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 September 30, 2026

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: 001-36620

ELEDON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-1000967**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
19800 MacArthur Blvd., Suite 250 Irvine, California	**92612**
(Address of principal executive offices)	**(Zip Code)**

(949) 238-8090
Registrant's telephone number, including area code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ELDN	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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of November 10, 2026, there were 84,459,713 shares of the Registrant's common stock outstanding.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. Any statements other than statements of historical or current fact in this Quarterly Report on Form 10-Q are forward-looking statements. In some instances, you can identify forward-looking statements by the use of words such as "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "could," "may," "will," "should," "potentially" and similar expressions, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding:

- our product development plans, expectations for and the timing of commencement, enrollment, completion, data, and release of results of clinical trials for our product candidates;
- our expectations regarding the potential uses, markets and efficacies of our product candidates;
- our estimates regarding our liquidity, expenses, capital requirements and needs for additional financing;
- our strategies with respect to our preclinical and clinical development programs, including our expectations regarding the production of clinical quantities of our product candidates;
- our plans, strategy and timing to obtain and maintain regulatory approvals of our product candidates;
- our expectations regarding competitive conditions for our product candidates; and
- our expectations about our future financial performance or condition.

Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including the factors listed under "Risk Factor Summary" below. These risks and uncertainties, as well as other risks and uncertainties that could cause the Company's actual results to differ significantly from the forward-looking statements contained herein, are described in greater detail in Part II, Item 1A. *Risk Factors* in this Quarterly Report on Form 10-Q.

Forward-looking statements contained in this Quarterly Report on Form 10-Q are based on our current beliefs, assumptions, expectations, estimates and projections, which may be impacted by known or unknown factors. Any forward-looking statements contained in this Quarterly Report on Form 10-Q speak only as of the date hereof and not as of any future date, and the Company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are therefore cautioned not to place undue reliance on the forward-looking statements included in this Quarterly Report on Form 10-Q.

The market data and certain other statistical information used in this Quarterly Report on Form 10-Q are based on independent industry publications, governmental publications, reports by market research firms or other independent sources. Some data are also based on our good faith estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

RISK FACTOR SUMMARY

The following summarizes the principal factors that make an investment in the Company speculative or risky, all of which are more fully described in Part II, Item 1A. *Risk Factors* in this Quarterly Report on Form 10-Q. This summary should be read in conjunction with the Risk Factors section and should not be relied upon as an exhaustive summary of the material risks facing our business. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

- We will require additional funding to be able to complete the development of our lead drug candidate. If we are unable to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.
- Our financial condition raises substantial doubt as to our ability to continue as a going concern if we are unable to raise additional financing to fund our operations. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.
- Our short operating history and shifts in our business strategy may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant operating losses since our inception and expect that we will continue to incur losses over the next several years and may never achieve or maintain profitability.
- Future issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.
- We have no products approved for commercial sale, and our lead product candidate, tegoprubart, remains in clinical development and may not be successfully developed or approved. If we are unable to successfully develop and commercialize tegoprubart or any other product candidate, or if we experience significant delays in doing so, our business will be materially harmed.
- Public health crises, including pandemics or epidemics, could adversely affect our business.
- Unfavorable global economic conditions could have a material adverse effect on our business.
- Adverse conditions in the financial markets, including bank failures, could adversely affect our liquidity and financial performance.
- Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration ("FDA") or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development, formulation and commercialization of our product candidates.
- The results of non-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and there is a risk that additional non-clinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States or that subsequent studies will not match results seen in prior studies.
- Delays or difficulties in the enrollment of patients in clinical trials could delay or prevent our receipt of necessary regulatory approvals and increase expenses for the development of our product candidates.
- Our ability to conduct clinical trials in some jurisdictions outside of the United States may be adversely affected.
- If severe adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.
- Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.

- Legislation regulating the pharmaceutical and healthcare industries may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.
- Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data and have a material adverse effect on our reputation, business, financial condition or results of operations.
- The compromise of privacy, security, integrity or confidentiality of sensitive information related to our business or failure to comply with confidentiality and data privacy obligations could have a material adverse effect on our business.
- Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.
- If our current product candidates, or a future product candidate receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.
- Our reliance on third parties for the manufacture of our product candidates for non-clinical and clinical trials, and for eventual commercialization, increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.
- We depend on contract research organizations ("CROs") and other contracted third parties to perform non-clinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control.
- If we are unable to obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- Our stock price could be volatile, and the market price of our common stock may drop unexpectedly.
- If we fail to maintain effective internal controls, we may conclude that our internal control over financial reporting is not effective, which could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.
- Provisions in our corporate charter and under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove our current management.

WEBSITE REFERENCES

In this Quarterly Report on Form 10-Q, we make references to our website at *www.eledon.com*. References to our website through this Form 10-Q are provided for convenience only and the content on our website does not constitute a part of, and shall not be deemed incorporated by reference into, this Quarterly Report on Form 10-Q.

ELEDON PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2026

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements - Unaudited

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,882	$ 22,808
Short-term investments	62,790	110,528
Prepaid expenses and other current assets	4,038	2,352
Total current assets	73,710	135,688
Operating lease asset, net	358	613
In-process research and development	32,386	32,386
Other assets	185	322
Total assets	$ 106,639	$ 169,009
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,842	$ 3,627
Current operating lease liabilities	341	358
Accrued expenses and other liabilities	8,519	14,359
Total current liabilities	11,702	18,344
Deferred tax liabilities	2,187	2,187
Non-current operating lease liabilities	35	283
Warrant liabilities	22,901	11,416
Total liabilities	36,825	32,230
Commitments and contingencies (Note 7)		
Convertible preferred stock, 5,000,000 shares authorized at September 30, 2026 and December 31, 2025:		
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at September 30, 2026 and December 31, 2025	2,151	2,151
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 75,800 and 110,086 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	36,867	53,543
Stockholders' equity:		
Common stock, $0.001 par value, 450,000,000 shares authorized at September 30, 2026 and 300,000,000 shares authorized at December 31, 2025; 81,442,402 and 75,430,033 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	82	75
Additional paid-in capital	506,631	482,189
Accumulated other comprehensive income (loss)	(126)	24
Accumulated deficit	(475,791)	(401,203)
Total stockholders' equity	30,796	81,085
Total liabilities, convertible preferred stock and stockholders' equity	$ 106,639	$ 169,009

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share data)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 17,761	$ 14,969	$ 53,188	$ 48,776
General and administrative	3,911	4,101	12,534	12,991
Total operating expenses	21,672	19,070	65,722	61,767
Loss from operations	(21,672)	(19,070)	(65,722)	(61,767)
Other income, net	714	1,047	2,694	3,680
Change in fair value of warrant liabilities	17,025	564	(11,560)	22,917
Net loss	$ (3,933)	$ (17,459)	$ (74,588)	$ (35,170)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities, net	(12)	57	(150)	(17)
Comprehensive loss	$ (3,945)	$ (17,402)	$ (74,738)	$ (35,187)
Basic and diluted net loss per share of common stock	$ (0.03)	$ (0.21)	$ (0.63)	$ (0.42)
Weighted-average common shares outstanding, basic and diluted	114,722,339	77,156,068	113,601,123	77,146,407
Basic and diluted net loss per share of Series X and Series X[1] non-voting convertible preferred stock	$ (1.83)	$ (11.61)	$ (34.84)	$ (23.40)
Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic and diluted	80,222	114,508	96,076	114,508

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Convertible Preferred Stock				Stockholders' Equity					
	Series X Non-Voting Convertible Preferred Stock		Series X[1] Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	(Loss)	Deficit	Equity
Balance as of December 31, 2025	4,422	$ 2,151	110,086	$ 53,543	75,430,033	$ 75	$ 482,189	$ 24	$ (401,203)	$ 81,085
Issuance of common stock in connection with vesting of restricted stock units					25,725					—
Issuance of common stock in settlement of liability					395,964	1	597			598
Stock-based compensation							2,202			2,202
Other comprehensive loss								(96)		(96)
Net loss									(39,025)	(39,025)
Balance as of March 31, 2026	4,422	$ 2,151	110,086	$ 53,543	75,851,722	$ 76	$ 484,988	$ (72)	$ (440,228)	$ 44,764
Stock option exercise					36,000		91			91
Issuance of common stock in connection with vesting of restricted stock units					12,500					—
Conversion of Series X[1] Preferred Stock to Common Stock			(34,286)	(16,676)	1,904,775	2	16,674			16,676
Pre-funded Warrants Exercise to Common Stock					3,086,407	3	(3)			—
Stock-based compensation							3,154			3,154
Other comprehensive loss								(42)		(42)
Net loss									(31,630)	(31,630)
Balance as of June 30, 2026	4,422	$ 2,151	75,800	$ 36,867	80,891,404	$ 81	$ 504,904	$ (114)	$ (471,858)	$ 33,013
Stock option exercise					181,250		242			242
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement					239,878		(903)			(903)
Issuance of common stock in connection with exercise of common stock warrants					129,870	1	464			465
Stock-based compensation							1,924			1,924
Other comprehensive loss								(12)		(12)
Net loss									(3,933)	(3,933)
Balance as of September 30, 2026	4,422	$ 2,151	75,800	$ 36,867	81,442,402	$ 82	$ 506,631	$ (126)	$ (475,791)	$ 30,796

	Convertible Preferred Stock				Stockholders' Equity					
	Series X Non-Voting Convertible Preferred Stock		Series X[1] Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	(Loss)	Deficit	Equity
Balance as of December 31, 2024	4,422	$ 2,151	110,086	$ 53,543	59,789,275	$ 60	$ 417,946	$ 26	$ (355,586)	$ 62,446
Issuance of common stock in connection with vesting of restricted stock units					42,500					—
Stock option exercise					50,000		115			115
Stock-based compensation							2,864			2,864
Other comprehensive loss								(44)		(44)
Net loss									(6,495)	(6,495)
Balance as of March 31, 2025	4,422	$ 2,151	110,086	$ 53,543	59,881,775	$ 60	$ 420,925	$ (18)	$ (362,081)	$ 58,886
Stock-based compensation							2,694			2,694
Other comprehensive loss								(30)		(30)
Net loss									(11,216)	(11,216)
Balance as of June 30, 2025	4,422	$ 2,151	110,086	$ 53,543	59,881,775	$ 60	$ 423,619	$ (48)	$ (373,297)	$ 50,334
Stock-based compensation	—	—	—	—	—	—	2,428	—	—	2,428
Other comprehensive income	—	—	—	—	—	—	—	57	—	57
Net loss	—	—	—	—	—	—	—	—	(17,459)	(17,459)
Balance as of September 30, 2025	4,422	$ 2,151	110,086	$ 53,543	59,881,775	$ 60	$ 426,047	$ 9	$ (390,756)	$ 35,360

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (74,588)	$ (35,170)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	255	232
Accretion of investment discounts	(934)	(1,375)
Stock-based compensation	7,280	7,986
Change in fair value of warrant liabilities	11,560	(22,917)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,549)	540
Accounts payable, accrued expenses and other liabilities	(6,028)	2,686
Operating lease liabilities	(265)	(232)
Net cash used in operating activities	(64,269)	(48,250)
Cash flows from investing activities:		
Purchase of available-for-sale short-term investments	(68,755)	(91,909)
Proceeds from maturities of available-for-sale short-term investments	117,278	123,164
Net cash provided by investing activities	48,523	31,255
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants	390	—
Payment of taxes withheld on issuance of restricted stock units	(903)	—
Proceeds from exercise of stock options	333	115
Net cash (used in) provided by financing activities	(180)	115
Net change in cash and cash equivalents	(15,926)	(16,880)
Cash and cash equivalents at beginning of period	22,808	20,549
Cash and cash equivalents at end of period	$ 6,882	$ 3,669
Supplemental disclosure of non-cash investing and financing activities		
Non-cash activities:		
Issuance of common stock in settlement of liability	$ 598	$ —
Cashless conversion of Series X[1] non-voting convertible preferred stock for common stock	$ 16,676	$ —
Settlement of warrant liability	$ 75	$ —
Unrealized loss on available-for-sale securities, net	$ (150)	$ (17)

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Description of Business

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company using its immunology expertise in targeting the CD40 Ligand ("CD40L") pathway to develop therapies to protect transplanted organs and prevent rejection, and to treat amyotrophic lateral sclerosis ("ALS"). The Company's lead compound in development is tegoprubart, an IgG1, anti-CD40L antibody with high affinity for the CD40L, a well-validated biological target that we believe has broad therapeutic potential. Unless otherwise indicated, references to the terms "Eledon," "our," "us," "we," or the "Company" refer to Eledon Pharmaceuticals, Inc. and its wholly owned subsidiaries, on a consolidated basis.

On September 14, 2020, Eledon acquired Anelixis Therapeutics, Inc. ("Anelixis"), a privately held clinical stage biotechnology company developing a next generation anti-CD40L antibody as a potential treatment for organ and cellular transplantation, autoimmune diseases, and neurodegenerative diseases. The Company maintains its corporate headquarters in Irvine, California and has research and development facilities in Burlington, Massachusetts.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and Article 8 of Regulation S-X requirements as set forth by the Securities and Exchange Commission ("SEC") for interim financial information and reflect all adjustments and disclosures, which are, in the opinion of management, of a normal and recurring nature, and considered necessary for a fair presentation of the financial information contained herein. Pursuant to these rules and regulations, the unaudited condensed consolidated financial statements do not include all information and notes necessary for a complete presentation of results of operations and comprehensive loss, financial position, and cash flows in conformity with GAAP.

The accompanying unaudited condensed consolidated financial statements and notes should be read in conjunction with the audited consolidated financial statements and accompanying notes of Eledon for the year ended December 31, 2025 included in the Company's Annual Report on Form 10-K filed by the Company with the SEC on March 19, 2026. The results of operations and comprehensive loss for the three and nine months ended September 30, 2026 are not necessarily indicative of results expected for the full fiscal year or any other future period.

Principles of Consolidation

Eledon, a Delaware corporation, owns 100% of the issued and outstanding common stock or other ownership interest in Anelixis Therapeutics, LLC, a Delaware limited liability company, and Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic"). Otic owns 100% of the issued and outstanding common stock or other ownership interest in its U.S. subsidiary, Otic Pharma, Inc.

The functional currency of the Company's foreign subsidiary is the U.S. Dollar; however, certain expenses, assets and liabilities are transacted at the local currency. These transactions are translated from the local currency into U.S. Dollars at exchange rates during or at the end of the reporting period. The activities of the Company's foreign subsidiary are not significant to the unaudited condensed consolidated financial statements.

All significant intercompany accounts and transactions among the entities have been eliminated from the unaudited condensed consolidated financial statements.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to stock-based compensation expense, warrant liabilities, the fair value of right-of-use ("ROU") assets and liabilities, accruals for liabilities, impairment of long-lived assets, and other matters that affect the consolidated financial statements and related disclosures. Management

bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ materially from those estimates under different assumptions or conditions and the differences may be material to the consolidated financial statements.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured institutions in excess of federally insured limits and invests in short-term investments with the primary objective of seeking to preserve principal, achieve liquidity requirements and safeguard invested funds. We believe that the Company is not exposed to significant credit risk due to the financial position of the depository institution in which those deposits are held and the nature, including the credit ratings, of our cash equivalents and short-term investments, but we have not eliminated all credit risk.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts, money market funds, U.S. government securities and U.S. government agency securities. Cash and cash equivalents are valued at cost, which approximates their fair value due to the short-term maturities of these investments.

Risks, Liquidity, and Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments that might result from the outcome of this uncertainty.

Since inception, the Company has devoted substantially all of its resources to research and development activities, including pre-clinical studies and clinical trials, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. The Company has incurred recurring net losses and negative cash flows from operating activities since its inception and expects to continue to incur significant operating losses and negative cash flows from operations for the foreseeable future as it advances the clinical development of its product candidates.

The Company recorded a net loss of $74.6 million for the nine months ended September 30, 2026. As of September 30, 2026, the Company had cash and cash equivalents and short-term investments of $69.7 million, working capital of $62.0 million and an accumulated deficit of $475.8 million. Based on the Company's current operating plan, the Company expects that, within the next twelve months, its existing cash, cash equivalents, short-term investments and other available resources will not be sufficient to fund its planned operations, including our planned initiation of a Phase 3 clinical trial in kidney transplantation or continued advancement of our islet cell transplantation program, and satisfy its obligations as they become due unless it obtains additional financing. Based on these conditions and events that are known and reasonably knowable as of the date these condensed consolidated financial statements are issued, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern.

Accordingly, the Company intends to seek additional capital through public or private equity or debt financings, including through its “at-the-market” equity offering program, or other securities issuances, strategic collaborations, licensing arrangements, credit or loan facilities and other available sources. The Company's ability to obtain additional financing is dependent on a number of factors, including, but not limited to, market conditions, investor demand for the Company's common stock or other securities, the progress of its development programs and other business risks and uncertainties. There can be no assurance that additional financing will be available when needed or on terms acceptable to the Company.

Although management intends to obtain additional financing through the sources described above, these plans are subject to market conditions and other factors outside the Company's control. Accordingly, management has concluded that its plans do not alleviate the substantial doubt about the Company's ability to continue as a going concern.

The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets, or the amounts and classification of liabilities, or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

Reportable Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company operates as one operating and one reportable segment, focused on the development of tegoprubart, to develop therapies to protect transplanted organs and prevent rejection, and to treat ALS. The Company's measure of segment profit or loss is net loss. The CODM is the chief executive officer. The CODM manages and allocates resources to the operations of the Company on a total company basis. Managing and allocating resources on a consolidated basis enables the CODM to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects that are in line with the Company's long-term company wide strategic goals. Consistent with this decision-making process, the CODM uses consolidated net income (loss) for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The measure of segment assets is reported on the balance sheet as total consolidated assets.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment. A reconciliation to the consolidated net loss for the three and nine months ended September 30, 2026 and 2025 is included at the bottom of the table below (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Tegoprubart - kidney transplantation programs	$ 6,526	$ 9,363	$ 17,632	$ 26,600
Tegoprubart - other development programs	—	—	—	(168)
Manufacturing	6,867	1,736	21,814	11,031
Personnel-related expenses	4,323	3,664	12,221	10,808
Stock-based compensation	1,924	2,428	7,280	7,986
Other segment items*	2,032	1,879	6,775	5,510
Total operating expenses	21,672	19,070	65,722	61,767
Loss from operations	(21,672)	(19,070)	(65,722)	(61,767)
Other income, net	714	1,047	2,694	3,680
Change in fair value of warrant liabilities	17,025	564	(11,560)	22,917
Net loss	$ (3,933)	$ (17,459)	$ (74,588)	$ (35,170)

** Other segment items included in total operating expenses primarily consist of consulting, professional fees, facilities, insurance and information technology.*

In-Process Research and Development

Amounts allocated to in-process research and development ("IPR&D") in connection with a business combination are recorded at fair value and are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and amortized over a period that best reflects the economic benefits provided by these assets. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested annually for impairment or more frequently if indicators of impairment exist.

The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value is less than its carrying amount, then a quantitative assessment is unnecessary. If the quantitative assessment is deemed necessary, the excess of the carrying value over fair value will be recorded as an impairment. The qualitative assessment focuses on the key inputs, assumptions and rationale utilized in the establishment of the carrying value and related changes since the last quantitative assessment. Based on the results of the Company's annual qualitative assessment, the Company concluded that it is not more likely than not that IPR&D was impaired for any of the periods presented.

Research and Development Expenses

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under contracts with third parties may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

The Company contracts with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to its vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. The Company's accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. These contracts may be terminated by the Company upon written notice and the Company is generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances the Company may be further responsible for termination fees and penalties. The Company estimates its research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to the Company at that time.

Stock-Based Compensation

The Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value.

The fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on publicly traded biotechnology and pharmaceutical companies with comparable business characteristics, clinical stages of development, and organizational scale, including employee headcount, primarily consisting of companies with Phase II or Phase III clinical programs. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, the Company determined the expected life assumption using the simplified method for stock options granted to employees, which is an average of the options' ordinary vesting period and the contractual term. For stock options granted to the Company's board of directors (the "Board"), the Company determined the expected life assumption using the simplified method as the starting point with an average period of 12 months added to take into account the extended range of time of 12 to 18 months that vested stock options granted to Board members may be exercised upon termination. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Restricted Stock Units ("RSUs") are measured and recognized based on the quoted market price of our common stock on the date of grant. Upon vesting, the Company typically net share settles RSUs to satisfy employees' minimum statutory tax withholding obligations. The Company withholds a number of shares with a fair value, based on the closing price of its common stock on the vesting date, equal to the required tax withholding, which does not exceed the maximum statutory tax rates in the applicable jurisdictions. The Company remits the cash equivalent of the withheld shares to the appropriate taxing authorities on behalf of the employees. These net-share settlements had the effect of share repurchases by the Company as they reduced the number of shares that would have otherwise been issued as a result of the vesting.

Employee Benefit Plan

The Company maintains a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code covering all employees who meet eligibility requirements. Participants may contribute a portion of their compensation subject to Internal Revenue Service limitations. The Company provides matching contributions in accordance with the terms of the plan.

The Company recognized expense related to employer contributions to the plan of $0.1 million for each of the three months ended September 30, 2026 and 2025 and $0.4 million for each of the nine months ended September 30, 2026 and

2025.

Net Loss Per Share

Basic and diluted net loss per share are calculated using the two-class method in accordance with Accounting Standards Codification ("ASC") Topic 260, Earnings Per Share. The two-class method allocates undistributed losses to the Company's outstanding common stock, and the Series X and Series X[1] non-voting convertible preferred stock, $0.001 par value (the "Preferred Stock"), based on each class's proportionate share of the total weighted-average shares outstanding. Since the Company has never declared dividends, net loss and undistributed losses are equivalent. The process is used for both common stock and Preferred Stock.

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. As the rights and preferences of the Preferred Stock are substantially identical to each other, they are considered a single class of common stock for earnings per share purposes.

Common Stock Warrants and Pre-Funded Warrants

The Company accounts for issued common stock warrants and pre-funded warrants either as a liability or equity in accordance with ASC 480-10, Distinguishing Liabilities from Equity ("ASC 480-10") and ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity ("ASC 815-40"). The Company first evaluates the warrants under ASC 480-10 to determine whether the instruments should be classified as liabilities, including whether the warrants embody an obligation to repurchase the Company's shares, require or may require cash settlement, or represent obligations to issue a variable number of shares with a monetary value that is fixed or indexed to something other than the Company's stock. If liability classification is not required under ASC 480-10, the Company then applies ASC 815-40. Under ASC 815-40, contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in the consolidated statements of operations and comprehensive loss as a gain or loss. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP standard. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Recent Accounting Pronouncements Issued But Not Adopted

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses," which requires disaggregated disclosure of income statement expenses for public business entities ("PBEs"). In January 2025, the FASB issued ASU No. 2025-01 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)," which clarified the effective date for ASU 2024-03. These amendments are intended to provide more information about types of expenses in commonly presented expense captions. The amendments in this update are effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, and early adoption is permitted. The Company is currently evaluating the impact on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-07, Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606) ("ASU 2025-07"), which amends the accounting guidance to exclude from derivative accounting non-exchange-traded contracts with underlyings that are based on operations or activities specific to one of the parties to the contract. ASU 2025-07 is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. The Company is currently evaluating the impact on its consolidated financial statements and related disclosures.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the SEC did not, or are not believed by management to, have a material impact on the Company's present or future financial position, results of operations or cash flows.

Note 3. Short-Term Investments

The objectives of the Company's investment policy are to preserve principal, meet the Company's liquidity requirements and safeguard invested funds. Short-term investments consist of U.S. treasuries and U.S. government securities. The Company has classified these investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore has classified all investments with maturity dates beyond three months at the date of purchase as current assets in the accompanying unaudited condensed consolidated balance sheets. Any premium or discount arising at purchase is amortized and/or accreted to interest income as an adjustment to yield using the straight-line method over the life of the instrument. The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. Investments are reported at their estimated fair value. Unrealized gains and losses are included in accumulated other comprehensive loss as a component of stockholders' equity until realized.

The following is a summary of short-term investments, which were classified as available-for-sale securities as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. treasuries	$ 29,850	$ —	$ (39)	$ 29,811
U.S. government securities	33,066	—	(87)	$ 32,979
Total short-term investments	$ 62,916	$ —	$ (126)	$ 62,790

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. treasuries	$ 59,839	$ 27	$ (5)	$ 59,861
U.S. government securities	50,667	9	(9)	50,667
Total short-term investments	$ 110,506	$ 36	$ (14)	$ 110,528

All of the Company's available-for-sale securities have a stated maturity of less than one year.

Note 4. Fair Value Measurements

Financial assets and liabilities are recorded at fair value.

The Company classifies fair value measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This 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 market prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2—Observable inputs other than quoted market prices included in Level 1, such as quoted market prices for 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 or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs. These fair values are obtained from independent pricing services which utilize Level 1 and Level 2 inputs.

Financial Assets

The following table summarizes the Company's financial asset instruments measured at fair value on a recurring basis as of September 30, 2026 and December 31, 2025 (in thousands). Included within cash and cash equivalents on the unaudited condensed consolidated balance sheets, but excluded from the fair value hierarchy table, are cash deposits held at financial institutions.

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 5,279	$ —	$ —	$ 5,279
Total cash equivalents	5,279	—	—	5,279
Short-term investments:				
U.S. treasuries	—	29,811	—	29,811
U.S. government securities	—	32,979	—	32,979
Total short-term investments	—	62,790	—	62,790
Total financial assets	$ 5,279	$ 62,790	$ —	$ 68,069

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 6,734	$ —	$ —	$ 6,734
U.S. treasuries	—	14,955	—	14,955
Total cash equivalents	6,734	14,955	—	21,689
Short-term investments:				
U.S. treasuries	—	59,861	—	59,861
U.S. government securities	—	50,667	—	50,667
Total short-term investments	—	110,528	—	110,528
Total financial assets	$ 6,734	$ 125,483	$ —	$ 132,217

Warrant Liabilities

The following table summarizes the Company's warrant liabilities (see *Note 8. Preferred Stock and Stockholders' Equity*) measured at fair value on a recurring basis as of September 30, 2026 and December 31, 2025 (in thousands) and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Warrant liabilities	$ —	$ —	$ 22,901	$ 22,901

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Warrant liabilities	$ —	$ —	$ 11,416	$ 11,416

On July 27, 2026, the Company issued 129,870 shares of its common stock upon the cash exercise of Common Warrants (as defined in Note 8) to purchase 129,870 shares of common stock by certain holders. The Company received aggregate cash proceeds of approximately $0.4 million from the exercise.

The following table provides a roll-forward of the aggregate fair value of the warrant liability categorized with Level 3 inputs (in thousands):

	Warrant Liability
Balance as of December 31, 2025	$ 11,416
Change in fair value of warrant liabilities	11,560
Settlement of warrant liability	(75)
Balance as of September 30, 2026	$ 22,901

The change in fair value of warrant liabilities of $11.6 million was recorded in the unaudited condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2026.

Note 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Prepaid clinical	$ 2,734	$ 578
Prepaid insurance	78	688
Prepaid manufacturing	16	340
Prepaid other	169	221
Interest income receivable	544	514
Other current assets	497	11
Total prepaid expenses and other current assets	$ 4,038	$ 2,352

Note 6. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026	December 31, 2025
Accrued clinical	$ 3,928	$ 6,531
Accrued compensation and related expenses	3,339	4,176
Accrued manufacturing	853	2,525
Accrued professional services	357	495
Accrued other	42	632
Total accrued expenses and other liabilities	$ 8,519	$ 14,359

Note 7. Commitments and Contingencies

Contract Obligations

As of September 30, 2026, the Company has non-cancelable purchase obligations related to manufacturing totaling $20.7 million. The Company expects to fulfill its commitments within the next twelve months under these agreements in the normal course of business, therefore, no related liability has been recorded on the unaudited condensed consolidated balance sheets as of that date.

Operating Leases

The Company leases office space under various operating leases. Total rent expense for all operating leases in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss was $0.1 million for each of the three months ended September 30, 2026 and 2025 and $0.3 million for each of the nine months ended September 30, 2026 and 2025.

On April 19, 2024, the Company entered into a 38-month operating lease for 5,817 square feet of office space in Irvine, California, that expires on June 30, 2027.

On September 4, 2024, the Company entered into a 36-month operating lease for 6,138 square feet of office space in Burlington, Massachusetts, that expires on November 21, 2027.

The Company determines if a contract contains a lease at inception. Our office leases have a remaining term of approximately 1 year and do not include options to extend the leases for additional periods.

Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of lease payments not yet paid. Operating lease assets represent our right to use an underlying asset and are based upon the operating lease liabilities as adjusted for prepayments or accrued lease payments, initial direct costs, lease incentives, and impairment of operating lease assets. To determine the present value of lease payments not yet paid, we estimate incremental secured borrowing rates corresponding to the maturities of the leases. As we have no outstanding debt nor committed credit facilities, secured or otherwise, we estimate this rate based on prevailing financial market conditions, comparable company and credit analysis, and management's judgment.

Our leases contain rent escalations over the lease term. We recognize expense for these leases on a straight-line basis over the lease term. Additionally, tenant incentives used to fund leasehold improvements are recognized when earned and reduce our ROU asset related to the lease. These are amortized through the ROU asset as reductions of expense over the lease term. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

While we do not currently have any lease agreement with lease and non-lease components, we elected to account for lease and non-lease components as separate components.

We have elected the short-term lease recognition exemption for all applicable classes of underlying assets. Short-term disclosures include only those leases with a term greater than one month and 12 months or less, and expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less, that do not include an option to purchase the underlying asset that we are reasonably certain to exercise, are not recorded on the unaudited condensed consolidated balance sheet.

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

	For the Nine Months Ended September 30,	
	2026	2025
Operating lease cost[(a)]	$ 298	$ 295

[(a)] Includes variable operating lease expenses, which are immaterial

Other supplemental cash flow information related to leases were as follows (in thousands):

	For the Nine Months Ended September 30,	
	2026	2025
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating leases	$ 301	$ 292

Other supplemental balance sheet information related to our operating leases (in thousands, except lease term and discount rate):

	September 30, 2026	December 31, 2025
Operating leases		
Operating lease right-of-use assets	$ 358	$ 613
Operating lease liabilities (current)	(341)	(358)
Operating lease liabilities (non-current)	(35)	(283)
Total lease obligations under operating leases	$ (376)	$ (641)
Weighted-average remaining lease term (in years)	1.0	1.7
Weighted-average discount rate	9.39%	9.44%

As of September 30, 2026, future minimum payments under non-cancelable operating leases, were as follows (in thousands):

	September 30, 2026
2026 (remainder of)	$ 101
2027	294
Total minimum lease payments	395
Less imputed interest	(19)
Present value of lease liabilities	376
Less current portion of operating lease liabilities	341
Non-current operating lease liabilities	$ 35

Grants and Licenses

ALS Therapy Development Institute License Agreement

In May 2015, Anelixis executed a License Agreement (the "ALS TDI Agreement"), which is an exclusive patent rights agreement with ALS Therapy Development Institute ("ALS TDI") for certain patents and "know-how" of ALS TDI. The ALS TDI Agreement continues until the licensee terminates the agreement with ninety days written notice. The ALS TDI Agreement requires license fees payable to ALS TDI, subject to the achievement of certain milestones and other conditions.

The first and second milestones of the ALS TDI Agreement are the dosing of the first subjects in a first toxicity study in non-human primates and the dosing of the first patient in a Phase I Clinical Trial, respectively. Both of these milestones were achieved prior to 2024. The fee due upon achievement of each milestone was $1.0 million, and as the payments became due, the Company settled the obligations through the issuance of common stock in lieu of cash payments.

The ALS TDI Agreement was amended and restated in February 2020, and a first amendment to the restated license agreement was executed in September 2020. As amended in September 2020, the remaining milestone payments for a first licensed product total $6.0 million. In the event that the Company develops a second licensed product, the Company is obligated to pay up to $2.5 million in additional milestone payments.

In addition to the milestone payments, the Company is required to pay ALS TDI an amended annual license maintenance fee of $0.1 million beginning on the earlier of January 1, 2022, the Company's first sublicense, or change in control, as defined in the ALS TDI Agreement. The Company has made a $0.1 million annual license maintenance fee each year since 2022.

Furthermore, the Company is required to pay ALS TDI fees based on reaching certain levels of annual net sales of any product produced with the patent rights. A royalty in the low single digits will be due on aggregate net sales. Upon the first

calendar year of reaching $500.0 million in aggregate net sales, the Company will be required to pay ALS TDI a one-time milestone payment of $15.0 million. Upon the first calendar year of reaching $1.0 billion in aggregate net sales, the Company is obligated to pay ALS TDI a one-time milestone payment of $30.0 million.

There were no milestones achieved during the nine months ended September 30, 2026 or 2025.

Lonza Sales AG License Agreement

In September 2018, Anelixis executed a License Agreement (the "Lonza Agreement"), which is a manufacturing know-how rights agreement with Lonza Sales AG ("Lonza") for the use of certain processes and know-how related to the manufacture of tegoprubart. The Lonza Agreement continues until the later of the last Valid Claim (as defined therein) or ten years from the First Commercial Sale of tegoprubart, as defined and subject to the conditions therein. A royalty in the low single digits will be due on aggregate net sales of tegoprubart that is manufactured by Lonza or any other third-party or licensee. For the nine months ended September 30, 2026 and 2025, the Company has not paid any royalties under the Lonza Agreement.

Legal Matters

The Company and its subsidiaries are not a party to or the subject of any claim or lawsuit that individually or in the aggregate is anticipated to have a material effect on the Company's results of operations, financial condition or cash flows.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future because of these indemnification obligations. No amounts associated with such indemnifications have been recorded to date.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual as of September 30, 2026 and December 31, 2025.

Note 8. Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

The Company has 5,000,000 authorized shares of preferred stock with a par value of $0.001 per share:

- Series X non-voting convertible preferred stock, 10,000 shares designated; 4,422 shares issued and outstanding at each at September 30, 2026 and December 31, 2025; and
- Series X[1] non-voting convertible preferred stock, 515,000 shares designated; 75,800 and 110,086 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively.

Each share of the Preferred Stock is convertible into 55.5556 shares of common stock, at the option of the holder at any time, subject to certain limitations, including, that the holder will be prohibited from converting the Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% or 9.9% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock or Series X[1] Preferred Stock, respectively. The holder of the Preferred Stock is entitled to receive dividends on shares of the Preferred Stock equal (on an as-if-converted-to-common-stock basis and without regard to any beneficial ownership limitations) to and in the same form as dividends actually paid on shares of the common stock. No other dividends will be paid on shares of the Preferred Stock. In the event of any liquidation, dissolution or winding up, the holder of the Preferred Stock will be entitled to receive out of the assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Preferred Stock were fully converted to common stock, which amounts shall be paid pari passu with all holders of common

stock. Shares of the Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of either series of outstanding Preferred Stock will be required to amend the terms of such series.

The Preferred Stock includes a provision that, in the event of a tender or exchange offer by a third party in which more than 50% of the common stockholders receive cash or other assets, allows holders of Preferred Stock, upon any subsequent conversion, to redeem their shares for the same form of consideration. In August 2025, the Company concluded that because this redemption right may be triggered by an event outside the Company's control and could result in settlement in cash, the Preferred Stock is classified as temporary equity. As of the current reporting date, a tender offer is not probable, and the Preferred Stock is not deemed probable of becoming redeemable. Because redemption is not considered probable, the Preferred Stock is not subsequently remeasured to its redemption value.

On April 9, 2026, the Company issued an aggregate of 1,248,832 shares of its common stock upon the conversion of an aggregate of 22,479 shares of its Series X[1] non-voting convertible preferred stock held by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC, in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X[1] non-voting convertible preferred stock. The conversion did not result in any cash proceeds to the Company.

On June 30, 2026, the Company issued an aggregate of 655,943 shares of its common stock upon the conversion of an aggregate of 11,807 shares of its Series X[1] non-voting convertible preferred stock held by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC, in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X[1] non-voting convertible preferred stock. The conversion did not result in any cash proceeds to the Company.

Subsequent to September 30, 2026, on October 15, 2026, the Company issued an aggregate of 3,017,311 shares of its common stock upon the conversion of an aggregate of 54,312 shares of its Series X[1] non-voting convertible preferred stock held by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC, in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X[1] non-voting convertible preferred stock. The Company did not receive any proceeds from the conversion. In accordance with ASC 855, Subsequent Events, this conversion is not reflected in the condensed consolidated financial statements as of September 30, 2026 and for the three and nine months then ended. Following the conversion, 21,488 shares of Series X[1] non-voting convertible preferred stock remain outstanding.

Common Stock

On June 10, 2025, the Company held its 2025 Annual Meeting of Stockholders (the "2025 Annual Meeting"). At the 2025 Annual Meeting, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation (as amended, the "Certificate of Incorporation") to increase the number of authorized shares of common stock from 200,000,000 to 300,000,000 shares.

On June 18, 2026, the Company held its 2026 Annual Meeting of Stockholders (the "2026 Annual Meeting"). At the 2026 Annual Meeting, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of common stock from 300,000,000 to 450,000,000 shares.

2023 Securities Purchase Agreement

On April 28, 2023, the Company entered into a securities purchase agreement with certain investors, pursuant to which the Company issued and sold, in a private placement, (i) in an initial closing (a) an aggregate of 15,151,518 shares of common stock, or pre-funded warrants in lieu thereof, and (b) common stock warrants exercisable into an aggregate of 15,151,518 shares of common stock (or pre-funded warrants in lieu thereof) (the "Common Warrants"), (ii) in a second closing, an aggregate of 909,088 shares of common stock; and (iii) in a third closing, an aggregate of 1,727,400 shares of common stock. The Common Warrants have an exercise price of $3.00 per share and a term of five years from issuance.

In August 2024, the Company concluded that the Common Warrants do not meet the conditions to be classified as equity instruments under ASC 815-40 and must instead be recorded as liabilities on the Company's consolidated balance sheets at their fair value and remeasured at fair value for each subsequent reporting period. The valuation of the Common Warrants is adjusted to fair value (Level 3) at each balance sheet date until the Common Warrants are settled or expired.

The following table presents the assumptions used in the Black-Scholes option pricing model to determine the fair value of the Common Warrants as of September 30, 2026 and December 31, 2025 as follows:

	September 30, 2026	December 31, 2025
Expected stock price volatility	132.4%	110.5%
Risk-free interest rate	4.9%	3.6%
Expected term (in years)	1.8	2.5
Share price	$ 2.53	$ 1.51

2024 Equity Distribution Agreement

On September 20, 2024, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Guggenheim Securities, LLC ("Guggenheim Securities") to sell shares of the Company's common stock, having aggregate sales proceeds of up to $75.0 million, from time to time, through an "at-the-market" equity offering program under which Guggenheim Securities will act as sales agent. In connection with the Sales Agreement, the Company filed on September 20, 2024 a registration statement on Form S-3 containing a prospectus and prospectus supplement (the "Initial Shelf Registration Statement") with the SEC. The Initial Shelf Registration Statement became effective on October 2, 2024. In advance of the expiration of the Initial Shelf Registration Statement, the Company filed on May 1, 2026 a new registration statement on Form S-3 containing a prospectus and prospectus supplement with the SEC, which became effective on May 11, 2026 and replaces the Initial Shelf Registration Statement. As of September 30, 2026, the Company has not sold any shares under the Sales Agreement.

2025 Underwritten Offering

On November 12, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Leerink Partners, LLC, as representative of the several underwriters named therein (the "Underwriters"), in connection with the underwritten public offering and sale by the Company (the "2025 Underwritten Offering") of 15,152,485 shares of the Company's common stock at a public offering price of $1.65 per share (the "Common Stock Purchase Price"), and pre-funded warrants (the "2025 Offering Pre-Funded Warrants") at a public offering price of $1.649 per 2025 Offering Pre-Funded Warrant, which are exercisable to purchase up to 15,151,515 shares of common stock at an exercise price of $0.001 per share. In addition, pursuant to the Underwriting Agreement, the Company granted the Underwriters an option (the "Option"), exercisable for 30 days, to purchase up to 4,545,600 additional shares of common stock at the Common Stock Purchase Price less the underwriting discounts and commissions, which Option was exercised in full by the Underwriters.

The 2025 Underwritten Offering closed on November 13, 2025 and resulted in gross proceeds of $57.5 million or net proceeds of approximately $53.6 million after deducting the underwriting discounts and commissions and offering expenses. The 2025 Underwritten Offering was made pursuant to the Initial Shelf Registration Statement and a prospectus supplement relating to the 2025 Underwritten Offering dated November 12, 2025.

The 2025 Offering Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital. The 2025 Offering Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, the 2025 Offering Pre-Funded Warrants do not provide any guarantee of value or return.

A holder of the 2025 Offering Pre-Funded Warrants (together with its affiliates) may not exercise any portion of a 2025 Offering Pre-Funded Warrant to the extent that, after giving effect to such exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such 2025 Offering Pre-Funded Warrant. A holder, upon notice to the Company, may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the 2025 Offering Pre-Funded Warrant.

2025 Warrant Exchange Agreement

On December 30, 2025, the Company entered into an exchange agreement (the "Warrant Exchange Agreement") with Coastlands Capital Partners LP ("Coastlands Capital"), pursuant to which Coastlands Capital agreed to exchange 4,203,764 shares of the Company's common stock for a pre-funded warrant to purchase an aggregate of 4,203,764 shares of common stock (the "Exchange Warrant"), and the Company cancelled the 4,203,764 shares of common stock delivered in the exchange.

Coastlands Capital (together with its affiliates) may not exercise any portion of the Exchange Warrant to the extent that, after giving effect to such exercise, Coastlands Capital (together with its affiliates and any other persons acting as a group together with Coastlands Capital or any of its affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of the Exchange Warrant. Coastlands Capital may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the Exchange Warrant.

On June 4, 2026, the Company issued 2,999,138 shares of its common stock to Coastlands Capital Partners LP upon the cashless exercise of 3,000,000 pre-funded warrants in accordance with the terms of the pre-funded warrant issued pursuant to the Warrant Exchange Agreement, dated December 30, 2025, by and between the Company and Coastlands Capital Partners LP. The exercise did not result in any cash proceeds to the Company.

Common Stock Warrants and Pre-Funded Warrants

As of September 30, 2026, common stock warrants and pre-funded warrants exercisable for an aggregate of 48,563,920 shares of common stock were outstanding. The pre-funded warrants are exercisable for shares of common stock at a nominal exercise price and were fully paid for at issuance, except for the nominal exercise amount. The pre-funded warrants are intended to be economically equivalent to the Company's common stock. The common stock warrants are exercisable for shares of common stock at an exercise price of $3.00 per share and expire on May 5, 2028.

On April 10, 2026, the Company issued 87,269 shares of its common stock to MSI BVF SPV, LLC upon the cashless exercise of 87,300 pre-funded warrants in accordance with the terms of the pre-funded warrants issued pursuant to the underwriting agreement, dated October 29, 2024, by and between the Company and Leerink Partners, LLC, as representative of the several underwriters named therein. The exercise did not result in any cash proceeds to the Company.

On July 27, 2026, the Company issued 129,870 shares of its common stock upon the cash exercise of Common Warrants to purchase 129,870 shares of common stock by certain holders. The Company received aggregate cash proceeds of approximately $0.4 million from the exercise.

The following table shows the warrants to purchase common stock activity:

	Roll-Forward of Warrant Activity		
	Common Stock Warrants	Pre-Funded Warrants	Total
Balance as of December 31, 2025	15,151,518	36,629,572	51,781,090
Issued	—	—	—
Exercised	(129,870)	(3,087,300)	(3,217,170)
Cancelled/Expired	—	—	—
Balance as of September 30, 2026	15,021,648	33,542,272	48,563,920

As of September 30, 2026 the Company's outstanding warrants to purchase shares of common stock consisted of the following:

Date Issued	Number of Shares of Common Stock Issuable	Exercise Price	Expiration Date
2023 Securities Purchase Agreement common warrants	15,021,648	$ 3.00	May 5, 2028
January 2021 pre-funded warrants	509,117	$ 0.001	December 31, 2030
2023 Securities Purchase Agreement pre-funded warrants	3,844,153	$ 0.001	N/A
2024 Securities Purchase Agreement pre-funded warrants	7,989,516	$ 0.001	N/A
2024 Underwritten Offering pre-funded warrants	4,844,207	$ 0.001	N/A
2025 Underwritten Offering pre-funded warrants	15,151,515	$ 0.001	N/A
2025 Warrant Exchange Agreement	1,203,764	$ 0.001	N/A
Balance as of September 30, 2026	48,563,920		

Note 9. Stock-Based Compensation

On July 10, 2024, the Company held its 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting"). At the 2024 Annual Meeting, the Company's stockholders approved an amendment to the Company's 2020 Long Term Incentive Plan (the "2020 Plan"). The 2020 Plan, as amended, (i) reflects an increase in the limit on the aggregate number of shares of the Company's common stock that may be delivered pursuant to all awards granted under the 2020 Plan by an additional 3,500,000 shares so that the new aggregate share limit under the 2020 Plan is 17,960,000 shares, and (ii) extends the date through which the Company may grant new awards under the 2020 Plan from November 15, 2030 to April 28, 2034.

The Company's 2014 Stock Incentive Plan (the "2014 Plan") was closed to new grants following the approval of the 2020 Plan, and therefore, there were no shares reserved for issuance under the 2014 Plan as of September 30, 2026. The number of shares reserved for issuance under the 2020 Plan and the Company's Employee Stock Purchase Plan was 2,574,552 and 24,077 shares, respectively, as of September 30, 2026.

Total stock-based compensation expense was recognized in our unaudited condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 894	$ 1,055	$ 4,065	$ 3,157
General and administrative	1,030	1,373	3,215	4,829
Total stock-based compensation	$ 1,924	$ 2,428	$ 7,280	$ 7,986

Note 10. Net Loss Per Share

Basic and diluted net loss per share are calculated using the two-class method in accordance with ASC Topic 260, Earnings Per Share. The two-class method allocates undistributed losses to the Company's outstanding common stock, and the Preferred Stock, based on each class's proportionate share of the total weighted-average shares outstanding. Since the Company has never declared dividends, net loss and undistributed losses are equivalent.

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. The process is used for both common stock and Preferred Stock. As the rights

and preferences of the Preferred Stock are substantially identical to each other, they are considered a single class of common stock for earnings per share purposes.

For purposes of the diluted net loss per share calculation, incentive stock options, RSUs and common warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Basic weighted average shares outstanding as of September 30, 2026 and 2025 include 33,542,272 and 17,274,293 shares, respectively, underlying pre-funded warrants to purchase common shares. As the shares underlying these pre-funded warrants can be issued for little consideration (an exercise price per share equal to $0.001 per share), these shares are deemed to be issued for purposes of basic earnings per share.

The calculation of basic and diluted net loss per share for our common stock and Preferred Stock were as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In thousands, except share and per share data)	**2026**	**2025**	**2026**	**2025**
Weighted-average common shares outstanding, basic and diluted	114,722,339	77,156,068	113,601,123	77,146,407
Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic and diluted	80,222	114,508	96,076	114,508
Net loss used in the calculation of basic and diluted loss per share	$ (3,933)	$ (17,459)	$ (74,588)	$ (35,170)
Net loss available to common stock	$ (3,786)	$ (16,130)	$ (71,241)	$ (32,492)
Net loss per share, common stock, basic and diluted	$ (0.03)	$ (0.21)	$ (0.63)	$ (0.42)
Net loss available to Series X and Series X[1] non-voting convertible preferred stock	$ (147)	$ (1,330)	$ (3,347)	$ (2,679)
Basic and diluted net loss per share of Series X and Series X[1] non-voting convertible preferred stock	$ (1.83)	$ (11.61)	$ (34.84)	$ (23.40)

The following table presents potentially dilutive securities outstanding based on the market price of the Company's common stock as of September 30, 2026 and 2025 that were excluded from the computation of diluted net loss per share because their inclusion would have been anti-dilutive. These securities consist of incentive stock options and RSUs outstanding during the respective periods.

	As of September 30,	
	2026	**2025**
Stock options outstanding and other equity awards	10,853,838	7,372,039
Total	10,853,838	7,372,039

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

The unaudited interim condensed consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and accompanying notes for the year ended December 31, 2025 included in the Annual Report on Form 10-K filed by the Company with the Securities and Exchange Commission (the "SEC") on March 19, 2026 (the "2025 Form 10-K"). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Please see Part II, Item 1A. *Risk Factors* in this Quarterly Report on Form 10-Q for a discussion of certain risk factors applicable to our business, financial condition, and results of operations. Operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period. See also "Special Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q. Unless otherwise indicated, references to the terms "Eledon", the "Company", "we", "our", and "us" refer to Eledon Pharmaceuticals, Inc.

ABOUT ELEDON PHARMACEUTICALS

Overview

Eledon is a clinical stage biotechnology company using our immunology expertise in targeting the CD40 Ligand ("CD40L") pathway to develop therapies to protect transplanted organs and prevent rejection, and to treat amyotrophic lateral sclerosis ("ALS"). Our lead compound in development is tegoprubart, an IgG1, anti-CD40L antibody with high affinity for the CD40L, a well-validated biological target that we believe has broad therapeutic potential. We believe the central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an attractive target for non-lymphocyte depleting, immunomodulatory therapeutic intervention.

Tegoprubart is engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The CD40L/CD40 pathway is recognized for its prominent role in immune regulation. CD40L is primarily expressed on activated CD4+ T cells, platelets and endothelial cells while the CD40 receptor is constitutively expressed on antigen presenting cells such as macrophages and dendritic cells, as well as B cells. By blocking CD40L and not the CD40 receptor, tegoprubart inhibits both the CD40 and CD11 costimulatory signaling pathways, providing the potential for improved efficacy compared to anti-CD40 receptor approaches. Blocking CD40L also increases polarization of CD4+ lymphocytes to Tregs, a specialized subpopulation of T cells that act to suppress an immune response, thus creating a more tolerogenic environment, which may play a therapeutic role in autoimmune diseases and in the prevention of allograft rejection after solid organ transplantation.

Tegoprubart is designed to negate the risk of thromboembolic events seen in the first-generation of anti-CD40L antibodies by introducing structural modifications that have been shown in preclinical models to eliminate binding to the Fcγ receptors associated with platelet activation without altering the binding of tegoprubart to CD40L. In non-human primate studies, dosing of tegoprubart up to 200 mg/kg per week for 26 weeks, demonstrated no adverse events regarding coagulation, platelet activation or thromboembolism.

Strategy

Our business strategy is to optimize the clinical and commercial value of tegoprubart and become a global biotechnology company with a focused immunology franchise. Our strategy is to develop tegoprubart for the prevention of rejection of allograft (i.e., transplanting an organ from one human to another) and xenograft (i.e., transplanting an organ from an animal to a human) organs and cells, and for the treatment of ALS. We selected our indications based on preclinical and clinical data that was generated with either tegoprubart or historical anti-CD40L molecules. We remain committed to further progressing ALS clinical development; however, we are unable to continue developing tegoprubart for ALS without additional funding.

Acquisition

In September 2020, we acquired Anelixis Therapeutics, Inc. ("Anelixis"), the company that owned and controlled the intellectual property related to tegoprubart. See *Note 7. Commitments and Contingencies* of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for further details of grants and licenses related to this acquisition.

Prior to our acquisition of Anelixis, we focused on developing medicines for patients with disorders of the ear, nose, and throat ("ENT"). In June 2020, we announced that our lead program did not achieve statistical significance for the primary

efficacy endpoints in the treatment of acute otitis media. As a result of this failure to achieve the primary study endpoint, we suspended the clinical development of our legacy ENT assets while we assessed potential development strategies. Following the June 2020 announcement, we significantly curtailed development expenses as we sought to identify strategic alternatives that would maximize stockholder value. As a result of these activities, we acquired Anelixis in September 2020, as described above. After acquiring Anelixis, we terminated our ENT activities and returned our product rights to the original license holders in July 2021.

Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in Kidney Transplantation

In January 2023, we announced plans to prioritize and focus resources on our kidney transplantation programs. We are first focusing on kidney transplantation as this is the most common type of solid organ transplantation in the U.S. with an estimated 270,000 Americans living with a transplanted kidney. There are an estimated 28,000 kidneys transplanted annually in the U.S. Approximately 100,000 people in the U.S. are on a waiting list where they typically wait an average 3-5 years for a kidney transplant while about 5,000 people in the U.S. in need of a kidney transplant die each year waiting for a suitable kidney. Approximately 11% of U.S. people on the waiting list are waiting for a repeat transplant. There remains a critical shortage of kidneys and other organs available for transplantation.

There has been little innovation in immunosuppression therapy for organ transplant patients over the past 30 years. The standard of care immunosuppressive drugs used post-transplant have been shown to reduce the risk of organ rejection, but they are also associated with potentially toxic side effects. Organ transplant recipients require immunosuppression therapy on a lifelong basis, and any disruption in the immunosuppression therapy can trigger transplant rejection. Calcineurin inhibitors ("CNIs") are a critical component of most immunosuppressive regimens for kidney transplants to prevent acute and long-term kidney transplant rejection. However, chronic exposure to CNIs (tacrolimus is the drug most commonly used) is associated with nephrotoxicity, hypertension, new onset diabetes due to pancreatic beta cell toxicity, as well as central nervous system ("CNS") side effects, like tremor. Over time, these CNI side effects may significantly damage the transplanted kidneys or result in a requirement for reduced exposures to CNIs which can lead to an increased risk of rejection. Moreover, CNS side effects like tremors may result in patients decreasing their adherence to their medicines. Today, a transplanted kidney is expected to fail within 10-15 years on average using currently available immunosuppression options. The fact that American transplant patients are on average in their 50s means that many of them will ultimately need a second or even third transplant procedure during their lifetime or a return to dialysis.

The central role of CD40L signaling in generating pro-inflammatory responses makes it a highly attractive candidate for therapeutic intervention in the protection of transplanted organs and prevention of transplant rejection. Results from prior studies demonstrate that targeting and blocking CD40L has the potential for better efficacy and improved safety, including reduced risk of nephrotoxicity, diabetes, hypertension, and other side effects associated with standard-of-care CNIs such as tacrolimus.

Tegoprubart seeks to address challenges associated with current immunosuppressive transplantation regimens using CNI-based therapies. The ability to prevent acute and chronic transplant rejection without the need for CNIs has the potential to transform the clinical management of preventing graft rejection by mitigating the adverse events associated with CNIs and improving long-term graft survival, thus potentially decreasing the need for repeat kidney transplants and increasing organ availability for other patients on the wait list. By identifying and advancing novel strategies in immunosuppression including targeting the CD40L pathway, we may be able to help organs remain functional for longer and potentially throughout the natural lifespan of each recipient.

Phase 1b Clinical Trial

We have received regulatory approvals in the United States, Brazil, Canada, the United Kingdom and Australia, for a Phase 1b clinical trial of tegoprubart in up to 36 subjects, replacing tacrolimus as an immunosuppressive regimen component in patients undergoing de novo kidney transplantation. Each participant receives rabbit antithymocyte globulin induction and a maintenance regimen consisting of tegoprubart, mycophenolate mofetil, and corticosteroids. The primary endpoint of the study is safety. Other endpoints include estimated glomerular filtration rate ("eGFR"), characterizing the pharmacokinetic profile of tegoprubart, and the incidence of biopsy-proven acute rejection ("BPAR").

Better graft function as assessed by eGFR has been associated with improved long-term patient and graft survival and is an early predictor of future graft failure. Historical studies have reported average eGFRs generally in the low 50

mL/min/1.73 m^2 range during the first year after kidney transplant using current standard of care immunosuppression. An eGFR of 60 mL/min/1.73 m^2 or below generally indicates chronic kidney disease.

The first subject in the Phase 1b study was dosed in July 2022. We reported interim safety and efficacy results from the Phase 1b clinical trial in March 2023, and provided updated data in November 2023, June 2024 and August 2025.

At the time of the August 2025 update, which reported data as of July 2025, 32 patients undergoing kidney transplantation were enrolled in the Phase 1b study. The updated data showed that kidney function, as assessed by eGFR, stabilized after the first month post-transplant and remained in the range of approximately 68 mL/min/1.73 m^2 through 12 months for patients (n = 12) who remained on tegoprubart. Kidney function in the intention-to-treat population (n=15) was approximately 63 mL/min/1.73 m^2 at 12 months. Data from historical studies using the standard of care, CNI-based immunosuppression therapy, typically report aggregate mean eGFR of approximately 53 mL/min/1.73 m^2 during the first year after kidney transplant. In addition, preliminary abbreviated iBox data was presented suggesting that tegoprubart may improve 5-year graft survival. Abbreviated iBox, a composite biomarker panel developed by the Paris Transplant Group, incorporates kidney function (eGFR, proteinuria) and immunologic response (donor-specific HLA antibodies) parameters into a single prognostic score. Based on data collected as of July 2025, abbreviated iBox scores were -3.75 in the intention-to-treat population and -4.11 in the on-treatment population, which compare favorably to a -2.98 historical mean for CNIs. A difference in abbreviated iBox score of -0.40 at 12 months is considered predictive of a 4-5% difference in 5-year graft survival suggesting that tegoprubart may have a predicted 5-year allograft survival rate of over 96%. As of July 2025, there were six (18.8%) rejection episodes, and 75% of patients who experienced a rejection had received low-dose rabbit antithymocyte globulin induction. All rejection episodes were successfully treated. Of the patients who experienced a rejection episode and completed a year in the study, three who remained on tegoprubart had a mean eGFR of approximately 73 mL/min/1.73 m^2 at 12 months, indicating full recovery of kidney function, while the two patients who switched to standard of care tacrolimus had a mean eGFR of approximately 34 mL/min/1.73 m^2 at 12 months.

In January 2026, we presented 24-month data from eight patients enrolled in the Phase 1b trial long-term extension evaluating tegoprubart in kidney transplantation at the American Society of Transplant Surgeons Winter Symposium held in Scottsdale, Arizona. During the reported follow-up period, no episodes of BPAR, graft loss, death, new-onset diabetes mellitus, or de novo donor-specific antibody formation were observed among participating patients. Mean eGFR increased over the measurement period from 67.0 mL/min/1.73 m^2 at 12 months to 74.2 mL/min/1.73 m^2 at 24 months.

Phase 2 BESTOW Trial

In July 2022, we received Investigational New Drug ("IND") application clearance from the FDA for our controlled, Phase 2 BESTOW trial of tegoprubart for the prevention of transplant rejection in persons receiving a kidney transplant. The BESTOW study is a multi-center, two-arm, active comparator, head-to-head superiority clinical study, with approximately 120 participants undergoing kidney transplantation in the U.S. and other countries to evaluate the safety, pharmacokinetics, and efficacy of tegoprubart compared to the CNI tacrolimus. The study's primary objective is to assess graft function as measured by eGFR at 12 months post-transplant in participants treated with tegoprubart compared to tacrolimus. Secondary objectives are the assessment of graft survival, BPAR, and the incidence of new onset diabetes mellitus after transplant. The BESTOW study is running in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation. The first subject in the BESTOW study was dosed in August 2023 and the last patient completed the 12-month primary endpoint assessment on September 4, 2025.

On November 6, 2025, we announced topline efficacy and safety data for 12 months post transplant from the Phase 2 BESTOW trial evaluating tegoprubart for the prevention of kidney transplant rejection. Safety and efficacy results supported the potential for tegoprubart to provide effective immunosuppression with a favorable safety and tolerability profile compared to tacrolimus. Safety findings underscore tegoprubart's potential to maintain effective immunosuppression while minimizing the metabolic, neurologic, and cardiovascular toxicities characteristic of tacrolimus-based therapy. Notably, new-onset diabetes developed in approximately 17% of patients receiving tacrolimus versus 2% receiving tegoprubart. Tremor was markedly higher in the tacrolimus group (25.0% vs. 1.6%) and cardiovascular effects, including hypertension (25.0% vs. 15.9%), hypertensive crisis (7.8% vs. 1.6%), and heart failure (4.7% vs. 0%) all favored tegoprubart. Delayed graft function occurred less often with tegoprubart and required shorter dialysis (14.3% vs. 25%; 4.6 days vs. 6.1 days) suggesting potential reductions of 115 days on dialysis post-transplant per 100 deceased donor kidney recipients on tegoprubart versus tacrolimus. Sepsis or bacteremia occurred more frequently in the tacrolimus arm (17.2% vs. 4.8%) and viral infection rates (CMV, BK, EBV, fungal) were similar across groups, with no cases of Post-Transplant Lymphoproliferative Disorder or Progressive Multifocal Leukoencephalopathy. Additionally, overall rates of serious adverse events were comparable between treatment arms. From an efficacy standpoint, tegoprubart achieved an eGFR of approximately 69 mL/min/1.73 m^2 (n=51) at 12 months compared to 66 mL/min/1.73 m^2 for tacrolimus (n=56). Although the primary endpoint did not reach statistical significance,

tegoprubart maintained strong renal function, delivering what the Company believes is one of the highest mean eGFR levels reported to date in kidney transplant clinical trials evaluating rejection prevention. Subgroup analyses showed higher eGFRs in nearly all tegoprubart subgroups compared to tacrolimus, particularly among living-related donor recipients (72 mL/min/1.73 m² vs. 62 mL/min/1.73 m²) and high Kidney Donor Profile Index (KDPI > 35) transplants (62 mL/min/1.73 m² vs. 53 mL/min/1.73 m²). The efficacy failure composite endpoint, comprising death, graft loss and BPAR, is the approval endpoint historically recognized by the FDA. The efficacy failure composite endpoint was 22% in the tegoprubart group versus 17% in the tacrolimus group, demonstrating non-inferiority for tegoprubart versus tacrolimus, using a 20% non-inferiority margin. We believe these results, if replicated in a Phase 3 LEGACY study, would be sufficient to support tegoprubart's approvability. The rate of acute rejection in all biopsies was 20.6% for tegoprubart group compared with 14.1% in the tacrolimus group. Among patients in the tegoprubart group who experienced acute rejection and remained on treatment through month 12, mean eGFR was 73 mL/min/1.73 m² compared to 50 mL/min/1.73 m² in those who switched to tacrolimus. Additionally, there was one case of donor-specific antibodies in the tegoprubart arm versus two in the tacrolimus arm.

In October 2026, we presented additional patient-reported outcomes data from the Phase 2 BESTOW trial in an oral presentation at the American Society of Nephrology Kidney Week 2026 Annual Meeting held in Denver, Colorado. Patient-reported outcomes were assessed using the Modified Transplant Symptom Occurrence and Symptom Distress Scale (MTSOSD-59R) and the Kidney Disease Quality of Life Short Form (KDQOL-SF) Symptoms and Problems Scale, both validated measures of symptom burden, and baseline scores were similar between treatment groups. On the MTSOSD-59R assessment, tegoprubart-treated patients reported continued reductions in symptom occurrence from baseline at months 6 and 12, whereas symptom occurrence in tacrolimus-treated patients initially declined through month 6 before returning to slightly above baseline levels at month 12. Tegoprubart demonstrated greater symptom improvement than tacrolimus in 22 of 23 symptom domains where differential improvement was observed, including neurological, gastrointestinal, metabolic and physical symptom categories, and tacrolimus demonstrated greater symptom worsening in 22 of 22 domains where differential symptom worsening was observed. On the KDQOL-SF assessment, tegoprubart-treated kidney transplant patients demonstrated improvements from baseline across all five subscales through month 12, including a statistically significant improvement on the Symptoms and Problems subscale compared to tacrolimus-treated patients at month 12 (mean change from baseline of 9.0 vs. 3.3 points; $p<0.05$). A difference that exceeds the 3–5 point change is generally considered clinically significant on the KDQOL-SF. In addition, the SF-12 mental component summary score increased by 1.5 points in the tegoprubart arm compared to a decline of 1.6 points in the tacrolimus arm, representing a 3.1-point between-group difference.

Phase 2 Open-Label Extension Study

In October 2023, we enrolled the first participant in a Phase 2 open-label extension study which is designed to evaluate the long-term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in either the ongoing Phase 1b study or the Phase 2 BESTOW study.

In June 2026, we announced new long-term data from our Phase 2 BESTOW clinical program evaluating tegoprubart for the prevention of kidney transplant rejection, including updated results from the Phase 2 BESTOW trial and new long-term follow-up data from the BESTOW long-term extension study. Among patients who completed 12 months of treatment in the BESTOW trial, 96% (49/51) of tegoprubart-treated patients and 86% (48/56) of tacrolimus-treated patients enrolled in the long-term extension study. As of the data cutoff, mean follow-up was 21 months, with 89 patients followed through 18 months, 20 patients followed through 24 months, and the longest-followed ongoing patient followed for approximately 33 months. Kidney graft function, as assessed by eGFR, stabilized after the first month of treatment and remained higher in tegoprubart-treated patients than in tacrolimus-treated patients at each reported time point. At month 18, tegoprubart-treated patients demonstrated a statistically significant, approximately 12 mL/min/1.73 m² higher mean eGFR compared to tacrolimus-treated patients (74 vs. 61 mL/min/1.73 m²; $p<0.05$). No BPAR events were observed in tegoprubart-treated patients after the first six months of treatment, whereas in the tacrolimus arm, seven of 11 total BPAR events (approximately 64%) occurred after six months, including two events after 12 months: one new case of active antibody-mediated rejection ("aAMR") and one recurrent case of active T-cell-mediated rejection with aAMR. In an exploratory analysis of patients who experienced rejection following transplantation, those who remained on tegoprubart maintained higher mean eGFR than tacrolimus-treated patients who experienced rejection, with the observed difference increasing from approximately 15 mL/min/1.73 m² at 12 months to approximately 25 mL/min/1.73 m² at 21 months. Patient-reported outcome measures demonstrated lower symptom burden among tegoprubart-treated patients compared to tacrolimus-treated patients at 52 weeks, with statistically significant improvements on the Modified Transplant Symptom Occurrence and Symptom Distress Scale (MTSOSD-59R; treatment difference: -12.2; 95% CI: -19.7, -4.6; $p<0.05$) and the KDQOL-36 Symptoms and Problems domain (treatment difference: 5.7; 95% CI: 1.0, 10.5; $p<0.05$). Long-term follow-up from our Phase 1b study for patients treated at the 20 mg/kg dose of tegoprubart was consistent with the Phase 2 BESTOW results, with no BPAR

episodes observed after six months in tegoprubart-treated patients. From a safety perspective, key central nervous system and kidney-related adverse events in the long-term extension study were observed more frequently in the tacrolimus arm than in the tegoprubart arm, including headache (12% vs. 2%), extremity pain (10% vs. 0%), fall or loss of balance (6% vs. 0%), acute kidney injury (6% vs. 2%), and diarrhea (21% vs. 10%). No graft loss, PML, PTLD, BK or CMV nephropathy/disease, or new malignancies were reported in the long-term extension study, and no new proteinuria was reported in the tegoprubart arm. One death occurred in the tegoprubart arm and was not attributed to the study drug.

In September 2026, we announced updated long-term data from our Phase 2 BESTOW clinical program evaluating tegoprubart for the prevention of kidney transplant rejection, which were presented at the International Congress of The Transplantation Society in Sydney, Australia. As of the August 31, 2026 data cutoff for the BESTOW long-term extension study, 90 patients had been followed through 18 months and 81 patients had been followed through 24 months. Among patients who completed 12 months of treatment in the BESTOW trial and enrolled in the long-term extension study, tegoprubart-treated patients maintained a statistically significantly higher mean eGFR than tacrolimus-treated patients at months 18, 21 and 24 ($p<0.05$), with an approximately 13 mL/min/1.73 m² higher mean eGFR at month 24 (71 vs. 58 mL/min/1.73 m²; 95% CI: 2.6, 23.3). Consistent with previously reported data, no BPAR events were observed in tegoprubart-treated patients after the first six months post-transplant, compared with seven BPAR events in tacrolimus-treated patients. One new case of graft loss was observed in the tacrolimus arm.

Phase 3 LEGACY Planning

In the second quarter of 2026, we held an End-of-Phase 2 meeting with the FDA, and following that meeting we have established the regulatory framework for our Phase 3 LEGACY kidney transplantation program and plan to initiate Phase 3 clinical development of tegoprubart in late 2026, subject to raising additional financing as described below. We expect the Phase 3 LEGACY primary endpoint to be non-inferiority of tegoprubart versus tacrolimus at 52 weeks on a composite of BPAR, graft loss and death with a global enrollment target of approximately 600 patients. The Phase 3 LEGACY study is expected to incorporate key learnings from the Phase 2 BESTOW trial and ongoing long-term extension study. We will need to raise additional financing to initiate a Phase 3 clinical trial in kidney transplantation. There can be no assurance such financing will be available to us on acceptable terms, or at all, for this trial, which could force us to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

In September 2026, the FDA granted Fast Track designation to tegoprubart for the prevention of rejection in kidney transplantation. Fast Track designation is intended to facilitate the development and expedite the review of drugs that treat serious conditions and address significant unmet medical needs. The designation provides for opportunities for more frequent interactions with the FDA regarding the development program and, if relevant criteria are met, may provide eligibility for rolling review of a future marketing application, and eligibility for Accelerated Approval and Priority Review.

Highly Sensitized Patients

In the first quarter of 2026, the first highly sensitized kidney transplant patient was dosed with tegoprubart under an investigator-initiated compassionate-use protocol at Duke University Medical Center. Highly sensitized patients requiring a kidney transplant face a substantial unmet need because pre-existing antibodies can significantly limit access to compatible donor organs. These antibodies can also increase the risk of antibody-mediated rejection and graft loss after transplant. We are not funding this protocol, and our involvement is limited to supplying tegoprubart.

Tolerance Induction

In the third quarter of 2026, the third patient was treated in the investigator-initiated study evaluating tegoprubart for kidney transplant tolerance induction at Massachusetts General Hospital. We are not funding this trial, and our involvement is limited to supplying tegoprubart.

Results from compassionate-use treatment from a single patient and from investigator-initiated trials and studies involving a limited number of patients may not be predictive of results in larger, controlled clinical trials.

Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in Xenotransplantation

While inhibition of CD40L has shown it may play an important role in immunosuppression in allograft kidney transplantation, this mechanism of action has also demonstrated that it may be a promising option in xenotransplantation (i.e., transplanting an organ from an animal to a human).

In January 2023, we entered into a non-exclusive collaborative research agreement with eGenesis, Inc., ("eGenesis"), under which eGenesis gained access to tegoprubart for preclinical and clinical xenotransplantation studies in support of eGenesis' kidney, heart and islet cell xenotransplantation programs.

To date, tegoprubart has been used as a key component of the immunosuppression regimen in six xenotransplantation procedures: five procedures involving genetically modified pig kidneys and one involving a genetically modified pig heart. One of the kidney transplant recipients continues to maintain kidney function with the transplanted pig kidney while two others transitioned to human kidney transplants.

We expect to continue discussions with regulatory authorities regarding the potential path to market for tegoprubart in kidney xenotransplantation.

Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in Islet Cell Transplantation ("ICT")

Type 1 diabetes ("T1D") is a T-cell-mediated autoimmune disease with progressive loss of insulin producing pancreatic beta cells and affects approximately 2 million persons in the United States. Approximately 33% of people with T1D report impaired awareness of hypoglycemia regardless of continuous glucose monitoring or automated insulin usage. Approximately 12% of people with T1D experience recurrent severe hypoglycemic episodes annually, putting them at higher risk for adverse outcomes such as seizures, coma, and death. ICT is gaining attention as a therapeutic option for T1D because it can restore physiological insulin secretion, minimize the risk of hypoglycemic unawareness, and reduce the risk of death due to severe hypoglycemia. The advances made in this field over the past decade have improved patient outcomes, and the procedure has been evolving from an experimental treatment to a clinical treatment option.

A number of issues are believed to continue to hamper the overall success of ICT and to need to be addressed in order for there to be widespread clinical acceptance. These include the acute loss of transplanted islets with current immunosuppressive treatments, particularly those with CNI-based therapies, due to islet cell toxicity and alloreactive immunologic responses to transplanted islets. Over time, the progressive loss of islet cells and decline in islet cell function can lead to the need for multiple transplants in order for T1D patients to have optimal response to blood glucose levels and possibly achieve insulin independence. In addition, the nephrotoxicity associated with CNIs has historically limited the use of ICT in patients with T1D who also have renal dysfunction, such as those with chronic kidney disease. Tegoprubart seeks to address the challenges associated with current ICT immunosuppressive regimens using CNI-based therapies, by replacing the CNIs with tegoprubart to prevent rejection and protect the transplanted cells. We believe that tegoprubart may unlock the ICT market by potentially improving islet cell graft survival and reducing the side effects associated with standard of care regimens.

Historical studies in nonhuman primate models of ICT have demonstrated that treatment with anti-CD40L antibodies induces long term islet cell function and graft survival, even as a monotherapy. Tegoprubart has shown pre-clinical, proof-of-concept efficacy in a non-human primate model of T1D, where animals undergoing ICT maintained glucose control and sustained levels of C-peptide with chronic tegoprubart treatment for up to a year. Compared to combination immunosuppressive therapy including CNIs, tegoprubart monotherapy was more effective in preventing long term islet cell rejection, associated with better graft function, and showed an improved safety profile.

In 2022, the FDA granted orphan drug designation to tegoprubart for the prevention of allograft rejection in pancreatic ICT.

Investigator-Initiated Trial in T1D Patients Undergoing ICT

In January 2024, we announced that tegoprubart would be evaluated in an investigator-initiated clinical trial conducted at the University of Chicago Medicine's Transplant Institute. The trial is designed to assess the safety of a CNI-free immunosuppression regimen utilizing tegoprubart in individuals with T1D undergoing ICT. We are not funding the trial and our involvement is limited to supplying tegoprubart.

In June 2026, we announced updated results from this investigator-initiated trial. All 12 adults enrolled in the trial showed stable islet graft function over a median and maximum post-transplant follow-up period of 8 and 22 months, respectively. All 12 patients continued to achieve insulin independence, meaning they no longer required chronic, exogenous insulin therapy to manage their T1D, and all patients demonstrated a most recent hemoglobin A1c ("HbA1c") below the diabetic threshold of 6.5%, with a mean most recent HbA1c of approximately 5.4% across the cohort. While all enrolled patients reported recurrent severe hypoglycemic events prior to transplantation, no severe hypoglycemic episodes were reported following transplantation. Higher levels of post-transplant islet cell engraftment were observed with the

tegoprubart-based immunosuppression regimen than in historical patients treated with a tacrolimus-based immunosuppression regimen at the same center. There were no rejection episodes, and no patients developed de novo donor-specific HLA antibodies. Tegoprubart-based immunosuppression was generally well tolerated, with immunosuppression-related adverse events generally successfully treated by lowering the mycophenolic acid dose, if necessary, and no evidence of nephrotoxicity, hypertension, or neurotoxicity, which are commonly associated with CNI-based immunosuppression regimens, was observed. We believe these findings further support the potential of CD40L blockade to enable effective islet graft protection while avoiding the toxicities of CNIs such as tacrolimus. In September 2026, we announced that all 12 patients in the University of Chicago Medicine study also achieved a HbA1c level below 7.0% following islet cell transplantation and treatment with tegoprubart.

In September 2026, the University of Chicago Medicine Transplant Institute expanded its ongoing investigator-initiated trial of tegoprubart as the core immunosuppressant in participants with T1D undergoing islet cell transplantation. The trial is adding three patients beyond the 12 treated to date.

In addition, one patient with T1D undergoing ICT at the University of Chicago Medicine Transplant Institute was dosed with tegoprubart in an investigator-initiated compassionate-use protocol that allowed the patient to switch from tacrolimus-based immunosuppression therapy due to CNI-related renal dysfunction. We are not funding this protocol, and our involvement is limited to supplying tegoprubart. Results from compassionate-use treatment from a single patient and from investigator-initiated trials and studies involving a limited number of patients may not be predictive of results in larger, controlled clinical trials.

Investigator-Initiated Trial in T1D Patients with Chronic Kidney Disease Undergoing ICT

In September 2026, we announced that the first patients had been enrolled in a new investigator-initiated clinical trial evaluating tegoprubart for the prevention of allograft rejection in patients with T1D and renal dysfunction from chronic kidney disease receiving an islet cell transplant. The study, underway at the University of Chicago Medicine Transplant Institute, evaluates a CNI-free, tegoprubart-based immunosuppression regimen in patients who are especially susceptible to tacrolimus toxicity, including kidney damage, which has long constrained the use of ICT. We are not funding this trial, and our involvement is limited to supplying tegoprubart.

Company-Sponsored Registrational Program

Following our interactions with the FDA, in August 2026 we submitted an IND application to the FDA for a planned Company-sponsored, registrational clinical trial evaluating tegoprubart for the prevention of allograft rejection in T1D patients undergoing pancreatic ICT. In October 2026, the FDA cleared the IND application. The planned study would be our first Company-sponsored clinical trial in ICT and represents an important step in our registrational pathway for tegoprubart in this patient population. We will need to raise additional financing to initiate this registrational study. There can be no assurance such financing will be available to us on acceptable terms, or at all, which could force us to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in Liver Transplantation

In March 2026, the FDA granted orphan drug designation to tegoprubart for the prevention of allograft rejection in liver transplantation, the third orphan drug designation received by tegoprubart from the FDA.

We plan to initiate an investigator-initiated trial evaluating tegoprubart for the prevention of allograft rejection in patients receiving a de novo liver transplant.

Clinical Development of Tegoprubart for ALS

ALS is a progressive, paralytic disorder characterized by degeneration of motor neurons in the brain and spinal cord. In the U.S., the incidence is estimated at approximately 5,000 cases per year with a prevalence of approximately 30,000 cases overall. Despite three approved drugs, in most cases, death from respiratory failure occurs between 3 to 5 years from diagnosis, with 50% of patients living at least 3 years from diagnosis and only 20% of patients living at least 5 years from diagnosis.

While the exact pathogenic mechanism of ALS is still not fully understood, there is strong evidence indicating that neuroinflammation plays an important role in the disease’s pathogenesis. Neuroinflammation in ALS is characterized by the

infiltration of lymphocytes and macrophages into the central nervous system, and the activation of microglia and reactive astrocytes. Reactive astrocytes and microglia as well as infiltrating lymphocytes, dendritic cells, monocytes, macrophages and immune complexes have been identified in cerebrospinal fluid and neural tissues in both animal models of ALS and at autopsy in ALS patients.

Tegoprubart is designed to block CD40L binding to CD40, thereby potentially inhibiting neuroinflammatory pathways leading to disease progression in ALS. In vitro proof-of-concept studies have shown that tegoprubart binds to CD40L in human cells and blocks the CD40L binding on antigen presenting cells and activated T cells. The potential for therapeutic benefit of CD40L blockage in treating ALS has been demonstrated in a SOD1 mouse model of ALS, where a murine anti-CD40L antibody prolonged survival and delayed the onset of neurological disease progression. These pathophysiological manifestations are believed to be due to reduced immune cell infiltration of macrophages into skeletal muscle and their destroying denervated nerves. The plasticity of the nervous system to repair itself in the absence of this immune cell attack is believed to result in improved neuromuscular junction occupancy and improved muscle function. Blocking CD40L signaling also prevents pro-inflammatory polarization of lymphocytes, reduced neuroinflammation and improved motor neuron survival in rodent ALS models.

In 2018, the FDA granted orphan drug designation to tegoprubart for ALS. In 2019, we completed a single ascending dose Phase 1 study of tegoprubart in healthy volunteers and people with ALS. In this study, the doses of tegoprubart studied were well tolerated in healthy adult subjects and adults with ALS. Tegoprubart demonstrated low anti-drug antibody responses that were not dose related, linear dose proportionality across the dose ranges, and a half-life of up to 26 days.

In October 2020, we initiated a Phase 2a, open-label, multi-center study to evaluate the safety and tolerability of multiple doses of tegoprubart in adult subjects with ALS. Fifty-four subjects with ALS were enrolled into the study in the United States and Canada at 13 ALS treatment sites. Ascending doses of tegoprubart were administered as IV infusions to four sequentially enrolling cohorts. The first two cohorts consisted of nine participants, and the last two cohorts of 18 participants each. All enrolled subjects received six infusions of tegoprubart over a 12 week period. Blood samples for target engagement, and exploratory biomarkers for inflammation and neurodegeneration were taken and analyzed. Participant-focused clinical outcomes were also assessed. In May 2022, we completed the Phase 2a study and released positive topline results. Tegoprubart successfully met the primary endpoints of safety and tolerability. Fifty of the fifty-four subjects completed all six study infusions, and adverse events were typical of an ALS patient population. Tegoprubart was well-tolerated, and no drug-related serious adverse events were observed. No new safety signals emerged. Anti-drug antibodies (“ADAs”) were present in less than 5 percent of samples. All ADAs were of low titer and did not impact tegoprubart drug levels. Tegoprubart target engagement was demonstrated in all dose cohorts with increasing target engagement in a dose-dependent manner, plateauing at the 4 and 8 mg / kg dosing levels using CD40L and CXCL13 biomarkers related to T cell and B cell function, respectively. Tegoprubart exposure decreased inflammatory biomarker levels, in a dose dependent manner, in 20 of 32 pro-inflammatory proteins. Pro-inflammatory biomarkers reduced included biomarkers also associated with IgA nephropathy and kidney transplant rejection, such as IgA, IgE, IgM, C3, CXCL9, and CXCL10.

We are seeking to further progress ALS clinical development; however, we will be unable to continue this program without additional financing dedicated to ALS, and we can provide no assurance that such financing will be available on acceptable terms, or at all.

Clinical Development of Tegoprubart for IgA Nephropathy

In January 2023, the Company announced the deprioritization of its IgA Nephropathy (“IgAN”) program and all IgAN clinical development activities were discontinued in 2023. IgAN is the leading cause of chronic glomerulonephritis, a state of inflammation producing damage to the filtering part of the kidney. Disease manifestation and clinical presentation involves renal dysfunction characterized by proteinuria with a slow relentless course. Approximately 30%-40% of persons living with IgAN ultimately reach end stage renal disease (“ESRD”). The standard of care for ESRD is dialysis or kidney transplant, which represents a significant economic burden as well as a major impact on a patient’s quality of life. With an estimated prevalence of approximately 150,000 persons in the United States, IgAN is one of the most common autoimmune glomerulonephropathies. In the United States, oral budesonide Tarpeyo was approved for use in IgAN by the FDA in December 2021 and Kinpeygo received conditional approval by the European Medicines Agency (“EMA”) in July 2022.

In August 2022, we received IND clearance from the FDA to evaluate tegoprubart for the treatment of IgAN. The Phase 2 global study was a 96-week open-label, dose ranging trial, and included both a high dose and a low dose cohort. The primary endpoint was change in urinary protein:creatinine ratio at week twenty-four. Secondary endpoints included change in eGFR at week 96 as well as safety and tolerability. The first subject was dosed in May 2022. We reported interim safety data from the Phase 2 high dose cohort in March 2023.

Financing Activities

2024 Equity Distribution Agreement

On September 20, 2024, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Guggenheim Securities, LLC ("Guggenheim Securities") to sell shares of the Company's common stock, having aggregate sales proceeds of up to $75.0 million, from time to time, through an "at-the-market" equity offering program under which Guggenheim Securities will act as sales agent. In connection with the Sales Agreement, the Company filed on September 20, 2024 a registration statement on Form S-3 containing a prospectus and prospectus supplement (the "Initial Shelf Registration Statement") with the SEC. The Initial Shelf Registration Statement became effective on October 2, 2024. In advance of the expiration of the Initial Shelf Registration Statement, the Company filed on May 1, 2026 a new registration statement on Form S-3 containing a prospectus and prospectus supplement with the SEC, which became effective on May 11, 2026 and replaces the Initial Shelf Registration Statement. As of September 30, 2026, we have not sold any shares under the Sales Agreement.

2025 Underwritten Offering

On November 12, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Leerink Partners, LLC, as representative of the several underwriters named therein (the "Underwriters"), in connection with the underwritten public offering and sale by the Company (the "2025 Underwritten Offering") of 15,152,485 shares of the Company's common stock at a public offering price of $1.65 per share (the "Common Stock Purchase Price"), and pre-funded warrants (the "2025 Offering Pre-Funded Warrants") at a public offering price of $1.649 per 2025 Offering Pre-Funded Warrant, which are exercisable to purchase up to 15,151,515 shares of common stock at an exercise price of $0.001 per share. In addition, pursuant to the Underwriting Agreement, the Company granted the Underwriters an option (the "Option"), exercisable for 30 days, to purchase up to 4,545,600 additional shares of common stock at the Common Stock Purchase Price less the underwriting discounts and commissions, which Option was exercised in full by the Underwriters.

The 2025 Underwritten Offering closed on November 13, 2025 and resulted in gross proceeds of $57.5 million or net proceeds of approximately $53.6 million after deducting the underwriting discounts and commissions and offering expenses. The 2025 Underwritten Offering was made pursuant to the Initial Shelf Registration Statement and a prospectus supplement relating to the 2025 Underwritten Offering dated November 12, 2025.

A holder of the 2025 Offering Pre-Funded Warrants (together with its affiliates) may not exercise any portion of a 2025 Offering Pre-Funded Warrant to the extent that, after giving effect to such exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such 2025 Offering Pre-Funded Warrant. A holder, upon notice to the Company, may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the 2025 Offering Pre-Funded Warrant.

2025 Warrant Exchange Agreement

On December 30, 2025, the Company entered into an exchange agreement (the "Warrant Exchange Agreement") with Coastlands Capital Partners LP ("Coastlands Capital"), pursuant to which Coastlands Capital agreed to exchange 4,203,764 shares of the Company's common stock for a pre-funded warrant to purchase an aggregate of 4,203,764 shares of the Company's common stock (the "Exchange Warrant"), and the Company cancelled the 4,203,764 shares of common stock delivered in the exchange.

Coastlands Capital (together with its affiliates) may not exercise any portion of the Exchange Warrant to the extent that, after giving effect to such exercise, Coastlands Capital (together with its affiliates and any other persons acting as a group together with Coastlands Capital or any of its affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of the Exchange Warrant. Coastlands Capital may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the Exchange Warrant.

On June 4, 2026, the Company issued 2,999,138 shares of its common stock to Coastlands Capital Partners LP upon the cashless exercise of 3,000,000 pre-funded warrants in accordance with the terms of the pre-funded warrant issued pursuant to the Warrant Exchange Agreement. The exercise did not result in any cash proceeds to the Company.

Common Stock Warrants, Convertible Preferred Stock and Pre-Funded Warrants

As of September 30, 2026, common stock warrants were exercisable into an aggregate of 15,021,648 shares of common stock (after rounding for fractional shares and subject to beneficial ownership conversion blockers) at an exercise price of $3.00 per share. These warrants expire on May 5, 2028. The shares of common stock underlying the common stock warrants are registered for offer and sale under the Securities Act pursuant to our effective registration statements on Forms S-3.

On April 9, 2026, the Company issued an aggregate of 1,248,832 shares of its common stock upon the conversion of an aggregate of 22,479 shares of its Series X[1] non-voting convertible preferred stock held by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC, in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X1 non-voting convertible preferred stock. The conversion did not result in any cash proceeds to the Company.

On April 10, 2026, the Company issued 87,269 shares of its common stock to MSI BVF SPV, LLC upon the cashless exercise of 87,300 pre-funded warrants in accordance with the terms of the pre-funded warrants issued pursuant to the underwriting agreement, dated October 29, 2024, by and between the Company and Leerink Partners, LLC, as representative of the several underwriters named therein. The exercise did not result in any cash proceeds to the Company.

On June 30, 2026, the Company issued an aggregate of 655,943 shares of its common stock upon the conversion of an aggregate of 11,807 shares of its Series X[1] non-voting convertible preferred stock held by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC, in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X[1] non-voting convertible preferred stock. The conversion did not result in any cash proceeds to the Company.

Subsequent to September 30, 2026, on October 15, 2026, the Company issued an aggregate of 3,017,311 shares of its common stock upon the conversion of an aggregate of 54,312 shares of its Series X[1] non-voting convertible preferred stock held by Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC, in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X[1] non-voting convertible preferred stock. The Company did not receive any proceeds from the conversion. This conversion is not reflected in the condensed consolidated financial statements as of September 30, 2026 and for the three and nine months then ended. Following the conversion, 21,488 shares of Series X[1] non-voting convertible preferred stock remain outstanding.

Financial Operations Overview

Operating Expenses

Our operating expenses consist primarily of costs associated with research and development activities and general and administrative activities.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of:

- personnel costs, including salaries, benefits, stock-based compensation and travel expenses, for employees engaged in research and development functions;
- expenses incurred under agreements with contract research organizations (“CROs”), and sites that conduct our non-clinical studies and clinical trials;
- expenses associated with manufacturing materials for use in non-clinical studies and clinical trials and developing external manufacturing capabilities;
- costs of outside consultants engaged in research and development activities, including their fees and travel expenses;

- other expenses related to our non-clinical studies and clinical trials and expenses related to our regulatory activities; and
- payments made under our third-party license agreements.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs that include salaries, benefits and travel expenses for our executive, finance, and other administrative functions, and stock-based compensation expense. General and administrative expenses also include professional fees for expenses incurred under agreements with third parties relating to public relations, audit, tax and legal services, including legal expenses to pursue patent protection of our intellectual property; and our information technology, facilities and other related expenses, including rent, maintenance of facilities, insurance and supplies.

Change in fair value of warrant liabilities

Change in fair value of warrant liabilities represents the initial recognition of warrant liabilities at fair value in excess of proceeds received, as well as subsequent period remeasurements of these warrant liabilities at fair value. These remeasurements reflect changes in market conditions, such as fluctuations in stock price, volatility, interest rates, and other valuation inputs that impact the fair value of the liability.

CRITICAL ACCOUNTING ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities as of the date of the financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions. In Part II, Item 7 of the 2025 Form 10-K, we disclosed our critical accounting estimates, which are those estimates made in accordance with GAAP that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operation. There have been no significant changes in our critical accounting estimates during the nine months ended September 30, 2026, as compared to those disclosed in the 2025 Form 10-K.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is set forth in *Note 2. Summary of Significant Accounting Policies*, of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

Market Trends and Uncertainties

The global economy, including the financial and credit markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, elevated inflation and interest rates, changes in U.S. trade policy and uncertainty about economic stability. Likewise, the current conflicts in Ukraine and the Middle East have created volatility in the global capital markets and global economic consequences, including disruptions of the global supply chain and energy markets. A severe or prolonged economic downturn or continued volatility in the financial and credit markets could negatively impact our ability to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business.

Any of the foregoing items could materially affect our business, possibly to a significant degree. The severity and duration of any such impacts cannot be predicted. See Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q for additional information.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table provides comparative unaudited results of operations for the three months ended September 30, 2026 and 2025 (in thousands):

	For the Three Months Ended September 30,		
	2026	2025	$ Variance
Operating expenses:			
Research and development	$ 17,761	$ 14,969	$ 2,792
General and administrative	3,911	4,101	(190)
Total operating expenses	21,672	19,070	2,602
Loss from operations	(21,672)	(19,070)	(2,602)
Other income, net	714	1,047	(333)
Change in fair value of warrant liabilities	17,025	564	16,461
Net loss	$ (3,933)	$ (17,459)	$ 13,526
Unrealized gain (loss) on available-for-sale securities, net	(12)	57	(69)
Comprehensive loss	$ (3,945)	$ (17,402)	$ 13,457

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses for the periods presented (in thousands):

	For the Three Months Ended September 30,		
	2026	2025	$ Variance
Tegoprubart - kidney transplantation programs	$ 6,526	$ 9,363	$ (2,837)
Manufacturing	6,867	1,736	5,131
Personnel-related	3,404	2,744	660
Stock-based compensation	894	1,055	(161)
Other expenses	70	71	(1)
Total research and development expenses	$ 17,761	$ 14,969	$ 2,792

Research and development expenses increased by $2.8 million for the three months ended September 30, 2026, compared to the three months ended September 30, 2025. The net increase was primarily attributable to the following:

- a decrease of $2.8 million in expenses related to our Tegoprubart - kidney transplantation programs, primarily driven by lower external CRO costs related to close-out activities for our Phase 2 BESTOW trial for kidney transplantation;
- an increase of $5.1 million in manufacturing costs, primarily due to contract manufacturing expenses associated with increased production of drug substance and drug product for clinical trial supply. We expect manufacturing costs to increase as we advance our clinical programs and as we prepare for a planned Phase 3 kidney transplantation trial and our planned ICT trial;
- an increase of $0.7 million in personnel-related expenses, driven by increased headcount supporting our ongoing clinical development programs. We expect personnel-related expenses to increase as we prepare for a planned Phase 3 kidney transplantation trial and our planned ICT trial; and
- a decrease of $0.2 million in stock-based compensation expense, primarily because certain equity awards granted in prior periods have fully vested, resulting in no further expense recognition for those awards.

General and Administrative Expenses

The following table summarizes the period-over-period changes in general and administrative expenses for the periods presented (in thousands):

	For the Three Months Ended September 30,		
	2026	2025	$ Variance
Professional services	$ 1,690	$ 1,395	$ 295
Personnel-related	919	920	(1)
Stock-based compensation	1,030	1,373	(343)
Other expenses	272	413	(141)
Total general and administrative expenses	$ 3,911	$ 4,101	$ (190)

General and administrative expenses decreased by $0.2 million for the three months ended September 30, 2026, compared to the three months ended September 30, 2025. The net decrease was primarily attributable to the following:

- an increase of $0.3 million in professional and consulting services, primarily driven by increased audit and corporate communication services, offset by;
- a decrease of $0.3 million in stock-based compensation expense, primarily because certain equity awards granted in prior periods have fully vested, resulting in no further expense recognition for those awards; and
- a decrease of $0.1 million in other expenses, primarily driven by a decrease in general operating costs.

Other Income, Net

Other income, net for the three months ended September 30, 2026 decreased by $0.3 million compared to the three months ended September 30, 2025, primarily due to a decrease in interest income, reflecting lower interest rates and lower average balances of cash, cash equivalents, and short-term investments.

Change in Fair Value of Warrant Liabilities

For the three months ended September 30, 2026, we recognized a gain of $17.0 million from the change in fair value of our warrant liabilities, primarily due to a decline in our stock price during the period.

For the three months ended September 30, 2025, we recognized a gain of $0.6 million from the change in fair value of our warrant liabilities, also primarily due to a decline in our stock price during the period.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table provides comparative unaudited results of operations for the nine months ended September 30, 2026 and 2025 (in thousands):

	For the Nine Months Ended September 30,		
	2026	2025	$ Variance
Operating expenses:			
Research and development	$ 53,188	$ 48,776	$ 4,412
General and administrative	12,534	12,991	(457)
Total operating expenses	65,722	61,767	3,955
Loss from operations	(65,722)	(61,767)	(3,955)
Other income, net	2,694	3,680	(986)
Change in fair value of warrant liabilities	(11,560)	22,917	(34,477)
Net loss	$ (74,588)	$ (35,170)	$ (39,418)
Unrealized loss on available-for-sale securities, net	(150)	(17)	(133)
Comprehensive loss	$ (74,738)	$ (35,187)	$ (39,551)

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses for the periods presented (in thousands):

	For the Nine Months Ended September 30,		
	2026	2025	$ Variance
Tegoprubart - kidney transplantation programs	$ 17,632	$ 26,600	$ (8,968)
Tegoprubart - other development programs	—	(168)	168
Manufacturing	21,814	11,031	10,783
Personnel-related	9,459	7,970	1,489
Stock-based compensation	4,065	3,157	908
Other expenses	218	186	32
Total research and development expenses	$ 53,188	$ 48,776	$ 4,412

Research and development expenses increased by $4.4 million for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025. The net increase was primarily attributable to the following:

- a decrease of $9.0 million in expenses related to our Tegoprubart - kidney transplantation programs, primarily driven by lower external CRO costs related to close-out activities of our Phase 2 BESTOW clinical trial, offset by;
- an increase of $0.2 million in expenses related to our Tegoprubart - other development programs, reflecting the absence in 2026 of a credit recognized in 2025 related to our IgAN program which was terminated in 2023;
- an increase of $10.8 million in manufacturing costs, primarily due to contract manufacturing expenses associated with increased production of drug substance and drug product for clinical trial supply. We expect manufacturing costs to increase as we advance our clinical programs and as we prepare for a planned Phase 3 kidney transplantation trial and our planned ICT trial;
- an increase of $1.5 million in personnel-related expenses, primarily due to increased headcount supporting our ongoing clinical development programs. We expect personnel-related expenses to increase as we prepare for a planned Phase 3 kidney transplantation trial and our planned ICT trial; and
- an increase of $0.9 million in stock-based compensation expense, due to the accelerated vesting of certain stock option grants.

General and Administrative Expenses

The following table summarizes the period-over-period changes in general and administrative expenses for the periods presented (in thousands):

	For the Nine Months Ended September 30,		
	2026	2025	$ Variance
Professional services	$ 5,632	$ 4,328	$ 1,304
Personnel-related	2,762	2,838	(76)
Stock-based compensation	3,215	4,829	(1,614)
Other expenses	925	996	(71)
Total general and administrative expenses	$ 12,534	$ 12,991	$ (457)

General and administrative expenses decreased by $0.5 million for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025. The net decrease was primarily attributable to the following:

- an increase of $1.3 million in professional and consulting services, primarily driven by increased audit and corporate communication services, offset by;
- a decrease of $0.1 million in personnel-related expenses, primarily due to a decrease in travel-related expenses;
- a decrease of $1.6 million in stock-based compensation expense, primarily because certain equity awards granted in prior periods have fully vested and fewer equity awards were granted in 2026; and
- a decrease of $0.1 million in other expenses, primarily driven by a decrease in general operating costs.

Other Income, Net

Other income, net for the nine months ended September 30, 2026 decreased by $1.0 million compared to the nine months ended September 30, 2025, primarily due to a decrease in interest income, reflecting lower interest rates and lower average balances of cash, cash equivalents, and short-term investments.

Change in Fair Value of Warrant Liabilities

For the nine months ended September 30, 2026, we recognized a loss of $11.6 million from the change in fair value of our warrant liabilities, primarily due to an increase in our stock price during the period.

In contrast, for the nine months ended September 30, 2025, we recognized a gain of $22.9 million from the change in fair value of our warrant liabilities, primarily due to a decline in our stock price during the period.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We do not have any approved products for commercial sale and have never generated revenue from product sales. We have incurred significant net losses and negative cash flows from operations since our inception and expect to continue to incur significant operating losses and negative cash flows from operations for the foreseeable future as we advance the clinical development of our product candidates. As of September 30, 2026, we had cash, cash equivalents and short-term investments of $69.7 million, working capital of $62.0 million and an accumulated deficit of $475.8 million. To date, we have financed our operations primarily through the sale of preferred stock, common stock and warrants.

Our current operating plan, including the planned initiation of a Phase 3 clinical trial in kidney transplantation and continued advancement of our islet cell transplantation program through a planned Company-sponsored registrational path study, requires substantial additional capital. We intend to seek additional capital through public or private equity or debt financings, or other securities issuances, strategic collaborations, licensing arrangements, credit or loan facilities and other available sources. Our ability to obtain additional financing is dependent on a number of factors, including, but not limited to, market conditions, investor demand for our common stock or other securities, the results of clinical trials or investigator-led studies and progress of our development programs and other business risks and uncertainties. There can be no assurance that additional financing will be available when needed or on terms acceptable to us, or at all, for our current operating plan,

which could force us to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. If we raise capital through the issuance of equity or convertible debt securities, existing stockholders may experience dilution, incur significant financing costs and the new securities may have rights, preferences and privileges senior to those of existing stockholders. If we incur additional indebtedness, it may become subject to additional debt service obligations and operating restrictions.

Based on our current operating plan, we do not currently have sufficient cash, cash equivalents, short-term investments and other available resources to fund our operations for at least twelve months from the date of issuance of the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. Accordingly, management has concluded that substantial doubt exists about our ability to continue as a going concern. Although management intends to obtain additional financing through the sources described above, these plans are subject to market conditions and other factors outside our control. Accordingly, management has concluded that its plans do not alleviate the substantial doubt about our ability to continue as a going concern. The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments that might result from the outcome of this uncertainty.

Material Cash Requirements

Our primary use of cash is to fund operating expenses, which consist of clinical research and development expenses, manufacturing expenses, legal and compliance expenses, compensation and related expenses, and general overhead costs. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses. As of September 30, 2026, there have been no changes in our material cash requirements from known contractual and other obligations, including commitments for capital expenditures, as disclosed under "Liquidity and Capital Resources—Material Cash Requirements" in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations in the 2025 Form 10-K.

We expect our expenses to increase in connection with our ongoing activities, particularly as we expand our clinical program with tegoprubart and continue the research and development of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We will continue to require additional financing in order to advance our drug product through clinical development, including initiation of a Phase 3 clinical trial in kidney transplantation and our planned ICT trial, to manufacture, obtain regulatory approval for and to commercialize our product candidates, to develop, acquire or in-license other potential product candidates, and to fund operations for the foreseeable future. Therefore, we will seek to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. The ability to raise substantial additional capital will depend on many factors, including:

- the initiation, progress, timing, costs and results of our ongoing and future clinical trials of tegoprubart, including as such activities may be adversely impacted by global events or macroeconomic conditions;
- the impact of global macroeconomic trends and uncertainties, which continue to experience volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, rising interest rates and uncertainty about economic stability;
- the number and scope of indications we decide to pursue for tegoprubart development;
- the cost, timing and outcome of regulatory review of any biologics license application, or BLA, we may submit for tegoprubart;
- the costs and timing of manufacturing for tegoprubart, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of tegoprubart;
- the costs associated with being a public company;

- the terms and timing of establishing and maintaining collaborations, strategic partnerships, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the cost associated with commercializing tegoprubart, if approved for commercial sale.

Conditions in the financial and credit markets may also limit the availability of funding or increase the cost of funding. As a result of any of the foregoing factors, adequate additional funding may not be available to us on acceptable terms on a timely basis, or at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. For example, without substantial additional financing, we will be unable to continue our planned initiation of a Phase 3 clinical trial in kidney transplantation and a potential company-sponsored study in islet cell transplantation, which could force us to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. The issuance of shares of common stock in our prior private placements and underwritten offerings diluted the ownership interests of our existing stockholders, and to the extent that we raise additional capital through the sale of additional equity, including through our "at-the-market" equity offering program, or convertible debt securities in the future, our stockholders' ownership interests may be further diluted, and the terms of these securities may also include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Please see Part II, Item 1A. *Risk Factors* in this Quarterly Report on Form 10-Q for additional risks associated with our substantial capital requirements and the challenges we may face in raising capital.

Cash Flows

The following table provides a summary of our net cash flow activity for the nine months ended September 30, 2026 and 2025 (in thousands):

	For the Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (64,269)	$ (48,250)
Net cash provided by investing activities	48,523	31,255
Net cash (used in) provided by financing activities	(180)	115
Net change in cash and cash equivalents	$ (15,926)	$ (16,880)

Operating Activities

For the nine months ended September 30, 2026, operating activities used $64.3 million of cash. This net use of cash reflects our net loss of $74.6 million, adjusted for net non-cash charges of $18.2 million, consisting primarily of an $11.6 million loss from the change in fair value of our warrant liabilities and $7.3 million of stock-based compensation expense, partially offset by $0.9 million of accretion of investment discounts. Changes in operating assets and liabilities used $7.8 million of cash, primarily due to a $6.0 million decrease in accounts payable, accrued expenses and other liabilities, reflecting lower clinical accruals following close-out activities for our Phase 2 BESTOW trial and lower manufacturing and compensation accruals, and a $1.5 million increase in prepaid expenses and other assets, primarily related to prepaid clinical costs for our planned Phase 3 LEGACY kidney transplantation trial.

For the nine months ended September 30, 2025, operating activities used $48.3 million of cash. This net use of cash reflects our net loss of $35.2 million, adjusted for net non-cash gains of $16.1 million, consisting primarily of a $22.9 million gain from the change in fair value of our warrant liabilities and $1.4 million of accretion of investment discounts, partially offset by $8.0 million of stock-based compensation expense. Changes in operating assets and liabilities provided $3.0 million of cash, primarily due to a $2.6 million increase in accounts payable, accrued expenses and other liabilities and a $0.5 million decrease in prepaid expenses and other assets.

Investing Activities

For the nine months ended September 30, 2026, investing activities provided $48.5 million of cash, reflecting $117.3 million of proceeds from maturities of available-for-sale short-term investments, partially offset by $68.8 million of purchases of available-for-sale short-term investments.

For the nine months ended September 30, 2025, investing activities provided $31.2 million of cash, reflecting $123.2 million of proceeds from maturities of available-for-sale short-term investments, partially offset by $91.9 million of purchases of available-for-sale short-term investments.

Financing Activities

For the nine months ended September 30, 2026, financing activities used $0.2 million of cash, reflecting $0.9 million of payments of taxes withheld upon the issuance of shares in settlement of restricted stock units, partially offset by $0.4 million of proceeds from the exercise of common stock warrants and $0.3 million of proceeds from the exercise of stock options.

For the nine months ended September 30, 2025, financing activities provided $0.1 million of cash, reflecting proceeds from the exercise of stock options.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Per §229.305 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of September 30, 2026, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Based on this evaluation, management concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2026.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) during the quarter ended September 30, 2026 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.

Neither we nor any of our subsidiaries is a party to, and none of their respective property is the subject of, any material legal proceeding, although we are from time-to-time party to legal proceedings that arise in the ordinary course of our business.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

Risks Related to Our Operations

Our short operating history and shifts in our business strategy may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a clinical stage biotechnology company. Our ongoing operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing technology, identifying potential product candidates and pursuing non-clinical and clinical trials. We have not yet demonstrated our ability to successfully manufacture drug products in large enough quantities and with stability to support additional clinical trials, execute pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. It can take many years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To successfully market any of our current or future product candidates, we will need to transition from a company with a clinical development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Our financial condition raises substantial doubt as to our ability to continue as a going concern if we are unable to raise additional financing to fund our operations.

We have incurred significant net losses since our inception and expect to continue to incur losses for the foreseeable future. As of September 30, 2026, we had cash, cash equivalents and short-term investments of $69.7 million and an accumulated deficit of $475.8 million. We do not currently have sufficient cash on hand to fund our operations for at least twelve months from the date of issuance of the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. Accordingly, management has concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern.

Our unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2026 have been prepared assuming we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. The going concern conclusion, and any going concern qualification or explanatory paragraph that may be included in the report of our independent registered public accounting firm on our future annual financial statements, may make it more difficult and more expensive for us to raise additional capital, may adversely affect the terms on which we are able to raise capital (including causing substantial dilution to existing stockholders), and may cause our suppliers, collaborators, clinical trial sites, or other counterparties to be unwilling to continue to do business with us or to demand more onerous terms.

Our ability to continue as a going concern will require us to obtain additional financing to fund our operations. We may seek to raise additional capital through the sale of equity or debt securities, entering into strategic collaborations or licensing arrangements, or other financing transactions. Additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on acceptable terms, we may be required to significantly delay,

scale back, or discontinue one or more of our research and development programs or other operations, relinquish rights to our technologies or product candidates on unfavorable terms, or liquidate and cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition, results of operations, and prospects, and could cause the market price of our common stock to decline significantly or to lose all of its value.

We have incurred significant operating losses since our inception and expect that we will continue to incur losses over the next several years and may never achieve or maintain profitability.

We have incurred significant annual net operating losses in every year since our inception. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other general and administrative expenses related to our ongoing operations. If tegoprubart or any future product candidates we develop are not successfully developed and approved, we may never generate any revenue from sales of products. We have experienced recurring net losses and negative cash flows from operating activities since our inception. Our net loss for the nine months ended September 30, 2026 was $74.6 million. As of September 30, 2026, we had cash and cash equivalents and short-term investments of $69.7 million, working capital of $62.0 million and an accumulated deficit of $475.8 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We expect it will be several years, if ever, before we have a product candidate ready for commercialization. We have financed our operations to date primarily through the sale of preferred and common stock, and the sale of warrants and we have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year and will depend, in part, on the rate at which we incur expenses and our ability to generate revenue. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We anticipate that we will continue to incur significant expenses as we:

- conduct non-clinical and clinical development of our product candidates or any future product candidate;
- seek to identify and acquire additional product candidates;
- acquire or in-license other products and technologies;
- enter into collaboration arrangements with regards to product discovery or development;
- develop manufacturing processes and/or enter into manufacturing agreements with third-party manufacturers;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- operate as a public company.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we obtain marketing approval. We may never succeed in these activities, including if we do not have available financial resources to allow us to pursue clinical trials and other clinical development activities, and, even if we are successful, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company, could impair our ability to raise capital, maintain our non-clinical and clinical development efforts, and expand our business or continue our operations and may require us to raise additional capital that may dilute the ownership interest of common stockholders. A decline in the value of the Company could also cause stockholders to lose all or part of their investment.

We will require additional funding to be able to complete the development of our lead drug candidate, including our planned initiation of a Phase 3 clinical trial in kidney transplantation and continued advancement of our islet cell transplantation program. If we are unable to raise capital, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

In view of our expectation to incur significant losses for the foreseeable future, we will be required to raise additional capital resources in the future in order to fund our operations. We can also provide no assurance that other funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. If we are unable to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. For example, the initiation of a Phase 3 clinical trial in kidney transplantation and a potential company-sponsored study in islet cell transplantation would require substantial additional capital, and we would need to raise additional financing to initiate such trials. However, there can be no assurance such financing or other alternatives will be available to us on acceptable terms, or at all, for this trial or our other programs, which could force us to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

Our funding needs may fluctuate significantly based on a number of factors, such as:

- the scope, progress, results and costs of formulation development and manufacture of drug product to support non-clinical and clinical development of our product candidates;
- the extent to which we enter into additional collaboration arrangements regarding product discovery or development, or acquire or in-license products or technologies;
- our ability to establish additional collaborations with favorable terms, if at all;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting formulation development, non-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Even if we generate positive clinical data or are able to successfully commercialize one or more of our product candidates, additional financing may not be available to us on acceptable terms, or at all.

In addition to the dilution of our current stockholders' ownership as a result of our prior private placements and underwritten offerings, we currently have a significant number of securities outstanding that are exercisable for our common stock, which could result in significant additional dilution and downward pressure on our stock price. Future issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

As of September 30, 2026, there were 81,442,402 shares of our common stock outstanding and pre-funded warrants and common stock warrants to purchase 48,563,920 shares of our common stock outstanding. The issuance of shares of common stock in our prior private placements and underwritten offerings, diluted the ownership interests of our existing stockholders. The issuance of shares of common stock pursuant to our "at-the-market" equity offering program or upon exercise of pre-funded warrants or common warrants issued in our prior private placements, underwritten offerings and exchange agreement would result in significant additional dilution to our current stockholders, which could adversely affect the price of our common stock and the terms on which we could raise additional capital. If we sell additional shares of common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such

sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

We have no products approved for commercial sale, and our lead product candidate, tegoprubart, remains in clinical development and may not be successfully developed or approved. If we are unable to successfully develop and commercialize tegoprubart or any other product candidate, or if we experience significant delays in doing so, our business will be materially harmed.

We currently do not have any products that have gained regulatory approval. We have invested substantially all of our efforts and financial resources in the development of our lead drug candidate tegoprubart, including funding non-clinical studies, clinical trials, drug formulation and the manufacturing of clinical trial materials. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of one or more drug candidates. As a result, our business is substantially dependent on our ability to successfully complete the development of and obtain approval for one of our potential future additional product candidates.

We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. For example, to execute our business plan, we will need to successfully:

- obtain additional financing in order to advance our drug product through clinical development, and to manufacture, obtain regulatory approval for and commercialize our product candidates;
- execute formulation, manufacturing, clinical, and non-clinical development activities;
- manufacture drug products at commercial scale;
- establish and confirm commercially acceptable stability (shelf-life) of our drug products;
- in-license or acquire other product candidates and advance them through clinical development;
- obtain required regulatory approvals for the development and commercialization of tegoprubart or other product candidates;
- maintain, leverage, and expand our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for any approved and marketed drug products;
- obtain and maintain adequate product pricing and reimbursement;
- develop and maintain any strategic relationships we elect to enter; and
- manage our spending as costs and expenses increase due to product manufacturing, non-clinical development, clinical trials, regulatory approvals, post-marketing commitments, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize our or other product candidates, and our business will suffer.

Public health crises, including pandemics or epidemics, could adversely affect our business.

Our business and operations, including but not limited to ongoing or planned research and development activities may be impacted by public health crises. For example, our business was adversely affected by the COVID-19 pandemic, which also caused significant disruption in the operations of third parties upon whom we rely. Other future public health crises, including any future pandemics or epidemics could have a similar impact on our business. We may experience, as we did with the COVID-19 pandemic, disruptions as a result of future public health crisis, such as a future pandemic or epidemic, that could severely impact our operations and development activities, including, but not limited to:

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delays in manufacturing of our drug candidates due to increased competition for manufacturing capacity as a result of the pandemic;

- limitations in employee resources that would otherwise be focused on the conduct of our development activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the U.S. Food and Drug Administration ("FDA") to accept data from clinical trials in affected geographies;
- delays in procuring drug substance and/or in manufacturing drug product due to limitations in employee resources or forced furloughs at our contract manufacturing organizations;
- delays in initiation of future clinical trials, including delays in receiving authorization from local regulatory authorities to initiate such clinical trials; and
- delays or disturbances in enrollment and trial execution, for example, because clinical trial sites may be unable to operate normally, or patients may elect to forego visits to medical facilities or undertake voluntary medical procedures.

Any of the foregoing factors, or other effects of any public health crisis, including any future pandemic or epidemic, could materially affect our business, possibly to a significant degree. The severity and duration of any such impacts cannot be predicted.

Unfavorable global economic conditions could adversely affect our business, financial condition and results of operations.

The global economy, including the financial and credit markets, continues to experience extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, elevated inflation and interest rates, changes in U.S. trade policy and uncertainty about economic stability. Likewise, the current conflicts in Ukraine and the Middle East have created volatility in the global capital markets and global economic consequences, including disruptions of the global supply chain and energy markets. A severe or prolonged economic downturn or continued volatility in the financial and credit markets could negatively impact our ability to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. For example, the initiation of a Phase 3 clinical trial in kidney transplantation and a potential company-sponsored study in islet cell transplantation would require substantial additional capital, and we would need to raise additional financing to initiate such trials. However, there can be no assurance such financing or other alternatives will be available to us on acceptable terms, or at all, for this trial or our other programs, which could force us to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

In addition, as a result of high levels of inflation, we have experienced and may continue to experience cost increases, including costs of clinical trials and research and development of our product candidates, production costs, the price of labor, administration and other costs of doing business. Although we may continue to take measures to mitigate the impact of this inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Further, in an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise more capital to fund our operations than expected, and such capital may not be available in sufficient amounts or on reasonable terms, if at all.

Adverse conditions in the financial markets, including bank failures, could adversely affect our liquidity and financial performance.

We currently maintain domestic cash deposits, for short term operating requirements, in Federal Deposit Insurance Corporation ("FDIC") insured banks, which exceed the FDIC insurance limits. Our additional cash and cash equivalents are held in accounts managed by third-party financial institutions and consist primarily of cash invested in money market funds and government bonds. Bank failures, events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to widespread demands for customer withdrawals and liquidity constraints that may result in market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank failed and was taken into receivership by the FDIC. At that time, we maintained deposits

amounting to approximately 78% of our total cash at Silicon Valley Bank. On March 26, 2023, the assets, deposits and loans of Silicon Valley Bank were acquired by First-Citizens Bank & Trust Company. In response to the failure of Silicon Valley Bank, we diversified our cash deposits into money market funds, U.S. treasuries and U.S. government agency securities and, as of the date of this report, our total cash maintained in FDIC insured banking accounts is less than 3% of our total cash and cash equivalents and short-term investments. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. Additionally, our cash investments outside of FDIC insured bank accounts are subject to general credit, liquidity, market, and interest rate risks. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition and could limit our access to liquidity.

Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development, formulation and commercialization of our product candidates.

Our product candidates remain in clinical development, and the risk of failure is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct non-clinical trials and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Formulation and device development, non-clinical and clinical testing are all expensive activities, difficult to design and implement, and can take years to complete. Failure can occur at any time during the development program, including during the clinical trial process. Further, the results of non-clinical studies and early clinical trials of our product candidates, as well as earlier generation formulations may not be predictive of the results of later-stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in non-clinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional non-clinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States and/or that subsequent studies will not match results seen in prior studies. It is impossible to predict when or if any of our product candidates will prove effective, safe and well-tolerated in humans or will receive regulatory approval.

We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the FDA or equivalent foreign regulatory bodies will approve investigational new drug applications and allow us to start clinical trials for any of our product candidates in the future, including for islet cell transplant. Once a clinical trial has commenced, there is also no assurance that the FDA or equivalent foreign regulatory body will not put any of our product candidates on clinical hold. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we want to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- delays in completing formulation development and manufacturing as a prerequisite to commencing clinical work;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;

- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our contract research organizations ("CROs") and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have difficulty partnering with experienced CROs and study sites that can identify patients that our product candidates are designed to target and run our clinical trials effectively;
- regulators or institutional review boards ("IRBs") may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions. For example, the Trump administration issued an Executive Order that paused the FDA's rulemaking ability and could affect recently finalized FDA rules that have not yet taken effect. The extent to which such existing or future executive orders impact the healthcare regulatory environment remains uncertain and could materially impact our development and commercialization activities. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government or reduction in funding or staffing at U.S. government agencies, including the FDA and SEC. For example, a prolonged shutdown or the reduction of funding or staffing at the FDA may significantly delay the FDA's ability to timely review and process any submissions we may file or cause other regulatory delays, which could materially and adversely affect our business. Further, government shutdowns and/or employee terminations or resignations at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-marketing restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our non-clinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant non-clinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or may allow our competitors to bring products to market before we

do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented and expenses for the development of our product candidates could increase.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. We do not know whether the ongoing or planned clinical trials will enroll subjects in a timely fashion, require redesign of essential trial elements or be completed on their projected schedules. In addition, competitors may have ongoing clinical trials for product candidates that treat related or the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

Patient enrollment is affected by other factors including:

- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same disease indication;
- the patient referral practices of physicians;
- the proximity and availability of clinical trial sites for prospective patients;
- ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results;
- feedback from regulatory authorities, IRBs, ethics committees ("ECs"), or data safety monitoring boards, or results from earlier stage or concurrent non-clinical and clinical trials, that might require modifications to the protocol;
- decisions by regulatory authorities, IRBs, ECs, or the Company, or recommendations by data safety monitoring boards, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and
- unacceptable risk-benefit profile or unforeseen safety issues or adverse effects.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing.

Our ability to conduct clinical trials in some jurisdictions outside of the United States may be adversely affected.

We currently have clinical trial sites in regions outside the United States, including Australia, Canada, Brazil, the European Union and the United Kingdom, and we will continue to conduct future clinical trials in these markets. Our ability to conduct clinical trials at sites located outside the United States is subject to numerous risks unique to conducting business in jurisdictions outside the United States, including:

- difficulty in establishing or managing relationships with qualified CROs, physicians and clinical trial sites;
- different local standards for the conduct of clinical trials;
- difficulty in complying with various and complex import laws and regulations when shipping drugs to certain countries;
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments;
- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries;

- instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts, social upheaval or political uncertainty;
- foreign exchange fluctuations;
- cultural differences in medical practice and clinical research; and
- changes in country or regional regulatory requirements.

The ongoing conflict in Ukraine and the resulting imposition of economic and other sanctions by the United States, European Union and many other nations on Russia, individuals in Russia, Russian businesses and the Russian central bank, or any escalation of tensions in the region, could have a broader impact that expands into other countries. The ongoing conflict in the Middle East could have similar impacts. Although the length and impact of any military action and expansion of the conflict into other countries are highly unpredictable, if either conflict spreads or has effects on additional countries, we may experience disruptions or delays in our plans to conduct clinical trial activities in affected regions outside the United States.

If severe adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidates are associated with severe adverse events or unacceptable side effects in non-clinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the adverse event or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Any occurrences of clinically significant adverse events or unacceptable side effects with our product candidates may harm our business, financial condition and prospects significantly.

Tegoprubart remains in clinical development, and its side effect profile in humans has not been fully established. Currently unknown, drug-related side effects may be identified through ongoing and future clinical trials and, as such, these possible drug-related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial, or result in potential product liability claims.

Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future.

We are highly dependent on the product development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executives and key employees, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel is critical to our success. Due to the small size of the Company and the limited number of employees, each of our executives and key employees serves in a critical role. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating drug product, non-clinical development, clinical development, regulatory strategy, and commercial strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Risks Related to Regulatory Approval of Our Product Candidates and Other Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.

Our product candidates must be approved by the FDA pursuant to a new drug application in the United States and by other regulatory authorities outside the United States prior to commercialization in the respective regions. The process of obtaining marketing approvals, both in the United States and outside the United States, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any country. We have no experience in filing and supporting the applications necessary to gain marketing approvals for our products and may engage third-party consultants to assist in this process. Securing marketing approval requires the submission of extensive non-clinical and clinical data, and other supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product formulation and manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional non-clinical, clinical or other data. In addition, varying interpretations of the data obtained from non-clinical and clinical trials could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

Any marketing approval we ultimately obtain may be for fewer or more limited indications than requested or subject to restrictions or post-approval commitments that render the approved product not commercially viable or its market potential significantly impaired. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In order to market and sell our products in the EU and other international jurisdictions outside of the United States, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may require additional non-clinical, clinical or health outcome data. In addition, the time required to obtain approval may differ substantially amongst international jurisdictions. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition to regulatory approval, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulations that are specific to those defined by regulatory authorities in the countries where the product is approved. In the United States and other countries that follow the International Conference on Harmonization, these requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, Current Good Manufacturing Practices ("cGMP") requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities, requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA, or other regulatory authorities, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval

marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Legislation regulating the pharmaceutical and healthcare industries may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes intended to contain healthcare costs and modify the regulation of drug and biologic products. These and other regulatory changes could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in 2022, the U.S. government enacted the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which took effect in 2023. The Inflation Reduction Act of 2022 requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for certain drugs used by Medicare beneficiaries. The mechanics of the rebate calculation are similar to those of the Medicaid rebate, but the expansion of inflation-based rebates may further complicate pricing strategies. In addition, in 2025, President Trump issued executive orders focused on lowering drug prices in the U.S. It is unclear how these drug pricing initiatives will affect what actions will be implemented by the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS"), or FDA, and how those actions will impact our industry and our business. The Inflation Reduction Act of 2022 or other similar legislation could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability.

We expect that additional state and federal healthcare reform measures and regulations will be adopted in the future. Any of these measures and regulations could limit the amounts that federal and state governments will pay for healthcare products and services, result in reduced demand for our product candidates or additional pricing pressures and affect our product development, testing, marketing approvals and post-market activities.

Recent administrative law cases decided by the U.S. Supreme Court in 2024 may create uncertainty with respect to actions taken by regulatory agencies to interpret, implement and enforce federal legislation. For example, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo* ("*Loper* decision"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in legal challenges to regulations and guidance issued by federal agencies that are currently applicable to or will be applicable to our business, including those issued by the FDA and the CMS. Further, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and delays in or other impacts to the agency rulemaking process, which could have a material adverse effect on our business, financial condition and results of operations.

Laws, restrictions, and other regulatory measures imposed in international jurisdictions present similar challenges to those in the United States, including increased difficulty and cost in obtaining marketing approval and commercializing of our product candidates, as well as potential limitations on the prices we may obtain.

In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our business operations and relationships with healthcare providers, physicians, third-party payers, and customers will be subject to applicable anti-kickback, fraud and abuse and other broadly applicable healthcare laws, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we receive marketing approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute the products for which we receive marketing approval. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, federal and state healthcare laws are and will be applicable to our business. Such laws include, but are not limited to federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act ("FCA"), the federal Anti-Kickback Statute, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), the federal transparency requirements under the Physician Payments Sunshine Act, and analogous state, local or foreign law.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Laws, restrictions, and other regulatory measures are also imposed by anti-kickback, fraud and abuse, and other healthcare laws and regulations in international jurisdictions, and in those jurisdictions we face the same issues as in the United States regarding exposure to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

We depend on our information systems and those of our third-party collaborators, service providers, contractors or consultants, which may fail or suffer cybersecurity incidents that could result in a material disruption of our development programs or loss of data and have a material adverse effect on our reputation, business, financial condition or results of operations.

We rely on our information systems and infrastructure to effectively manage our business, including our clinical trials and studies. Our information systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from cybersecurity incidents, including computer viruses, denial-of-service attacks, hacking, phishing and other social engineering attacks, unauthorized access or use resulting from malware, as well as disruptions due to natural disasters, terrorism, war, mistakes or technical errors, including due to software updates and telecommunication and electrical failures. We may also experience cybersecurity incidents stemming from persons inside our organizations (including employees or contractors), or other persons with access to information systems inside our organization. Attacks on information systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. Further, cybersecurity threats and the techniques used in cyberattacks change, develop and evolve rapidly, including from emerging technologies, such as advanced forms of artificial intelligence and quantum computing. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. Information system disruptions, even if inadvertent, may limit or disable our access or important third parties' access to our systems. While to our knowledge none of the cybersecurity incidents we have experienced to date have had a material adverse impact on our business, financial condition or operations, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors or consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm.

The compromise of privacy, security, integrity or confidentiality of sensitive information related to our business or failure to comply with confidentiality and data privacy obligations could have a material adverse effect on our business.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our information systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could be found to have violated applicable U.S. and international privacy, data protection and other laws, which could subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the U.S. and by international regulatory entities, resulting in exposure to material civil and/or criminal liability, and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to cybersecurity incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our

privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements.

European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

We may collect, process, use or transfer personal information from individuals located in the European Economic Area (the "EEA") in connection with our business, including in connection with conducting clinical trials in the EEA. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the EEA. The collection and use of personal health data in the EEA is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) (the "GDPR"), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the EEA, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the EEA and other states in the EEA may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our non-clinical or clinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other novel products to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- the ability to develop or partner with third-party collaborators to develop companion diagnostics;

- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If our current product candidates, or a future product candidate receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, the ability to market the product could be compromised.

Clinical trials are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent beneficial effect of a product candidate that is greater than the actual positive effect in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- the product may be required to be recalled or changes may be required to the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- the creation of a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- additional restrictions may be imposed on the distribution or use of the product via a Risk Evaluation and Mitigation Strategy;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business. The commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We currently have no marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming, will require significant attention of our executive officers to manage and may nonetheless fail to effectively market and sell our product candidates. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

If approved, we expect that tegoprubart will face competition from FDA-approved therapeutics for the prevention of transplant rejection, including PROGRAF®, ASTAGRAF XL®, ENVARSUS XR®, NULOJIX®, CELLCEPT®, MYFORTIC®, and numerous other branded and generic immunosuppressive agents. Multiple companies and academic institutions are developing approaches in kidney transplantation, including tolerance-induction regimens that combine donor stem cell transplantation with kidney transplantation, that may ultimately reduce or eliminate the need for immunosuppressive agents in that setting.

We have an open IND for a planned Company-sponsored, registrational clinical trial of tegoprubart for the prevention of allograft rejection in patients with T1D undergoing transplantation of pancreatic islet cells from deceased donors. If approved for this indication, we expect that tegoprubart will face competition from islet cell replacement approaches that are designed to eliminate the need for immunosuppression, including hypoimmune gene-edited and immune-protected stem cell-derived islet cell therapies, which are not limited by the supply of deceased-donor islets. Companies that are developing, or have developed, such approaches include APstem Therapeutics, Aspect Biosystems, Century Therapeutics, Sana Biotechnology, Seraxis and Vertex Pharmaceuticals. Some of these companies are larger than we are and have significantly greater financial, manufacturing and regulatory resources. In addition, companies currently developing islet cell therapies intended to be administered with immunosuppression, including companies with which we collaborate, may pursue immune-evasive approaches in the future. If approved and adopted, these approaches could reduce the use of deceased-donor islet cell transplantation or the need for immunosuppressive agents such as tegoprubart in this setting.

In addition, there are a number of companies that are developing, or have developed, competing anti-CD40 and anti-CD40L therapeutics for transplant, autoimmune or central nervous system indications, including: Amgen (post-acquisition of Horizon Therapeutics), Bristol Myers Squibb, Kiniksa Pharmaceuticals, Novartis, Sanofi, Spero Therapeutics, Tonix Pharmaceuticals and UCB. Most of these companies are larger than we are and have significantly greater resources to develop their drug candidates. Companies that have deprioritized or discontinued development of such therapeutics may resume development, or may license or sell those assets to third parties that do so. We also face competition from companies developing novel immunosuppressive agents and other approaches for transplantation, including LifeMine Therapeutics, which is developing a novel calcineurin activation inhibitor for transplant indications and Veloxis Pharmaceuticals, which is developing an anti-CD28 antibody fragment for transplant indications.

If approved for the treatment of ALS, we expect that tegoprubart will face competition from FDA-approved therapeutics for ALS, including QALSODY® (tofersen), RADICAVA® (edaravone) and riluzole, and numerous other branded and generic immunosuppressive agents. Multiple pharmaceutical and biotechnology companies are developing, or have developed, competing ALS pharmaceutical, gene therapy and cell therapy approaches, including Alexion Pharmaceuticals, Apic Bio, Argenx, AZTherapies, Biogen, Brainstorm Cell Therapeutics, Coya Therapeutics, Cytokinetics, Ionis Pharmaceuticals, Orion Pharma, Orphazyme and Voyager Therapeutics.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products.

Generic products are currently available, with additional generic products expected to become available over the coming years, potentially creating pricing pressure. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting non-clinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payers, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Increased expense is incurred to cover costs of health outcome focused research used to generate data necessary to justify the value of our products in order to secure reimbursement. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition, many private payers contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that we

may develop; injury to our reputation and significant negative media attention; withdrawal of clinical trial participants; significant costs to defend the related litigation; substantial monetary awards to trial participants or patients; loss of revenue; reduced resources of our management to pursue our business strategy; and the inability to commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

We contract with third parties for the manufacture of our product candidates for non-clinical and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.

We have utilized, and intend to continue utilizing, third parties to formulate, manufacture, package, and distribute clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we rely on third parties for the manufacturing of drug substance and drug product for non-clinical and clinical activities. Our manufacturing vendors utilize proprietary cell culture media, cell lines, buffers, manufacturing equipment, manufacturing supplies, and storage buffers for the manufacturing of tegoprubart and other product candidates. These materials are custom-made and available from only a limited number of sources. Although we believe that our third-party suppliers maintain a significant supply of these materials and equipment on hand, any sustained disruption in this supply, could adversely affect our operations. We do not have any long-term agreements in place with our current suppliers. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with regulatory requirements and our specifications. Any delays or difficulties in obtaining or in manufacturing, packaging or distributing approved product candidates could negatively impact our clinical trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval. Despite drug substance and product risk management, this reliance on third parties presents a risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, these third parties experienced disruptions in their operations in conjunction with the COVID-19 pandemic. Additionally, on April 16, 2025, the U.S. Department of Commerce announced an investigation under Section 232 of the Trade Expansion Act of 1962 into imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. The investigation will examine the impact of these imports on U.S. national security culminating in a decision by the President whether to take action to remedy any identified threats, including by imposing additional tariffs. Further, the U.S. government has proposed a 100% tariff on branded and patented pharmaceutical products. All of these current and threatened tariffs are subject to implementation or change with little notice. Any delay, performance failure, or increase in costs on the part of our existing or future manufacturers of drug substance or drug products could delay or increase the cost of our clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If suppliers cannot supply us with our requirements, we may be required to identify alternative manufacturers, which would lead us to incur added costs and delays in identifying and qualifying any such replacement.

Formulations and devices used in early studies are not final formulations and devices for commercialization. Additional changes may be required by the FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies and may result in a delay in our clinical trials and commercialization activities.

We also expect to rely on other third parties to label, store, and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The third parties we rely on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our clinical or commercialization activities. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Additionally, macro-economic conditions may adversely affect these third parties, causing them to suffer liquidity or operational problems. If a key third-party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We depend on CROs and other contracted third parties to perform non-clinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control.

The nature of outsourcing a substantial portion of our business will require that we rely on CROs and other contractors to assist us with research and development, clinical testing activities, patient enrollment, data collection, and regulatory submissions to the FDA or other regulatory bodies. As a result, our success will depend partially on the success of these third parties in performing their responsibilities. Although we intend to pre-qualify our CROs and other contractors and we believe that the contractors selected will be fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, macro-economic conditions may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. If our contractors do not perform their obligations in an adequate and timely manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed, and our prospects could be adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in relevant countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and internationally that are related to our novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering pharmaceutical compositions and methods of use.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent

protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and non-clinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the EU, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The risks described pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

The United States Patent and Trademark Office ("USPTO") and various non-U.S. governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In certain situations, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

In addition, we have acquired rights to tegoprubart and other product candidates through a license agreement with The ALS Therapy Development Institute and a manufacturing know-how rights license agreement with Lonza Sales AG for the use of certain processes and know-how related to the manufacture of tegoprubart, and may in the future enter into other license agreements with third parties for other intellectual property rights or assets. These license agreements do, and future license agreements may, impose various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates than if we had developed the licensed technology internally.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third

parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license or are not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any NDAs or similar agreements entered into by the Company may not be with all relevant parties, or adequately protect the confidentiality of our trade secrets. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We may be subject to claims of misappropriation of trade secrets from former employers of Company personnel.

Many of our employees and certain of our directors were previously employed at or affiliated with research foundations or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees and directors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director's former employer. Litigation may be necessary to defend against these

claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Common Stock

We expect our stock price to be volatile, and the market price of our common stock may drop unexpectedly.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- uncertainties regarding our financial condition and our ability to raise sufficient capital to fund our ongoing operations;
- our ability to obtain regulatory approvals for our product candidates or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- issues in manufacturing our approved products, if any, or product candidates;
- the results of our current and any future clinical trials of our product candidates;
- uncertainties about the ability of tegoprubart to prevent rejection in connection with kidney, xeno or islet cell transplantations;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress, or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies that compete with our potential products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- changes in the structure of healthcare payment systems;
- period-to-period fluctuations in our financial results; and
- future issuances of shares of common stock.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We have previously identified and remediated a material weakness in our internal control over financial reporting. If we fail to maintain effective internal controls, we may conclude that our internal control over financial reporting is not effective, which could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("GAAP"). Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our disclosure controls and procedures,

and to disclose any material weaknesses and any changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, such controls. Ensuring that we will have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently.

We have previously identified and remediated a material weakness in our internal controls over financial reporting, including as described in Part II Item 9A, Controls and Procedures of the Annual Report on Form 10-K for the year ended December 31, 2025, filed on March 19, 2026. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. Although the Company concluded that as of December 31, 2025 its internal control over financial reporting was effective, the Company cannot provide assurances that the remediated material weakness will not reoccur, or that a new material weakness will not occur in the future. The existence of any material weakness could require management to devote significant time and incur significant expense to remediate any such material weakness and management may not be able to remediate any such material weakness in a timely manner. If we fail to maintain effective internal controls or any such material weakness is not remediated effectively or in a sufficient amount of time, our ability to report our results of operations and financial condition accurately and in a timely manner could be adversely impacted. Further, we could be impacted by a material misstatement of our annual or interim financial statements that was not prevented or detected on a timely basis, which could have a negative effect on our results of operations and/or the trading price of our securities.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of the Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

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

- establish a classified Board such that not all members of the Board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board;
- limit the manner in which stockholders can remove directors from our Board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of the Company's charter or bylaws.

We do not expect to pay any cash dividends in the foreseeable future.

We expect to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for any stockholders for the foreseeable future.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Insider Trading Arrangements

During the three months ended September 30, 2026, none of our officers or directors adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or constituted a "non-Rule 10b5-1 trading arrangement."

Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Novus Therapeutics, Inc., a Delaware corporation, dated September 22, 2014 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on September 26, 2014).
3.2	Certificate of Amendment to Certificate of Incorporation of Novus Therapeutics, Inc. (effecting, among other things a reverse stock-split), filed with the Secretary of the State of Delaware on May 9, 2017 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on May 15, 2017).
3.3	Certificate of Amendment to Certificate of Incorporation of Novus Therapeutics, Inc. (effecting, among other things a change in the corporation's name to "Novus Therapeutics, Inc."), filed with the Secretary of the State of Delaware on May 9, 2017 (filed with the SEC as Exhibit 3.2 on the Company's Current Report on Form 8-K filed on May 15, 2017).
3.4	Certificate of Amendment to the Restated Certificate of Incorporation of Novus Therapeutics, Inc., (effecting, among other things a reverse stock-split) effective as of October 5, 2020 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on October 6, 2020).
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of Novus Therapeutics, Inc., (effecting, among other things a change in the corporation's name to "Eledon Pharmaceuticals, Inc.") effective as of January 5, 2021 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on January 5, 2021).
3.6	Certificate of Amendment to the Restated Certificate of Incorporation, as amended, of Eledon Pharmaceuticals, Inc., (effecting an increase in authorized shares of common stock) effective June 10, 2025 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on June 12, 2025).
3.7	Certificate of Amendment to the Restated Certificate of Incorporation, as amended, of Eledon Pharmaceuticals, Inc., (providing for exculpation of certain officers) effective June 10, 2025 (filed with the SEC as Exhibit 3.2 on the Company's Current Report on Form 8-K filed on June 12, 2025).
3.8	Certificate of Amendment to the Restated Certificate of Incorporation, as amended, of Eledon Pharmaceuticals, Inc., (effecting an increase in authorized shares of common stock) effective June 22, 2026 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on June 22, 2026).
3.9	Certificate of Designations of Series X Convertible Preferred Stock (filed with the SEC as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 19, 2020).
3.10	Certificate of Designations of Series X[1] Convertible Preferred Stock (filed with the SEC as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 15, 2020).
3.11	Amended and Restated Bylaws of Eledon Pharmaceuticals, Inc. (filed with the SEC as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 5, 2021).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	INLINE XBRL Instance Document– the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	INLINE XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page formatted as INLINE XBRL and contained in Exhibit 101

* Filed herewith.

** Furnished herewith.

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.

Eledon Pharmaceuticals, Inc.

Date: November 12, 2026

By: /s/ David-Alexandre C. Gros, M.D.

David-Alexandre C. Gros, M.D.
Chief Executive Officer and Director (Principal Executive Officer)

Date: November 12, 2026

By: /s/ Paul Little

Paul Little
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS

I, David-Alexandre C. Gros, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eledon Pharmaceuticals, 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: November 12, 2026

By: /s/ David-Alexandre C. Gros, M.D.
David-Alexandre C. Gros, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Paul Little, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eledon Pharmaceuticals, 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: November 12, 2026

By: /s/ Paul Little
Paul Little
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Eledon Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David-Alexandre C. Gros, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(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: November 12, 2026

By: /s/ David-Alexandre C. Gros, M.D.
David-Alexandre C. Gros, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

**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 on Form 10-Q of Eledon Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Little, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(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: November 12, 2026

By: /s/ Paul Little
Paul Little
Chief Financial Officer
(Principal Financial Officer)