UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

OR

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

For the transition period from to

Commission File Number: 001-40708

ELIEM THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-2273741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
PMB #117 **2801 Centerville Road 1st Floor** **Wilmington, DE**	**19808-1609**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 1-877-ELIEMTX (354-3689)

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, par value $0.0001 per share	**ELYM**	**The Nasdaq Stock Market LLC (The Nasdaq Global Market)**

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

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

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

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

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

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

As of August 9, 2024, the registrant had 67,060,163 shares of common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risk and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- the anticipated timing of the submission and clearance of investigational new drug applications (INDs) and comparable foreign applications for budoprutug (previously referred to as TNT119) and any future product candidates we may develop;
- our estimates regarding the potential patient populations for budoprutug and any future product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements, need for additional financing and the period over which we believe our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- our plans to develop and, if approved, subsequently commercialize budoprutug and any future product candidates we may develop;
- the timing of and our ability to submit applications for, and obtain and maintain regulatory approvals for budoprutug and any future product candidates we may develop;
- our intellectual property position and our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for budoprutug and any future product candidates we may develop;
- our estimates regarding the size of the potential markets for our product candidates and our ability to serve those markets;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing products that are or might become available;
- the impact of government laws and regulations;
- our ability to enter into future collaborations, strategic alliances, or option and license arrangements; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in this Quarterly Report on Form 10-Q, particularly in the “Risk Factor Summary” below and in Part II, Item 1A, “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference hereto completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those risks discussed in further detail below. These risks include, among others, the following:

•We have incurred significant losses since our inception, anticipate that we will incur substantial losses for the foreseeable future, and may never achieve or maintain profitability.

•We will need substantial additional funding for our continuing operations, and if we are unable to access capital when needed, it could force us to delay, reduce or terminate our product development programs, commercialization efforts, or other operations.

•We have never generated revenue from product sales and may never achieve or maintain profitability.

•Our future success is dependent primarily on regulatory approval and commercialization of budoprutug and any future product candidates we may develop.

•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 payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.

•Preliminary, initial, or interim results from clinical trials that we announce, present, or publish from time to time may change as more data and information become available (or are updated based upon audit, validation and verification procedures of the data/information commonly performed for clinical trials) that could result in material changes in the final trial results.

•Preclinical and clinical development involves a lengthy, complex and expensive process with an uncertain outcome. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of any future clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration (the FDA) or comparable foreign regulatory authorities.

•We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.

•We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, less expensive or more advanced or effective than us, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.

•We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

•We rely heavily on certain in-licensed patents and other intellectual property rights in connection with our development of budoprutug and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize budoprutug.

•We have four pending U.S. provisional patent applications with respect to budoprutug. We can provide no assurance that any of our other current or future patent applications will result in issued patents. If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

•We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

•The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

Eliem Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

Assets	**June 30, 2024**	**December 31, 2023**
Current assets:		
Cash and cash equivalents	$ 223,140	$ 93,112
Short-term marketable securities	—	13,686
Prepaid expenses and other current assets	2,857	3,457
Total current assets	$ 225,997	$ 110,255
Operating lease right-of-use assets	21	199
Other long-term assets	—	15
Total assets	$ 226,018	$ 110,469
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	509	66
Accounts payable, related party	101	—
Accrued expenses and other current liabilities	2,950	2,433
Accrued expenses and other current liabilities, related party	81	—
Operating lease liabilities	100	334
Total current liabilities	$ 3,741	$ 2,833
Operating lease liabilities, net of current portion	—	22
Other long-term liabilities	—	15
Total liabilities	$ 3,741	$ 2,870
Commitments and contingencies (Note 7)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 250,000,000 shares authorized; 66,785,449 and 27,699,446 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	7	3
Additional paid-in capital	434,835	263,577
Accumulated other comprehensive loss	—	(2)
Accumulated deficit	(212,565)	(155,979)
Total stockholders' equity	$ 222,277	$ 107,599
Total liabilities and stockholders' equity	$ 226,018	$ 110,469

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

Eliem Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Acquired in-process research and development, related party	$ 51,659	$ —	$ 51,659	$ —
Research and development	1,046	3,688	2,137	9,408
General and administrative	3,667	3,026	5,581	20,744
Total operating expenses	56,372	6,714	59,377	30,152
Loss from operations	(56,372)	(6,714)	(59,377)	(30,152)
Other income (expense):				
Foreign currency gain (loss)	(2)	384	(35)	632
Other income, net	1,485	1,110	2,826	2,010
Total other income (expense)	1,483	1,494	2,791	2,642
Net loss	$ (54,889)	$ (5,220)	$ (56,586)	$ (27,510)
Net loss per share, basic and diluted	$ (1.81)	$ (0.19)	$ (1.95)	$ (1.03)
Weighted-average number of shares outstanding used to compute net loss per share, basic and diluted	30,349,562	26,840,555	28,994,045	26,667,458
Comprehensive loss:				
Net loss	$ (54,889)	$ (5,220)	$ (56,586)	$ (27,510)
Other comprehensive loss:				
Unrealized gain on investments, net of tax of $0	—	60	2	323
Comprehensive loss	$ (54,889)	$ (5,160)	$ (56,584)	$ (27,187)

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

Eliem Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(unaudited)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2023	27,626,435	$ 3	$ 263,577	$ (2)	$ (155,979)	$ 107,599
Vesting of restricted stock awards and units	24,579	—	—	—	—	—
Exercise of stock options	10,999	—	15	—	—	15
Stock-based compensation	—	—	465	—	—	465
Other comprehensive income	—	—	—	2	—	2
Net loss	—	—	—	—	(1,697)	(1,697)
Balance as of March 31, 2024	27,662,013	$ 3	$ 264,057	$ —	$ (157,676)	$ 106,384
Vesting of restricted stock awards and units	32,453	—	—	—	—	—
Exercise of stock options	2,248,504	—	8,652	—	—	8,652
Stock-based compensation	—	—	512	—	—	512
Issuance of common stock in private placement, net of issuance costs of $250	31,238,282	3	119,747	—	—	119,750
Issuance of common stock for the acquisition of in-process research and development from a related party	5,560,047	1	41,867	—	—	41,868
Net loss	—	—	—	—	(54,889)	(54,889)
Balance as of June 30, 2024	66,741,299	$ 7	$ 434,835	$ —	$ (212,565)	$ 222,277

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2022	26,390,186	$ 3	$ 249,930	$ (358)	$ (120,860)	$ 128,715
Vesting of restricted stock awards	19,608	—	—	—	—	—
Exercise of stock options	406,194	—	1	—	—	1
Stock-based compensation	—	—	10,171	—	—	10,171
Other comprehensive income	—	—	—	263	—	263
Net loss	—	—	—	—	(22,290)	(22,290)
Balance as of March 31, 2023	26,815,988	$ 3	$ 260,102	$ (95)	$ (143,150)	$ 116,860
Vesting of restricted stock awards and units	44,038	—	—	—	—	—
Exercise of stock options	23,526	—	24	—	—	24
Stock-based compensation	—	—	777	—	—	777
Other comprehensive income	—	—	—	60	—	60
Net loss	—	—	—	—	(5,220)	(5,220)
Balance as of June 30, 2023	26,883,552	$ 3	$ 260,903	$ (35)	$ (148,370)	$ 112,501

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

Eliem Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (56,586)	$ (27,510)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	977	10,948
Right-of-use asset impairment	—	180
Non-cash operating lease expense	178	232
Accretion of discounts and amortization of premiums on investments, net	(63)	(1,232)
In-process research and development, related party	51,659	—
Foreign currency (gain) loss from remeasurement	9	(630)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,425	(784)
Long-term assets	15	(1,528)
Accounts payable	(1,160)	128
Accounts payable and accrued liabilities, related party	5	—
Accrued liabilities	326	(2,792)
Operating lease liabilities	(249)	(209)
Long-term liabilities	(22)	55
Net cash used in operating activities	$ (2,486)	$ (23,142)
Cash flows from investing activities:		
Issuance of promissory loan in connection with asset acquisition	(5,000)	—
Cash paid in connection with asset acquisition, net of cash acquired	(4,645)	—
Purchase of marketable securities	—	(55,985)
Proceeds from maturities of marketable securities	13,751	60,181
Net cash provided by investing activities	$ 4,106	$ 4,196
Cash flows from financing activities:		
Proceeds from issuance of common stock in private placement, net of issuance costs	119,750	—
Proceeds from the exercise of stock options	8,667	25
Net cash provided by financing activities	$ 128,417	$ 25
Effect of exchange rate changes on cash and cash equivalents	(9)	630
Net change in cash and cash equivalents	$ 130,028	$ (18,291)
Cash and cash equivalents at beginning of period	93,112	43,585
Cash and cash equivalents at end of period	$ 223,140	$ 25,294
Supplemental disclosure of cash operating activities:		
Cash paid for leases included in operating cash outflows	$ 263	$ 244
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of common stock in exchange for in-process research and development	$ 41,867	$ —
Settlement of promissory loan in connection with asset acquisition	$ 5,036	$ —
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 313

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

Eliem Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of Organization and Summary of Significant Accounting Policies

Organization

Eliem Therapeutics, Inc. (the Company) is a biotechnology company focused on developing therapeutics for autoimmune-driven inflammatory diseases, including budoprutug (previously referred to as TNT119), an anti-CD19 monoclonal antibody designed for a broad range of autoimmune diseases, including systemic lupus erythematosus and lupus nephritis (SLE/LN), immune thrombocytopenia (ITP), and membranous nephropathy (MN). The Company was incorporated on October 18, 2018 as a Delaware corporation and is headquartered in Delaware.

On June 27, 2024, the Company completed its acquisition of Tenet Medicines, Inc. (the Acquisition). In connection with the closing of the Acquisition, the Company issued and sold 31,238,282 shares of its common stock at a price of $3.84 per share in a private placement to several accredited institutional investors (the Private Placement). The Company received aggregate gross proceeds from the Private Placement of approximately $120.0 million, before deducting offering costs of $0.3 million.

For additional information on the Acquisition and Private Placement, please refer to Note 2, *Asset Acquisition and Private Placement with a Related Party*, in these interim condensed consolidated financial statements.

Previously, the Company focused primarily on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems, and the Company's lead program was ETX-123, a Kv7.2/3 potassium channel opener. ETX-123 is designed to harness the efficacy of the Kv7.2/3 channel mechanism while attempting to improve the safety and tolerability relative to earlier molecules, based on the Company's insights into the mechanisms of toxicity and the potency and selectivity profile. In July 2023, the Company made the determination to pause further development of its Kv7 program, and the Company continues to evaluate its Kv7 program, including seeking a partner for further development of both Kv7 and its clinical stage program ETX-155.

Basis of Presentation and Principles of Consolidation

The accompanying interim condensed consolidated financial statements of the Company and its wholly owned subsidiaries have been prepared in conformity with accounting principles generally accepted in the United States (U.S. GAAP) and accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC) for Quarterly Reports on Form 10-Q. All intercompany transactions and balances have been eliminated in consolidation.

The accompanying condensed consolidated balance sheet as of June 30, 2024, and condensed consolidated statements of operations and comprehensive loss, condensed consolidated statements of cash flows, and condensed consolidated statements of stockholders' equity for the three and six months ended June 30, 2024 and 2023, are unaudited. The consolidated balance sheet as of December 31, 2023 was derived from the audited financial statements as of and for the year ended December 31, 2023, but does not include all disclosures required by U.S. GAAP. The unaudited interim condensed financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2023, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2024, the condensed results of its operations as of the three and six months ended June 30, 2024 and 2023, and its cash flows for the six months ended June 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2024 and 2023 are also unaudited. The condensed consolidated results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the results to be expected for the full year ending December 31, 2024 or any other period. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2024.

Liquidity

Since inception, the Company has experienced recurring losses from operations and generated negative cash flows from operations. The Company has an accumulated deficit of $212.6 million as of June 30, 2024 and expects to incur additional losses from operations in the future. The Company received net proceeds of $119.7 million from the sale and issuance of shares in the Private Placement.

The Company estimates the available cash and cash equivalents of $223.1 million as of June 30, 2024 will be sufficient to meet its projected operating requirements for at least the next twelve months from the filing date of these unaudited condensed consolidated financial statements and the Company anticipates that it will need to raise substantial financing in the future to fund its operations.

The Company may finance future cash needs through equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In addition, the Company may continue to rely on capital markets for funding. There are no assurances that the Company will be able to raise sufficient amounts of funding in the future on acceptable terms, or at all.

Use of Estimates

The preparation of the interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Key management estimates include those related to the accrual of research and development expenses, recoverable research and development tax credits, and the valuation of stock-based awards. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash is held by three financial institutions in the United States (U.S.) and two financial institutions in the United Kingdom (U.K.). The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's deposits held in the U.S. and U.K. may exceed the insured limits of the Federal Depository Insurance Corporation and Financial Services Compensation Scheme, respectively. As of June 30, 2024, the Company has investments in money market funds which are held in segregated accounts at a third-party custodian. The Company has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. Through June 30, 2024, and the date of this filing, the Company has not experienced any losses on such deposits.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on single-source vendors and collaborators, availability of raw materials, patentability of the Company's product candidates and processes and clinical efficacy and safety of budoprutug or any future product candidate the Company may develop, compliance with government regulations and the need to obtain additional financing to fund operations. Budoprutug or any future product candidate the Company may develop will require significant additional research and development efforts, including extensive preclinical studies, clinical trials, and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

There can be no assurance that any future research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any product candidates developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker (the CODM). The Company's CODM is its chief executive officer who reviews financial information together with certain operating metrics principally to make decisions about how to allocate resources and to measure the Company's performance. Management has determined that the Company operates as a single operating and reportable segment. The Company's CODM evaluates financial information on a consolidated basis. As the Company operates as one operating segment, all required segment financial information is found in the interim condensed consolidated financial statements.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The Company measures fair value based on a three-tier hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liabilities. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

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.

In determining fair value, the Company utilizes quoted market prices, or valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

There were no transfers into or out of Level 3 for any of the periods presented.

The Company's fair value measurements as of June 30, 2024 and December 31, 2023 was as follows (in thousands):

	June 30, 2024		
	Level 1	**Level 2**	**Balance**
Assets:			
Cash equivalents:			
Money market funds	$ 218,118	$ —	$ 218,118
Total assets	$ 218,118	$ —	$ 218,118

	December 31, 2023		
	Level 1	**Level 2**	**Balance**
Assets:			
Cash equivalents:			
Money market funds	$ 89,197	$ —	$ 89,197
Marketable securities:			
U.S. Treasury securities	8,962	—	8,962
U.S. government agency debt securities	—	4,724	4,724
Total marketable securities	8,962	4,724	13,686
Total assets	$ 98,159	$ 4,724	$ 102,883

Summary of Significant Accounting Policies

Asset Acquisitions

In accordance with the guidance in Topic 805, *Business Combinations*, in the Financial Accounting Standards Board's (the FASB) Accounting Standards Codification (ASC), the Company evaluates acquisitions of assets and related liabilities and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the requirements of a business. The Company accounts for an asset acquisition by recognizing net assets based on the cost to the acquiring entity on a relative fair value basis. Goodwill is not recognized in an asset acquisition; any excess consideration transferred over the fair value of the net assets acquired is allocated to the non-monetary identifiable assets and liabilities assumed based on relative fair values. In-process research and development acquired in an asset acquisition is expensed provided there is no alternative future use. The Company accounts for future payments such as those upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying milestones are achieved. Milestone payments made to third parties subsequent to regulatory approval may be capitalized as intangible assets, if deemed to have alternative future use, and amortized over the estimated remaining useful life of the related product.

There have been no other material revisions in the Company's significant accounting policies described in Note 2 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued Accounting Standards Update (ASU) No. 2020-06 (ASU 2020-06), *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging —Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting For Convertible Instruments and Contracts in an Entity's Own Equity*. The standard simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The standard also simplifies the diluted net income per share calculation in certain areas. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2023, including interim periods therein. Early adoption is permitted for fiscal years beginning after December 15, 2020 and interim periods therein. The Company adopted ASU 2020-06 on January 1, 2024, which did not have a material impact on its consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07 (ASU 2023-07), *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* which requires, among other things, the following: (i) enhanced disclosures about significant segment expenses that are regularly provided to the CODM and included in a segment's reported measure of profit or loss; (ii) disclosure of the amount and description of the composition of other segment items, as defined in ASU 2023-07, by reportable segment; and (iii) reporting the disclosures about each reportable segment's profit or loss and assets on an annual and interim basis. The provisions of ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024; early adoption is permitted. The Company expects ASU 2023-07 to require additional disclosures in the notes to its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09 (ASU 2023-09), *Income Taxes (Topic 740): Improvements to Income Tax Disclosures,* which requires, among other things, the following for public business entities: (i) enhanced disclosures of specific categories of reconciling items included in the rate reconciliation, as well as additional information for any of these items meeting certain qualitative and quantitative thresholds; (ii) disclosure of the nature, effect and underlying causes of each individual reconciling item disclosed in the rate reconciliation and the judgment used in categorizing them if not otherwise evident; and (iii) enhanced disclosures for income taxes paid, which includes federal, state, and foreign taxes, as well as for individual jurisdictions over a certain quantitative threshold. The amendments in ASU 2023-09 eliminate the requirement to disclose the nature and estimate of the range of the reasonably possible change in unrecognized tax benefits for the 12 months after the balance sheet date. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2025; early adoption is permitted. The Company expects ASU 2023-09 to require additional disclosures in the notes to its consolidated financial statements.

There were no other significant updates to the recently issued accounting standards other than as disclosed herewith for the six months ended June 30, 2024. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

2. Asset Acquisition and Private Placement with a Related Party

Background

The Company entered into (i) an Agreement and Plan of Merger and Reorganization, dated as of April 10, 2024 (the Acquisition Agreement), by and among the Company, Tango Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (Transitory Subsidiary), Tenet Medicines, Inc. (Tenet), a Delaware corporation, and, solely in his capacity as Tenet equityholder representative, Stephen Thomas, providing for the acquisition of Tenet by the Company through the merger of Transitory Subsidiary into Tenet, with Tenet surviving as a wholly owned subsidiary of the Company, (ii) a Securities Purchase Agreement, dated as of April 10, 2024 (the Securities Purchase Agreement), by and among the Company and several accredited institutional investors (the PIPE Investors) including funds affiliated with RA Capital Management, L.P. (RA Capital Management), pursuant to which the Company agreed to issue and sell to the PIPE Investors in the Private Placement an aggregate of 31,238,282 shares (the PIPE Shares) of the Company's common stock , and (iii) a registration rights agreement with the PIPE Investors, pursuant to which the Company agreed to register for resale the PIPE Shares.

On June 27, 2024, the Company completed its acquisition of Tenet in accordance with the terms of the Acquisition Agreement. Tenet is a development stage biotechnology company that was majority-owned by funds affiliated with RA Capital Management prior to the closing of the Acquisition. Immediately prior to the closing of the Acquisition and Private Placement, RA Capital Management beneficially owned approximately 43.9% of the Company's outstanding common stock. The Private Placement closed immediately following the closing of the Acquisition. The Company received aggregate gross proceeds from the Private Placement of approximately $120.0 million, before deducting offering costs of $0.3 million. The offering costs were recorded as a reduction of additional paid-in capital generated in connection with the Private Placement.

At the effective time of the Acquisition, by virtue of the Acquisition and without any action on the part of the holders of common stock of Tenet, (i) all issued and outstanding shares of the common stock of Tenet and (ii) all securities convertible into shares of common stock of Tenet were converted into the right to receive, in the aggregate, 5,560,047 shares of the Company's common stock.

Basis of Presentation

In accordance with the ASC Topic 805, *Business Combinations*, the Company first evaluated the initial screen test to determine if substantially all of the fair value of the gross assets acquired of Tenet was concentrated in a single asset or a group of similar assets. The Company concluded that substantially all of the fair value of the gross assets being acquired of Tenet was concentrated in the in-process research and development related to the budoprutug asset (IPR&D). Accordingly, the Company accounted for the Acquisition as an asset acquisition. In accordance with the asset acquisition method of accounting, the cost of the asset acquisition, which reflects the consideration transferred, (i) was allocated to the assets acquired and liabilities assumed on a relative fair value basis, (ii) no goodwill was recorded and (iii) all direct transaction costs were included in the total consideration transferred.

As illustrated further below, the amount of the consideration transferred that was allocated to the IPR&D was $51.7 million, which was expensed on the condensed consolidated statements of operations and comprehensive loss, as the IPR&D was determined to have no future alternative use at the closing of the Acquisition.

Consideration Transferred

The fair value of the total consideration was approximately $52.8 million and is comprised of the following components (in thousands):

Equity consideration	$ 41,867
Settlement of pre-existing loan	5,036
Direct transaction costs	5,849
Total consideration	$ 52,752

- *Equity consideration:* Based on: (i) the issuance of 5,560,047 shares of the Company's common stock issued to the equityholders of Tenet and (ii) the closing stock price of the Company's common stock on the Nasdaq Global Market on June 27, 2024, which was $7.53 per share.
- *Settlement of pre-existing loan:* In May 2024, the Company and Tenet entered into a Senior Secured Promissory Note (the Note) providing for the Company to make short-term loans to Tenet up to an aggregate principal amount of $15.0 million. Pursuant to the Note, the Company made a loan (the Loan) of $5.0 million to Tenet in order to provide it with sufficient cash to fund its operations prior to the consummation of the Acquisition. The Loan included simple interest at a fixed rate per annum of 6%. Upon closing of the Acquisition, the Loan and accrued interest were eliminated in the interim condensed consolidated financial statements as the preexisting relationship was effectively settled and included in consideration transferred. Further, as the carrying value of the Loan was determined to approximate fair value at the time of the Acquisition, no gain or loss was recorded upon the effective settlement.
- *Transaction costs*: Represents the direct transaction costs, primarily legal and advisory services incurred by the Company in connection with the Acquisition.

Purchase Price Allocation

The following is the allocation of the purchase consideration for the Acquisition based on the fair value of the net assets acquired by the Company (in thousands):

Assets acquired	
In-process research and development	$ 51,659
Cash and cash equivalents	1,204
Prepaid expenses and other current assets	1,861
Total assets acquired	$ 54,724
Liabilities assumed	
Accounts payable	(1,603)
Accounts payable, related party	(101)
Accrued expenses and other current liabilities	(192)
Accrued expenses, related party	(76)
Total liabilities assumed	$ (1,972)
Net assets acquired	$ 52,752

3. Investments

As of June 30, 2024, the Company had no available-for-sale securities.

As of December 31, 2023, investments consisted of the following available-for-sale securities (in thousands):

	December 31, 2023		
	Amortized Cost	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:			
U.S. Treasury securities	$ 8,962	$ —	$ 8,962
U.S. government agency debt securities	4,726	(2)	$ 4,724
Total short-term marketable securities	$ 13,688	$ (2)	$ 13,686

There was no material realized gain or loss on available-for-sale securities during the period ended June 30, 2024 or December 31, 2023.

As of December 31, 2023, investments in a continual unrealized loss position for less than 12 months consist of the following (in thousands):

	December 31, 2023 Fair Value
U.S. Treasury securities	$ 5,967
U.S government agency debt securities	2,234
Total available-for-sale securities	$ 8,201

4. Certain Balance Sheet Accounts

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Research and development expenses	1,858	34
Other assets	696	552
Prepaid expenses	303	847
Recoverable research and development tax credits	—	2,024
Total prepaid expenses and other current assets	$ 2,857	$ 3,457

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued payroll expenses	$ 1,342	$ 1,111
Other accrued expenses	1,283	90
Other current liabilities	231	138
Accrued expenses, related party	81	—
Accrued research and development expenses	60	28
Accrued restructuring costs	34	1,066
Total accrued expenses	$ 3,031	$ 2,433

5. Related Party Transactions

As a result of the Acquisition, the following agreement of Tenet effectively became an agreement of the Company.

Services Agreement with Sera Services, Inc.

In November 2023, Tenet entered into an agreement (the Sera Services Agreement) with Sera Services, Inc. (Sera Services), a wholly-owned subsidiary of Sera Medicines, LLC (Sera Medicines), which was subsequently transferred to the Company by operation of law upon the closing of the Acquisition, pursuant to which Sera Services provides research and other services to the Company. Sera Medicines is an entity controlled by RA Capital Management. Dr. Stephen Thomas, a current board member of the Company, owns a minority ownership in and is also a board member of Sera Medicines.

Under the terms of the Sera Services Agreement, the Company compensates Sera Services on a fully burdened cost basis for personnel time devoted to Company projects. In addition, the Company reimburses Sera Services on a cost basis for any subcontractor costs incurred. The Company pays Sera Services on a monthly basis, in arrears, for services performed and costs incurred. The Sera Services Agreement has a term of two years and will automatically renew on its anniversary date for additional one-year terms. The Company may terminate the Sera Services Agreement by giving 30 days' prior notice to Sera Services.

In connection with the closing of the Acquisition, the Company assumed accounts payable of $0.1 million and accrued liabilities of $0.1 million related to the Sera Services Agreement, which are reflected in the interim condensed consolidated balance sheet as of June 30, 2024. There were no material costs incurred under the Sera Services Agreement recorded in the interim condensed consolidated statement of operations.

Refer to Note 2, *Asset Acquisition and Private Placement with a Related Party*, in these interim condensed consolidated financial statements for additional related party transactions.

6. License Agreements

As a result of the Acquisition, the following agreements of Tenet effectively became agreements of the Company.

Acelyrin Asset Purchase Agreement

On January 11, 2024, Tenet entered into an asset purchase agreement (the Asset Purchase Agreement) with Acelyrin, Inc. (Acelyrin) and WH2, LLC, which was subsequently transferred to the Company by operation of law upon the closing of the Acquisition, providing for the acquisition of certain assets of Acelyrin related to budoprutug (the Transferred Assets), including certain assigned contracts. Under these assigned contracts, the Company (i) received worldwide licenses (with the right to sublicense) to certain patents, know-how and other intellectual property rights to develop, manufacture, use and commercialize budoprutug for any non-oncology indication, and (ii) assumed certain liabilities of Acelyrin arising from (1) governmental authority action or notification relating to budoprutug, (2) contracts assigned to the Company pursuant to the Asset Purchase Agreement and (3) the Company's ownership, lease or operation of the Transferred Assets.

In addition, the Company inherited the rights and obligations, including financial obligations, under the CRH Agreement (as defined below) and the ProBioGen Agreement (as defined below). In consideration for the license and other rights the Company received under the Asset Purchase Agreement, the Company is obligated to (i) make total payments of up to $157.5 million to Acelyrin upon the achievement of various development, regulatory and commercial milestones, (ii) pay royalties in the single-digit percentages, subject to specified reductions, to Acelyrin on worldwide net sales in a given calendar year, and (iii) make non-refundable and non-creditable payments to Acelyrin on sublicense income with rates ranging from the low single digit to mid teen percent depending on the stage of development of the most advanced Products (as defined below) at the time of such sublicense. The royalty term continues for each licensed product incorporating or comprising budoprutug (a Product) on a country-by-country and Product-by-Product basis beginning on the first commercial sale of such Product and ending on the latest of (a) the date when such Product is no longer covered by a valid claim of a royalty-bearing patent in such country, (b) the expiration of any regulatory exclusivity period for such Product in such country, and (c) the twelfth anniversary of the first commercial sale of such Product in such country.

The Company is obligated to use commercially reasonable efforts to commercialize at least one Product in the United States and to achieve specified development, regulatory and commercial milestones set forth in the Asset Purchase Agreement. If Acelyrin asserts that the Company has failed to meet one or more of these diligence obligations within specified time periods, and such failure is finally determined through a dispute resolution process, Acelyrin shall have the right to repurchase the Transferred Assets at the then-fair market value of such Transferred Assets, as Acelyrin's sole and exclusive remedy for such breach.

If, within a specified period, the Company receives a bona fide offer or proposal from a third party to sell, transfer or otherwise divest all or substantially all of the rights to the Transferred Assets or Products, or grant an exclusive license or exclusive sublicense to such third party to develop and commercialize Products under specified terms, then prior to entering into any discussions or negotiations with any third party in relation to such a transaction, the Company shall provide written notice to Acelyrin of such intent or receipt of proposal. Acelyrin shall have the right to negotiate with the Company the terms for a definitive agreement with respect to such sale, transfer or grant of the rights to Products for a specified period of time. If Acelyrin does not exercise its right to negotiate or the parties are unable to agree on the terms of a definitive agreement, the Company shall have the right to negotiate or enter into an agreement with a third party with respect to such transaction, subject to specified conditions.

For a specified period after the Asset Purchase Agreement closing date, the Company shall not solicit, induce, or attempt to induce any employees of Acelyrin to become employees or independent contractors of the Company. If the Company does hire or engage an employee of Acelyrin during such period, the Company is obligated to make a certain payment to Acelyrin.

The Company may not sell, assign or transfer all or substantially all of the rights to develop or commercialize a Product unless, as a condition to such sale, assignment or transfer, the purchaser, assignee or transferee (as applicable) assumes in writing all obligations of the Company as set forth in the Asset Purchase Agreement with respect to the applicable Products.

As of June 30, 2024, the Company has not recognized milestone payments under the Asset Purchase Agreement as the underlying milestones were not achieved and are not assessed as probable.

CRH Agreement

In connection with the Asset Purchase Agreement, in January 2024 Tenet was assigned a license agreement with Cancer Research Technology Limited (CRH) and, in connection with such assignment, Tenet entered into an amended and restated license agreement with CRH (the CRH Agreement) which was subsequently transferred to the Company by operation of law upon the closing of the Acquisition. The CRH Agreement granted the Company a worldwide exclusive license (other than specified patent rights and materials, which are licensed to the Company on a non-exclusive basis) under certain know-how, patents and materials, or the licensed rights, to research, develop, test, manufacture or sell certain licensed products related to budoprutug, for all therapeutic uses except for oncology indications. The Company is permitted to grant a sublicense under these licenses with CRH's prior written consent.

CRH retains, on behalf of itself and the charitable company Cancer Research U.K., a worldwide, fully paid-up, perpetual and irrevocable right in the licensed rights and in certain intellectual property owned or controlled by the Company that is necessary to exploit the licensed products and used, conceived or generated in the course of exercising the license or exploiting any licensed product, or product-specific foreground intellectual property, for the purpose of non-commercial, non-clinical scientific research.

The Company is obligated to use commercially reasonable efforts to perform all activities set forth in a mutually agreed-upon development plan within the timelines set forth therein. The Company is also obligated to develop at least one licensed product in an autoimmune indication and to pursue worldwide regulatory authorization for licensed products. The Company must use commercially reasonable efforts to commercialize each licensed product throughout each of the specified major markets as soon as practicable following receipt of regulatory authorization for such product in such market. Additionally, the Company must make the licensed product available through the U.K. and negotiate with relevant regulatory authorities to make each licensed product available through the National Health Service in England and Wales within a specified time of the licensed product being made available elsewhere in the territory. If the Company fails to meet one or more of these diligence obligations, and such failure is not remedied within the specified cure period, CRH shall have the right to terminate the CRH Agreement with respect to the relevant licensed product.

The Company is obligated to pay CRH a mid-five figure digit fee on each anniversary of the effective date. The Company is obligated pay up to an aggregate of £106.8 million ($135.1 million) upon the achievement of specified development, regulatory, commercial and sales milestone events, including: (i) payments of up to mid-six figure digits in pounds sterling for certain development milestones, (ii) payments of up to low-eight figures in pounds sterling per indication (for up to three indications) for certain regulatory and commercial milestones and (iii) payments up to mid-eight figures in pounds sterling for certain sales milestones. The Company is also obligated to pay tiered royalties ranging from a rate in the mid-single digit to high-single digit percentage on net sales. The royalty term continues for each licensed product on a country-by-country basis beginning on the first commercial sale of such licensed product and ending on the latest of (a) the date when such licensed product is no longer covered by a valid claim of a licensed patent in such country, (b) the expiration of the exclusivity period for such licensed product in such country, and (c) the tenth anniversary of the first commercial sale of such licensed product in such country. The Company is also responsible for a sublicensing revenue payment ranging from a rate in the mid-single digit to mid-double digits for any sublicense revenue.

The CRH Agreement shall remain in effect in each country in the territory until the expiry of the Company's obligation to pay royalties in such country. Either party may terminate the CRH Agreement if the other party is in material breach that has not been remedied within the specified cure period or if the other party becomes insolvent. CRH also has the right to terminate the CRH Agreement if the Company or one of the Company's sublicensees or affiliates challenges a licensed patent, or if the Company is acquired by a tobacco company.

As of June 30, 2024, the Company has not recognized milestone payments under the CRH Agreement as the underlying milestones were not achieved and are not assessed as probable.

ProBioGen Agreement

Under the Asset Purchase Agreement, Tenet was assigned a cell line development, manufacturing services and license agreement (the ProBioGen Agreement) originally entered into by ValenzaBio, Inc. and ProBioGen AG (ProBioGen) in February 2021, which was subsequently transferred to the Company by operation of law upon the closing of the Acquisition.

The ProBioGen Agreement granted the Company a non-exclusive license under certain know-how, patents and materials, to use cell lines in which ProBioGen's proprietary technology is applied, to research, develop, manufacture, use, sell, offer to sell, import or export budoprutug. This license includes a non-exclusive sublicense by ProBioGen of certain third-party patent rights, limited to the use of budoprutug.

The Company is obligated to (i) make payments of up to €10.0 million ($10.7 million) upon the achievement of certain development, manufacturing and commercial milestones, including the start of a Phase 2 clinical trial for budoprutug, and (ii) make milestone payments of up to €7.0 million ($7.5 million) upon the achievement of certain sales milestones. If the Company elects to contract ProBioGen to perform certain manufacturing services for budoprutug, the milestone payments would be reduced by €1.1 million ($1.1 million).

The ProBioGen Agreement will remain in effect until the services are completed for the service-related component and until the payment obligations expire in connection with the commercial license component. Both parties have the right to terminate the ProBioGen Agreement if the other party becomes insolvent, or materially breaches the ProBioGen Agreement and fails to remedy such default within the specified cure period.

As of June 30, 2024, the Company has not recognized milestone payments under the ProBioGen Agreement as the underlying milestones were not achieved and are not assessed as probable.

7. Commitments and Contingencies

Facility Leases

The Company leases office space in the U.S. under a non-cancelable operating lease and leased office space in Cambridge, U.K. from May 2021 until June 30, 2024.

In November 2021, the Company agreed to lease approximately 5,000 square feet of office space in Bellevue, Washington. The term of this lease is 39 months, which commenced on November 1, 2021. The lease contains rent escalation clauses and an option to extend the term of the lease for an additional 3-year period at a market rate determined according to the lease. At the lease's inception and as of December 31, 2023, the Company does not expect that it will exercise its option to extend the lease, and therefore the period covered by this option is not included in the lease term.

In July 2023, the Company entered into a non-cancellable sublease agreement for the Bellevue office space, under the terms of which the Company is entitled to receive $0.2 million in lease payments over the term of the sublease, which commenced in July 2023 and ends concurrently with the original lease in January 2025. In advance of the sublease, the Company ceased use of and vacated the Bellevue office space in June 2023. The Company considered these circumstances to be an indicator of impairment and recorded an ROU asset impairment loss during the second quarter of 2023 of $0.2 million, which was the amount by which the carrying value of the lease ROU asset exceeded the fair value. The fair value is based on the discounted cash flows of anticipated net rental income for the office space subleased.

As of June 30, 2024, the remaining lease term was 0.6 years and the incremental borrowing rate used to determine the operating lease liability was 7.5%.

For each of the three months ended June 30, 2024 and 2023, the Company incurred $0.1 million in rent expense. For the six months ended June 30, 2024 and 2023, the Company incurred $0.1 million and $0.2 million in rent expense, respectively. Sublease income for the three and six months ended June 30, 2024 was $33,000 and $66,000 respectively, which was classified as a reduction in rent expense.

As of June 30, 2024, the annual future minimum lease payments due under the Company's non-cancelable operating lease were as follows (in thousands):

Year Ending December 31,	Operating Lease Payments	Sublease Income	Net Operating Lease Payments
2024 (remaining 6 months)	$ 87	(66)	21
2025	15	(11)	4
Total undiscounted lease payments	$ 102	$ (77)	$ 25
Present value adjustment	(2)		
Total operating lease liabilities	$ 100		

Legal Proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. As of the date of these condensed consolidated financial statements, the Company is not party to any material legal matters or claims.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless, and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company intends to enter into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is immaterial.

8. Stock-Based Compensation

2019 Plan

In 2019, the Company adopted the 2019 Equity Incentive Plan (the 2019 Plan). The 2019 Plan provided for the Company to grant qualified stock options, non-qualified stock options, and restricted stock awards to employees, non-employee directors and consultants of the Company under terms and provisions established by the Company's board of directors. Under the terms of the 2019 Plan, options were granted at an exercise price no less than fair value of the Company's common stock on the grant date, except in certain cases related to employees outside of the U.S. Option awards granted typically had 10-year terms measured from the option grant date. While no shares are available for future issuance under the 2019 Plan, it continues to govern outstanding equity awards granted thereunder.

2021 Plan and ESPP

The compensation committee of the Company's board of directors adopted and the Company's stockholders approved the 2021 Equity Incentive Plan (the 2021 Plan) and the 2021 Employee Stock Purchase Plan (the ESPP), which became effective in August 2021. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company's employees, officers, directors and consultants are eligible to receive awards under the 2021 Plan. Under the terms of the 2021 Plan, options are granted at an exercise price no less than fair value of the Company's common stock on the grant date, except in certain cases related to significant corporate transactions. Option awards granted typically have 10-year terms measured from the option grant date. As of June 30, 2024, the total number of shares authorized for issuance under the 2021 Plan was 7,010,850. Any shares that are returned under the 2019 Plan as a result of cancellation or forfeiture become available under the 2021 Plan. Further, the number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on January 1 of each year, beginning on January 1, 2022, and continuing through and including January 1, 2031, by 5% of the total number of shares of common stock outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by the Company's board of directors prior to the applicable January 1st.

The ESPP allows employees, including executive officers, to contribute up to 15% of their earnings, subject to certain limitations, for the purchase of the Company's common stock at a price per share equal to the lower of (a) 85% of the fair market value of a share of common stock on the first day of the offering period, or (b) 85% of the fair market value of a share of common stock on the last day of the offering period. As of June 30, 2024, there were 1,064,225 shares of common stock reserved for future issuance under the ESPP. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year or (2) a number of shares determined by the Company's board of directors. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP.

As of June 30, 2024, no shares have been granted or purchased under the ESPP.

Stock Options

Awards with vesting conditions under both plans typically include either: (i) vesting 25% on the first anniversary of the grant date with the remainder vesting monthly over the following three years or (ii) monthly vesting over four years.

The activity for stock options is as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contract Terms (in years)	Aggregate Intrinsic Values (in thousands)
Balance as of December 31, 2023	4,586,476	$ 5.40	2.28	$ 1,060
Options granted	935,100	7.55		
Options cancelled and forfeited	(427,892)	7.59		
Options exercised	(2,259,503)	3.84		5,415
Balance as of June 30, 2024	2,834,181	$ 7.02	5.93	$ 2,788
Vested and expected to vest, June 30, 2024	2,834,181	$ 7.02	5.93	$ 2,788
Options exercisable as of June 30, 2024	1,545,134	$ 7.21	3.04	$ 1,809

The aggregate intrinsic value disclosed in the above table is based on the difference between the exercise price of the stock option and the fair value of the Company's common stock as of the respective period-end dates. The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2024 and 2023 was $6.93 and $2.25 per share, respectively.

The Black-Scholes option pricing model for employee and nonemployee stock options incorporates the following assumptions:

- *Fair Value of Common Stock* — The fair value of each share of common stock is based on the closing price of the Company's common stock on the date of grant as reported on the Nasdaq Global Market.
- *Volatility* — The expected stock price volatilities are estimated based on the historical and implied volatilities of comparable publicly traded companies as the Company does not have sufficient history of trading in its common stock.
- *Risk-free Interest Rate* — The risk-free interest rates are based on US Treasury yields in effect at the grant date for notes with comparable terms as the awards.
- *Expected Term* — The expected term represents the period that the Company's stock options are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).
- *Dividend Yield* — The expected dividend yield assumption is based on the Company's current expectations about its anticipated dividend policy.

The fair value of the Company's stock option awards was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,	
	2024	2023
Expected term (in years)	5.50 - 6.08	5.50
Expected volatility	136.07% - 139.57%	92.90%
Risk-free interest rate	4.28% - 4.32%	3.69%
Expected dividend yield	0.00%	0.00%

Restricted Stock

The Company has: (i) restricted stock awards with service conditions that vest 25% on the first anniversary of the grant date and the remainder vesting monthly over the following three years, (ii) restricted stock units (RSUs) with service conditions that vest quarterly over a two year or two-and-a-half-year period, or vest 25% annually over a four year period, and (iii) RSUs with performance-based vesting conditions. The restricted stock awards are subject to repurchase by the Company at the original purchase price in the event that the award recipient's employment or relationship is terminated prior to the shares vesting.

Upon the closing of the Acquisition, the Company granted a total of 803,000 RSUs to certain consultants. Of these RSUs, 401,500 are subject to service conditions, with 50% of such RSUs vesting on January 1, 2025, 25% of such RSUs vesting on March 27, 2025 and the remaining 25% of such RSUs vesting on June 27, 2025. The remaining 401,500 RSUs will vest subject to the satisfaction of performance conditions, including the achievement of specific operational milestones before September 30, 2025 (Performance-Based RSUs). For the Performance-Based RSUs, no stock-based compensation expense has been recognized because the vesting conditions are not probable of being achieved.

The activity for restricted stock awards and units is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	149,975	$ 6.03
Granted	1,141,000	7.27
Vested	(57,032)	5.70
Unvested at June 30, 2024	1,233,943	$ 7.18

Modifications & Accelerations

Certain equity awards are subject to provisions in which the vesting of these awards is automatically accelerated upon the occurrence of events such as an involuntary termination in connection with a reduction in force. Further, in connection with the restructuring plan approved by the Company's board of directors in February 2023 (the Restructuring Plan), the Company modified the terms of certain equity awards for impacted employees including partial or full acceleration of vesting of stock options and restricted stock awards upon separation and extension of exercise periods for stock options post-separation.

As a result of: (i) the contractual acceleration and (ii) the discretionary modification of equity awards in connection with the Restructuring Plan, the Company recorded incremental stock-based compensation expense of $9.2 million for the six months ended June, 2023, of which $0.5 million and $8.7 million is included in research and development expense and general and administrative expense, respectively.

Stock-Based Compensation

The following table sets forth stock-based compensation expense for stock options, restricted stock awards, and restricted stock units included in the Company's condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expense	$ 287	$ 427	$ 556	$ 1,459
General and administrative expense	225	350	421	9,489
Total stock-based compensation expense	$ 512	$ 777	$ 977	$ 10,948

As of June 30, 2024, there was $7.7 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 3.43 years. Further, there was $5.8 million of unrecognized compensation cost related to unvested restricted stock awards and RSUs, which is expected to be recognized over a weighted average period of 2.08 years.

9. Net Loss Per Share

The following table shows the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	$ (54,889)	$ (5,220)	$ (56,586)	$ (27,510)
Weighted-average number of shares outstanding used to compute net loss per share, basic and diluted	30,349,562	26,840,555	28,994,045	26,667,458
Net loss per share, basic and diluted	$ (1.81)	$ (0.19)	$ (1.95)	$ (1.03)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	Three and Six Months Ended June 30,	
	2024	2023
Common stock options	2,834,181	5,354,618
Unvested restricted stock awards and units	1,233,943	213,436
Total potentially dilutive shares	4,068,124	5,568,054

10. Restructuring Plan

On February 7, 2023, the Company's board of directors approved a restructuring plan to conserve financial resources and better align the Company's workforce with current business needs. As part of the Restructuring Plan, the Company's workforce was reduced by approximately 55%, with substantially all of the reduction in personnel completed in the first half of 2023. The Company further reduced its workforce by 10 employees in October 2023.

The Company incurred aggregate restructuring costs of $18.8 million, substantially all of which were recognized in 2023 and have been fully recognized as of March 31, 2024. In addition, substantially all of the restructuring payments were made by April 2024.

The activity in the restructuring liability was as follows for the three and six months ended June 30, 2024 (in thousands):

	Restructuring Liability 2024
Restructuring liability as of December 31, 2023	$ 1,077
Restructuring costs incurred during the period	20
Restructuring costs paid during the period	(782)
Restructuring liability as of March 31, 2024	315
Restructuring costs incurred during the period	—
Restructuring costs paid during the period	(281)
Restructuring liability as of June 30, 2024	$ 34

During the three and six months ended June 30, 2023, the Company recorded restructuring costs of $0.7 million and $16.5 million, respectively. These costs primarily related to severance payments, healthcare benefits and stock-based compensation.

A summary of the restructuring costs recorded in the statement of operations and comprehensive loss for the three and six months ended June 30, 2023 is as follows (in thousands):

	Three Months Ended June 30, 2023			
	ROU Asset Impairment	Severance and Benefits Costs	Stock-based Compensation	Total Restructuring Cost Recorded
General and administrative expense	$ 180	$ 399	$ 154	$ 733
Total restructuring costs	$ 180	$ 399	$ 154	$ 733

	Six Months Ended June 30, 2023			
	ROU Asset Impairment	Severance and Benefits Costs	Stock-based Compensation	Total Restructuring Cost Recorded
General and administrative expense	$ 180	$ 5,836	$ 8,674	$ 14,690
Research and development expense	—	1,342	488	1,830
Total restructuring costs	$ 180	$ 7,178	$ 9,162	$ 16,520

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the SEC on March 28, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve substantial risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A. "Risk Factors" of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. For further information regarding our forward-looking statements, see "Cautionary Note Regarding Forward-Looking Statements" in this Quarterly Report. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us" and "our" refer to Eliem Therapeutics, Inc. and its wholly owned subsidiaries.

Overview

We are a biotechnology company primarily focused on developing therapeutics for autoimmune-driven inflammatory diseases, including advancing budoprutug (previously referred to as TNT119), an anti-CD19 monoclonal antibody designed for a broad range of autoimmune diseases, including systemic lupus erythematosus and lupus nephritis (SLE/LN) immune thrombocytopenia (ITP) and membranous nephropathy (MN). Budoprutug is designed to achieve broad and deep depletion of pathogenic B cells with a favorable tolerability profile and convenient dosing regimen with the potential for subcutaneous administration. We believe this reduction of autoantibodies has the potential to be disease modifying in autoantibody driven diseases, such as SLE/LN, ITP and MN. In a Phase 1b clinical trial of budoprutug in MN, 3 out of 5 (or 60%) of patients that received four doses of budoprutug achieved a complete remission of proteinuria, a primary symptom of MN.

We are developing budoprutug for the treatment of SLE/LN, the underlying pathology of which involves production of autoantibodies by autoreactive B cells that contribute to inflammation and tissue damage. CD19 is a protein expressed on the surface of these B cells and plays a key role in B cell activation. Because budoprutug is designed to target and deplete CD19-expressing B cells known to produce autoantibodies, we believe budoprutug has the potential to treat SLE/LN. In ITP, we believe targeting plasmablasts and plasma cells is likely to decrease the production of autoantibodies, increase platelet count and ameliorate disease. B cell depletion with anti-CD20 targeting monoclonal antibodies (mAbs) whose expression initiates somewhat later and is lost somewhat earlier than anti-CD19, has demonstrated efficacy in ITP disease for some patients in clinical trials by third parties. For those patients who do not respond to anti-CD20 therapy, we believe an anti-CD19 approach, such as budoprutug, may have the ability to further deplete pathogenic CD20-CD19+ cells.

Based on the preliminary results of the Phase 1b clinical trial of budoprutug in MN, we are working towards the submission of an investigational new drug application (IND) and/or clinical trial application (CTA) for budoprutug in SLE/LN and ITP. Subject to regulatory clearance, we plan to conduct a Phase 2 clinical trial of budoprutug for each of these indications. Further, by the end of 2024, we expect to have finalized a high concentration formulation of budoprutug to potentially support subcutaneous dosing. In addition, we expect to disclose more comprehensive MN data from the Phase 1b clinical trial in the fourth quarter of 2024. In connection with the closing of our acquisition of Tenet Medicines, Inc. (Tenet) in June 2024, our board of directors appointed Dr. Aoife Brennan as our President and Chief Executive Officer. Our management team, led by Dr. Brennan, is currently evaluating and considering revisions to our development plan on a go-forward basis. We expect to provide a comprehensive update on our corporate and budoprutug development strategy and timelines at an Investor Day later this year.

Previously, we focused primarily on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems, and our lead program was ETX-123, a Kv7.2/3 potassium channel opener. ETX-123 is designed to harness the efficacy of the Kv7.2/3 channel mechanism while attempting to improve the safety and tolerability relative to earlier molecules, based on our insights into the mechanisms of toxicity and the potency and selectivity profile. In July 2023, we made the determination to pause further development of our Kv7 program, and we continue to evaluate our Kv7 program, including seeking a partner for further development of both Kv7 and ETX-155.

On June 27, 2024, we completed our acquisition of Tenet (the Acquisition). In connection with the closing of the Acquisition, we issued and sold 31,238,282 shares of our common stock at a price of $3.84 per share in a private placement (the Private Placement) to several accredited institutional investors. We received aggregate gross proceeds from the private placement of approximately $120.0 million, before deducting offering expenses of $0.3 million.

We have incurred significant operating losses since inception, as we have devoted substantially all of our resources to organizing and staffing our company, identifying potential product candidates, business planning, raising capital, undertaking research, executing preclinical studies and clinical development trials, and providing general and administrative support for business activities. We incurred net losses of $54.9 million and $5.2 million for the three months ended June 30, 2024 and 2023, respectively, and $56.6 million and $27.5 million for the six months ended June 30, 2024 and 2023, respectively. We had an accumulated deficit of $212.6 million and $156.0 million as of June 30, 2024 and December 31, 2023, respectively.

Since our inception, we have primarily funded our operations with an aggregate of $328.0 million in net proceeds from the sale and issuance of shares of our redeemable convertible preferred stock, our initial public offering of our common stock and the sale and issuance of shares in the Private Placement of our common stock that was completed in June 2024. We had cash and cash equivalents of $223.1 million and cash, cash equivalents, and marketable securities of $106.8 million as of June 30, 2024 and December 31, 2023, respectively. Based on our current operating plan, we estimate that our cash and cash equivalents will be sufficient to fund our planned operations into 2027. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently anticipate, which case we would be required to obtain additional financing, which may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate significant revenue from product sales, if ever, we may finance our operations through equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Adequate funding may not be available when needed or on terms acceptable to us, or at all. If we are unable to raise additional capital as needed, we may have to significantly delay, scale back or discontinue any future development of our product candidates. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, resulting from increased volatility in the trading prices for shares in the biopharmaceutical industry, or otherwise. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates, if approved. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities. We expect to continue to incur operating losses for the foreseeable future.

Tenet Acquisition

On June 27, 2024, we acquired 100% of the share capital of Tenet in exchange for 5,560,047 shares of our common stock, valued at $41.9 million, or $7.53 per share. The Acquisition is accounted for as an asset acquisition. The total cost of the asset acquisition was $52.8 million, which also included (i) $5.8 million of direct transaction costs incurred and (ii) $5.0 million related to a loan provided to Tenet prior to the closing of the Acquisition that was effectively settled upon the closing of the Acquisition. We recognized in-process research and development (IPR&D) expense of $51.7 million for the three and six months ended June 30, 2024, as the IPR&D was determined to have no future alternative use.

Components of Operating Results

Operating Expenses

Our operating expenses consist of (i) acquired IPR&D, related party, (ii) research and development expenses, and (iii) general and administrative expenses.

Acquired In-Process Research and Development, Related Party

Our acquired IPR&D expense consists of the relative fair value of the assets acquired and consideration transferred in connection with the Acquisition. As the assets acquired were in the research and development phase and were determined to not have any alternative future use, it was expensed as IPR&D.

Research and Development

Our research and development expenses consist primarily of direct and indirect costs incurred in connection with our discovery efforts, preclinical studies, and clinical trial activities related to our pipeline, including our paused product candidates ETX-123 and ETX-155. Research and development expenses related to our recently acquired product candidate budoprutug as part of the Tenet Acquisition were not material in the three and six months ended June 30, 2024.

Our direct research and development costs include:

- expenses incurred in connection with research, laboratory consumables and preclinical and clinical trial activities;
- the cost to manufacture drug products for use in our preclinical studies and clinical trials; and
- consulting fees.

Our indirect research and development costs include:

- personnel-related expenses, such as salaries, bonuses, benefits, stock-based compensation expense, and termination benefits, for our scientific personnel performing research and development activities; and
- facility rent.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed.

Given our stage of development and the utilization of our resources across our various programs, we have not historically tracked our research and development costs by program. Research and development expenses are presented net of refundable research and development tax credits from the U.K. government.

We expect our research and development expenses to increase substantially for the foreseeable future as we conduct our ongoing research and development activities. The process of conducting preclinical studies, acquiring drug product supply, and conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for budoprutug or any future product candidate we may develop.

The timelines and costs associated with research and development activities are uncertain and can vary significantly among product candidates and development programs due to the inherently unpredictable nature of preclinical and clinical development. We anticipate that we will make determinations as to which indications to pursue in connection with our clinical development of budoprutug or any future product candidates we may develop and how much funding to direct to each such indication on an ongoing basis in response to preclinical and clinical results, regulatory developments, and ongoing assessments as to each such indication's commercial potential. We will need to raise substantial additional capital in the future.

Our future research and development costs may vary significantly based on factors such as:

- the timing, cost and progress of our research, preclinical, and clinical development activities;
- the number and scope of development, preclinical and clinical programs we decide to pursue;
- the terms of any collaborations and/or research and development agreements we may enter into, which may impact the cost, timing and development plans of one or more of our product candidate programs;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals;
- the potential delays in our preclinical studies, our development programs and our ongoing and planned clinical trial activities due to the effects of global events, including macroeconomic conditions and continued supply chain disruptions;
- the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, among other things;
- the cost of commercialization activities if budoprutug or any future product candidates we may develop are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire personnel to support development of budoprutug or any future product candidates we may develop.

A change in the outcome of any of these variables with respect to the development of budoprutug or any future product candidates we may develop could significantly change the costs and timing associated with the development.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses such as salaries, bonuses, benefits, stock-based compensation, and termination benefits, for our personnel in executive, finance and accounting, human resources, business development and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, audit, regulatory, tax and consulting services, insurance costs, as well as investor and public relations costs.

We expect that our general and administrative expenses will significantly increase in the future as we increase our headcount to support our operations.

Other Income (Expense)

Foreign Currency Gain (Loss)

Our foreign currency gain (loss) consists of foreign exchange losses resulting from remeasurement and foreign currency transactions between the British Pound and the U.S. Dollar.

Interest Income, net

Our interest income consists of interest earned on our cash, cash equivalents and marketable securities and adjustments related to amortization of purchase premiums and accretion of discounts of marketable securities.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and June 30, 2023

The following table sets forth our results of operations (dollars in thousands):

	Three Months Ended June 30,		Change	
	2024	2023	$	%
Operating expenses:				
Acquired in-process research and development, related party	$ 51,659	$ —	$ 51,659	100.0%
Research and development	1,046	3,688	(2,642)	(71.6)%
General and administrative	3,667	3,026	641	21.2%
Total operating expenses	56,372	6,714	49,658	739.6%
Loss from operations	(56,372)	(6,714)	(49,658)	739.6%
Other income (expense):				
Foreign currency gain (loss)	(2)	384	(386)	(100.5)%
Interest income, net	1,485	1,110	375	33.8%
Total other income (expense)	1,483	1,494	(11)	(0.7)%
Net loss	$ (54,889)	$ (5,220)	$ (49,669)	951.5%

Operating Expenses

Acquired In-Process Research and Development, Related Party

Acquired IPR&D expense, related party was $51.7 million for the three months ended June 30, 2024. This amount represents the recognition of IPR&D expense from the Acquisition completed on June 27, 2024.

Research and Development

Research and development expenses decreased by 71.6% from $3.7 million for the three months ended June 30, 2023 to $1.0 million for the three months ended June 30, 2024. The decrease was due to a (i) a $2.1 million decrease in direct clinical and preclinical expenses, primarily due to the pause of ETX-123 in July 2023, and (ii) a $1.0 million reduction in personnel-related expenses from reduced headcount. This decrease was partially offset by a $0.5 million decrease in the U.K. refundable research and development tax credits due to the overall reduction in qualifying research and development expenses.

General and Administrative

General and administrative expenses increased by 21.2% from $3.0 million for the three months ended June 30, 2023 to $3.7 million for the three months ended June 30, 2024. This increase was due to a (i) $1.1 million increase in other general and administrative expenses, primarily driven by an increase in consulting fees and legal expenses, and (ii) an increase of $0.3 million in personnel-related expenses from increased headcount. The increase was partially offset by a $0.6 million decrease in restructuring costs in the prior period and a $0.2 million decrease in insurance costs.

Other Income (Expense)

Foreign Currency Gain (Loss)

Foreign currency gain (loss) decreased from a $0.4 million gain for the three months ended June 30, 2023 to a $2,000 loss for the three months ended June 30, 2024. The decrease was driven by unfavorable changes in foreign currency exchange rates between the British Pound and the U.S. Dollar in the three months ended June 30, 2024.

Interest Income, net

Interest income, net increased from $1.1 million for the three months ended June 30, 2023 to $1.5 million for the three months ended June 30, 2024, which was driven by an increase in investment income. The increase was due to greater rates of return on our investments as a result of higher interest rates in the three months ended June 30, 2024.

Comparison of the Six Months Ended June 30, 2024 and June 30, 2023

The following table sets forth our results of operations (dollars in thousands):

	Six Months Ended June 30,		Change	
	2024	2023	$	%
Operating expenses:				
Acquired in-process research and development, related party	$ 51,659	$ —	$ 51,659	100.0%
Research and development	2,137	9,408	(7,271)	(77.3)%
General and administrative	5,581	20,744	(15,163)	(73.1)%
Total operating expenses	59,377	30,152	29,225	96.9%
Loss from operations	(59,377)	(30,152)	(29,225)	96.9%
Other income (expense):				
Foreign currency gain (loss)	(35)	632	(667)	(105.5)%
Interest income, net	2,826	2,010	816	40.6%
Total other income (expense)	2,791	2,642	149	5.6%
Net loss	$ (56,586)	$ (27,510)	$ (29,076)	105.7%

Operating Expenses

Acquired In-Process Research and Development, Related Party

Acquired IPR&D expense, related party was $51.7 million for the six months ended June 30, 2024. This amount represents the recognition of IPR&D expense from the Acquisition completed on June 27, 2024.

Research and Development

Research and development expenses decreased by 77.3% from $9.4 million for the six months ended June 30, 2023 to $2.1 million for the six months ended June 30, 2024. The decrease was due to a (i) a $4.7 million decrease in direct clinical and preclinical expenses, primarily due to the pause of ETX-123 in July 2023 and ETX-155 in February 2023, and (ii) a $4.2 million decrease in personnel-related expenses, which was driven by restructuring costs of $1.8 million in the prior period and $2.4 million from reduced headcount. This decrease was partially offset by a $1.6 million decrease in the U.K. refundable research and development tax credits due to the overall reduction in qualifying research and development expenses.

General and Administrative

General and administrative expenses decreased by 73.1% from $20.7 million for the six months ended June 30, 2023 to $5.6 million for the six months ended June 30, 2024. This decrease was due to (i) a $15.3 million reduction in personnel-related expenses, which was driven by restructuring costs of $14.5 million in the prior period and $0.7 million from reduced headcount. The decrease was partially offset by a $0.2 million increase in other general and administrative expenses, largely driven by an increase in consulting fees and legal expenses.

Other Income (Expense)

Foreign Currency Gain (Loss)

Foreign currency gain (loss) decreased from a $0.6 million gain for the six months ended June 30, 2023 to a $35,000 loss for the six months ended June 30, 2024. The decrease was driven by unfavorable changes in foreign currency exchange rates between the British Pound and the U.S. Dollar in the six months ended June 30, 2024.

Interest Income net

Interest income, net increased from $2.0 million for the six months ended June 30, 2023 to $2.8 million for the six months ended June 30, 2024, which was driven by an increase in investment income. The increase was due to greater rates of return on our investments as a result of higher interest rates in the six months ended June 30, 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have primarily funded our operations with an aggregate of $328.0 million in net proceeds from the sale and issuance of shares of our redeemable convertible preferred stock, our initial public offering of our common stock and the sale and issuance of shares of our common stock in the Private Placement. We have not generated any revenue from product sales or otherwise. We have incurred net losses from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of June 30, 2024 and December 31, 2023, we had cash and cash equivalents of $223.1 million and cash, cash equivalents, and marketable securities of $106.8 million, respectively, and an accumulated deficit of $212.6 million and $156.0 million, respectively.

Funding Requirements

We believe our cash and cash equivalents of $223.1 million as of June 30, 2024 will be sufficient to fund our operations into 2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We anticipate that our expenses will increase for the foreseeable future as we continue to advance budoprutug and any future product candidates we may develop, expand our corporate infrastructure, and incur costs associated with potential commercialization. We are subject to all of the risks typically related to the development of biopharmaceutical candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business.

Our future funding requirements will depend on many factors, including the following:

- the timing, cost and progress of our research, preclinical, and clinical development activities;
- the number and scope of development, preclinical and clinical programs we decide to pursue;
- the terms of any collaborations and/or research and development agreements we may enter into, which may impact the cost, timing and development plans of one or more of our product candidate programs;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals;
- the potential delays in our preclinical studies, our development programs and our ongoing and planned clinical trial activities due to the effects of global events, including macroeconomic conditions and continued supply chain disruptions;
- the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, among other things;
- the cost of commercialization activities if budoprutug or any future product candidates we may develop are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire personnel to support development of budoprutug or any future product candidates we may develop.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Until such time, if ever, as we can generate substantial revenue from product sales, we may finance our operations through equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or budoprutug, or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market budoprutug or any future product candidates we may develop even if we would otherwise prefer to develop and market such product candidates ourselves.

Cash Flows

The following table summarizes our cash flows (in thousands):

	Six Months Ended June 30,	
	2024	**2023**
Net cash used in operating activities	$ (2,486)	$ (23,142)
Net cash provided by investing activities	4,106	4,196
Net cash provided by financing activities	128,417	25

Operating activities

For the six months ended June 30, 2024, net cash used in operating activities was $2.5 million. This consisted primarily of net loss of $56.6 million. The decrease in cash was partially offset by total non-cash adjustments of $52.8 million that primarily related to IPR&D and stock-based compensation expense, as well as changes in our operating assets and liabilities that resulted in a net increase in cash of $1.3 million.

For the six months ended June 30, 2023, net cash used in operating activities was $23.1 million. This consisted primarily of net loss of $27.5 million and changes in our operating assets and liabilities that resulted in a net decrease in cash of $5.1 million, primarily related to personnel and research and development activities. The decrease in cash was partially offset by total non-cash adjustments of $9.5 million that primarily related to stock-based compensation expense.

Investing activities

For the six months ended June 30, 2024, net cash provided by investing activities was $4.1 million. This consisted of $13.8 million in proceeds received from maturities of marketable securities, primarily offset by the issuance of a promissory loan of $5.0 million and cash paid of $4.6 million in connection with the Acquisition.

For the six months ended June 30, 2023, net cash provided by investing activities was $4.2 million. This consisted of $60.2 million in proceeds received from maturities of marketable securities, primarily offset by purchases of $56.0 million of marketable securities.

Financing activities

For the six months ended June 30, 2024, net cash provided by financing activities was $128.4 million. This consisted of $119.7 million in proceeds received from the issuance of our common stock in the Private Placement and $8.7 million in proceeds from exercises of stock options.

Contractual Commitments and Obligations

In the normal course of business, we enter into contracts with contract research organizations (CROs), contract development and manufacturing organizations (CDMOs), and other third parties for preclinical studies and clinical trials, research and development supplies, and other testing and manufacturing services. These contracts do not contain material minimum purchase commitments and generally provide us with the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. However, it is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each agreement.

Following the Acquisition, we have obligations under an asset purchase agreement and certain license agreements that obligate us to make specified milestone and royalty payments. The payment obligations under these agreements are contingent upon future events, such as our achievement of specified development, regulatory and commercial milestones, or generating product sales. We are unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See Note 6 in our condensed consolidated financial statements included herein for a discussion of these milestone and royalty obligations.

We also have obligations under a non-cancelable operating lease. See Note 7 in our condensed consolidated financial statements included herein for a discussion of our lease obligations.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of our condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and notes to the condensed consolidated financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions and conditions.

Asset Acquisitions

In accordance with the guidance in Topic 805, *Business Combinations*, in the Financial Accounting Standards Board's (the FASB) Accounting Standards Codification (ASC), we evaluate acquisitions of assets and related liabilities and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether or not we have acquired inputs and processes that have the ability to create outputs which would meet the requirements of a business. We account for an asset acquisition by recognizing net assets based on the cost to the acquiring entity on a relative fair value basis. Goodwill is not recognized in an asset acquisition; any excess consideration transferred over the fair value of the net assets acquired is allocated to the non-monetary identifiable assets and liabilities assumed based on relative fair values. IPR&D acquired in an asset acquisition is expensed provided there is no alternative future use. We account for future payments such as those upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying milestones are achieved. Milestone payments made to third parties subsequent to regulatory approval may be capitalized as intangible assets, if deemed to have alternative future use, and amortized over the estimated remaining useful life of the related product.

A summary of our critical accounting policies is presented in our audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2023 included in our Annual Report on Form 10-K. There were no other material changes to our critical accounting policies during the six months ended June 30, 2024.

Recent Accounting Pronouncements

See Note 1 in our condensed consolidated financial statements included herein and see Note 2 to our annual consolidated financial statements included in our Annual Report on Form 10-K.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited consolidated financial statements in a registration statement for an initial public offering (IPO), an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will remain an emerging growth company under the JOBS Act until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of $1.235 billion or more, (ii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years, (iii) the date on which we are deemed a “large accelerated filer” under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, or (iv) December 31, 2026.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305(e) of Regulation S-K.

Item 4. Controls and Procedures

Disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer (our principal executive officer) and executive chairman (our principal financial officer) or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our chief executive officer and executive chairman (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2024. Based on our evaluation, our chief executive officer and executive chairman have concluded that our disclosure controls and procedures (as such term is defined in Rule(s) 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective as of June 30, 2024 because of the material weaknesses in our internal control over financial reporting described below.

Notwithstanding the material weaknesses, management believes the condensed consolidated financial statements as included in Part I of this Quarterly Report on Form 10-Q present fairly, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with generally accepted accounting principles in the United States.

Material Weaknesses in Internal Control Over Financial Reporting

Management identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses are as follows:

- We did not design or maintain an effective control environment. Specifically, we lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters commensurate with accounting and reporting requirements. The lack of personnel contributed to the following material weakness.
- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including segregation of duties and controls over the preparation and review of journal entries, account reconciliations and consolidation.

These material weaknesses did not result in a misstatement to the condensed consolidated financial statements. However, these material weaknesses could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected.

Remediation Efforts to Address Material Weaknesses

Management has concluded that the material weaknesses in internal control over financial reporting were due to the fact that we were a private company with limited resources when the material weaknesses were identified and did not have the necessary business processes and related internal controls formally designed and implemented, coupled with the appropriate resources with the appropriate level of experience and technical expertise, to oversee our business processes and controls.

We have implemented measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to our material weaknesses. The remediation measures we have taken include:

- Hired qualified personnel with appropriate expertise to perform specific functions and ensure adequate segregation of key duties and responsibilities;

- Designed and implemented improved policies, processes, and internal controls, including senior management review and audit committee oversight, to achieve complete, accurate and timely financial accounting, reporting and disclosures;
- Implemented and formalized policies, processes, and internal controls to identify and assess complex accounting transactions and other technical accounting and financial reporting matters; and
- Implemented financial systems to improve segregation of duties and controls and reliability of system generated data.

We believe we have made substantial progress toward achieving the effectiveness of our internal control over financial reporting and disclosure controls and procedures. The actions that have been taken are subject to continued review and testing by management as well as oversight by the audit committee of our board of directors. We will not be able to conclude whether the steps we have taken will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter to which this Quarterly Report on Form 10-Q relates 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.

From time to time, in the ordinary course of business, we may be involved in various claims, lawsuits and other proceedings. As of the date of filing of this Quarterly Report on Form 10-Q, we were not involved in any material legal proceedings.

Item 1A. Risk Factors.

RISK FACTORS

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will incur substantial losses for the foreseeable future and may never achieve or maintain profitability.

We are a biotechnology company with a limited operating history. Our efforts are focused primarily on the treatment of unmet needs in autoantibody-mediated diseases, in particular the clinical development of budoprutug. To date, we have not received regulatory approvals for any of our product candidates or generated any revenue from the sale of products, and we do not expect to generate any revenue in the foreseeable future. Budoprutug is in early stages of research and development. As a result, we are not profitable, and we have incurred significant operating losses since inception. Our net losses were $56.6 million and $27.5 million for the six months ended June 30, 2024 and 2023, respectively. We had an accumulated deficit of $212.6 million and $156.0 million as of June 30, 2024 and December 31, 2023, respectively. We expect to continue to incur substantial expenses and operating losses for the foreseeable future as we continue to develop budoprutug and any future product candidates we may develop. As a result, we expect to continue to incur significant losses for the foreseeable future as we:

- continue development of budoprutug and any future product candidates we may develop;
- conduct clinical trials of budoprutug and any future product candidates we may develop;
- initiate and continue research and development, including preclinical, clinical and discovery efforts for any future product candidates we may develop;
- seek regulatory approvals for budoprutug or any future product candidates we may develop that successfully complete clinical development;
- incur legal, accounting, or other expenses in operating our business;
- hire and retain qualified personnel, including to expand our general and administrative functions to support our future growth;
- maintain, expand and protect our intellectual property portfolio;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval; and
- acquire or in-license other product candidates and technologies.

If we are unable to access capital when needed, it could force us to delay, reduce or terminate our product development programs, commercialization efforts, or other operations.

We had cash and cash equivalents of $223.1 million and cash, cash equivalents, and marketable securities of $106.8 million at June 30, 2024 and December 31, 2023, respectively.

Based upon our current operating plan and assumptions, we believe that our existing cash and cash equivalents will be sufficient to fund our operations into 2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, we will need additional capital to advance and expand our research pipeline, conduct preclinical studies, proceed to develop and commercialize any approved products, and explore other pipeline opportunities. Our estimates of the sufficiency of our cash and cash equivalents are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Conducting preclinical studies, conducting clinical trials, pursuing regulatory approvals, establishing outsourced manufacturing relationships and successfully manufacturing and commercializing our product candidates is, and will be, very time-consuming, expensive and an uncertain process that takes years to complete. Our future need for additional funding depends on many factors, including:

- the timing, cost and progress of our research, preclinical, and clinical development activities;
- the number and scope of development, preclinical and clinical programs we decide to pursue;
- the terms of any collaborations and/or research and development agreements we may enter into, which may impact the cost, timing and development plans of one or more of our product candidate programs;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals;
- the potential delays in our preclinical studies, our development programs and our ongoing and planned clinical trial activities due to the effects of global events, including macroeconomic conditions and continued supply chain disruptions;
- the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, among other things;
- the cost of commercialization activities if budoprutug or any future product candidates we may develop are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire personnel to support development of budoprutug or any future product candidates we may develop.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Our ability to raise additional capital may be adversely impacted by disruptions to, or continuing volatility in, the credit and financial markets in the United States and worldwide, including increased volatility in the trading prices for shares of public companies in the biopharmaceutical sector, actual and perceived changes in interest rates and inflation, macroeconomic uncertainties, or otherwise. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues from product sales, we may need or may seek to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may 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, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Further, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

Additional capital may not be available to us, or even if it is, the cost of such capital may be high. We may be forced to obtain additional capital before reaching clinical or regulatory milestones, when our stock price or trading volume or both are low, or when the general market for life sciences companies is weak. Raising capital under any of these or similar scenarios, if we can raise any at all, may lead to significant dilution to our existing stockholders.

Further, we have issued, and may in the future issue additional, equity securities as consideration for business development transactions, which may also dilute our existing stockholders' ownership interests. For example, we issued additional shares of our common stock in connection with the Acquisition, as well as in the concurrent private placement of shares of our common stock to certain institutional investors.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Drug development is highly uncertain, and if we are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be harmed.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. For example, previously we paused or discontinued the development of all of our product candidates for the treatment of neuronal excitability disorders, including ETX-155 and Kv7, which were still in drug discovery stages, and we may not ever obtain regulatory approval for budoprutug or any future product candidates we may develop. In addition, as a company, we have not developed any product candidates for the autoimmune diseases, and following the closing of the Acquisition, we are focused on the clinical development of our lead product candidate, budoprutug, for systemic lupus erythematosus and lupus nephritis (SLE/LN), immune thrombocytopenia (ITP). We also have no prior experience developing biological product candidates. As such, we may encounter delays or difficulties in our efforts to develop and commercialize budoprutug.

To date, we have not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted the sales and marketing activities necessary for successful product commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biotechnology companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business may be harmed.

We currently have no source of product revenue and may never become profitable

We have never commercialized a product or generated any revenues from commercial product sales, or otherwise, and we may never become profitable. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain marketing approval for budoprutug or any other product candidates or generate revenue from the sale of budoprutug any products for which we may obtain marketing approval. Our ability to generate revenue from product sales or achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize budoprutug or any products that we may develop, in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for budoprutug or any other product candidate, we do not know when budoprutug or any other product candidate will generate revenue from product sales for us, if at all. Our ability to generate revenue from budoprutug or any future product candidates we may develop also depends on a number of additional factors, including our or any future collaborators' ability to:

- complete and submit investigational new drug applications (INDs) to the U.S Food and Drug Administration (the FDA) that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- complete development activities, including the necessary clinical trials;
- complete and submit biologics license applications (BLAs) to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;

•establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;

•develop a commercial organization capable of sales, marketing and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;

•find suitable distribution partners to help us market, sell and distribute our approved products in other markets;

•obtain coverage and adequate reimbursement from third-party payors, including government and private payors;

•achieve market acceptance for our products, if any;

•establish, maintain and protect our intellectual property rights; and

•attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, budoprutug or any future product candidates we may develop may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we can complete the development and regulatory process for budoprutug or any future product candidates we may develop, we anticipate incurring significant costs associated with commercializing these products.

Even if we can generate revenues from the sale of budoprutug or any future product candidates we may develop that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Risks Related to our Business and the Development of our Product Candidates

Our future success is dependent primarily on the regulatory approval and commercialization of budoprutug and any future product candidates we may develop.

We do not have any product candidates that have gained regulatory approval, and we are substantially dependent on the success of budoprutug and any other product candidates we may develop in the future. As a result, our prospects, including our ability to finance our operations and generate revenue, are substantially dependent on our ability to obtain regulatory approval for budoprutug, and, if approved, to successfully commercialize budoprutug and any future product candidates we may develop. We cannot commercialize budoprutug or any future product candidates we may develop in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize budoprutug or any future product candidates we may develop outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process for a BLA typically takes more than a year to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of budoprutug or any future product candidates we may develop for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical trials, generally including at least two well-controlled Phase 3 trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is potent, safe and pure for use for that target indication and that the manufacturing facilities, processes and controls are adequate. If budoprutug encounters undesirable safety signals, insufficient efficacy results, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

Further, under the Pediatric Research Equity Act, a BLA or supplement to a BLA for certain biological products must contain data to assess the safety, potency and purity of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe, potent and pure, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety, potency and purity data need to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency (EMA) or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Obtaining regulatory approval for marketing of budoprutug or any future product candidates we may develop in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if budoprutug or future product candidates we may develop were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, gender or subpopulation of target indication, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any of budoprutug or any of our future product candidate that we may discover, in-license, develop or acquire in the future. Also, any regulatory approval of budoprutug or any future product candidates we may develop, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for budoprutug or any future product candidates we may develop, such product's commercial success will depend on a number of factors, including the following:

- development of a commercial organization or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and adequate reimbursement from third-party and government payors;
- the ability of our third-party manufacturers to manufacture quantities of our products in commercially sufficient processes and at a scale sufficient to meet anticipated demand and enable us to reduce our cost of manufacturing;
- our success in educating physicians and patients about the benefits, administration and use of our products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations;
- acceptance of our products as potent, safe and pure by patients and the medical community; and
- a continued acceptable safety profile of our products following approval.

Many of these factors are beyond our control. If we, or our potential commercialization collaborators, are unable to successfully commercialize budoprutug or any future product candidates we may develop, we may not be able to earn sufficient revenues to continue our business.

Even if budoprutug or any future product candidates we may develop receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for budoprutug or a future product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of budoprutug or any future product candidate, they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy (REMS) or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice (cGMP) requirements and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose restrictions on the marketing or manufacturing of the product candidates;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

•require us or any future collaborator to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific remediation actions and penalties for noncompliance;

•seek an injunction or impose civil or criminal penalties or monetary fines;

•suspend or withdraw regulatory approval;

•suspend any ongoing clinical trials;

•refuse to approve pending applications or supplements to applications filed by us;

•suspend or impose restrictions on operations, including costly new manufacturing requirements; or

•seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize budoprutug or any future product candidates we may develop and generate revenue.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services (HHS) state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA and other enforcement authorities. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities.

In the United States, engaging in impermissible promotion products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to numerous actions, including civil, criminal and/or administrative penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows the federal government, or any individual relator or whistleblower on behalf of the federal government to bring a lawsuit against a pharmaceutical company alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual relator may share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect our business, results of operations, financial condition and cash flows and future prospects.

Existing government regulations may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of budoprutug or any future product candidates we may develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and/or be subject to fines or enhanced government oversight and reporting obligations, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product, which was originally approved in 2000, and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, our ability to develop budoprutug or future product candidates we may develop may be at risk and could be delayed, undermined or subject to protracted litigation.

Finally, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, Inc., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as FDA acted within its statutory authority under the Administrative Procedure Act (APA). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System,* the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Centers for Medicare & Medicaid Services (CMS) that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Preliminary, initial, or interim results from clinical trials that we announce, present, or publish from time to time may change as more data and information become available (or are updated based upon audit, validation and verification procedures of the data/information commonly performed for clinical trials) that could result in material changes in the final trial results.

From time to time, we may announce, present or publish preliminary, initial, or interim data or other information from our clinical trials, such as the preliminary data from the Phase 1b clinical trial of budoprutug for the treatment of membranous nephropathy (MN). Any such data and other results from our clinical trials may materially change as more patient data and information become available. Such data and information may also undergo significant change following subsequent auditing, validation and/or verification procedures that are commonly conducted in clinical trials. Thus, any preliminary, initial, or interim data or other information may not be predictive of final results from the clinical trial and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or other determinations that may qualify such results, once we have received and fully evaluated the additional data. Differences between preliminary, initial or interim results and final results could lead to significantly different interpretations or conclusions of the trial outcomes.

Further, others, including regulatory authorities and collaboration or regional partners, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of budoprutug, the approvability or commercialization of budoprutug, and our business, in general. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and investors may not agree with what we determine is material or otherwise appropriate information to publicly disclose.

If the preliminary, initial or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize budoprutug may be harmed, which could significantly harm our reputation, business, results of operations, financial condition and prospects.

Preclinical and clinical development involves a lengthy, complex and expensive process with an uncertain outcome. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

To obtain the requisite regulatory approvals to commercialize budoprutug or any future product candidates we may develop, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are potent, safe and pure in humans to the satisfaction of FDA. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, in the United States, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds to thousands of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signs of activity in earlier preclinical studies or clinical trials, as demonstrated by the failure of ETX-810 to achieve statistically significant separation from placebo on the primary endpoint in either of our Phase 2a clinical trials in diabetic peripheral neuropathic pain and lumbosacral radicular pain, respectively. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials.

A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or emergence of unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our future clinical trials will ultimately be successful or support further preclinical or clinical development of budoprutug or any future product candidates we may develop. Our success is heavily dependent on the progress and outcomes of our upcoming Phase 2 clinical trials of budoprutug in SLE/LN and ITP. The commencement and rate of completion of preclinical studies and clinical trials may be delayed by many factors, including:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- delays in reaching a consensus with regulatory authorities on trial design ,including the planned IND submission for budoprutug for SLE/LN and ITP and the potential for a delay in initiation of the related Phase 2 trials of budoprutug for SLE/LN and ITP and any preclinical or nonclinical studies required in support of an IND submission for budoprutug;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of TNT19 or future product candidates we may develop for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's or any other regulatory authority's GCPs or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, or after an inspection of trial sites or manufacturing facilities or otherwise;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- transfer of manufacturing processes to larger-scale facilities operated by a third-party contract development and manufacturing organization (CDMO) and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process; and

- third parties being unwilling or unable to satisfy their contractual obligations to us.

Any inability to successfully initiate or complete preclinical studies or clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act (FDORA) Congress required sponsors to develop and submit a diversity action plan (DAP) for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

Further, in January 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one member state of the European Union will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the member states of the European Union and the public.

Further, clinical trials that we may undertake in the future will likely contain endpoints that require subjective assessments and subject us to a substantial risk of "placebo effect". While a product candidate may show clinical activity or therapeutic benefit, a high placebo effect in a clinical trial will make it difficult to ascertain that benefit or to show statistically significant effect of the product candidate as compared to the control arm and may ultimately cause a clinical trial to fail.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Delays in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and jurisdictions and may include all of the risks associated with FDA approval described above and risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ jurisdiction-to-jurisdiction from that required to obtain FDA approval. Approval by foreign regulatory authorities does not ensure approval by the FDA and, similarly, approval by the FDA does not ensure approval by regulatory authorities outside the United States.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to foreign regulatory authorities or the FDA, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

We may experience negative or inconclusive results, or regulators may be unwilling to accept preclinical or clinical data obtained in foreign jurisdictions, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could harm our business.

In addition, the FDA and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. our product development costs will increase if it experiences delays in testing or marketing approvals. In addition, if we make manufacturing or other changes to budoprutug, we may need to conduct additional studies to bridge such new formulation of budoprutug to earlier versions. For example, we expect we will need to conduct additional non-clinical studies of budoprutug to bridge our new planned formulation of budoprutug to our earlier formulation. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also decide to change the design or protocol of one or more of our clinical trials, which could result in delays. Significant clinical trial delays with respect to budoprutug could also shorten any periods during which we may have the exclusive right to commercialize budoprutug or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize budoprutug.

Our product candidates may cause adverse events and/or undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Certain adverse events and undesirable side effects caused by budoprutug or any future product candidates we may develop could cause us or regulatory authorities to interrupt, delay or pause clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. If undesirable side effects do occur in our future clinical trials they could cause delay or even discontinuance of further development of budoprutug or any future product candidates we may develop, which would impair our ability to generate revenues and would have a material adverse effect on our business, results of operations, financial condition and cash flows and prospects.

As a result of undesirable side effects or further safety issues that we may experience in our clinical trials in the future, we may not receive approval to market budoprutug or any future product candidates we may develop, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition and cash flows and prospects.

Additionally, if budoprutug or any of our future product candidates we may develop receives marketing approval, and we, or others, later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a REMS or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

If we encounter difficulties enrolling and/or retaining patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

If we are able to move budoprutug or any future product candidates we may develop to the clinical trial stage, we may not be able to initiate or continue our planned clinical trials on a timely basis or at all if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. There may be limited patient pools from which to draw for clinical studies. The eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Patient enrollment for our future clinical trials may be affected by other factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- the availability and efficacy of approved drugs for the disease under investigation;
- perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- our ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as budoprutug or any future product candidates we may develop, and this competition would reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Our inability to enroll enough patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing if needed. Furthermore, even if we can enroll enough patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, such as www.ClinicalTrials.gov in the United States, within certain time frames. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following our products' marketing approval and commercialization. Product liability lawsuits brought against us or any of our future collaborators could divert our resources and attention, require us to cease clinical testing, cause us to incur substantial liabilities or limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biotechnology products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials may expose us to liability claims. We will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. Such claims could be made by participants enrolled in our clinical trials, patients, health care providers, biotechnology companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which any approved drug products may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If budoprutug or any future product candidates we may develop are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from physicians' or patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business.

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, less expensive or more advanced or effective than us, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.

The development and commercialization of new drug products is highly competitive. Moreover, the immunology and inflammation field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will face competition with respect to budoprutug and any future product candidates we may develop from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. 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 development, manufacturing, and commercialization.

There are a number of 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 budoprutug. 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.

Companies developing biologics and other modalities include Roche Holding AG (currently markets Rituxan (rituximab), which is used for a broad number of autoimmune diseases), Amgen (UPLINZA (inebilizumab) for the treatment of neuromyelitis optica spectrum disorder) and Ocrevus (ocrelizumab for the treatment of multiple sclerosis), each of which target CD20 on B cells, and others who have biologics aimed at other targets relevant to autoimmune diseases, including, for example, AbbVie Inc., Johnson & Johnson, Bristol-Myers Squibb Company and Novartis AG.

If we successfully develop and commercialize budoprutug, it will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for budoprutug. This may include other types of therapies, such as small molecule, chimeric antigen receptor T cells (CAR-T), antibody, and/or protein therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise than we do in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management consultants and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than budoprutug or that would render budoprutug obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for budoprutug, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render budoprutug uneconomical or obsolete, and we may not be successful in marketing budoprutug against competitors. In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for budoprutug.

Our estimates of market opportunity and forecasts of market growth for budoprutug may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. We currently focus our research and product development on budoprutug for the treatment of SLE/LN, ITP, and MN. Our understanding of the patient populations with these diseases is based on estimates in published literature. These estimates, and our estimates and forecasts relating to size and expected growth based on these estimates, may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with budoprutug or patients may become increasingly difficult to identify and access. Even if the patient populations meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for budoprutug, the ability to obtain coverage and reimbursement, the ability to gain market share and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of budoprutug, even if approved.

Further, there are several factors that could contribute to making the actual number of patients who receive budoprutug less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing our product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize budoprutug or any future product candidate, we must either develop our own sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. If we decides to market or distribute budoprutug or any future product candidate on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize budoprutug, which would adversely affect our business, results of operations, financial condition and cash flows and prospects.

Disruptions at the FDA, the U.S. Securities and Exchange Commission and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the U.S. Securities and Exchange Commission (SEC) and other government agencies on which our operations may rely, including those that fund research and development activities, are subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

In addition, disruptions may result from events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA’s inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue at its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Risks Related to Legal and Regulatory Compliance

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialize our product candidates, if and when approved, and may affect the prices we may charge for such product candidates, if and when approved.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that 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 for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act (ACA) was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how any additional challenges or future healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments including the Infrastructure Investment and Jobs Act and the Consolidated Appropriations Act of 2023, will stay in effect until 2032 unless Congress takes additional action.

Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The order directs HHS to create a plan within 45 days to combat “excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging.” On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 additional Medicare Part D drugs in 2027, 15 additional Medicare Part B or Part D drugs in 2028, and 20 additional Medicare Part B or Part D drugs per year in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if budoprutug or any future products we may develop are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on any of our product candidates, if approved, or the full value of our patents protecting any such approved drug products if prices are set after any such approved products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for budoprutug, if and when approved, or any future products we may develop, any of which could adversely affect our business, results of operations and financial condition.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas Pharma US, Inc., Novo Nordisk Inc., Janssen Pharmaceuticals, Inc., Novartis Pharmaceutical Corporation, AstraZeneca L.P. and Boehringer Ingelheim Pharmaceuticals, Inc., also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for budoprutug, if and when approved, and any other products we may develop, any of which could adversely affect our business, results of operations and financial condition.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for budoprutug, if and when approved, and any other products we may develop, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize budoprutug, if and when approved, and any other products we may develop. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. 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 or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product 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 materially harmed.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Although we do not currently have any products on the market, our operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations.

These laws may impact, among other things, our current business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims laws, including the False Claims Act (FCA) which can be enforced through "qui tam" or "whistleblower" actions, and civil monetary penalty law, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing such an obligation to pay money to the federal government. In addition, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

- the U.S. federal Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS, an agency within the HHS under the Open Payments Program, information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- U.S. federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

•analogous U.S. state laws and regulations, including state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and

•European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

We process personal data and other sensitive data (including health data we collect about study or trial participants in connection with our preclinical studies or clinical trials); proprietary and confidential business data; trade secrets; intellectual property; and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. These privacy laws include, without limitation, the following laws and regulations: Section 5 of the Federal Trade Commission Act, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) (which imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information), and the California Consumer Privacy Act of 2018 (CCPA). The CCPA applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the CPRA amended the CCPA and expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law.

In addition to California, at least 18 other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities.

There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New Hampshire and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the equivalent law in the U.K. (UK GDPR) and, together with EU GDPR, the GDPR, impose strict requirements for processing the personal data of individuals, including sensitive data that we may process such as health data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, as well as fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. Our inability or failure to do so could result in adverse consequences.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. The European Economic Area (EEA) the U.K. and certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. In particular, the EEA and the U.K. have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and U.K. to the United States in compliance with law, such as the EEA standard contractual clauses, the U.K. International Data Transfer Agreement and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant United States-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the U.K. or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and U.K. to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparation for and compliance with these obligations requires us to devote significant resources. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Although we try to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived as having failed). Despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the third-party providers (such as research institutions) who share this information with us, may contractually limit our ability to use and disclose the information.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences.

These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our product candidates; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United States, and PRIME Designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for budoprutug or other future product candidates we may develop that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track review products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track review product may be effective.

We may also seek a priority review designation for budoprutug or future product candidates we may develop. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal is for the FDA to review an application for marketing approval in six months, rather than the standard review period of 10 months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that budoprutug or a future product candidate meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the European Union, we may seek PRIME designation for budoprutug or other future product candidates we may develop. The PRIME program focuses on product candidates that target conditions for which there exists no satisfactory method of treatment in the European Union, or even if such a method exists, the product candidate may offer a major therapeutic advantage over existing treatments. To be accepted for PRIME designation, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a rapporteur of the Committee for Medicinal Products for Human Use to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for budoprutug or a future product candidate, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

Accelerated approval by the FDA, even if granted for budoprutug or any future product candidates we may develop, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that budoprutug or any future product candidates we may develop will receive marketing approval.

We may seek approval of budoprutug or any future product candidates we may develop using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well-controlled post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval for budoprutug or any future product candidates we may develop. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

With passage of the FDORA, in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: (i) require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded; (ii) require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months until the study is completed; and (iii) use expedited procedures to withdraw accelerated approval of a new drug application or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the agency to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will not be legally binding even when finalized, we will need to consider the FDA's guidance closely if we seek accelerated approval for any of our products. Accordingly, even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions.

Once the applicable pending studies are provided, a conditional marketing authorization can become a “standard” marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

We have received orphan drug designation for budoprutug for the treatment of MN, but we may be unable to realize the benefits associated with orphan drug designation, including market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if budoprutug receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture a sufficient supply of budoprutug or if a subsequent applicant demonstrates clinical superiority over budoprutug.

The FDA granted orphan drug designation to budoprutug for the treatment of MN. We may seek orphan drug designation for budoprutug in other specific orphan indications in which there is a medically plausible basis for the use of budoprutug but may never receive such designations. In addition, even with orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of budoprutug to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over budoprutug, if approved.

If approved, budoprutug or other future products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA) which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of regulatory exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company’s product.

In December 2022, Congress clarified through the FDORA, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA.

We believe that if budoprutug or any future product candidate that may be approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. Nonetheless, the approval of biosimilar products referencing budoprutug or any future product candidate would have a material adverse impact on our business due to increased competition and pricing pressures. Moreover, there is a risk that any exclusivity we do receive could be shortened due to congressional action or otherwise, or that the FDA will not consider our products to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation.

The extent to which a biosimilar, once licensed, will be substituted for budoprutug or any future reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars referencing budoprutug or any future product, such product may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. The ultimate impact, implementation, and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our biological product candidates.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted relating to non-patent exclusivity. For instance, the European Union pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products, which may reduce the duration of regulatory data protection and exclusivity periods for orphan drugs, and revise the eligibility for expedited pathways in addition to other changes, was published on April 26, 2023. On April 10, 2024, the European Parliament adopted a position on the proposal requesting several amendments to the package. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

We plan to conduct clinical trials at sites outside the United States. The FDA may not accept data from trials conducted in such locations, and the conduct of trials outside the United States could subject us to additional delays and expense.

We plan to conduct one or more clinical trials with one or more trial sites that are located outside the United States. The acceptance by the FDA or other regulatory authorities of trial data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the trial is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in budoprutug or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. Conducting clinical trials outside the U.S. will also expose us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Our failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing budoprutug or any future product candidates we may develop outside the U.S.

If we succeed in developing budoprutug, we intend to market budoprutug in foreign jurisdictions in addition to the U.S. In order to market and sell products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing.

The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., we must secure product pricing and reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of budoprutug in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we fail to obtain approval of budoprutug or any future product candidates we may develop by regulatory authorities in another country, we will be unable to commercialize our products in that country, and the commercial prospects of that product candidate and our business prospects could decline. In addition, failure to obtain regulatory approval in one country or region could adversely affect future regulatory approvals in other countries.

Further, in many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the U.K. as a result of the withdrawal of the U.K. from the European Union, commonly referred to as Brexit. The U.K. is no longer part of the European Single Market and EU Customs Union. As of January 1, 2021, the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland Protocol, Northern Ireland is currently subject to European Union rules. The U.K. and the European Union have, however, agreed to the Windsor Framework, which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the U.K.. From January 1, 2025 on, the changes introduced by the Windsor Framework will see the MHRA be responsible for approving all medicinal products destined for the U.K. market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. Any delay in obtaining, or an inability to obtain, any marketing authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the U.K. for our product candidates, which could significantly and materially harm our business.

Risks Related to the Acquisition of Tenet

We may fail to realize the anticipated benefits of the Acquisition and/or those benefits may take longer to realize than expected.

On June 27, 2024, we completed the Acquisition. Our ability to realize the anticipated benefits of the Acquisition is substantially dependent on our ability to develop and obtain regulatory approval of budoprutug, an anti-CD19 antibody designed for a broad range of autoimmune diseases. If we fail to obtain positive results from our clinical trials of budoprutug, or we are otherwise unable to obtain regulatory approval of budoprutug on the anticipated timelines or at all, such failure could materially adversely impact our business, financial condition and results of operations, and the market price of our common stock. Further, our ability to realize the anticipated benefits from the Acquisition is substantially dependent on the successful integration of Tenet into our business. The integration process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all, and could be adversely impacted by, among other things, unexpected costs and delays, the loss of key personnel, the loss of key suppliers and/or third parties with whom we do business, and other unanticipated issues. The failure to meet the challenges involved and to realize the anticipated benefits of the Acquisition could adversely affect our business, financial condition and results of operations.

We are involved and may in the future become involved in securities litigation or stockholder derivative litigation in connection with the Acquisition, the related private placement and the other transactions contemplated by the Acquisition Agreement, and this could divert the attention of our management and harm our business.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of an acquisition or a business combination transaction.

We are involved and may in the future become involved in this type of litigation in connection with the Acquisition, the related private placement and/or the other transactions contemplated by the Acquisition Agreement, and we may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. For example, as previously disclosed, certain of our purported stockholders sent demand letters and two lawsuits were filed by our purported stockholders, generally alleging that the preliminary proxy statement and/or definitive proxy statement in connection with the Acquisition omitted certain purportedly material information, and sought corrective disclosure to the proxy statement, as well as an assertion of a claim for breach of fiduciary duty against us and our directors. We deny any breach of any duties to our stockholders and believes that no supplemental disclosures were required under applicable law, but there can be no assurance that any of these or other disputes can be resolved favorably or at all.

Risks Related to our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We rely on third parties in winding down our development of our former clinical product candidates, and we expect to rely on third-party CROs to conduct, supervise, and monitor our future preclinical studies and clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or future clinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our future preclinical studies and clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for various reasons, including a failure to perform by the third parties; if we need to enter into alternative arrangements, that will delay our product development activities and harm our business.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice (GLP) as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, monitoring, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. As a clinical trial sponsor, we will also have regulatory requirements that directly apply to us. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs, we or our CROs may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials.

In addition, if and when we have an approved product, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA and comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests or significant payments of other sorts.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified time frames. Failure to do so can result in enforcement actions and adverse publicity.

Our CROs may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to any of our clinical, non-clinical, and preclinical programs.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct any of our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be harmed.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not harm our business.

We contract with third parties for the manufacture of materials and expect to continue to do so for our clinical trials and for commercialization of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials or that such supply will not be available to us at an acceptable cost or timelines, which could delay, prevent, or impair its development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely and expect to continue to rely on third party manufacturers for the manufacture of budoprutug for nonclinical and clinical testing and for commercial supply of budoprutug, if approved.

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

- the possible failure of the third party to manufacture budoprutug according to our schedule, or at all, including if the third party gives greater priority to the supply of other products over budoprutug or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- 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;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

Any performance failure on the part of our existing or future manufacturers could delay any potential clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer, or we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture budoprutug may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce budoprutug according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop or commercialize budoprutug in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of budoprutug that such third-party manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third-party manufacturer manufacture budoprutug.

In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between its prior clinical supply used in its clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our current and anticipated future dependence upon others for the manufacture of budoprutug may adversely affect our future expenses and our ability to commercialize budoprutug, if we receives marketing approval, on a timely and competitive basis.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and workplace health and safety. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations, financial condition, and prospects. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

We may not have access to the raw materials and other components necessary for the manufacturing of budoprutug.

We are dependent on third parties for the supply of various materials that are necessary to produce budoprutug for our clinical trials and do not have any supply agreements currently in place. Even if and when we have supply agreements, it is possible that the supply may be reduced or interrupted at any time. In such case, we may not be able to find other suppliers of acceptable materials in appropriate quantities at an acceptable cost. If we lose key suppliers or the supply of materials is diminished or discontinued, it may not be able to continue to develop, manufacture and market budoprutug in a timely and competitive manner. In addition, these materials are subject to stringent manufacturing processes and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect our ability to complete trials and commercialize our products in a cost-effective and timely manner. If we encounter difficulties in the supply of these materials or other necessary products, or if we are not able to maintain our supply agreements or establish new supply agreements in the future or incur increased production costs as a result of any of the foregoing, our product development and business prospects could be significantly compromised.

We rely significantly upon the information technology systems of our third-party service providers and any failure, inadequacy, interruption or security lapse of those systems could harm our ability to operate our business effectively. We have limited control and oversight over the information security systems and practices of third parties.

In the ordinary course of business, we rely on third parties, including clinical trial sites, CROs, CDMOs and other service providers, to collect, process and maintain personal and other sensitive data on their respective networks for our research and development activities and other business operations. These data include our intellectual property and other proprietary or confidential information relating to our business, as well as personal information relating to our clinical trial participants, employees and contractors, and clinical investigators, study staff and other healthcare professionals. The maintenance of our data by third parties does not absolve us of our responsibility for the security and integrity of this data.

We have limited control and oversight over the information security systems and practices of third parties. Those systems and practices vary widely in sophistication and robustness. We have limited personnel and resources to oversee the information security systems of third parties with whom we work.

Like our information security systems, those of our third-party service providers are vulnerable to compromise, damage, loss or exfiltration from cyber-attacks, computer viruses, unauthorized access and other causes. Our third-party service providers may not anticipate or immediately detect such incidents and the damage caused by such incidents or notify us in a timely or complete manner. System failures, data breaches and any unauthorized access, use or disclosure of our information or data maintained by our third-party service providers could lead to similar consequences for us as similar events involving our information technology systems, including compromise of our intellectual property or other sensitive personal or business information, disruptions and delays to our research and development activities and other operations, contractual and regulatory liability, data breach notifications, expenditure of significant costs and resources for remediation and harm to our reputation. Over the past few years, there has been an increasing number of and severity of cyber-attacks, especially ransomware attacks, against the information security systems of companies across the supply chain and other critical infrastructure service providers.

If we are not able to establish future collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the potential commercialization of budoprutug or any future product candidates we may develop will require substantial additional capital to fund expenses. We may decide to collaborate for the future development and potential commercialization of budoprutug, or any future product candidates we may develop. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

We face significant competition in seeking appropriate collaborators, and many more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, the MHRA, or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. Doing so will likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our budoprutug or any future product candidates we may develop or bring them to market and generate product revenue.

Risks Related to Intellectual Property

We rely heavily on certain in-licensed patents and other intellectual property rights in connection with our development of budoprutug and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize budoprutug.

We rely heavily on patents, know-how and other intellectual property licensed from others. We are party to a license agreement with Cancer Research Technology Limited (CRH) under which we are granted rights to intellectual property that are important to our business. Additionally, we may need to acquire or license intellectual property rights from additional third parties in order to continue to develop or commercialize budoprutug. Any future license agreements where we in-licenses intellectual property may impose on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with any of the obligations under such license agreements, including payment terms and diligence terms, the licensors may have the right to terminate these agreements, in which case we may lose important intellectual property rights and we may not be able to develop, manufacture, market or sell budoprutug or may face other penalties under such agreements or be subject to litigation for breach of these agreements. In addition, such a termination could result in the licensor reacquiring the intellectual property rights and subsequently enabling a competitor to access the technology. Any such occurrence could materially adversely affect the value of budoprutug. Termination of license agreements or reduction or elimination of our rights under them may result in us having to negotiate a new or reinstated agreement, which may not be available on equally favorable terms, or at all, which may mean we are unable to develop or commercialize budoprutug. For instance, these licenses may not provide exclusive rights to use the subject intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and budoprutug in the future, such as provisions under the license agreement with CRH prohibiting us from developing budoprutug for oncology indications. In that event, we may be required to expend significant time and resources to redesign our technology or the methods for manufacturing or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

Further, the agreements under which we currently license, and may license in the future, intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, material disputes may arise between us and our licensors, regarding intellectual property subject to such license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- the scope and practice of any rights reserved by our licensors;
- whether a licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- its right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of budoprutug;
- our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the creation or use of intellectual property by our licensors and by us and our partners, including jointly developed intellectual property; and
- the amounts of royalties, milestones or other payments due under the license agreement.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the financial or other benefits it might otherwise receive under the relevant agreement. If material disputes over intellectual property that we have licensed prevent or impair our ability to maintain licensing arrangements on acceptable terms or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize budoprutug. If we or any such licensors fail to adequately protect the relevant in-licensed intellectual property, our ability to commercialize budoprutug could suffer. Any material disputes with licensors or any termination of the licenses on which we depend could have a material adverse effect on our business, results of operations, financial condition and prospects.

We have four pending U.S. provisional patent applications with respect to budoprutug. We can provide no assurance that any of our other current or future patent applications will result in issued patents. If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of our licensors, or future licensors, licensees or collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others. We own four pending U.S. provisional patent applications with respect to budoprutug, and we can provide no assurance that any of these current patent applications or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. Failure to obtain issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates. Furthermore, other parties may successfully challenge, invalidate or circumvent our issued patents so that our patent rights do not create an effective competitive barrier or revenue source.

A U.S. provisional patent application is not eligible to become an issued patent until, among other things, we file non-provisional patent application within 12 months of filing of the provisional patent application. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our or our licensors' patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others, or other proceedings in the USPTO or applicable foreign offices that challenge priority of invention or other features of patentability. An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or freedom to operate, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, limit the scope or duration of the patent protection of budoprutug or any other product candidates that we may identify, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates or approved products (if any) without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize budoprutug or future product candidates we may develop, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

We cannot be certain that the USPTO and courts in the United States or the patent offices and courts in foreign countries will consider the claims in our patents and applications covering budoprutug and future product candidates we may develop as patentable. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent, including through legal action.

If we cannot obtain or lose patent protection for budoprutug or other future product candidates, it could have a material adverse impact on our business.

Additionally, as a licensee, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. For example, under the license agreement with CRH, CRH is responsible for prosecuting and maintaining intellectual property protection for budoprutug in consultation with us. We have not had and do not have primary control over these activities for certain of our in-licensed patents or patent applications and other intellectual property rights. For example, we cannot be certain that such activities by CRH or other licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

We have limited control over the manner in which CRH or our other licensors may initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that CRH or our other licensors infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves.

We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect its interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering budoprutug, our ability to develop and commercialize budoprutug may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to our assuming control over patent prosecution.

The patent prosecution process is expensive and time-consuming. We and our licensors, and any future licensors, licensees or collaborators, may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's or other third party's patent application may pose obstacles to our ability to obtain patent protection or limit the scope of the patent protection we may obtain.

Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, 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 be certain that we or our future licensors were the first to make the inventions claimed in our owned or any future licensed patents or pending patent applications, or were the first to file for patent protection of such inventions.

In addition, our technology acquired or licensed from various third parties, including our licensors, may be subject to retained rights. Our licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to its licensed technology in the event of misuse by the licensor.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain. Our and our future licensors' pending, and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our future licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or license, or may in-license in the future may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether budoprutug or any future product candidate will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Any of the foregoing could impair our competitive position and harm our business.

The patent protection we obtain for our product candidates and technologies may be challenged and rendered invalid and/or unenforceable.

Even if our owned patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents or patents we license from third parties, may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the United States and abroad, or circumvented. We or our licensors may be subject to a third-party preissuance submission of prior art to the USPTO or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and inter partes review or interference proceedings challenging our or our licensors' patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing could harm our business.

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

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

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and harm our business.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Competitors and other third parties may infringe, misappropriate or otherwise violate our owned and licensed patents or other intellectual property. In addition, our owned and licensed patents may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other 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 or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that an owned or licensed 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 owned and licensed patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable product candidates or technology covered by the patent rendered invalid or unenforceable. Such a loss of patent protection would harm our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. In addition, if we, our existing licensors or any future licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned, licensed or any future in-licensed patents. The loss of exclusivity or the narrowing of such patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could harm our business. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceeding.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to initiate anticipated clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally.

Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including EU countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could harm our business.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000, and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or their use. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents or if we are unable to obtain licenses to relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could harm our business.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from our licensors, otherwise experience disruption to our business relationships with our licensors, or we are unable to obtain licenses from other third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, we could lose license rights that our important to our business and our business could be harmed.

We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business, and we may enter into additional license agreements in the future for budoprutug or other future product candidates we may develop. Our existing license agreements impose on us, and we expect that any future license agreements where we in-licenses intellectual property will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, our licensors may have the right to terminate our licenses, in which case, we would not be able to market products covered by the licenses.

We obtained our right to a number of existing license agreements pursuant to an asset purchase agreement with Acelyrin, Inc., Acelyrin, which imposes on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under the asset purchase agreement, Acelyrin may have the right to re-purchase the obtained asset, including our rights to the licenses subject to the asset purchase agreement, in which case, we may not be able to market or develop budoprutug.

We may need to obtain additional licenses from third parties to advance our research or commercialize budoprutug or any future product candidates we may develop, and we cannot provide any assurances that third party patents do not exist that might be enforced against budoprutug or such other future product candidates in the absence of such a license. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize budoprutug or future product candidates we may develop, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of budoprutug, and what activities satisfy those diligence obligations;
- our right to transfer or assign licenses; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and our affiliates and sublicensees and by us and our partners and sublicensees.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize budoprutug, which would have a material adverse effect on our business.

Moreover, some of our patents and patent applications in the future may be co-owned with third parties. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. In addition, we intend, or understand that our licensors intend, to pursue additional patent protection covering, when possible, compositions, methods of use, methods of manufacture, and dosing and formulations of budoprutug. Any patent that may be issued from our owned pending patent applications is expected to expire in 2045, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations. Additionally, the issued patents, or patents that may be issued from the pending patent applications that we exclusively in-licenses from CRH are expected to expire in 2026, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations. In each instance of the above, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to budoprutug.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. owned or licensed patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and one or more of our foreign owned or licensed patents may be eligible for patent term extension under similar legislation, for example, in the European Union. In the United States, the Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced.

Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position and business could be harmed.

Changes in patent law could diminish the value of our patents, thereby impairing our ability to protect our intellectual property for our product candidates.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce existing or future patents. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued and licensed patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (Leahy-Smith Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued or licensed patents, all of which could harm our business.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any patents and patent applications are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we may rely on our licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process.

Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors, or any future licensors or collaborators, fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.

Our commercial success depends upon our ability and the ability of any of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including re-examination, interference, post-grant review, inter partes review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are not valid or that we would be able to replace such technology with alternative, non-infringing technology. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could adversely affect our ability to commercialize any product candidates we may develop, and any other product candidates or technologies covered by the asserted third- party patents. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a 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, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business.

We may be subject to claims by third parties asserting that we or our employees have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors 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 individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. Litigation may be necessary to defend against these claims.

In addition, we or our future licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned, licensed or any future in-licensed patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives, develops or reduces to practice intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to initiate anticipated clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize our product candidates, if approved. Any of the foregoing events would harm our business.

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

We rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensors, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, 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 or other third party, we would have no right to prevent 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 or other third party, our competitive position would be harmed. If we or our licensors do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

As is common in the biopharmaceutical industry, we engage the services of consultants to assist us in the development of budoprutug. Many of these consultants were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we or our consultants inadvertently or otherwise used or disclosed trade secrets or other information proprietary to our consultants' former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

We intend to rely on both registered and common law rights for our trademarks. We plan to apply to register these trademarks with the USPTO and may in the future seek to register additional trademarks in the United States and other countries. Our trademark applications may not be allowed for registration in a timely fashion or at all, and our future registered trademarks may not be maintained or enforced. In addition, any registered or unregistered trademarks or trade names that we own or will own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our technologies, products or services. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may in the future be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, third parties may file first for our trademarks in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could harm our business.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license now or own or license in the future;
- we, or our current or future licensors, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license now or own or license in the future;
- we, or our current or future licensors, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents; issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in the United States under FDA-related safe harbor patent infringement exemptions and/or in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could harm our business.

Risks Related to our Business Operations and Employee Matters

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on recruiting and retaining our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of budoprutug or any future product candidates we may develop, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact its ability to implement successfully its business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, licensors, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, the MHRA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and harm our reputation.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

Our international operations in the U.K. may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the United States. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, including those related to Brexit related changes, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; rejection or qualification of foreign clinical trial data by the competent authorities of other countries;

- •delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- •additional potentially relevant third-party patent and other intellectual property rights;
- •complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- •difficulties in staffing and managing foreign operations;
- •complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- •limits in our ability to penetrate international markets;
- •financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- •currency exchange rate fluctuations and the resulting effect on our revenue and expenses and the cost and risk of entering into hedging transactions if we chose to do so in the future;
- •natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including related public health guidance measures, boycotts, curtailment of trade and other business restrictions;
- •certain expenses including, among others, expenses for travel and insurance; and
- •regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

We may not be able to utilize a significant portion of our net operating loss carryforwards.

As of December 31, 2023, we had net operating loss (NOL) carryforwards of approximately $13.1 million for federal income tax purposes, $55.5 million for foreign income tax purposes and $8.3 million for state income tax purposes. The federal net operating loss may be used up to 80% of future taxable income while the state and foreign losses may be used to offset up to 100% of future taxable income. The federal net operating loss carryforward can be carried forward indefinitely while the state net operating loss carryforward will begin to expire in varying amounts in 2038. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act (Tax Act) as modified by the Coronavirus Aid, Relief and Economic Security Act (CARES Act) federal net operating losses incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited.

Separately, under Section 382 of the Internal Revenue Code of 1986, as amended (Internal Revenue Code) and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by certain stockholders over a rolling three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of our IPO, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382 of the Internal Revenue Code. We have not completed a Section 382 analysis, and therefore, there can be no assurances that the NOLs carryforward are not already limited. However, we believe a limitation, if any, would have an immaterial impact on our ability to utilize existing NOLs in the future.

In addition, we may experience ownership changes due to subsequent shifts in our stock ownership, some of which are out of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances, including the Acquisition, involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations; issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, sales agents, health care facilities, surgeons and other health care providers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. For example, in June 2024 we issued 5,560,047 shares of our common stock as consideration in connection with the closing of the Acquisition, and we issued 31,238,282 shares of our common in connection with the closing of the related private placement, resulting in the issuance of a total of an additional 36,798,329 shares of our common stock.

If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms favorable to us, or at all.

Risks Related to our Common Stock

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been volatile, fluctuating from a high trading price of $29.69 per share in August 2021 to a low trading price of $2.21 in February 2023. Recently, following the announcement of the Acquisition on April 11, 2024 to August 9, 2024, our stock price has fluctuated from a high trading price of $11.55 per share to a low trading price of $3.32 per share. The stock market in general and the market for biotechnology companies in particular have also experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may continue to be volatile in the future and may be influenced by many factors, including:

- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the commencement, enrollment or results of any clinical trials or preclinical development activities we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of our clinical trials or those of our competitors;
- unanticipated serious safety concerns related to the use of our product candidates;

- adverse regulatory decisions, including results of regulatory interactions and review for our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of strategic transactions, significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- actions by institutional or activist investors;
- changes to our business, including pipeline reprioritizations and restructurings;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- threats of or actual significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, including the other factors described in this "Risk Factors" section, many of which are beyond our control.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock, in particular following significant drops in stock price. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. In addition, in the current volatile market for biotechnology stocks, in particular where shares are trading below cash balances, certain biotechnology investors have advocated for increases in short-term stockholder value through proposed corporate actions such as financial restructurings, special dividends, stock repurchases, mergers, other business combinations or sales of assets. Any such proposals directed at us could cause us to incur substantial costs and divert management's attention and resources from our business.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

Our management has broad discretion in the application of our cash and cash equivalents and could use such funds in ways that do not improve our results of operations or enhance the value of our common stock or in ways that our stockholders may not agree with.

The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest these funds in a manner that does not produce income or that loses value.

A significant portion of our common stock may be sold into the market, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Additionally, the holders of an aggregate of 15.7 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

In connection with the private placement related to the Acquisition, we entered into a registration rights agreement, pursuant to which we are required to register for resale the shares to be purchased in the private placement and the consideration issued in the Acquisition. Pursuant to this agreement, in July 2024, we filed a registration statement covering the resale of the shares purchased by the purchasers in the private placement and the consideration issued in connection with the Acquisition. In addition, we have agreed to use commercially reasonable efforts to cause such registration statement to become effective as soon as practicable after it is filed with the SEC and to keep such registration statement effective until the date the shares covered by the registration statement have been sold or can be resold without restriction under Rule 144 of the Securities Act.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as currently in effect, may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- provide for a classified board of directors whose members serve staggered terms;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of at least 66 2/3% of our outstanding shares of common stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of common stock to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (DGCL) which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnities, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders, including affiliates of RA Capital Management L.P., may limit or prevent new investors from influencing significant corporate decisions and also reduces the public float for our common stock, which could make our common stock less attractive to some investors or otherwise harm our stock price.

Based upon our common stock outstanding as of June 30, 2024, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own approximately 69.6% of our outstanding common stock. In particular, affiliates of RA Capital Management, L.P., own approximately 47.1% of our outstanding common stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transaction. The interests of this group of stockholders may not coincide with the interests of other stockholders.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in the IPO and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

In addition, as a result of this concentration of ownership, there is a limited number of number of shares of our common stock that are not held by officers, directors and controlling stockholders (which is referred to as our public float), thereby adversely impacting the liquidity of our common stock and potentially depressing the price at which you may be able to sell shares of common stock.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Prior to the completion of the IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the preparation of our consolidated financial statements for the year ended December 31, 2020, we identified material weaknesses in our internal control over financial reporting, two of which remain unremediated as of June 30, 2024. The unremediated material weaknesses, and our remediation plan, are disclosed in Item 4 of this Quarterly Report on Form 10-Q.

We believe we have made substantial progress toward achieving the effectiveness of our internal control over financial reporting and disclosure controls and procedures. The actions that have been taken are subject to continued review and testing by management as well as oversight by the audit committee of our board of directors. We will not be able to conclude whether the steps we have taken will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market. Section 302 of the Sarbanes-Oxley Act requires, among other things, that we report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filings.

We cannot assure you that the measures we have taken to date, and are continuing to implement, or any measures we may take in the future, will be sufficient to identify or prevent future material weaknesses. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company or a smaller reporting company with less than $100 million in revenue.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on the Nasdaq Stock Market or any other securities exchange.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America as the exclusive forums for substantially all disputes between us and our stockholders, which restricts our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of claims or causes of action under Delaware statutory or common law: any derivative claims or causes of action brought on our behalf; any claims or causes of action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

Such provisions are intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters for any offering giving rise to such complaint and any other professional or entity who has prepared or certified any part of the document underlying the offering and may result in increased costs for stockholders to bring a claim.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

General Risk Factors

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that equity research analysts publish about us and our business. We currently have limited equity analyst coverage, and such a lack of research coverage may adversely affect the market price of our common stock. For instance, lack of regular coverage may result in demand for our stock to decrease, which in turn could cause our stock price or trading volume to decline. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research.

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

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine and Israel and Hamas, terrorism, or other geopolitical events. Sanctions imposed by the U.S. and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

If our information technology systems or data, or those of third parties upon which we rely, such as CROs, are or were compromised or interrupted, we could experience adverse consequences resulting from such compromise or interruption, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity and availability of our data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, and are becoming increasingly difficult to detect. These threats come from a variety of sources.

In addition to traditional computer “hackers,” threat actors, “hacktivists”, organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage in attacks. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely, such as CROs, may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may become increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, geopolitical developments, earthquakes, fires, floods, and other similar threats. Ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We also rely upon third-party service providers and technologies to operate critical business systems to process confidential information and personal data in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties’ cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties, and if they experience a security incident or other interruption, we could experience adverse consequences. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners’ supply chains have not been affected. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Our remote workforce poses increased risks to our information technology systems and data, as more of our personnel work from home, utilizing network connections outside our premises. Future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our data or our information technology systems, or those of the third parties upon whom we rely. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also harm our business.

We may expend significant resources or modify our business activities (including future clinical trial activities) to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities but we may be unable in the future to detect and remediate vulnerabilities because such threats and techniques change frequently, are often sophisticated in nature, and therefore may not be detected until after a security incident has occurred. These vulnerabilities therefore may pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary expenditures; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Security incidents and attendant consequences may cause delays in the development of our product candidates and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient of protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We are an "emerging growth company" and a "smaller reporting company," and as a result of the reduced reporting requirements applicable to "emerging growth companies" and "smaller reporting companies," our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" until December 31, 2026, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year-end). We are also a "smaller reporting company," as defined in the Exchange Act. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

We may be unable to maintain adequate insurance coverage.

We presently have general liability, workers' compensation, directors' and officers' and product liability insurance coverage. Although we believe we will be able to maintain such coverage for a reasonable cost and obtain any additional coverages that our business may require, no assurances can be made that we will be able to do so.

Changes in tax laws or regulations that are applied adversely to us may seriously harm our business.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

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

Recent Sales of Unregistered Securities

We did not sell any securities during the three and six months ended June 30, 2024 that were not registered under the Securities Act of 1933, as amended (the Securities Act) and that have not otherwise been described in a Current Report on Form 8-K.

Use of Proceeds

On August 9, 2021, our Registration Statement on Form S-1, as amended (File No. 333-257980), was declared effective in connection with our initial public offering (IPO). The aggregate net proceeds from our IPO were $83.1 million. We intend to use the proceeds from our IPO to advance our development pipeline, business development activities, working capital and other general corporate purposes.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On April 27, 2024, Emily Pimblett, Chief Accounting Officer, entered into a Rule 10b5-1 trading arrangement that is intended to qualify as an “eligible sell-to-cover transaction” (as described in Rule 10b5-1(c)(1)(ii)(D)(3) under the Exchange Act). The sell-to-cover arrangement applies to restricted stock units (RSU) that vest based on the passage of time. The arrangement provides for the automatic sale of shares of the Company’s common stock that would otherwise be issuable on each settlement date of a covered RSU in an amount necessary to satisfy the applicable withholding obligation, with the proceeds of the sale delivered to the Company in satisfaction of the applicable withholding obligation. The number of shares that will be sold under this arrangement is not currently determinable as the number will vary based on the extent to which vesting conditions are satisfied and the market price of our common stock at the time of settlement.

None of our directors or officers terminated a Rule 10b5-1 trading arrangement or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization, dated as of April 10, 2024, by and among Eliem Therapeutics, Inc., Tango Merger Sub, Inc., Tenet Medicines, Inc. and, solely in his capacity as the Company Equityholder Representative, Stephen Thomas.	8-K	001-40708	2.1	4/11/2024
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-40708	3.1	8/12/2021
3.2	Amended and Restated Bylaws of the Registrant	S-1	333-257980	3.4	8/2/2021
4.2	Form of common stock certificate of the Registrant	S-1	333-257980	4.1	8/2/2021
4.3	Amended and Restated Investors Rights Agreement, dated May 21, 2021, by and among the Registrant and the investors listed on Schedule A thereto	S-1	333-257980	10.1	7/16/2021
10.1	Form of Company Support Agreement.	8-K	001-40708	10.1	4/11/2024
10.2	Form of Tenet Support and Joinder Agreement.	8-K	001-40708	10.2	4/11/2024
10.3	Form of Lock-Up Agreement.	8-K	001-40708	10.3	4/11/2024
10.4	Securities Purchase Agreement, dated April 10, 2024, by and among Eliem Therapeutics, Inc. and the persons party thereto.	8-K	001-40708	10.4	4/11/2024
10.5	Registration Rights Agreement, dated April 10, 2024, by and among Eliem Therapeutics, Inc. and the persons party thereto.	8-K	001-40708	10.5	4/11/2024
10.6	Senior Secured Promissory Note, dated as of May 14, 2024, between Eliem Therapeutics, Inc. and Tenet Medicines, Inc.	10-Q	001-40708	10.6	5/15/2024
10.7+	Offer Letter, dated June 12, 2024, between Eliem and Aoife Brennan	8-K	001-40708	10.1	6/12/2024
10.8†	Asset Purchase Agreement, dated as of January 11, 2024, by and between Tenet Medicines, Inc., Acelyrin, Inc. and WH2, LLC	8-K	001-40708	10.1	6/27/2024
10.9†	Amended and Restated License Agreement, dated as of January 11, 2024, by and between Tenet Medicines, Inc. and Cancer Research Technology Limited	8-K	001-40708	10.2	6/27/2024
10.10†	Cell Line Development, Manufacturing Services and License Agreement, effective as of February 9, 2021, by and between ValenzaBio, Inc. and ProBioGen, Inc.	8-K	001-40708	10.3	6/27/2024
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 File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Scheme Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

+ Indicates management contract or compensatory plan.

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.

Eliem Therapeutics, Inc.

Date: August 14, 2024

By: /s/ Aoife Brennan
Aoife Brennan, M.D., Ch.B.
President and Chief Executive officer
(*Principal Executive Officer*)

Eliem Therapeutics, Inc.

Date: August 14, 2024

By: /s/ Andrew Levin
Andrew Levin, M.D., Ph.D.
Executive Chairman of the Board of Directors
(*Principal Financial Officer*)

Exhibit 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

I, Aoife Brennan, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Eliem Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2024

By: /s/ Aoife Brennan
Aoife Brennan, M.D., Ch.B.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, Andrew Levin, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Eliem Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2024

By: /s/ Andrew Levin
Andrew Levin, M.D., Ph.D.
Executive Chairman of the Board of Directors
(Principal Financial Officer)

Exhibit 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

In connection with the Quarterly Report of Eliem Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 14, 2024

By: /s/ Aoife Brennan
Aoife Brennan, M.D., Ch.B.
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eliem Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 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

In connection with the Quarterly Report of Eliem Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 14, 2024

By: /s/ Andrew Levin
Andrew Levin, M.D., Ph.D.
Executive Chairman of the Board of Directors
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eliem Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.