Expenses:				
Royalties	100	—	100	100%
Research and development	15,884	16,425	(541)	(3)%
Selling, general and administrative	26,935	15,769	11,166	71%
Total expenses	42,919	32,194	10,725	33%
Loss from operations	(42,519)	(32,194)	(10,325)	32%
Interest income	2,337	2,034	303	15%
Interest expense	(1,955)	(2,024)	69	(3)%
Change in fair value of warrant and derivative liabilities	1,857	7,626	(5,769)	(76)%
Gain from sale of priority review voucher, net	152,366	—	152,366	100%
Other income	230	386	(156)	(40)%
Income (loss) before income taxes	112,316	(24,172)	136,488	(565)%
Income tax expense	15,512	—	15,512	100%
Net income (loss)	$ 96,804	$ (24,172)	$ 120,976	(500)%

License and other revenues

License and other revenues for the six months ended June 30, 2024 was $0.4 million as compared to nil for the same period of 2024. The revenue in 2025 of $0.4 million consists of revenue resulting from a third party exercising its option to license certain of our AAV capsids.

Royalties

Total royalty expense for the six months ended June 30, 2025 was $0.1 million as compared to nil for the same period of 2024. The increase in expense was due to royalties owed to the University of North Carolina at Chapel Hill resulting from the milestones due from the exercise of an option by a third party to license certain of our AAV capsids.

Research and development

Total research and development spending for the six months ended June 30, 2025 was $15.9 million, as compared to $16.4 million for the same period of 2024, a decrease of $0.5 million. The reduction in expenses was primarily due to $1.4 million of costs capitalized into inventory and $4.9 million of costs such as engineering runs and other production costs that are no longer considered research and development due to FDA approval of ZEVASKYN™ in April of 2025. Excluding this, total costs would have increased by $5.8 million due to $3.0 million increase in salaries and non-cash stock-based compensation costs due to increased headcount related to scale up of manufacturing capacity in preparation for the planned launch of ZEVASKYN™ and $2.8 million in pre-clinical development work.

We expect our research and development activities to continue as we work towards advancing our product candidates towards potential regulatory approval, reflecting costs associated with the following:

- employee and consultant-related expenses;
- preclinical and developmental costs;
- clinical trial costs;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with regulatory approvals.

Selling, general and administrative

Selling, general and administrative expenses primarily consist of payroll and personnel costs, office facility costs, public reporting company related costs, professional fees (e.g., legal expenses), selling and other costs for planned commercial launch and other general operating expenses not otherwise included in research and development expenses.

Total general and administrative expenses were $26.9 million for the six months ended June 30, 2025, as compared to $15.8 million for the same period of 2024, an increase of $11.1 million. The increase in expenses was primarily due to approximately $4.9 million of costs such as engineering runs and other production costs that are no longer considered research and development due to FDA approval of ZEVASKYN™ in April of 2025.

Excluding these costs, the increase in expenses of $6.2 million was primarily due to:

- increased salary and related costs of $2.6 million;
- increased non-cash stock-based compensation of $1.9 million; and
- increased other costs such as professional fees, rent, and recruiting of $1.7 million.

Interest income

Interest income was $2.3 million for the six months ended June 30, 2025, as compared to $2.0 million in the same period of 2024. The increase resulted from higher earnings on short-term investments driven by increased average short-term investment balances.

Interest expense

Interest expense was $2.0 million for the six months ended June 30, 2025 and 2024. Interest expense is due to the credit facility entered into by the Company in January 2024.

Change in fair value of warrant and derivative liabilities

The change in fair value of warrant liabilities was a gain of $1.9 million for the six months ended June 30, 2025. We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. The gain in the fair value of warrant liabilities was primarily due to the shorter term period over period.

The change in fair value of warrant and derivative liabilities was a gain of $7.6 million for the six months ended June 30, 2024. In 2024, we issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. In addition, the conversion feature in our loan agreement was required to be classified as a liability through September 30, 2024 and was valued at fair market value at each reporting period during the nine-month period ending September 30, 2024. The change in the fair value of warrant and derivative liabilities was primarily due to the decrease in our stock price year as of June 30, 2024 compared to December 31, 2023.

Gain from sale of priority review voucher, net

In May, 2025, we sold our PRV awarded to us following the FDA approval of ZEVASKYN™. We received gross proceeds of $155.0 million during the six months ended June 30, 2025 and recognized a gain from the PRV sale of $152.4 million, net of transaction costs of $2.6 million, as it did not have a carrying value at the time of sale.

Other income

Other income was $0.2 million for the six months ended June 30, 2025, as compared to $0.4 million in the same period of 2024. Other income includes sublease income, which had a minor reduction period over period.

Income tax expense

We recorded a current income tax expense of $15.5 million for the six months ended June 30, 2025. We did not record an income tax expense for the six months ended June 30, 2024 as we generated sufficient tax losses, after consideration of discrete items. The current income tax expense for the six months ended June 30, 2025 was driven by pre-tax income from the gain on sale of the PRV, resulting in $14.6 million of federal income tax expense and $0.9 million of state income tax expense. We are currently evaluating the impact of the One Big Beautiful Bill Act on future periods; however, we expect that the favorable changes from the new law will significantly reduce current tax due for 2025. The legislation includes several changes to federal tax law that generally allow for more favorable deductibility of certain business expenses beginning in 2025, including the restoration of immediate expensing of domestic R&D expenditures, reinstatement of 100% bonus depreciation, and more favorable rules for determining the limitation on business interest expense.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows for the Six Months Ended June 30, 2025 and 2024

	For the six months ended June 30,	
($ in thousands)	**2025**	**2024**
Total cash, cash equivalents and restricted cash provided by (used in):		
Operating activities	$ (37,186)	$ (27,222)
Investing activities	160,101	(51,949)
Financing activities	17,263	99,124
Net increase in cash, cash equivalents and restricted cash	$ 140,178	$ 19,953

Operating activities

Net cash used in operating activities was $37.2 million for the six months ended June 30, 2025, primarily comprised of our net income of $96.8 million and increases in operating assets and liabilities of $12.4 million offset by net non-cash charges of $146.2 million. Non-cash charges consisted primarily of $152.4 million gain on sale of priority review voucher for which the cash proceeds are recorded in investing activities, $1.9 million of gain as a result of the change in fair value of warrant and derivative liabilities, $5.5 million of stock-based compensation and $1.1 million of depreciation and amortization.

Net cash used in operating activities was $27.2 million for the six months ended June 30, 2024, primarily comprised of our net loss of $24.2 million and decreases in operating assets and liabilities of $0.4 million and net non-cash charges of $2.6 million. Non-cash charges consisted primarily of $(7.6) million of the change in fair value of warrant and derivative liabilities, $2.9 million of stock-based compensation and $1.0 million of depreciation and amortization.

Investing activities

Net cash provided by investing activities was $160.1 million for the six months ended June 30, 2025, primarily comprised of net proceeds from sale of priority review voucher of $152.4 million, proceeds from maturities of short-term investments of $80.5 million, offset by purchases of short-term investments of $68.5 million and capital expenditures of $4.3 million.

Net cash used in investing activities was $51.9 million for the six months ended June 30, 2024, primarily comprised of proceeds from maturities of short-term investments of $39.4 million, offset by purchases of short-term investments of $89.9 million and capital expenditures of $1.4 million.

Financing activities

Net cash provided by financing activities was $17.3 million for the six months ended June 30, 2025, primarily comprised of proceeds of $17.3 million from open market sales of common stock pursuant to the ATM Agreement (as defined below).

Net cash provided by financing activities was $99.1 million for the six months ended June 30, 2024, primarily comprised of $70.2 million in net proceeds from sales of common stock, $10.0 million from open market sales of common stock pursuant to the ATM Agreement (as defined below) and net proceeds of $19.0 million from our January 2024 Loan Agreement.

We have historically funded our operations primarily through our sale of equity securities, our most recent gain on sale of our PRV, and strategic collaboration arrangements.

Our principal source of liquidity is cash, cash equivalents, restricted cash and short-term investments, collectively referred to as our cash resources. As of June 30, 2025, our cash resources were $225.9 million, which include the $155.0 million in gross proceeds from the sale of our priority review voucher. We believe that our current cash and cash equivalents, restricted cash and short-term investments are sufficient to fund operations through at least the next 12 months from the date of this report on Form 10-Q. We may need to secure additional funding to carry out all of our planned research and development and potential commercialization activities. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity and sufficient capital resources could have a material adverse effect on our future prospects.

We have an open market sale agreement with Jefferies LLC (as amended, the "ATM Agreement") pursuant to which, we may sell from time to time, through Jefferies LLC, shares of our common stock for an aggregate sales price of up to $75.0 million. Any sales of shares pursuant to this agreement are made under our effective "shelf" registration statement on Form S-3 that is on file with and has been declared effective by the SEC. We sold 3,510,889 shares of our common stock under the ATM Agreement and received $17.3 million of net proceeds during the six months ended June 30, 2025. We sold 1,902,376 shares of our common stock under the ATM Agreement and received $10.0 million of net proceeds during the six months ended June 30, 2024. Under the ATM Agreement and as of June 30, 2025, we have remaining shares of our common stock for an aggregate sales price of up to $51.5 million.

Since our inception and excluding the gain on sale of our priority review voucher, we have incurred negative cash flows from operations and have expended, and expect to continue to expend, substantial funds to complete our planned product development and commercialization efforts. Excluding the gain on sale of our priority review voucher, we have not been profitable since inception and to date have received limited revenues from the sale of products or licenses. As a result, we have incurred significant operating losses and negative cash flows from operations since our inception and anticipate such losses and negative cash flows will continue until ZEVASKYN™ can provide sufficient revenue for us to be profitable and cash flow generating.

We may incur losses for the next several years as we continue to invest in commercialization, product research and development, preclinical studies, clinical trials, and regulatory compliance and cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis, or at all.

If we raise additional funds by selling additional equity securities, the relative equity ownership of our existing investors will be diluted, and the new investors could obtain terms more favorable than previous investors. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Our future capital requirements and adequacy of available funds depend on many factors, including:

- the successful commercialization of ZEVASKYN™;
- the successful development, regulatory approval and commercialization of our cell and gene therapy and other product candidates;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development, and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting, and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- the successful outcome of our regulatory filings.

Due to uncertainties and certain of the risks described above, under “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risks above.

We plan to continue our policy of investing any available funds in suitable certificates of deposit, money market funds, government securities and investment-grade, interest-bearing securities. We do not invest in derivative financial instruments.

Critical Accounting Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate or different estimates that could have been selected could have a material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. For a discussion of the critical accounting estimates that affect the unaudited condensed consolidated financial statements, see "Critical Accounting Estimates" included in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

See Note 2 to our unaudited condensed consolidated financial statements for a discussion of our significant accounting policies.

Recently Issued Accounting Standards Not Yet Effective or Adopted

See Note 2 to our unaudited condensed consolidated financial statements for a discussion of recently issued accounting standards not yet effective or adopted.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management and consultants, including the Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls and Procedures"), as of June 30, 2025, as such term is defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Conclusion of Evaluation — Based on this Disclosure Controls and Procedures evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our Disclosure Controls and Procedures as of June 30, 2025 were effective.

Changes in Internal Control Over Financial Reporting – There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the quarter ended June 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Our business and financial results are subject to numerous risks and uncertainties. As a result, the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2024 should be carefully considered. There have been no material changes in the assessment of our risk factors from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2024 except as set forth below.

We recently received approval to market our first product, ZEVASKYN™, and will begin commercial sales, which make it difficult to assess our future viability.

We are a commercial-stage biopharmaceutical company. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. On April 28, 2025, the United States Food and Drug Administration ("FDA") approved our Biologics License Application ("BLA") for ZEVASKYN™ for treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa ("RDEB"), a series and debilitating genetic skin disease. To date we have not recorded any revenue from ZEVASKYN™ and recorded minimal other revenue and may recognize minimal revenue in the foreseeable future. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have limited experience in generating revenue from product sales.

Although ZEVASKYN™ has been approved by the FDA, our ability to generate significant revenue from product sales depends on ZEVASKYN™ successful commercialization. Successful commercialization requires success in many areas, including, but not limited to:

- launching ZEVASKYN™ and enrolling new patients;
- obtaining market acceptance of ZEVASKYN™ as a viable treatment option;
- obtaining adequate market share, reimbursement and pricing for ZEVASKYN™;
- our ability to find patients who have been diagnosed with RDEB and wish to begin receiving treatment;
- addressing any competing products and technological and market developments;
- negotiating favorable terms, including commercial rights, in any collaboration, licensing, or other arrangements into which we may enter, any amendments thereto, or extensions thereof;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

If the patient demand is not as significant as we estimate, or the reasonably predicted population for treatment is narrowed by competition, physician choice, or treatment guidelines, or for any other reason, we may not generate significant revenue from the sale of ZEVASKYN™.

Our financial performance depends on the commercial success of ZEVASKYN™.

Our financial performance depends heavily on the commercial success of ZEVASKYN™, which received FDA approval on April 28, 2025. If ZEVASKYN™ faces problems such as unexpected side effects, loss of intellectual property protection, data integrity issues, manufacturing or supply chain issues or other product shortages, regulatory proceedings, changes in labeling, publicity affecting doctor or patient confidence in the product, material product liability litigation, or pressure from new competitive products, the adverse impact on our revenue could be significant. Our revenues could be significantly affected by the timing and rate of commercial acceptance of our product. The commercial success of our approved product also requires significant attention and focus from key members of our management.

Even if we succeed in commercializing ZEVASKYN™, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of any future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses before we become profitable have had and may continue to have an adverse effect on our stockholders' equity and working capital.

Our ability to use our net operating loss carryforwards to offset future taxable income and taxes may be subject to certain limitations.

As of December 31, 2024, we had $416.1 million of U.S. federal net operating loss carryforwards and $6.0 million of general business credit carryforwards, which may be utilized against future federal and state income taxes. Federal NOL carryforwards we generated in tax years through December 31, 2017 generally may be carried forward for 20 years and may fully offset taxable income in the year utilized, and federal NOLs we generated in tax years beginning after December 31, 2017 generally may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually for tax years beginning after December 31, 2017.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes or applicable state tax law. An ownership change may limit our ability to use our NOL carryforwards attributable to the period prior to the change. We are currently in the process of determining if a Section 382 change has occurred and to what extent the use of our NOL carryforwards may be limited. Preliminary results indicate that we have experienced multiple ownership changes and may have a material limitation on the use of our NOL carryforwards. We expect to complete our Section 382 analysis by December 31, 2025.

If we are limited in our ability to use our NOLs and tax credits this year or in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits, and we could be required to pay taxes earlier than we would otherwise be required, which could cause such NOLs to expire unused. This could adversely affect our results of operations.

Disruptions at FDA and other government agencies, such as those that may be caused by funding shortages, could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. Disruptions at FDA and other agencies may also increase the time necessary to meet with and provide feedback to entities developing drug products, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or otherwise authorize our actions requiring regulatory approval, which would adversely affect our business. In addition, government funding of FDA and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. For example, the executive branch recently established the Department of Government Efficiency ("DOGE"), which implemented a federal government hiring freeze and large scale layoffs of current federal employees and also announced additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the executive branch will impact the regulatory authorities that oversee our business. These budgetary pressures may reduce FDA's ability to perform its responsibilities. If a significant reorganization or reduction in FDA's workforce occurs, FDA's budget is significantly reduced, or there are other disruptions at FDA and other agencies, more time may be necessary for biological products, or biologics, or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which could increase our costs and would adversely affect our business. In addition, if a prolonged government shutdown occurs, it could significantly impact the ability of FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as FDA, have had to furlough critical employees and stop critical activities. Additionally, Congress may introduce and ultimately pass healthcare-related legislation that could impact the drug approval process.

We are subject to extensive governmental regulation, which increases our cost of doing business and may affect our ability to commercialize any new products that we may develop.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish safety and efficacy. All of our drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of our drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity, and novelty of the product.

Due to the time-consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, we cannot be certain when we, independently or with our collaborative partners, might submit a BLA for FDA or other regulatory review. Further, our ability to commence and/or complete development projects will be subject to our ability to raise enough funds to pay for the development costs of these projects. Government regulation also affects the manufacturing and marketing of pharmaceutical products. Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could adversely affect our marketing as well as our ability to generate significant revenues from commercial sales.

Our drug candidates may not receive FDA or other regulatory approvals on a timely basis or at all. Moreover, if regulatory approval of a drug candidate is granted, such approval may impose limitations on the indicated use for which such drug may be marketed. Even if we obtain initial regulatory approvals for our drug candidates, our drugs and our manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, manufacturer or facility may result in restrictions on the marketing or manufacture of such drug, including withdrawal of the drug from the market. The FDA and other regulatory authorities stringently apply regulatory standards and failure to comply with regulatory standards can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions, and criminal prosecution.

Further, the current federal administration has announced that it is looking for opportunities to improve efficiency and identify fraud and ineffective use of resources at government agencies, including through DOGE. This includes government agencies we may interact with like the FDA. There is a possibility that changes will be made at the FDA, and other governmental agencies that we may interact with, and that these changes could have a material adverse impact on our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(c) The following table provides information about purchases of equity securities that are registered pursuant to Section 12 of the Exchange Act for the quarter ended June 30, 2025:

	Total number of shares (or units) purchased [(a)]	Average price paid per share (or unit)
Shares delivered or withheld pursuant to restricted stock awards		
April 1, 2025 - April 30, 2025	—	$ —
May 1, 2025 - May 31, 2025	—	$ —
June 1, 2025 - June 30, 2025	885	$ 6.24
	885	$ 6.24

(a) Reflects shares of common stock surrendered to the Company for payment of tax withholding obligations in connection with the vesting of restricted stock.

ITEM 5. OTHER INFORMATION

Securities Trading Arrangements of Directors and Executive Officers

During the fiscal quarter ended June 30, 2025, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 105b-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K).

ITEM 6. EXHIBITS

See Exhibit Index below, which is incorporated by reference herein.

Exhibit Index

Exhibits:	Description of Document
10.1†	Priority Review Voucher Asset Purchase Agreement dated May 9, 2025.*
31.1	Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.*
31.2	Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934. *
32**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at June 30, 2025 and December 31, 2024 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2025 and 2024 (unaudited), (iii) Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three and six months ended June 30, 2025 and 2024 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2025 and 2024 (unaudited), and (v) Notes to Condensed Consolidated Financial Statements (unaudited).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Pursuant to Item 601(b)(32)(ii) of Regulation S-K, this exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.
† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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.

ABEONA THERAPEUTICS INC.

Date: August 14, 2025

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2025

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

Execution Version

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. [***] denotes omissions.

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of May 9, 2025 (the "***Effective Date***"), by and between [***], a corporation organized under the laws of [***] ("***Buyer***") and Abeona Therapeutics Inc., a corporation organized under the laws of Delaware ("***Seller***"). Buyer and Seller may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties***".

RECITALS

WHEREAS, Seller is the holder of all right, title and interest in and to the Priority Review Voucher (as defined below);

WHEREAS, Seller and Buyer each (i) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Purchased Assets (as defined below), all on the terms set forth herein (such transaction, the "***Asset Purchase***") and (ii) in furtherance thereof, have duly authorized, approved and executed this Agreement and the other transactions contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below); and

WHEREAS, Seller and Buyer desire to make certain representations, warranties, covenants and other agreements in connection with the Asset Purchase as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties agree as follows:

ARTICLE I.
DEFINITIONS

Section 1.01 Certain Definitions. As used in this Agreement, the following terms shall have the meanings indicated below:

(a) "***Affiliate***" means with respect to any Person, any other Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person, for so long as such control exists, whether such Person is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it: (i) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) or more of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, has other comparable ownership interest; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(b) "***Agreement***" has the meaning set forth in the preamble.

(c) "***Alternative Transaction***" means, other than the transactions contemplated by this Agreement, any proposal or offer from any Person or group of Persons (other than Buyer or its Affiliates or their respective Representatives) for any acquisition by, or transfer, assignment, encumbrance, license or other grant of rights or disposition to, such Person or group of Persons of any right, title or interest in or to the Purchased Assets; provided, that "***Alternative Transaction***" shall not include any debt or equity financing transaction of the Seller or any acquisition of substantially all of Seller's assets or a majority of the direct or indirect equity interests in Seller (whether through a stock purchase, merger, sale of all or substantially all assets or otherwise) so long as such acquisition provides that this Agreement continues to be binding, enforceable and in full force and effect on the same terms in effect as of the Effective Date.

(d) "***Approval Letter***" means the letter from the FDA to Seller dated April 28, 2025, approving the Subject BLA, attached hereto as Exhibit A.

(e) "***Asset Purchase***" has the meaning set forth in the recitals.

(f) "***BLA***" means a biologics license application submitted to the FDA.

(g) "***Business Day***" means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in New York, New York.

(h) "***Buyer***" has the meaning set forth in the preamble.

(i) "***Confidential Information***" means (i) any and all confidential and proprietary information, including but not limited to, data, results, conclusions, know-how, experience, financial information, plans and forecasts, that may be delivered, made available, disclosed or communicated by a Party or its Affiliates or their respective Representatives to the other Party or its Affiliates or their respective Representatives, related to the subject matter hereof or otherwise in connection with this Agreement and (ii) the terms, conditions and existence of this Agreement. "Confidential Information" will not include information that (A) at the time of disclosure, is generally available to the public, (B) after disclosure hereunder, becomes generally available to the public, except as a result of a breach of this Agreement by the recipient of such information, (C) becomes available to the recipient of such information from a Third Party that is not legally or contractually prohibited by the disclosing Party from disclosing such Confidential Information; or (D) was developed by or for the recipient of such information without the use of or reference to any of the Confidential Information of the disclosing Party or its Affiliates, as evidenced by the recipient's contemporaneous written records. Notwithstanding anything herein to the contrary, all Confidential Information included within the Purchased Assets shall constitute Confidential Information of the Buyer from and after the Closing Date.

(j) "***Contract***" means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(k) "***Effective Date***" has the meaning set forth in the preamble.

(l) "***Encumbrance***" means any lien, pledge, charge, mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, lease, security interest, encumbrance, right of negotiation or refusal, adverse claim, interference or any other restriction on use, ownership or transfer.

(m) "***FDA***" means the United States Food and Drug Administration.

(n) "***FDCA***" means the United States Federal Food, Drug, and Cosmetic Act.

(o) "***Fraud***" means a Party's actual and intentional fraud under Delaware common law in the making of any representations and warranties made by such Party as expressly set forth in Article IV or Article V hereof, as applicable.

(p) "***Fundamental Representations***" means the representations and warranties contained in [***].

(q) "***Governmental Entity***" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, taxing or other governmental or quasi-governmental authority, in each case whether domestic or foreign.

(r) "***HSR Act***" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and the rules and regulations promulgated thereunder.

(s) "***Knowledge***" means [***].

(t) "***Legal Requirements***" means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, with respect to Seller, any obligations, responsibilities, requirements, parameters and conditions relating to the Priority Review Voucher set forth in (i) the Approval Letter, (ii) any other correspondence received by Seller or its respective Affiliates from the FDA, to the extent regarding the Priority Review Voucher, or (iii) Section 529 of the FDCA (21 U.S.C. § 360ff), including as interpreted by the FDA in FDA's Draft Guidance, "Rare Pediatric Disease Priority Review Vouchers – Guidance for Industry" (July 2019).

(u) "***Liabilities***" means all debts, Taxes, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any Legal Requirement or any Contract.

(v) "***Notice of Intent to Use***" means notification to the FDA not later than ninety (90) days prior to the submission of a human drug application of the intent to use the Priority Review Voucher to obtain Priority Review of a human drug application, as described in 21 U.S.C. § 360ff(b)(4)(B)(i).

(w) "***Order***" means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.

(x) "***Party***" has the meaning set forth in the preamble.

(y) "***Person***" means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

(z) "***Priority Review***" has the meaning set forth in 21 U.S.C. § 360ff(a)(1).

(aa) "***Priority Review Fee***" has the meaning set forth in Section 11.02.

(bb) "***Priority Review Voucher***" means the priority review voucher issued by the United States Secretary of Health and Human Services, Food and Drug Administration, to the Seller, as evidenced in the Approval Letter, identified by priority review voucher number PRV BLA 125807.

(cc) "***Proceeding***" means any action, arbitration, audit, hearing, investigation, proceeding, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Entity or arbitrator.

(dd) "***Purchased Assets***" means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements afforded to the holder of the Priority Review Voucher.

(ee) "***Regulatory Change***" means any (i) new Legal Requirement, amendment, or supplement to any then existing Legal Requirement or (ii) new term or condition imposed on the Priority Review Voucher that is not generally imposed on priority review vouchers as of the Effective Date, that in either case (i) or (ii) has been enacted, adopted, approved, or imposed between the Effective Date and the Closing Date and adversely impacts, in any material respect, the manner in which Buyer may use, transfer, receive, hold or otherwise exploit the Priority Review Voucher.

(ff) "***Representative***" means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(gg) "***Seller***" has the meaning set forth in the preamble.

(hh) "***Seller Notice of Transfer Submission***" has the meaning set forth in Section 3.02(e).

(ii) "***Subject BLA***" means BLA Number 125807, approved by the FDA on April 28, 2025, for ZEVASKYN™ (prademagene zamikeracel) for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

(jj) "***Tax***" or "***Taxes***" means any and all domestic and non-U.S., federal, state, provincial, local, municipal and other taxes, fees, levies, duties, tariffs, imposts and like assessments or charges of whatever kind, including taxes or charges on, or measured by or with respect to, gross or net income, gain, gross receipts, capital, franchise, windfall and other profits, sales, use, real or personal property, payroll, as well as any value added, ad valorem, transfer, license, withholding, employment, unemployment, excise, severance, stamp, occupation, municipal, municipal surcharge, environmental, social security, escheat, unclaimed property and other tax, together with any interest or any penalty thereon and addition thereto, whether disputed or not.

(kk) "***Tax Authority***" means, with respect to any Tax, the Governmental Entity having jurisdiction over the assessment, determination, collection or imposition of such Tax.

(ll) "***Third Party***" means any Person other than a Party and such Party's Affiliates.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.01 shall have the meanings assigned to such terms in this Agreement.

ARTICLE II.
PURCHASE AND SALE

Section 2.01 Purchase and Sale; No Assumed Liabilities.

(a) Upon the terms and subject to the conditions of this Agreement, Buyer agrees to purchase from Seller, and Seller agrees to sell, transfer, convey, assign and deliver to Buyer, at the Closing all of Seller's right, title and interest in, to and under the Purchased Assets, in each case free and clear of all Encumbrances.

(b) For the avoidance of doubt, (i) the sale, assignment, transfer, conveyance and delivery of the Purchased Assets from Seller to Buyer shall not include the sale, transfer, conveyance, assignment, delivery, or assumption of any Liabilities from Seller to Buyer, and (ii) Buyer shall not assume or be liable for, or otherwise be obligated to pay, perform or discharge any Liabilities of Seller or its Affiliates (fixed, contingent or otherwise, and whether or not accrued), including Liabilities relating to the Purchased Assets (other than such obligations as are imposed generally by applicable Legal Requirements on the holder of the Priority Review Voucher and in respect of its use or transfer following the sale thereof pursuant to this Agreement, including, without limitation, the Priority Review Fee) (such Liabilities, "***Excluded Liabilities***"). Seller shall be solely responsible for all such Excluded Liabilities.

Section 2.02 Purchase Price. The total consideration (the "***Purchase Price***") to be paid by Buyer to Seller for all of the Purchased Assets shall be an amount equal to One Hundred Fifty-Five Million Dollars (U.S. $155,000,000) due and payable upon the Closing Date.

Section 2.03 Method of Payment. Payment of the Purchase Price to Seller shall be made in cash by wire transfer of immediately available funds to a bank account specified by Seller in writing to Buyer in the form of Valid Account Details, such designation to be made no later than three (3) Business Days prior to the Closing Date. "***Valid Account Details***" means, with respect to any bank account, the valid (a) name of bank, (b) bank's address, (c) account number, (d) account name and (e) ABA/Routing number.

Section 2.04 Tax Withholding. Buyer shall be entitled to deduct and withhold from the Purchase Price otherwise payable pursuant to this Agreement to Seller any amount required to be deducted or withheld therefrom on account of Taxes under applicable Legal Requirements relating to Taxes. Before making any such deduction or withholding, (a) Buyer shall provide to Seller no less than ten (10) days' written notice of Buyer's intention to make such deduction and withholding, and (b) Buyer shall cooperate with Seller to the extent reasonable in efforts by Seller to obtain any available reduction of or relief from such deduction or withholding to the extent permitted by applicable Legal Requirements. To the extent that any such amounts are so deducted, withheld and properly remitted to the appropriate Tax Authority in accordance with the applicable Legal Requirements, such amounts will be treated for all purposes of this Agreement as having been paid to Seller. Notwithstanding the foregoing, the Parties agree that as of the date of this Agreement, Legal Requirements do not require any amount of withholding on the Purchase Price payable to Seller.

ARTICLE III.
CLOSING

Section 3.01 Closing. The consummation of the Asset Purchase (the "***Closing***") shall be conducted telephonically or via email or other similar means of correspondence on such date to be mutually agreed upon by Buyer and Seller, which date shall be no later than the third (3rd) succeeding Business Day after all of the conditions set forth in Article VI have been satisfied or waived (other than those conditions which, by their terms, are intended to be satisfied at the Closing, but subject to satisfaction or waiver of such conditions). The date on which the Closing actually takes place is referred to in this Agreement as the "***Closing Date***."

Section 3.02 Transactions to be Effected at Closing. At the Closing,

(a) Seller shall deliver, or cause to be delivered, to Buyer an executed Bill of Sale substantially in the form attached hereto as Exhibit B;

(b) Seller shall deliver, or cause to be delivered, to Buyer an executed certificate from a duly authorized officer of the Seller certifying as to the matters set forth in Section 6.02(c);

(c) Buyer shall deliver, or cause to be delivered, to Seller an executed certificate from a duly authorized officer of the Buyer certifying as to the matters set forth in Section 6.03(c);

(d) Seller shall deliver, or cause to be delivered, to Buyer an executed certificate of the secretary (or equivalent duly authorized officer or other representative) of Seller certifying (i) that attached thereto are true and complete copies of all resolutions adopted by the board of directors of Seller authorizing the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby, and (ii) as to the incumbency of each person executing this Agreement and any other document delivered in connection herewith on behalf of Seller and that the signature of each such person on this Agreement and such other document is such person's genuine signature;

(e) Seller shall (on behalf of Buyer) submit, or cause to be submitted, to the FDA the separate notifications referred to in Section 3.02(g) and Section 3.02(h), respectively, as a submission to the Subject BLA through the FDA's Electronic Submissions Gateway under the cover letter in the form attached as Exhibit C. Seller shall provide to Buyer, promptly following their submission to the FDA, confirmation from the FDA of successful submission and a complete electronic copy of such submission (the "***Seller Notice of Transfer Submission***"). Buyer may also submit the duly executed letters provided to be delivered in Section 3.02(g) and Section 3.02(h) hereof to the FDA following Seller's notification to Buyer of its submission, and Buyer's receipt from Seller, of an electronic copy of the Seller Notice of Transfer Submission.

(f) Buyer shall pay the Purchase Price to Seller by wire transfer of immediately available funds to an account or accounts designated in writing by Seller to Buyer in the form of Valid Account Details, such designation to occur at least three (3) Business Days prior to the Closing Date;

(g) Seller shall deliver to Buyer a letter addressed to Buyer, substantially in the form set forth on Exhibit D hereto and duly executed by Seller, acknowledging the transfer of the Priority Review Voucher from Seller to Buyer, in accordance with this Agreement;

(h) Buyer shall deliver to Seller a letter addressed to Seller, substantially in the form set forth on Exhibit E hereto and duly executed by Buyer, acknowledging the transfer of the Priority Review Voucher from Seller to Buyer, in accordance with this Agreement; and

(i) Seller shall deliver to Buyer a properly completed, validly executed, true and correct Internal Revenue Service Form W-9 certifying that Seller is not subject to backup withholding for United States federal income tax purposes.

Section 3.03 Title Passage. Upon the Closing, all of the right, title and interest of Seller in and to the Purchased Assets shall pass to Buyer, free and clear of all Encumbrances.

ARTICLE IV.
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer, as of the Effective Date and the Closing Date, as follows:

Section 4.01 Organization, Standing and Power. Seller is a corporation duly organized and validly existing under the laws of Delaware. Seller has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Purchased Assets, Seller's ability to consummate the transactions contemplated by this Agreement, or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing. Seller is not in violation of its certificate of incorporation or bylaws, in each case as amended to date.

Section 4.02 Due Authority. Seller has all requisite corporate power and authority to enter into, deliver and perform its obligations under, and consummate the transactions contemplated by, this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Seller, and this Agreement has been duly executed and delivered by Seller. This Agreement, upon execution and delivery by the Parties, will constitute a valid and binding obligation of Seller enforceable against Seller in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies. The approval of Seller's stockholders is not required for the execution, delivery and performance of this Agreement or the consummation of the Asset Purchase.

Section 4.03 Noncontravention. The execution and delivery by Seller of this Agreement does not, and the consummation of the transactions contemplated hereby, including the transfer of title to, ownership in, and possession of the Purchased Assets, will not, (a) result in the creation of any Encumbrance on any of the Purchased Assets or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (i) any provision of the certificate of incorporation or bylaws of Seller, in each case as amended to date (ii) the Approval Letter or any Contract to which Seller is a party or by which it is bound or (iii) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Seller or any of the Purchased Assets (except, in the case of clauses (ii) and (iii) above, as would not, individually or in the aggregate, have an adverse effect on the ability of Seller to consummate the sale of the Purchased Assets at Closing and perform its other obligations under this Agreement or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing).

Section 4.04 No Consents. Except for the letters referenced in Section 3.02(g) and the filing of any Premerger Notification and Report Form required under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Seller to enter into, and to perform its obligations under, this Agreement.

Section 4.05 Title to Purchased Assets. Seller is the sole and exclusive owner of all right, title, and interest in and to the Purchased Assets and owns and at the Closing will transfer to Buyer good and transferable title to the Purchased Assets free and clear of any Encumbrances. Seller has performed all actions necessary to perfect its ownership of, and its ability to transfer, the Purchased Assets pursuant to this Agreement. Seller has provided to Buyer a true, correct and complete electronic copy of the Priority Review Voucher. Neither Seller nor any of its Affiliates has sold, transferred, conveyed, assigned, or delivered any Purchased Assets, to any Person, and Seller has the full and sole right to sell, transfer, convey, assign, and deliver the Purchased Assets to Buyer free and clear. At the Closing, Seller will sell, transfer, convey, assign and deliver to Buyer good and transferable title to the Purchased Assets free and clear of any Encumbrances. No Third Party is entitled to any portion of the proceeds of the transactions contemplated by this Agreement.

Section 4.06 Contracts. Except for this Agreement, there is no Contract to which Seller or any Affiliate of Seller is a party to or bound by that involves or affects (or would reasonably be expected to involve or affect) the issuance of, the ownership of, transfer or licensing of, title to, or use of any of the Purchased Assets.

Section 4.07 Compliance With Legal Requirements; FDA Communication. Seller and its Affiliates are, and at all times have been, in full compliance with each Legal Requirement that is or was applicable to (a) Seller's and its Affiliates' conduct, acts, or omissions with respect to any of the Purchased Assets or (b) any of the Purchased Assets. Seller and its Affiliates have not received any notice or other communication (whether written or oral) from any Person regarding any actual, alleged, possible or potential violation of, or failure to comply with, any such Legal Requirement, except where the failure to be in full compliance with such Legal Requirement would not reasonably be expected to have an adverse impact on the effectiveness of the Priority Review Voucher or the Buyer's ability to use, transfer, receive, hold or otherwise exploit the Priority Review Voucher after the Closing. Seller has provided to Buyer true and complete copies of the Approval Letter and all other material communications between Seller or any of its Affiliates and FDA regarding the Purchased Assets.

Section 4.08 Legal Proceedings. There is no pending, or to Seller's Knowledge, threatened, Proceeding involving Seller or any of its Affiliates, nor has there been any Proceeding involving Seller or any of its Affiliates, and neither Seller nor any of its Affiliates are a party or subject to the provisions of any Order, in each case, (a) that involves or affects (or may involve or affect) the issuance of, continued validity of, ownership of, transfer or license of, title to, or use of any of the Purchased Assets (including any such Order that seeks to prohibit or limit in any respect, or place any conditions on, the ownership or use by Buyer or its Affiliates of any of the Purchased Assets, in each case, as a result of the transactions contemplated by this Agreement), or (b) that otherwise challenges or seeks to restrain, prohibit, prevent, enjoin, alter, or delay the consummation of the transactions contemplated by this Agreement. None of the Purchased Assets are subject to any Order (other than the Approval Letter) of any Governmental Entity or arbitrator.

Section 4.09 Governmental Authorizations. Neither Seller nor any of its Affiliates is required to hold any license, registration, or permit issued by any Governmental Entity to own, use or transfer the Purchased Assets, other than such licenses, registrations or permits that have already been obtained.

Section 4.10 Revocation; Regulatory Change. The Priority Review Voucher has been duly granted and issued and has not been terminated, cancelled or revoked. Neither Seller nor any of its Affiliates or any of their respective Representatives has taken or omitted to take any action, and, to Seller's Knowledge, there are no facts or circumstances that would reasonably be expected to (with or without notice or lapse of time or both) (a) result in the termination, cancellation, or revocation of the Priority Review Voucher, or (b) result in the redemption or transfer of the Priority Review Voucher (other than pursuant to the transactions contemplated by this Agreement), or (c) preclude or interfere with the sale and transfer of the Purchased Assets to Buyer or Buyer's use of the Purchased Assets following the Closing to obtain Priority Review. To the Knowledge of the Seller, there is no term or condition imposed by the FDA on the Priority Review Voucher that is not set forth in the Approval Letter or provided for under applicable Legal Requirements. From the date that the Priority Review Voucher was issued until the Effective Date, to the Knowledge of the Seller, there has not occurred any Regulatory Change.

Section 4.11 Marketed Product. Seller or any of its Affiliates has initiated or, if not yet initiated, covenants to initiate marketing in the United States of the product approved under the Subject BLA and for which the Priority Review Voucher was awarded within the 365-day period beginning on the date of the FDA approval of the Subject BLA to the extent and in a manner required under applicable Legal Requirements so as to preclude the FDA from exercising its authority to revoke the Priority Review Voucher in each case pursuant to 21 U.S.C.§ 360ff(e)(1). In accordance with Section 529(b)(5) of the FDCA, the product approved under the Subject BLA and for which the Priority Review Voucher was awarded (a) was a drug designated for a rare pediatric disease on or prior to December 20, 2024, and (b) was approved by FDA under Section 505(b)(1) of the FDCA or Section 351(a) of the United States Public Health Service Act on or prior to September 30, 2026.

Section 4.12 Document Disclosure. Attached as Schedule 4.12 is a true, correct and complete list of all documents for which true, correct and complete copies have been made available to Buyer as of the close of business on the last Business Day immediately preceding each of the Effective Date and the Closing Date, which list includes any and all communications between Seller or its Affiliates, on the one hand, and the FDA, on the other hand, with respect to the Purchased Assets.

Section 4.13 Intent to Use. Neither Seller nor any of its Affiliates has filed or submitted, or permitted any Third Party to file or submit, to the FDA a Notice of Intent to Use the Priority Review Voucher.

Section 4.14 No Broker. Seller nor any of its Affiliates have engaged, retained or entered into any agreement with any investment banker, broker, finder or other intermediary which has been authorized to act on behalf of Seller who might be entitled to any fee or commission payable by Buyer or its Affiliates in connection with the transactions contemplated by this Agreement.

Section 4.15 Solvency. Seller is not entering into this Agreement with the intent to hinder, delay or defraud any creditor of Seller. The remaining assets of Seller after the Closing will not be unreasonably small in relation to the business in which Seller will engage after the Closing. Upon and immediately following Closing, after giving effect to all of the transactions contemplated by and in this Agreement (including the payment of the Purchase Price), Seller will not be insolvent and will have sufficient capital to continue in business and pay its debts as they become due.

Section 4.16 No Other Representations. Neither Seller nor any of its Representatives is making any representation or warranty of any kind or nature whatsoever, oral or written, express or implied, except as otherwise expressly set forth in this Article IV, and Seller hereby disclaims any such other representations and warranties.

ARTICLE V.
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller, as of the Effective Date and the Closing Date, as follows:

Section 5.01 Organization, Standing and Power. Buyer is a corporation duly organized and validly existing under the laws of [***]. Buyer has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect Buyer's ability to consummate the transactions contemplated by this Agreement. Buyer is not in violation of its certificate of incorporation or bylaws, in each case as amended to date.

Section 5.02 Authority. Buyer has all requisite corporate power and authority to enter into and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the Asset Purchase, have been duly and validly approved and authorized by all necessary corporate action on the part of Buyer, and this Agreement has been duly executed and delivered by Buyer. This Agreement, upon execution and delivery by the Parties, will constitute a valid and binding obligation of Buyer enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

Section 5.03 Noncontravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the transactions contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, revocation, suspension, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the certificate of incorporation or bylaws of Buyer, in each case as amended to date, (b) any Contract to which Buyer is a party or by which it is bound or (c) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Buyer.

Section 5.04 No Consents. Except for the letters referenced in Section 3.02(h) and the filing of any Premerger Notification and Report Form required under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Buyer to enter into, and to perform its obligations under, this Agreement.

Section 5.05 Financing. Buyer has, and will at Closing have, sufficient funds to consummate the transactions contemplated by this Agreement.

Section 5.06 No Broker. Buyer has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Buyer who would be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 5.07 Non-Reliance. Neither Seller nor any of its Affiliates nor any of their Representatives makes, or has made any representation or warranty, oral or written, express or implied, as to the accuracy or completeness of any information concerning the Purchased Assets contained herein or made available in connection with Buyer's investigation of the foregoing, except as expressly set forth in this Agreement, and Seller, its Affiliates and their Representatives expressly disclaim any and all liability that may be based on such information or errors therein or omissions therefrom. Buyer has not relied and is not relying on any statement, representation or warranty, oral or written, express or implied (including any representation or warranty as to merchantability or fitness for a particular purpose), made by Seller, any of its Affiliates or any of their Representatives, except as expressly set forth in Article IV. Neither Seller nor its Affiliates nor any of their Representatives shall have or be subject to any liability to Buyer or any other Person resulting from the distribution to Buyer, or Buyer's use of, any information, documents or materials made available to Buyer, whether orally or in writing, in any presentations, due diligence discussions or in any other form in expectation of, or in connection with, the Asset Purchase, other than as expressly set forth in this Agreement.

ARTICLE VI.
CONDITIONS TO CLOSING

Section 6.01 Conditions Precedent of Buyer and Seller. Each Party's obligations to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) HSR Act. The applicable waiting period under the HSR Act relating to the transactions contemplated by this Agreement shall have expired or been terminated.

(b) No Injunctions or Restraints. No temporary restraining order, preliminary or permanent injunction, legal restraint, prohibition or other Order issued or promulgated by a Governmental Entity preventing, prohibiting or restraining the consummation of the transactions contemplated by this Agreement shall be in effect, and there shall not be any applicable Legal Requirement that makes consummation of the transactions contemplated by this Agreement illegal.

(c) No Governmental Litigation. There shall not be any Proceeding commenced or pending by a Governmental Entity seeking to prohibit, limit, delay, or otherwise restrain the consummation of this Agreement and/or the transactions contemplated hereby.

(d) Deliverables. The Parties shall have made the deliveries contemplated under Section 3.02.

Section 6.02 Buyer's Conditions Precedent. The obligations of Buyer to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Seller in this Agreement (other than the Fundamental Representations) shall be true and correct (without giving effect to any limitation or qualification as to "materiality" (including the word "material") or "material adverse effect" set forth therein) in all material respects at and as of the Effective Date and as of the Closing Date (or, if made as of a specified period or date, as of such period or date). Each of the Fundamental Representations shall be true and correct in all respects at and as of the Effective Date and as of the Closing Date (or, in each case, if made as of a specified period or date, as of such period or date).

(b) Performance of Covenants. All of the covenants and obligations that Seller is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Seller shall have delivered to Buyer a certificate, dated as of the Closing Date and duly executed by Seller, certifying that the conditions set forth in Section 6.02(a) and Section 6.02(b) have been satisfied.

(d) No Regulatory Change. Since the Effective Date there shall not have occurred and remain in effect any Regulatory Change.

Section 6.03 Seller's Conditions Precedent. The obligations of Seller to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Buyer in this Agreement shall be true and correct in all material respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date), except to the extent that such representations and warranties are qualified by the term "material", or words of similar import, in which case such representations and warranties (as so written, including the terms "material", or words of similar import) shall be true and correct in all respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date).

(b) Performance of Covenants. All of the covenants and obligations that Buyer is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Buyer shall have delivered to Seller a certificate, dated as of the Closing Date and duly executed by Buyer, certifying that the conditions set forth in Section 6.03(a) and Section 6.03(b) have been satisfied.

ARTICLE VII.
PRE-CLOSING COVENANTS AND AGREEMENTS

Section 7.01 Antitrust Notification.

(a) The Parties shall use their commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary or desirable under applicable Legal Requirements to consummate the transactions contemplated by this Agreement. Without limiting the foregoing, Seller and Buyer shall file, or shall cause their ultimate parent entities as defined in the HSR Act to file, as soon as practicable (but not later than thirty (30) days) after the Effective Date, any notifications required under the HSR Act, and shall respond as promptly as practicable to all inquiries or requests received from the Federal Trade Commission, the Antitrust Division of the U.S. Department of Justice or any other Governmental Entity for additional information or documentation. In connection therewith, the Parties shall, or shall cause their respective Affiliates to, (i) furnish to the other Party such necessary information and reasonable assistance as the other Party may reasonably request in connection with its preparation of any filing or submission that is necessary under the HSR Act, and (ii) keep the other Party reasonably apprised of the status of any communications with, and any inquiries or requests for additional information from the applicable Governmental Entity. If made available by the relevant Governmental Entity, the Parties shall request early termination of the waiting period under the HSR Act.

(b) Subject to applicable confidentiality restrictions or restrictions required by applicable Legal Requirements, each Party will notify the other promptly upon the receipt of (a) any comments or questions from any Governmental Entity in connection with any filings made pursuant to Section 7.01 or the transactions contemplated by this Agreement and (b) any request by any Governmental Entity for information or documents relating to an investigation of the transactions contemplated by this Agreement. Without limiting the generality of the foregoing, each Party shall provide to the other (or the other's respective advisors) upon request copies of all correspondence between such Party and any Governmental Entity relating to the transactions contemplated by this Agreement. The Parties may, as they deem advisable and necessary, designate any competitively sensitive materials provided to the other under this Section 7.01 as "outside counsel only." Such materials and the information contained therein shall be given only to outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient without the advance written consent of the Party providing such materials. In addition, to the extent reasonably practicable, all discussions, telephone calls, and meetings with a Governmental Entity regarding the transactions contemplated by this Agreement shall include representatives of both Parties to the extent permitted by such Governmental Entity. Subject to applicable Legal Requirements, the Parties will consult and cooperate with each other in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, and proposals made or submitted to any Governmental Entity regarding the transactions contemplated by this Agreement by or on behalf of any Party.

(c) Notwithstanding the foregoing, nothing in this Agreement shall require, or be construed to require, the Parties or any of their respective Affiliates to offer or agree to (i) (A) sell, hold, hold separate, divest, license, discontinue or limit, before or after the Closing Date, any assets, businesses, equity holdings, intellectual property, or other interests or (B) any conditions relating to, or changes or restrictions in, the operations of any such assets, businesses, equity holdings, intellectual property or interests (including but not limited to any requirements to enter into new Contracts or modify or terminate existing Contracts), including with respect to the Purchased Assets and use of the Priority Review Voucher to obtain Priority Review of a product candidate of Buyer or its Affiliates or any other benefit associated with the Purchased Assets or (ii) any material modification or waiver of the terms and conditions of this Agreement.

(d) [***] all filing fees related to any notifications under the HSR Act.

Section 7.02 Regulatory Change Notification. Until the earlier of the Closing or the termination of this Agreement, Seller shall provide Buyer with prompt written notification of the occurrence of any Regulatory Change of which Seller becomes aware.

Section 7.03 Efforts. Without limiting the other obligations under this Agreement, during the period from the Effective Date and continuing until the earlier of the Closing or the termination of this Agreement (the "***Pre-Closing Period***"), except as otherwise expressly contemplated by this Agreement or with such other Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, each Party shall not, and shall cause its Affiliates not to, knowingly take or permit any action that, or omit to take any action the absence of which, could reasonably be expected to prevent or materially delay the satisfaction of the conditions set forth in Article VI.

Section 7.04 No Solicitation. During the Pre-Closing Period, Seller shall not and shall cause its controlled Affiliates and its or their Representatives not to, nor shall it authorize or instruct any of its other Affiliates or its or their Representatives to, (a) solicit, seek, initiate, entertain, respond to, facilitate the making of, encourage, or omit to take any action that is reasonably likely to lead to or encourage the initiation or submission of any inquiry, expression of interest, proposal or offer related to or in connection with, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) or any inquiry, proposal or offer that is reasonably likely to lead to an Alternative Transaction, (b) engage, continue, maintain or participate in any discussions or negotiations or enter into any agreement with, or provide any information to, regarding, or take any other action intended or reasonably expected to facilitate the making of any inquiry, proposal or offer to Seller that constitutes, or may reasonably be expected to lead to, any Alternative Transaction by any Person (other than Buyer or its Affiliates or their respective Representatives) other than to state that they are not permitted to have discussions, (c) release any Third Party from, or waive any provision of, any confidentiality agreement to which such Party is a party in connection with Alternative Transaction, (d) accept any inquiry, proposal or offer from any Person (other than Buyer) in respect of an Alternative Transaction, or (e) resolve to propose or agree to do any of the foregoing. Upon execution of this Agreement, Seller and its Affiliates and their respective Representatives shall immediately discontinue any ongoing discussions or negotiations (other than any ongoing discussions or negotiations with Buyer) related to an Alternative Transaction.

Section 7.05 Broker Fees. Seller shall be solely responsible for any and all fees, commissions, or other amounts payable to any investment banker, broker, finder or other intermediary engaged, retained or otherwise a party to an agreement with Seller or any of its Affiliates which has been authorized to act on behalf of Seller in connection with the transactions contemplated by this Agreement.

Section 7.06 Exclusivity; Maintenance of Priority Review Voucher. Until the earlier of the Closing or the termination of this Agreement, Seller shall not (a) transfer or assign the Priority Review Voucher to any Person other than Buyer or enter into any Contract with respect thereto, or (b) encumber or otherwise grant or allow to exist any Encumbrance on the Priority Review Voucher (other than pursuant to this Agreement), or (c) take any action or inaction that would reasonably be expected to prevent the satisfaction of the conditions set forth in Article VI, adversely affect any of the Purchased Assets or Buyer's ownership and rights with respect to any of the Purchased Assets after the Closing.

ARTICLE VIII.
INDEMNIFICATION

Section 8.01 Indemnification.

(a) Indemnification by Seller. [***] Seller will indemnify, defend and hold Buyer and its Affiliates, and their respective Representatives, successors and assigns (each a, "***Buyer Indemnitee***") harmless for, from and against any and all Liabilities, losses, damages, claims, costs and expenses (including reasonable attorneys' fees) (collectively, "***Damages***"), whether or not arising from, relating to, or otherwise in connection with a claim of a Third Party (each, a "***Third Party Claim***"), which any Buyer Indemnitee may suffer, incur, sustain, or become subject to, to the extent arising from, relating to or otherwise in connection with (i) any breach of, or inaccuracy in, any of Seller's representations and warranties made under this Agreement or any certificate delivered by Seller hereunder; (ii) any breach of, or failure to perform, any of Seller's covenants or obligations made under this Agreement or any certificate delivered by Seller hereunder; (iii) Seller's fraudulent, and/or wrongful acts, omission or misrepresentations, regardless of the form of action, related to this Agreement, and/or (iv) any Excluded Liabilities.

(b) Indemnification by Buyer. [***] Buyer will indemnify, defend and hold Seller and its Affiliates, and their respective Representatives, successors and assigns (each a, "***Seller Indemnitee***") harmless for, from and against any and all Damages whether or not arising from, relating to, or otherwise in connection with a Third Party Claim, which any Seller Indemnitee may suffer, incur, sustain, or become subject to, to the extent arising from, relating to or otherwise in connection with (i) any breach of, or inaccuracy in. any of Buyer's representations and warranties made under this Agreement or any certificate delivered by Buyer hereunder; (ii) any breach of, or failure to perform, any of Buyer's covenants or obligations made under this Agreement or any certificate delivered by Buyer hereunder; and/or (iii) Buyer's fraudulent, and/or wrongful acts, omission or misrepresentations, regardless of the form of action, related to this Agreement.

Section 8.02 Indemnification Procedures.

(a) A Person entitled to indemnification pursuant to Section 8.01 will hereinafter be referred to as an *"**Indemnitee**."* A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an *"**Indemnitor**."*

(b) A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice to the Indemnitor. Such notice shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based and an estimate, to the extent known, of the amount of Damages suffered or reasonably expected to be suffered by the Indemnitee; *provided* that the failure to give such notification or any deficiency in such notification will not relieve such Indemnitor from any obligation under this Article VIII, except to the extent such failure to give such notification or such deficiency in such notification actually and materially prejudices such Indemnitor. If the Indemnitor does not notify the Indemnitee within twenty (20) Business Days following its receipt of such notice that the Indemnitor rejects liability in the specified amount for the indemnity claimed by the Indemnitee under Section 8.01(a) or Section 8.01(b), as applicable, such indemnity claim specified by the Indemnitee in such notice shall be deemed accepted by the Indemnitor, in which case, the Indemnitee will be obligated to promptly pay the Indemnitee the full amount (subject, however, to the limitations set forth in Section 8.03) set forth in such notice with respect to such indemnity claim under this Article VIII in accordance with the terms hereof.

(c) In the event of any instituted or asserted Third Party Claim against an Indemnitee, Indemnitee shall inform Indemnitor of such Third Party Claim as soon as reasonably practicable after such Third Party Claim arises; *provided* that the failure to give such notification or any deficiency in such notification will not relieve such Indemnitor from any obligation under this Article VIII, except to the extent such failure to give such notification or such deficiency in such notification actually and materially prejudices such Indemnitor.

(d) The Indemnitor shall have the right to defend, at its sole cost and expense (with counsel reasonably selected by the Indemnitor and approved by the Indemnitee, such approval not to be unreasonably withheld, conditioned or delayed), a Third Party Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnitor to a final conclusion or settled at the discretion of the Indemnitor; provided, however, that the Indemnitor may not assume control of defense to a Third Party Claim (i) unless it covenants to the Indemnitee in writing within ten (10) Business Days after the Indemnitee has given written notice of the Third Party Claim to the Indemnitor to indemnify, defend and hold harmless the Indemnitee from and against the entirety of any and all Damages that the Indemnitee may suffer resulting from or arising out of the Third Party Claim (subject, however, to the limitations set forth in Section 8.03), (ii) in which equitable relief other than monetary damages is sought, (iii) if such Third Party Claim is brought by a Governmental Entity or is otherwise related to or arises in connection with any FDA, Tax or criminal or regulatory enforcement matter, (iv) if the Indemnitee has been advised in writing by outside counsel that a legal conflict or potential legal conflict exists between the Indemnitee and the Indemnitor in connection with conducting the defense of the Third Party Claim, or (v) settlement of, an adverse Order with respect to, or conduct of the defense of the Third Party Claim by the Indemnitor is, in the good faith judgment of the Indemnitee, likely to be materially adverse to the Indemnitee's or its Affiliates' reputation or continuing business interests (including its relationships with current or potential customers, licensors, distributors, suppliers, or other parties material to the conduct of its business); provided, further, however, that the Indemnitor may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnitee of a release from all liability in respect of such Third Party Claim; and (ii) the Indemnitee consents to such compromise or settlement, which consent shall not be unreasonably withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnitee, (B) any payment by the Indemnitee that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnitee, in which case ((A) – (C)) the Indemnitee may withhold its consent in its sole discretion. If the Indemnitor does not elect to assume control of the defense of such Third Party Claim, or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, upon at least ten (10) Business Days' prior written notice to the Indemnitor of its intent to do so, to undertake the defense of such Third Party Claim for the account of the Indemnitor (with counsel reasonably selected by the Indemnitee and approved by the Indemnitor, such approval not to be unreasonably withheld or delayed). If the Indemnitee is defending such Third Party Claim, the Indemnitee shall keep the Indemnitor apprised of all material developments with respect to such Third Party Claim and promptly provide the Indemnitor with copies of all correspondence and documents exchanged by the Indemnitee and the opposing party(ies) to such litigation. If the Indemnitor has elected to defend such Third Party Claim or if the Indemnitor has otherwise acknowledged in writing its responsibility for indemnifying a Third Party Claim, the Indemnitee may not compromise or settle such litigation without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed.

(e) The Indemnitee may participate in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnitor pursuant to this Section 8.02 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnitor shall bear such costs and expenses (i) if counsel for the Indemnitor or counsel for the Indemnitee shall have reasonably determined that counsel for the Indemnitor may not properly represent both the Indemnitor and the Indemnitee or (ii) if such participation is requested by the Indemnitor.

Section 8.03 Limitations on Indemnification. Notwithstanding anything to the contrary contained in this Agreement, the maximum aggregate amount of indemnifiable Damages that may be recovered from (a) Seller pursuant to Section 8.01(a) shall equal [***], and (b) Buyer pursuant to Section 8.01(b) shall equal [***]. Notwithstanding anything to the contrary set forth herein, except to the extent actually awarded against an Indemnitee pursuant to an Order with respect to a Third Party Claim and except for another Party's fraud, no Party shall have any liability under any provision of this Agreement (including this Article VIII) for any punitive, incidental, special or indirect damages or damages for or otherwise based on business interruption, diminution of value, loss of future revenue, profits or income, or loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement.

Section 8.04 Exclusive Remedy. From and after the Closing, except in the case of fraud and as otherwise provided in Section 11.09, the sole and exclusive remedy of any Indemnitee for any Damages that such Indemnitee may at any time suffer or incur, or become subject to, as a result of, or in connection with this Agreement, including any inaccuracy, violation or breach of any representation and warranty contained in this Agreement by any Party, or any failure by any Party to perform or comply with any covenant or agreement that, by its terms, was to have been performed, or complied with, under this Agreement, shall be indemnification in accordance with this Article VIII (subject to the applicable qualifications and limitations set forth in this Agreement).

ARTICLE IX.
TERMINATION

Section 9.01 Termination Prior to Closing. Notwithstanding any contrary provisions of this Agreement, this Agreement and the respective obligations of the Parties to consummate the transactions contemplated by this Agreement may be terminated and abandoned at any time before the Closing only as follows:

(a) upon the mutual written consent of Buyer and Seller; or

(b) by either Party, by written notice to the other Party if the Closing has not occurred on or before 11:59 p.m., Eastern Standard Time, on the date that is one hundred twenty (120) days following the Effective Date (the "***Outside Date***"); provided, however, that the right to terminate this Agreement under this Section 9.01(b) shall not be available to any Party whose material breach of any provision set forth in this Agreement is the primary cause of the failure of the Closing to occur on or before such date;

(c) by Buyer or Seller, if (i) any Legal Requirement having the effect referred to in Section 6.01(b) has been enacted, issued, promulgated, enforced or entered or (ii) any order, injunction or decree having the effect referred to in Section 6.01(b) is in effect and has become final and non-appealable;

(d) by Buyer, if Buyer is not in material breach of its obligations under this Agreement and there has been a violation or breach by Seller of any of its representations, warranties, covenants or other agreements contained in this Agreement, which has prevented or would prevent the satisfaction of any condition to the obligations of Buyer at the Closing set forth in Section 6.02, and (i) such violation or breach has not been waived by Buyer, (ii) Buyer has provided written notice to Seller of such violation or breach setting forth the allegations of violation or breach in reasonable detail, and (iii) such violation or breach cannot be or has not been cured by Seller within twenty (20) Business Days after receiving written notice thereof from Buyer (provided that in no event shall such twenty (20) Business Day extend beyond the Outside Date); or

(e) by Seller, if Seller is not in material breach of its obligations under this Agreement and there has been a violation or breach by Buyer of any of its representations, warranties, covenants or other agreements contained in this Agreement, which has prevented or would prevent the satisfaction of any condition to the obligations of Seller at the Closing set forth in Section 6.03 and (i) such violation or breach has not been waived by Seller, (ii) Seller has provided written notice to Buyer of such violation or breach setting forth the allegations of violation or breach in reasonable detail, and (iii) such violation or breach cannot be or has not been cured by Buyer within twenty (20) Business Days after receiving written notice thereof from Seller (provided that in no event shall such twenty (20) Business Day extend beyond the Outside Date).

Section 9.02 Effect of Termination. In the event of the termination of this Agreement as provided in Section 9.01: (a) written notice thereof shall forthwith be given to the other Party specifying the provision hereof pursuant to which such termination is made, (b) this Agreement shall forthwith become null and void and of no effect (except for the provisions of this Section 9.02, Section 10.04, Article I and Article XI, which shall survive any such termination), and (c) there shall be no liability on the part of Buyer or Seller except for damages resulting from any breach of this Agreement prior to termination of this Agreement by Buyer or Seller.

ARTICLE X.
ADDITIONAL COVENANTS

Section 10.01 Further Assurances.

(a) The Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including without limitation any notifications or filings required to be made to the FDA in connection with the transfer of the Purchased Assets, and shall (i) furnish upon request to each other such further information, (ii) execute and deliver to each other such other documents, and (iii) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the transactions contemplated by this Agreement, including the use by Buyer, its Affiliates or their respective successors and assigns of the Priority Review Voucher in accordance with its terms and applicable Legal Requirements.

(b) Without limiting the foregoing, Buyer and Seller agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment of the Purchased Assets.

Section 10.02 Compliance with Legal Requirements. Seller shall, and shall cause its Affiliates and each of their respective successors in interest and assigns to the product approved under the Subject BLA to, at all times comply with all Legal Requirements applicable to the Purchased Assets, including any and all Legal Requirements applicable to the validity, use or transfer of the Priority Review Voucher. Seller shall promptly forward to Buyer any communications or notices it or its Affiliates, or any successors in interest to the product approved under the Subject BLA receive from any Governmental Entity in respect of or otherwise impacting the Purchased Assets.

Section 10.03 Marketing. Seller shall, and shall cause its Affiliates and each of their respective successors in interest and assigns to market the product approved under the Subject BLA in the United States within the three hundred and sixty-five (365) day period beginning on the date of the FDA approval of the Subject BLA, to the extent and in a manner required under Section 529(e)(1) of the FDCA to preclude FDA from exercising its authority to revoke the Priority Review Voucher.

Section 10.04 Nondisclosure.

(a) Subject to disclosures permitted or contemplated by Section 10.05, with respect to Confidential Information received from or on behalf of a Party, the other Party will (i) keep such Confidential Information confidential, (ii) not use any such Confidential Information for any reason other than to carry out the intent and purpose of this Agreement, and (iii) not disclose any such Confidential Information to any Person, except in each case as otherwise expressly permitted by this Agreement or with the prior written consent of the disclosing Party.

(b) Each Party may disclose Confidential Information of the other Party only to its Affiliates and to their respective Representatives.

(c) Each Party will (i) enforce the terms of this Section 10.04 as to its Affiliates and their respective Representatives, (ii) take such action to the extent necessary to cause its Affiliates and their respective Representatives to comply with the terms and conditions of this Section 10.04, and (iii) be responsible and liable for any breach of this Section 10.04 by it or its Affiliates and their respective Representatives.

(d) If a Party becomes compelled by a court or is requested by a Governmental Entity to make any disclosure that is prohibited or otherwise constrained by this Section 10.04, such Party shall provide the disclosing Party with prompt notice of such compulsion or request (to the extent legally permitted) so that it may seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section 10.04. In the absence of a protective order or other remedy, the Party subject to the requirement to disclose may disclose that portion (and only that portion) of the Confidential Information that, based upon advice of its counsel, it is legally compelled to disclose or that has been requested by such Governmental Entity; provided, however, that such Person shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any Person to whom any Confidential Information is so disclosed.

(e) Nothing herein shall prohibit or otherwise restrict the disclosure of any Confidential Information by or on behalf of Buyer or its Affiliates to the FDA or other Governmental Entity to the extent required by the FDA or such other Governmental Entity in connection with any filing, application or request for regulatory approval or to enable the use or transfer of the Priority Review Voucher; provided that Buyer, its Affiliates and their respective Representatives shall use commercially reasonable efforts to obtain confidential treatment for any such disclosures.

Section 10.05 Disclosures Concerning this Agreement. The press release with respect to the execution of this Agreement that is attached as Exhibit F hereto shall be issued by Seller on or on the next Business Day following the Effective Date. Buyer and Seller agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement, or that identifies the other Party as party to this Agreement or the acquiror of the Priority Review Voucher, without the prior written consent of the other Party, except as required by a Governmental Entity or applicable Legal Requirement (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party with advance notice of such required disclosure, and an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party). Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate only such information concerning this Agreement as was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement. Each Party acknowledges that the other Party, or the other Party's parent entity, as a publicly traded company is legally obligated to make timely disclosures of material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission.

Section 10.06 Expenses. Whether or not the Asset Purchase and the other transactions contemplated by this Agreement are consummated, and except as otherwise expressly set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred or owed in connection with the purchase and sale of the Purchased Assets, this Agreement and the transactions contemplated hereby.

ARTICLE XI.
GENERAL PROVISIONS

Section 11.01 Survival. The representations and warranties of Seller and Buyer contained in this Agreement, and liability for the breach thereof, shall survive the Closing and shall remain in full force and effect for a period of twenty-four (24) months following the Closing Date; provided, however, that (a) all covenants that by their terms was to be performed at or prior to the Closing and all Fundamental Representations and any claims for Fraud shall survive the Closing Date and remain in full force and effect until the later of (i) the date that is six (6) years after the Closing Date, and (ii) the expiration of the applicable statute of limitations, and (b) covenants which are by their terms to be performed following the Closing shall survive the Closing and remain in full force and effect until performed in accordance with their terms. Notwithstanding the foregoing, if written notice of a claim has been given in the manner required by Section 8.02 prior to the expiration of the applicable survival period by the Party seeking indemnification for such claim, then the relevant covenants, representations and warranties of the other Party shall survive as to such claim until such claim has been finally resolved pursuant to Article VIII.

Section 11.02 Transfer Taxes and Fees. Any and all sales, excise, use, value-added and similar taxes, fees or duties assessed or incurred by reason of the sale by Seller and the purchase by Buyer of the Purchased Assets hereunder ("***Transfer Taxes***") shall be borne by Buyer regardless of which Party such taxes, fees or duties are assessed against. The Party that is primarily responsible for the filing of any Tax return or other documentation with respect to Transfer Taxes shall promptly prepare and file such Tax return or documentation, as applicable, and the other Party shall provide such cooperation in connection therewith as may be reasonably requested by the filing Party. Buyer, its Affiliates, or any Buyer transferee of the Priority Review Voucher shall be solely responsible for the payment of the priority review fee described in 21 U.S.C. § 360ff(c) (the "***Priority Review Fee***") and all other user fees applicable to the human drug application for which the Priority Review Voucher is redeemed, following the Closing. For the avoidance of doubt, following the Closing, Seller shall have no liability or obligation for any such fees or Transfer Taxes.

Section 11.03 Notices. Any notice or other communication required or permitted to be delivered to any Party shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; (b) on the date sent by e-mail of a PDF document (with confirmation of transmission) if sent prior to 5:00 p.m. in the time zone of the intended recipient on a Business Day, and otherwise on the next Business Day or (c) upon such Party's receipt after being sent by registered mail, by courier or express delivery service; or (d) upon confirmation of receipt during normal business hours on a Business Day or, if received after normal business hours, on the next Business Day, after being sent by facsimile, in any case to the address or facsimile number set forth beneath the name of such Party below (or to such other address as such Party shall have specified in a written notice given to the other Party in accordance with this Section 11.03):

(a) if to Buyer, to:

[***]

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

[***]

(b) if to Seller, to:

Abeona Therapeutics, Inc.
6555 Carnegie Avenue, 4th Floor
Cleveland, OH 44103
Attention: Chief Legal Officer
Email: [***]

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

Covington & Burling LLP
620 8th Avenue
New York, NY 10018
Attention: Stephen Infante
Email: [***]

Section 11.04 Construction.

(a) The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

(b) As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation" and the word "or" is not intended to be exclusive unless expressly indicated otherwise. The words "will" and "shall" have the same meaning. "Extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if."

(c) The words "hereof," "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. Except as otherwise indicated, (i) all references in this Agreement to "Articles," "Sections," "Schedules" or "Exhibits" are intended to refer to Articles, Sections, Schedules or Exhibits of this Agreement, and (ii) references in any Section to any clause are references to such clause of such Section.

(d) Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or).

(e) Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

(f) The captions, table of contents and headings in this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement.

(g) Unless otherwise specified, (i) references to any applicable law or other Legal Requirement shall be deemed to refer to such law or Legal Requirement as amended from time to time and to any rules, regulations or interpretations promulgated thereunder and (ii) references to any agreement or Contract are to that agreement or Contract as amended, modified, supplemented, extended or renewed from time to time in accordance with the terms hereof and thereof.

Section 11.05 Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that all Parties need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission or facsimile shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

Section 11.06 Entire Agreement. This Agreement, including all exhibits and schedules attached hereto and the Mutual Confidentiality Agreement by and between the Parties (or, in the case of Buyer, its Affiliate), dated [***], sets forth the entire understanding of the Parties relating to the subject matter hereof and supersedes all prior agreements and understandings among or between the Parties relating to the subject matter hereof.

Section 11.07 Assignment. No Party will have the right to assign this Agreement, in whole or in part, by operation of law or otherwise, without the other Party's express prior written consent. Any attempt to assign this Agreement without such consent, will be null and void. Notwithstanding the foregoing, any Party may assign this Agreement, in whole or in part, without the consent of the other Party: (a) to a Third Party that succeeds to all or substantially all of its assets or business related to this Agreement (whether by sale, merger, operation of law or otherwise); or (b) to an Affiliate of such Party. For the avoidance of doubt, no assignment made pursuant to this Section 11.07 shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the foregoing, this Agreement will bind and inure to the benefit of each Party's successors and permitted assigns.

Section 11.08 Severability. If any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the Parties. The Parties shall use commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

Section 11.09 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by law or equity upon such Party, and the exercise by a Party of any one remedy shall not preclude the exercise of any other remedy and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief. The Parties agree that irreparable harm would occur in the event that the transactions contemplated hereby are not consummated in accordance with the terms of this Agreement, and that money damages or other legal remedies would not be an adequate remedy for any such harm. Accordingly, the Parties acknowledge and hereby covenant and agree that in the event of any failure to strictly comply with or breach or threatened breach of the covenants, agreements, or obligations set forth in this Agreement, then in addition to any other remedy available at law or in equity, the non-breaching Party will be entitled to receive an injunction or injunctions to prevent or restrain any noncompliance, breaches or threatened breaches of this Agreement, and to specifically enforce the terms and provisions of this Agreement to enforce compliance with the covenants, agreements, and obligations under this Agreement. Each Party hereby covenants and agrees not to raise, and irrevocably waives, any objections to the availability of such relief that a remedy at law would be adequate and that a bond or other security will be required.

Section 11.10 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of law. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the state and federal courts in Delaware solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

Section 11.11 WAIVER OF JURY TRIAL. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

Section 11.12 Amendment; Extension; Waiver. Subject to the provisions of applicable Legal Requirements, the Parties may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties. At any time, any Party may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Party, (b) waive any inaccuracies in the representations and warranties made to such Party contained herein or (c) waive compliance with any of the agreements or conditions for the benefit of such Party contained herein. Any agreement on the part of a Party to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such Party. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement.

Section 11.13 Representation By Counsel; Interpretation. Seller and Buyer each acknowledge that it has been represented by its own legal counsel in connection with this Agreement and the transactions contemplated by this Agreement. Accordingly, any rule of law, or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it, has no application and is expressly waived.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, this Agreement has been executed on behalf of each of the Parties hereto as of the date first above written.

ABEONA THERAPEUTICS INC.

By: /s/ Vishwas Seshadri
Name: Vishwas Seshadri, Ph.D., M.B.A.
Title: Chief Executive Officer

[Signature Page to APA]

IN WITNESS WHEREOF, this Agreement has been executed on behalf of each of the Parties hereto as of the date first above written.

[***]

By: [***]
Name: [***]
Title: [***]

[Signature Page to APA]

EXHIBIT 31.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Vishwas Seshadri, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended June 30, 2025, of Abeona Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2025

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Vazzano, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended June 30, 2025, of Abeona Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2025

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Vishwas Seshadri, President and Chief Executive Officer of the Company, and Joseph Vazzano, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2025

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2025

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)