UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-41331

AN2 Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-0606654**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1800 El Camino Real, Suite D Menlo Park, California	**94027**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 331-9090

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	ANTX	The Nasdaq Global Select Market

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

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

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

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

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

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

As of November 6, 2024, the registrant had 29,878,890 shares of common stock, $0.00001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Form 10-Q") contains forward-looking statements. All statements other than statements of historical facts contained in this Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical and nonclinical studies and clinical trials, results of preclinical and nonclinical studies, clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue," or the negative of these terms or other similar expressions. Forward-looking statements contained in this Form 10-Q include, but are not limited to, statements about:

- the initiation, timing, progress, and results of our preclinical and nonclinical studies and clinical trials, and our research and development programs, including the manufacture of clinical trial material and drug product for launch;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our use of the net proceeds from financing activities;
- the translation of our preclinical results and data and early clinical trial results, in particular relating to safety, efficacy and durability, into future clinical trial results;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
- our ability to advance our initial product candidate and any other product candidates we may develop into, and successfully complete, clinical trials;
- the timing of and our ability to obtain and maintain regulatory approvals for our initial product candidate and any other product candidates we may develop;
- the commercialization of our initial product candidate and any other product candidates we may develop, if approved;
- the implementation of our business model, strategic plans for our business, and our initial product candidate and any other product candidates we may develop;
- our ability to identify additional product candidates and advance them into clinical development;
- our financial performance;
- developments relating to our competitors and our industry; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Form 10-Q and are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in this Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AN2 THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 33,504	$ 15,647
Short-term investments	59,922	91,648
Prepaid expenses and other current assets	4,263	3,212
Total current assets	97,689	110,507
Long-term investments	—	27,194
Other assets, long-term	—	1,043
Total assets	$ 97,689	$ 138,744
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,711	$ 2,676
Accrued compensation	2,110	4,018
Accrued liabilities	4,921	6,681
Other current liabilities	1,275	668
Total current liabilities	10,017	14,043
Total liabilities	10,017	14,043
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.00001 par value; 500,000,000 shares authorized at September 30, 2024 and December 31, 2023; 29,868,583 and 29,741,445 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	285,814	278,881
Accumulated other comprehensive gain	112	275
Accumulated deficit	(198,254)	(154,455)
Total stockholders' equity	87,672	124,701
Total liabilities and stockholders' equity	$ 97,689	$ 138,744

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

AN2 THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 8,287	$ 14,429	$ 35,091	$ 39,952
General and administrative	3,484	3,751	10,856	10,868
Restructuring charges	2,243	—	2,243	—
Total operating expenses	14,014	18,180	48,190	50,820
Loss from operations	(14,014)	(18,180)	(48,190)	(50,820)
Other income, net	1,267	1,473	4,391	2,986
Net loss attributable to common stockholders	$ (12,747)	$ (16,707)	$ (43,799)	$ (47,834)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (0.65)	$ (1.47)	$ (2.22)
Weighted-average number of shares used in computing net loss per share, basic and diluted	29,841,169	25,645,421	29,809,839	21,532,537
Other comprehensive loss:				
Unrealized gain (loss) on investments	139	(3)	(163)	252
Comprehensive loss	$ (12,608)	$ (16,710)	$ (43,962)	$ (47,582)

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

AN2 THERAPEUTICS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
Balances at December 31, 2023	29,741,445	$ —	$ 278,881	$ 275	$ (154,455)	$ 124,701
Issuance of common stock under the ESPP	45,288	—	124	—	—	124
Issuance of common stock upon exercise of stock options	28,930	—	225	—	—	225
Vesting of early exercised stock options	—	—	1	—	—	1
Stock-based compensation	—	—	2,385	—	—	2,385
Unrealized loss on available-for-sale investments	—	—	—	(222)	—	(222)
Net loss	—	—	—	—	(16,617)	(16,617)
Balances at March 31, 2024	29,815,663	—	281,616	53	(171,072)	110,597
Vesting of early exercised stock options	—	—	1	—	—	1
Issuance of common stock upon release of restricted stock units	13,377	—	—	—	—	—
Stock-based compensation	—	—	2,271	—	—	2,271
Unrealized loss on available-for-sale investments	—	—	—	(80)	—	(80)
Net loss	—	—	—	—	(14,435)	(14,435)
Balances at June 30, 2024	29,829,040	—	283,888	(27)	(185,507)	98,354
Issuance of common stock under the ESPP	25,412	—	23	—	—	23
Vesting of early exercised stock options	—	—	1	—	—	1
Issuance of common stock upon release of restricted stock units	14,131	—	—	—	—	—
Stock-based compensation	—	—	1,902	—	—	1,902
Unrealized gain on available-for-sale investments	—	—	—	139	—	139
Net loss	—	—	—	—	(12,747)	(12,747)
Balances at September 30, 2024	29,868,583	$ —	$ 285,814	$ 112	$ (198,254)	$ 87,672

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2022	19,402,658	$ —	$ 185,469	$ (374)	$ (89,723)	$ 95,372
Issuance of common stock under the ESPP	23,794	—	199	—	—	199
Vesting of early exercised stock options	—	—	2	—	—	2
Stock-based compensation	—	—	2,068	—	—	2,068
Unrealized gain on available-for-sale investments	—	—	—	199	—	199
Net loss	—	—	—	—	(15,323)	(15,323)
Balances at March 31, 2023	19,426,452	—	187,738	(175)	(105,046)	82,517
Issuance of common stock in the "at-the-market" offering, net of commissions and offering costs of $0.9 million	2,502,000	—	19,050	—	—	19,050
Vesting of early exercised stock options	—	—	2	—	—	2
Stock-based compensation	—	—	1,943	—	—	1,943
Unrealized gain on available-for-sale investments	—	—	—	56	—	56
Net loss	—	—	—	—	(15,804)	(15,804)
Balances at June 30, 2023	21,928,452	—	208,733	(119)	(120,850)	87,764
Issuance of common stock in the Underwritten Offering, net of underwriters' commission and offering costs of $4.5 million	7,777,778	—	65,479	—	—	65,479
Issuance of common stock under the ESPP	20,215	—	167	—	—	167
Issuance of common stock upon exercise of stock options	15,000	—	99	—	—	99
Vesting of early exercised stock options	—	—	1	—	—	1
Stock-based compensation	—	—	2,169	—	—	2,169
Unrealized loss on available-for-sale investments	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(16,707)	(16,707)
Balances at September 30, 2023	29,741,445	$ —	$ 276,648	$ (122)	$ (137,557)	$ 138,969

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

AN2 THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows used in operating activities		
Net loss	$ (43,799)	$ (47,834)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,558	6,180
Non-cash operating lease expense	—	53
Net accretion of discount on investments	(2,712)	(1,549)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(8)	(405)
Accounts payable	(965)	2,660
Accrued compensation	(1,908)	28
Accrued liabilities	(1,760)	3,727
Operating lease liabilities	—	(53)
Other current liabilities	610	973
Net cash used in operating activities	(43,984)	(36,220)
Cash flows from investing activities		
Purchases of investments	(22,371)	(112,348)
Maturities of investments	83,840	68,650
Net cash provided by (used in) investing activities	61,469	(43,698)
Cash flows from financing activities		
Proceeds from issuance of common stock from the Underwritten Offering, net of commissions and offering expenses	—	65,800
Proceeds from issuance of common stock from the "at-the-market" offering, net of commissions and offering expenses	—	19,050
Proceeds from issuance of common stock under the ESPP	147	366
Proceeds from exercise of stock options	225	99
Net cash provided by financing activities	372	85,315
Net increase in cash and cash equivalents	17,857	5,397
Cash and cash equivalents at the beginning of the period	15,647	27,219
Cash and cash equivalents at the end of the period	$ 33,504	$ 32,616
Supplemental disclosure of noncash financing items		
Deferred offering costs included in accounts payable and accrued liabilities	$ —	$ 321

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

AN2 Therapeutics, Inc.
Notes to Unaudited Condensed Financial Statements

Note 1. Organization and Description of the Business

Description of Business

AN2 Therapeutics, Inc. (the "Company") is a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics derived from its boron chemistry platform. AN2 has a pipeline of boron-based compounds in development for Chagas disease, non-tuberculous mycobacterial ("NTM"), and melioidosis, along with early-stage programs focused on targets in infectious diseases and oncology. The Company was incorporated in the state of Delaware in February 2017, began operations in November 2019, began trading on the Nasdaq Global Select Market on March 25, 2022 under the symbol "ANTX", and is based in Menlo Park, California.

Since launching operations in November 2019, the Company has devoted substantially all of its resources to performing research and development activities, including with respect to its initial product candidate, epetraborole, and other product candidates, business planning and restructuring, hiring personnel, raising capital, and providing general and administrative support for these operations.

Initial Public Offering

On March 24, 2022, the Company's registration statement on Form S-1 (File No. 333-263295) relating to its initial public offering ("IPO") of common stock became effective. The IPO closed on March 29, 2022, at which time the Company issued an aggregate of 4,600,000 shares of its common stock at a price to the public of $15.00 per share. In addition, immediately prior to the closing of the IPO, all outstanding shares of the Company's then existing redeemable convertible preferred stock automatically converted into 11,409,488 shares of common stock. The aggregate offering proceeds for shares sold in the IPO was $69.0 million. After deducting underwriting discounts and commissions of $4.8 million and offering costs paid or payable by the Company of $3.3 million, the net proceeds from the offering were approximately $60.9 million.

On April 8, 2022, the underwriters from the IPO exercised an option to purchase 690,000 additional shares of the Company's common stock at a public offering price of $15.00 per share, resulting in additional gross proceeds to the Company of $10.4 million, and additional net proceeds of approximately $9.5 million. After giving effect to this exercise of the overallotment option, the total number of shares sold by the Company in the IPO increased to 5,290,000 shares with total net proceeds to the Company of approximately $70.4 million.

At-The-Market Offering

On April 6, 2023, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC as the Company's sales agent ("Agent") to issue and sell up to an aggregate gross sales of $100.0 million in shares ("Shares") of the Company's common stock through an "at-the-market" equity offering program ("ATM Offering"). The Company will pay commissions to the Agent of up to 3.0% of the gross proceeds of the sale of the Shares sold under the Sales Agreement and reimburse the Agent for certain expenses. During the year ended December 31, 2023, the Company issued and sold 2,502,000 shares of common stock under the ATM Offering, resulting in net proceeds of $19.1 million, after deducting commissions and other offering costs. The Company did not sell any shares of common stock through the ATM Offering during the nine months ended September 30, 2024.

Underwritten Offering

On August 15, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cowen and Company, LLC, Leerink Partners LLC and Evercore Group L.L.C., as representatives of several underwriters, to issue and sell 7,777,778 shares of common stock at an offering price of $9.00 per share, resulting in net proceeds of $65.5 million, after deducting commissions and other offering costs (the "Underwritten Offering").

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP").

Unaudited Interim Condensed Financial Information

The accompanying condensed balance sheet as of September 30, 2024, the condensed statements of operations and comprehensive loss and the condensed statements of stockholders' equity for the three and nine months ended September 30, 2024 and 2023, and the condensed statements of cash flows for the nine months ended September 30, 2024 and 2023 are unaudited. The unaudited interim condensed financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2024, the results of its operations for the three and nine months ended September 30, 2024 and 2023 and its cash flows for the nine months ended September 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2024 and 2023 are also unaudited. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. The balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. Certain disclosures have been condensed or omitted from the interim condensed financial statements. Accordingly, these unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements as of and for the year ended December 31, 2023, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the U.S. Securities and Exchange Commission ("SEC"), dated March 29, 2024.

Risks and Uncertainties

Liquidity

Prior to the IPO, the Company's operations had historically been financed through the issuance of redeemable convertible preferred stock. Since inception, the Company has incurred significant losses and negative net cash flows from operations. During the nine months ended September 30, 2024 and 2023, the Company incurred a net loss of $43.8 million and $47.8 million, respectively, and had cash flows used in operating activities of $44.0 million and $36.2 million, respectively. The Company has an accumulated deficit of $198.3 million and $154.5 million as of September 30, 2024 and December 31, 2023, respectively, and will require substantial additional capital for research and development activities. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidate currently in development.

As of September 30, 2024, the Company had cash, cash equivalents, and investments of $93.4 million. Management believes that its cash, cash equivalents, and investments as of September 30, 2024 will be sufficient to fund its current operating plan through at least 12 months from the issuance date of these condensed financial statements. Future capital requirements will depend on many factors, including the timing and extent of spending on research and development, including costs for preclinical and nonclinical studies, clinical trials, and clinical trial and material manufacturing. There can be no assurance that, in the event the Company requires additional financing, such financing will be available at terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on the Company's ability to achieve its intended business objectives.

Segments

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on a company-wide basis for purposes of allocating resources and assessing financial performance.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to research and development accruals, fair value of assets and liabilities and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Research and Development Expenses

All research and development costs, including work performed by third parties, are expensed as incurred. Research and development costs consist of salaries and other personnel-related expenses, including associated stock-based compensation, consulting fees, and facility costs, as well as fees paid to other entities that conduct certain research and development activities on behalf of the Company. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or services are rendered.

As part of the process of preparing its financial statements, the Company estimates its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of services performed and the associated cost incurred for services for which the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses at the end of each reporting period based on the facts and circumstances known to the Company at that time. The significant estimates in the Company's accrued research and development expenses relate to expenses incurred with respect to contract manufacturing and clinical and other research organizations, academic research centers, and other vendors in connection with research and development activities for which the Company has not yet been invoiced.

Stock-Based Compensation

The Company measures and recognizes compensation expense for equity-classified stock-based awards made to employees, directors and non-employees based on the grant date estimated fair value of each award. Compensation expense for employee and director awards is recognized on a straight-line basis over the requisite service period which is generally the vesting period for the entire award. Expense is adjusted for forfeitures as they occur. Compensation expense for non-employee awards is recognized in the same period and manner as if the Company had paid cash for the goods or services provided.

The valuation model used for calculating the fair value of stock options for stock-based compensation expense is the Black-Scholes option-pricing model (the Black-Scholes model). The Black-Scholes model requires management to make assumptions and judgments about the variables used in the calculation, including the expected term, the expected volatility of common stock, an assumed risk-free interest rate, and expected dividends the Company may pay. Management uses the simplified calculation (based on the mid-point between the vesting date and the end of the contractual term) of the expected term for its stock options as the Company has concluded that its stock option history does not provide a reasonable basis upon which to estimate expected term. Volatility is based on an average of the historical volatilities of the common stock of entities with characteristics similar to the Company's. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

For option awards that contain performance conditions, compensation cost is recognized in the period in which it becomes probable that the performance condition will be satisfied. For option awards that vest upon a liquidity event or a change in control, the performance condition is not probable of being achieved until the event occurs. As a result, no compensation expense would be recognized until the performance-based vesting condition is achieved.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents, which consist of money market funds, are stated at fair value. As of September 30, 2024 and December 31, 2023, the Company had cash and cash equivalents of $33.5 million and $15.6 million, respectively.

Investments

Investments consist of U.S. Treasury securities, commercial paper, U.S. Government agency securities, asset-backed securities, and corporate debt securities. All of the Company's investments are classified as available-for-sale and are carried at estimated fair values and reported in cash equivalents, short-term investments or long-term investments. Management determines the appropriate classification of the investments at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. Investments with contractual maturities greater than 12 months are considered long-term investments. The cost of investments sold, if any, is based on the specific identification method.

Unrealized gains and losses on available-for-sale investments are reported in accumulated other comprehensive (loss) gain as a separate component of stockholders' equity (deficit). For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value and recognized in other income (expense) in the statements of operations and comprehensive loss. If neither criterion is met, the Company evaluates whether the decline in fair value is related to credit-related factors or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. Credit-related impairment losses, limited by the amount that the fair value is less than the amortized cost basis, are recorded through an allowance for credit losses in other income, net. Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit factors are recognized in accumulated other comprehensive income (loss) as a separate component of stockholders' equity, along with unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in other income, net in the statements of operations and comprehensive loss.

For purposes of identifying and measuring credit-related impairments, the Company's policy is to exclude applicable accrued interest from both the fair value and amortized cost basis of the related security. The Company has elected to write-off uncollectible accrued interest receivable balances in a timely manner, which is defined by the Company as when interest due becomes 90 days delinquent. The accrued interest write-off will be recorded by reversing interest income. Accrued interest receivable is recorded to prepaid expenses and other current assets on the Company's unaudited interim condensed balance sheets.

As of September 30, 2024 and December 31, 2023, the Company had investments of $59.9 million and $118.8 million, respectively.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents and investments. The Company's cash is invested through financial institutions in the United States. The Company's investments consist of debt securities, issued by highly rated corporate entities or the U.S. government, and asset-backed securities. The Company's exposure to any individual corporate entity is limited by its investment policy. Deposits have and will continue to exceed federally insured limits. The Company invests its cash equivalents in highly rated money market funds. The Company has not experienced any credit losses in such accounts.

The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the condensed balance sheets. In March 2023, one of the financial institutions utilized by the Company was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Through September 30, 2024, the Company had no off-balance sheet concentrations of credit risk.

Government Contract

In September 2022, the Company received a cost-reimbursement contract award under which the Company is eligible to receive up to $17.8 million from the U.S. National Institute of Allergy and Infectious Diseases ("NIAID") to support preclinical, Phase 1 studies and other activities to enable advancement of epetraborole into late-stage development for acute systemic melioidosis and other biothreat pathogens. This project will be funded in whole or in part with Federal funds from the NIAID, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N93022C00059. Accounting for this contract does not fall under ASC 606, Revenue from Contracts with Customers, as NIAID will not benefit directly from the advancement of epetraborole. As there is no authoritative guidance under U.S. GAAP on accounting for government assistance to for-profit business entities, the Company applied International Accounting Standards (IAS) 20, Accounting for Government Grants and Disclosure of Government Assistance, by analogy when accounting for the NIAID contract payments to the Company. Under IAS 20, government contract proceeds are recognized when there is reasonable assurance the conditions of the contract will be met and the contract funding will be received. For the NIAID contract, this occurs after the qualifying expenses related to the contract have been incurred, or the Company concludes the conditions of the contract have been substantially met. The income related to the reimbursement of operating expenses is then recorded as a reduction of those expenses (see Note 4—Funding Arrangements).

Grant Agreements

In September 2022, the Company entered into a subcontract agreement with the University of Georgia Research Foundation ("UGARF") to receive up to $1.4 million from the UGARF to support preclinical development of a boron-containing small molecule for Chagas disease.

In September 2023, the Company entered into a grant agreement with the Bill and Melinda Gates Foundation ("BMGF") to fund up to $1.8 million to generate new boron-based lead compounds with the potential to be developed into drugs that treat tuberculosis ("TB") and malaria.

In July 2024, the Company entered into an amendment to the 2022 subcontract agreement with the UGARF for additional funding in the amount of $0.2 million.

In September 2024, the Company entered into a second-year continuation grant agreement with BMGF to fund up to $2.0 million to support an early-stage research program focused on delivering novel leads as starting points for new drugs that can be combined to deliver shorter, safer and simpler TB drug regimens.

The Company recognizes grant proceeds in accordance with ASC 958-605, Not-for-Profit Entities - Revenue Recognition, when qualifying costs are incurred and the conditions of the grant agreement have been met. When receipt of grant proceeds is reasonably assured, the Company records a reduction to the research and development expenses incurred and a corresponding grant receivable. Cash received from grants in advance of incurring qualifying costs is recorded as a liability and recognized as a reduction to the qualifying research and development expenses incurred (see Note 4—Funding Arrangements).

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss. The Company's other comprehensive loss consists of net changes in unrealized gains and losses on its available-for-sale investments. For the nine months ended September 30, 2024 and 2023, the Company had $0.2 million of net unrealized loss and $0.3 million of net unrealized gain, on available-for-sale investments, respectively.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options, unvested RSUs, and common stock subject to repurchase related to unvested early exercise of stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods because the impact of potentially dilutive securities would be anti-dilutive.

Restructuring Charges

Restructuring charges consist primarily of employee severance payments and other employee termination-related expenses, offset by a reduction in stock-based compensation expense related to consulting agreements entered into with certain terminated employees. The Company records restructuring charges based on whether the termination benefits are provided under an on-going benefit arrangement or under a one-time benefit arrangement. The Company accounts for on-going benefit arrangements, such as those documented by employment agreements or a pre-existing severance policy, in accordance with ASC 712, Nonretirement Postemployment Benefits. Under ASC 712, liabilities for postemployment benefits are recorded at the time the obligations are probable of being incurred and can be reasonably estimated. The Company accounts for one-time employment benefit arrangements in accordance with ASC 420, Exit or Disposal Cost Obligations.

JOBS Act Accounting Election

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "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. The Company has elected to use this 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 the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. The Company may take advantage of these provisions for up to five years (which is through March 2027), unless the Company ceases to be an emerging growth company at an earlier date. As a result, these financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise noted, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its condensed financial statements and disclosures. As an "emerging growth" company, it has been the Company's intention to take advantage of certain temporary exemptions from various reporting requirements, as well as taking advantage of additional transitional relief.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). The amendments in ASU 2023-07 are intended to improve reportable segment disclosure, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is permitted. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this standard on its financial statements and related disclosures.

Note 3. Fair Value Measurements

The Company adopted ASU 2016-13 beginning January 1, 2023. The Company records certain financial assets and liabilities at fair value. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level 2: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- 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.

The Company's primary financial instruments include cash, cash equivalents and investments, prepaid expenses, accounts payable, and accrued liabilities. The carrying amounts of the Company's financial instruments, other than cash equivalents and investments, approximate fair value due to their relatively short maturities.

The following table presents the Company's financial assets, which consist of cash equivalents and investments classified as available-for-sale investments, that are measured at fair value on a recurring basis (in thousands):

		September 30, 2024			
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 12,025	$ —	$ —	$ 12,025
Commercial paper	Level 2	9,933	2	—	9,935
Short-term investments:					
U.S. Treasury securities	Level 1	31,626	69	—	31,695
Commercial paper	Level 2	17,706	23	—	17,729
U.S. Government agency securities	Level 2	8,498	15	—	8,513
Corporate debt securities	Level 2	1,982	3	—	1,985
Total		$ 81,770	$ 112	$ —	$ 81,882

		December 31, 2023			
	Level	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 4,478	$ —	$ —	$ 4,478
Short-term investments:					
U.S. Treasury securities	Level 1	15,649	31	—	15,680
U.S. Treasury securities	Level 2	1,247	—	(1)	1,246
Commercial paper	Level 2	41,472	47	(2)	41,517
U.S. Government agency securities	Level 2	19,479	30	(5)	19,504
Asset-backed securities	Level 2	8,770	12	(3)	8,779
Corporate debt securities	Level 2	4,914	8	—	4,922
Long-term investments:					
U.S. Treasury securities	Level 1	23,542	131	—	23,673
U.S. Government agency securities	Level 2	3,494	28	(1)	3,521
Total		$ 123,045	$ 287	$ (12)	$ 123,320

The Company classifies its money market funds and U.S. Treasury securities, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The Company classifies its investments in U.S. Treasury securities, commercial paper, U.S. government agency securities, asset-backed securities, and corporate debt securities as Level 2 within the fair value hierarchy. The fair values of these investments are estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs. There were no transfers of financial instruments between valuation levels during the nine months ended September 30, 2024.

As of September 30, 2024, none of the Company's available-for-sale investments that were in an unrealized loss position had been in an unrealized loss position for more than 12 months. During the nine months ended September 30, 2024 and 2023, the Company did not sell any available-for-sale investments.

As of September 30, 2024, the Company's short-term investments had maturities of less than one year from the balance sheet date.

The Company does not intend to sell the securities in an unrealized loss position and does not expect they will be required to sell the securities before recovery of the unamortized cost basis. Additionally, the Company evaluated its securities for credit losses and considered the decline in market value to be primarily attributable to current economic and market conditions and not credit related. Accordingly, no allowance for credit losses had been recognized as of September 30, 2024 and December 31, 2023. During the nine months ended September 30, 2024 and 2023, the Company did not recognize any impairment losses related to investments.

As of September 30, 2024 and December 31, 2023, the Company had accrued interest receivable of $0.3 million and $0.4 million, respectively, which was included in prepaid expenses and other current assets on the unaudited interim condensed balance sheets.

Note 4. Funding Arrangements

NIAID Contract

In September 2022, the Company received a cost-reimbursement contract award from the NIAID to support preclinical, Phase 1 studies and other activities to enable the advancement of epetraborole into late-stage development for acute systemic melioidosis and other biothreat pathogens. The Company is eligible to receive up to $17.8 million in funding over a total term of 48 months, consisting of a base period and seven option periods. In July 2023 and May 2024, the NIAID exercised two of seven available options under the NIAID contract (No: 75N93022C00059), resulting in an increase in committed contract funding of $0.7 million and $3.8 million, respectively, for a cumulative total of $8.8 million. Funding for these options extends the estimated completion of the current contract by 29 months beyond the base period of 18 months to August 2026. As of September 30, 2024, a total of $8.8 million of funding for the 18-month base period plus an additional 29 months for a total of 47 months has been committed.

As of September 30, 2024 and December 31, 2023, the Company had recorded a receivable of $0.7 million and $0.4 million, respectively, which was included in prepaid expenses and other current assets on the balance sheets. During the three and nine months ended September 30, 2024, the Company recorded $0.7 million of income under the NIAID contract as a reduction in research and development operating expenses. During the three and nine months ended September 30, 2023, the Company recorded zero income under the NIAID contract as a reduction in research and development operating expenses.

UGARF Grant

In September 2022, the Company entered into a subcontract agreement with the UGARF to conduct preclinical activities on behalf of UGARF (“UGARF Agreement”). The UGARF reimburses the Company under an award from Wellcome. The Company is eligible to receive up to $1.4 million from the UGARF to support preclinical development of a boron-containing small molecule for Chagas disease. In July 2024, the Company signed an amendment to the UGARF Agreement for additional funding in the amount of $0.2 million. As of September 30, 2024 and December 31, 2023, the Company had recorded a grant receivable of zero and $0.6 million, respectively, which was included in prepaid expenses and other current assets on the balance sheets. During the three and nine months ended September 30, 2024, the Company recorded income of zero and $0.1 million, respectively, as a reduction in research and development operating expenses under the UGARF Agreement. During the three and nine months ended September 30, 2023, the Company recorded income of $0.4 million and $0.7 million, respectively, as a reduction in research and development operating expenses under the UGARF Agreement.

BMGF Grants

In September 2023, the Company received a cost-reimbursement contract award from the Bill and Melinda Gates Foundation (“2023 BMGF Agreement”) under which the Company was awarded $1.8 million to support the discovery of novel, boron containing small molecules for the treatment of tuberculosis and malaria. The Company is required to apply the funds it receives under the 2023 BMGF Agreement solely toward direct costs related to this research program. The Company received $1.0 million of funding in advance and tracks and reports eligible expenses incurred to the BMGF. In April 2024, the Company received $0.8 million in funding, making the grant fully funded. Any unspent funds and any funds spent that have not yet been incurred are recorded as part of other current liabilities on the balance sheets.

In September 2024, the Company entered into a second-year continuation cost-reimbursement contract award with the Bill and Melinda Gates Foundation (“2024 BMGF Agreement”) under which the Company was awarded $2.0 million to support an early-stage research program focused on delivering novel leads as starting points for new drugs that can be combined to deliver shorter, safer and simpler TB drug regimens. The Company is required to apply the funds it receives under the 2024 BMGF Agreement solely toward direct costs related to this research program. The Company received $1.1 million of funding in advance and tracks and reports eligible expenses incurred to the BMGF. Any unspent funds and any funds spent that have not yet been incurred are recorded as part of other current liabilities on the balance sheets.

As of September 30, 2024 and December 31, 2023, the Company recorded $1.3 million and $0.7 million, respectively, to other current liabilities on the balance sheets. During the three and nine months ended September 30, 2024, the Company recorded income of $0.4 million and $1.3 million, respectively, as a reduction in research and development operating expenses under the 2023 BMGF Agreement. During the three and nine months ended September 30, 2023, the Company recorded income of $24 thousand as a reduction in research and development operating expenses under the 2023 BMGF Agreement.

Note 5. Collaboration and License Agreements

Anacor Licensing Agreement

In November 2019, the Company entered into an exclusive worldwide license agreement with Anacor Pharmaceuticals, Inc. (“Anacor”) for certain compounds and other intellectual property controlled by Anacor for the treatment, diagnosis, or prevention of all human diseases (the “Anacor License”). The Anacor License will expire upon expiration of the last to expire royalty term. Either party may terminate the Anacor License for the other party’s material breach following a cure period or immediately upon certain insolvency events relating to the other party. The Company has the right to terminate the agreement at its convenience upon 90-day written notice until the first regulatory approval or one-year notice thereafter. Furthermore, upon termination of the Anacor License for any of the foregoing reasons, the rights and licenses within will terminate.

In exchange for the worldwide, sublicensable, exclusive right and licenses to develop, manufacture, and commercialize the specified compounds, the Company paid Anacor a non-refundable $2.0 million upfront payment and granted Anacor shares of Series A redeemable convertible preferred stock.

The Company agreed to make further payments to Anacor upon achievement of various development milestones for an aggregate maximum of $2.0 million, upon achievement of various commercial and sales threshold milestones for an aggregate maximum payment of $125.0 million, and up to 50% of royalties received under certain sublicensing arrangements. Royalties are subject to certain customary reductions, including lack of patent coverage and generic product entry. The Company also agreed to pay Anacor non-refundable, non-creditable sales royalties on a tiered marginal royalty rate based on the country’s status as a developing or developed country as defined in the license agreement. Sales royalties are a percentage of net sales, as specified in the Anacor License, and range from mid-single digits for developing countries (as classified by the World Bank) and single to mid-teens for all other countries or the China, Hong Kong, Taiwan, and Macau territories, upon reaching a minimum of net sales in the low-teen millions. The sales royalties are required to be paid on a product-by-product and country-by-country basis, until the latest to occur of 15 years following the date of first commercial sale of a product, the expiration of all regulatory or data exclusivity, or the date upon of the expiration of the last to expire valid claim of a licensed patent covering such product in such country. Currently, the date of the expiration of the last to expire valid claim of a licensed patent covering epetraborole in the licensed territory is June 2028. In addition, Anacor is entitled to certain milestone payments upon a change of control of the Company.

In December 2021, the Company entered into an amendment to the Anacor License for certain compounds and other intellectual property controlled by Anacor for the treatment, diagnosis, or prevention of certain bacterial pathogens (the “Anacor License Amendment”). The Anacor License Amendment has no impact on the Anacor License financial terms.

None of the development, regulatory, commercial or sales milestones or royalty payments were recognized during the three and nine months ended September 30, 2024 and 2023. As a result, the Company did not record any research and development expense—related party in the condensed statements of operations for the three and nine months ended September 30, 2024 and 2023.

Brii Biosciences Agreement

In November 2019, the Company entered into a license agreement granting Brii Biosciences Limited the exclusive development and commercialization rights of certain compounds in China, Hong Kong, Taiwan, and Macau for the treatment of human diseases. The Company did not receive an upfront payment but is eligible to receive up to $15.0 million in the aggregate for development and regulatory milestones and up to $150.0 million in commercial milestones upon achieving sales thresholds. The Company is also entitled to tiered mid-single digits to high-first decile percentage sales-based royalties. The sales royalties are required to be paid on a product-by-product and region-by-region basis, until the latest to occur of 15 years following the date of first commercial sale of a product, the expiration of all regulatory or data exclusivity, or the date upon the expiration of the last to expire claim of a licensed patent covering the composition of matter or approved use of such product in such region. The last to expire valid claim of a licensed patent covering the composition of matter or approved use of such product in the licensed territory is June 2028. Future milestone payments and royalties will be accounted for under ASC 606.

Note 6. Balance Sheet Components

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued research and development-related expenses	$ 4,838	$ 6,555
Accrued professional services expenses	47	24
Other	36	102
Total accrued liabilities	$ 4,921	$ 6,681

Note 7. Commitments and Contingencies

Contingencies

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company was not subject to any material legal proceedings as of September 30, 2024 and December 31, 2023, and the Company is not currently a party to any legal proceeding that, if determined adversely to the Company, in management’s opinion, is currently expected to individually or in the aggregate have a material adverse effect on the Company’s business, financial condition or results of operations taken as a whole.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its certification of incorporation, as amended, and bylaws, and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, which the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

Adjuvant Global Health Agreement

In conjunction with Adjuvant Global Health Technology Fund L.P.'s ("Adjuvant") investment in the Company's Series A redeemable convertible preferred stock financing in 2019 and 2020, the Company entered into a Global Health Agreement with Adjuvant, pursuant to which the Company agreed to support the creation of innovative and affordable drugs to treat disease, through public health programs and private purchasers in Low and Lower-Middle-Income Countries (as such terms are defined by the World Bank and in the agreement).

Adjuvant's investment supports the development of the Company's product candidate, epetraborole, for use in melioidosis-endemic and melioidosis-at-risk countries as defined in the agreement. These global access commitments became effective as of the Series A redeemable convertible preferred stock financing closing date and will remain in effect until the latter of either that Adjuvant ceases to be a shareholder of the Company, or ten years following epetraborole approval for the treatment of melioidosis by a regulatory authority.

The Global Health Agreement contains various affirmative and negative covenants agreed to by the Company, including its use of reasonably diligent endeavors to develop the agreed-upon products using non-dilutive funding and make accessible to people in need in the target countries so long as the Company does not sell products at a loss. Other covenants include prohibition of use of investment for propaganda, attempt to influence legislation, influence of any public election or voter registration drive or promotion of terrorist activities, as well as compliance with certain environmental, social, and governance requirements and anti-corruption requirements. If the Company does not maintain compliance with these non-financial covenants, Adjuvant may be entitled to repayment for any portion of its investment that is not used for the purposes outlined in the Global Health Agreement.

In conjunction with Adjuvant's investment in the Company's Series B redeemable convertible preferred stock financing in 2021, the Company entered into an Amended and Restated Global Health Agreement (the "Adjuvant Amendment"). The Adjuvant Amendment expands Adjuvant's investment support to include the development of the Company's product candidate, epetraborole, for use in tuberculosis-endemic and tuberculosis-at-risk countries as defined in the agreement.

In connection with Adjuvant's investment in the Company's common stock as part of the IPO, the Company entered into an Amended and Restated Global Health Agreement dated March 24, 2022 (the "Adjuvant IPO Amendment"). As part of the Adjuvant IPO Amendment, Adjuvant purchased 166,666 shares of the Company's common stock in March 2022 for a total additional investment of $2.5 million, which was subject to Adjuvant's right of repayment should the Company not utilize the proceeds from Adjuvant's investment towards the agreed-upon purpose.

Note 8. Equity

Common Stock

The Company's certificate of incorporation, as amended, authorizes the Company to issue up to 500,000,000 shares of $0.00001 par value common stock. Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors (the "Board"). No dividends have been declared to date.

On April 6, 2023, the Company entered into a Sales Agreement with Cowen and Company, LLC as the Company's Agent, to issue and sell up to an aggregate gross sales of $100.0 million in Shares of the Company's common stock through the ATM Offering. During the year ended December 31, 2023, the Company issued and sold 2,502,000 shares of common stock under the ATM Offering, resulting in net proceeds of $19.1 million, after deducting commissions and other offering costs. The Company did not sell any shares of common stock through the ATM Offering during the nine months ended September 30, 2024.

On August 15, 2023, the Company entered into an Underwriting Agreement with Cowen and Company, LLC, Leerink Partners LLC and Evercore Group L.L.C. as representatives of several underwriters to issue and sell 7,777,778 shares of common stock at an offering price of $9.00 per share through the Underwritten Offering, resulting in net proceeds of $65.5 million, after deducting commissions and other offering costs.

Shares of common stock reserved for future issuance, on an as-if-converted basis, as of September 30, 2024 and December 31, 2023, consisted of the following:

	September 30, 2024	December 31, 2023
Stock options, issued and outstanding	4,848,549	3,930,306
Unvested restricted stock units	470,809	—
Stock options, authorized for future issuance	998,888	1,254,721
ESPP, authorized for future issuance	563,731	337,017
Total	6,881,977	5,522,044

Preferred Stock

The Company's certificate of incorporation, as amended, authorizes the Company to issue up to 10,000,000 shares of $0.00001 par value preferred stock. The preferred stock is not convertible. No shares of preferred stock were issued and outstanding as of September 30, 2024 and December 31, 2023.

Shareholder Rights Plan

On August 15, 2024, the Company entered into a Rights Agreement between the Company and Equiniti Trust Company, LLC as Rights Agent (as amended from time to time, the "Rights Agreement"), which was previously approved by the Board. In connection with the Rights Agreement, a dividend was declared of one preferred stock purchase right (individually, a "Right" and collectively, the "Rights") for each share of the common stock, par value $0.00001 per share, of the Company outstanding at the close of business on August 29, 2024 (the "Record Date"). Each Right entitles the registered holder thereof, after the Rights become exercisable and until August 15, 2025 (or the earlier redemption, exchange or termination of the Rights), to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.00001 per share, (the "Series A Preferred"), of the Company at a price of $6.50 per one one-thousandth of a share of Series A Preferred, subject to adjustment. The Rights are not exercisable until the Distribution Date (as defined in the Rights Agreement") and the Rights will expire on August 15, 2025, subject to the Company's right to extend such date, unless earlier redeemed or exchanged by the Company or terminated. Additional information regarding the Rights Agreement is contained in a Current Report on Form 8-K filed with the SEC on August 19, 2024. The adoption of the Shareholder Rights Plan had no impact on the financial position of the Company.

Note 9. Equity Incentive Plan and Stock-Based Compensation

2022 Equity Incentive Plan

The Company adopted the 2022 Equity Incentive Plan (the "2022 Plan") effective upon the closing of the IPO, which provides for the granting of incentive stock options ("ISOs") to the Company's employees, and for the grant of nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock units ("RSUs"), performance awards, and other forms of awards to employees, directors, and consultants. As of September 30, 2024, no stock appreciation rights, restricted stock awards or performance awards were issued.

The Company initially reserved for issuance 1,870,000 new shares of common stock pursuant to the 2022 Plan. The Company's 2017 Equity Incentive Plan (the "2017 Plan") was terminated in 2022; however, shares underlying outstanding stock awards granted under the 2017 Plan will continue to be governed by the 2017 Plan. Shares available under the 2017 Plan were added to the available shares in the 2022 Plan. Shares underlying outstanding stock awards granted under the 2017 Plan that expire or are repurchased by, forfeited to, cancelled or withheld by the Company will also be reserved for issuance under the 2022 Plan.

The initial number of shares of the Company's common stock that may be issued under the 2022 Plan will not exceed 4,423,920 shares of the Company's common stock, which is the sum of (i) 1,870,000 new shares, plus (ii) 2,553,920 shares related to the 2017 Plan. In addition, the number of shares of the Company's common stock reserved for issuance under the 2022 Plan will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2023 and continuing through January 1, 2032, in an amount equal to (1) 4% of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by the Company's board of directors no later than December 31 of the immediately preceding year. Accordingly, effective January 1, 2024, the number of shares in the 2022 Plan increased by 1,189,657 shares, representing 4% of the prior year end's common stock outstanding. The maximum number of shares of the Company's common stock that may be issued on the exercise of stock options or vesting of RSUs under the 2022 Plan is 13,271,760 shares.

Since the date of incorporation and through September 30, 2024, the Company has issued stock options and RSUs to its employees, directors, and consultants. As of September 30, 2024, 998,888 shares of common stock remained available for future issuance under the 2022 Plan.

ISOs granted to newly hired employees under the 2022 Plan generally vest 25% after the completion of 12 months of service, and the balance vests in equal monthly installments over the next 36 months of service and expire ten years from the grant date, unless subject to provisions regarding 10% stockholders. ISOs granted to existing employees generally vest ratably over a 48-month period of service and expire ten years from the grant date. NSOs vest in accordance with the terms of the specific agreement under which the options were provided and expire ten years from the date of grant. RSUs granted to employees generally vest quarterly or annually over a two to four year period of service and expire ten years from the grant date.

Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's condensed statements of operations and comprehensive loss during the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	$ 796	$ 1,045	$ 3,164	$ 3,113
General and administrative expenses	1,106	1,124	3,394	3,067
Total	$ 1,902	$ 2,169	$ 6,558	$ 6,180

Stock Option Activity

A summary of the stock option activity is as follows:

	Total Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	3,930,306	$ 10.86	8.14	$ 37,853
Granted	1,471,199	$ 2.63		
Exercised	(28,930)	$ 7.78		
Forfeited	(524,026)	$ 8.78		
Vested and expected to vest at September 30, 2024	4,848,549	$ 8.61	6.54	$ 176
Exercisable as of September 30, 2024	2,773,130	$ 9.36	5.45	$ 176

As of September 30, 2024, there was unrecognized stock-based compensation expense of $10.6 million related to unvested stock options which the Company expects to recognize over a weighted-average period of 1.7 years.

Weighted-average grant-date fair value of the options granted during the nine months ended September 30, 2024 was $2.23 per share.

RSU Activity

RSUs entitle the holder to receive shares of the Company's common stock upon vesting. The fair value of RSUs is based upon the closing sales price of the Company's common stock on the grant date.

A summary of the RSU activity is as follows:

	Number of Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	—	$ —
Issued	698,096	$ 2.73
Vested and released	(27,508)	$ 2.98
Forfeited	(199,779)	$ 2.62
Unvested at September 30, 2024	470,809	$ 2.76

2022 Employee Stock Purchase Plan

The Company's 2022 Employee Stock Purchase Plan ("ESPP") has two components: a component that is intended to qualify as an "employee stock purchase plan" under Section 423 of the Code (the "423 Component") and a component that is not intended to qualify (the "Non-423 Component"). The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation. At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock at the beginning of the offering period or at the end of each applicable purchase period.

Subject to adjustment in the case of certain capitalization events, 187,000 shares of the Company's common stock were available for purchase at the adoption of the ESPP. Pursuant to the ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 1% of the Company's common stock outstanding as of December 31 of the immediately preceding year, (ii) 561,000 shares, or (iii) such number of shares as determined by the Board. Accordingly, effective January 1, 2024, the number of shares in the ESPP increased by 297,414 shares, representing 1% of the prior year end's common stock outstanding. As of September 30, 2024, 563,731 shares of common stock remained available for issuance under the ESPP.

During the three and nine months ended September 30, 2024, the Company recognized an insignificant amount and $0.1 million, respectively, in stock-based compensation expense related to the ESPP. During the three and nine months ended September 30, 2023, the Company recognized $0.1 million and $0.2 million in stock-based compensation expense related to the ESPP, respectively.

Note 10. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders	$ (12,747)	$ (16,707)	$ (43,799)	$ (47,834)
Denominator:				
Weighted-average common shares outstanding used to calculate net loss per share attributable to common stockholders, basic and diluted	29,841,169	25,645,421	29,809,839	21,532,537
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (0.65)	$ (1.47)	$ (2.22)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	September 30,	
	2024	2023
Options issued and outstanding	4,848,549	3,821,869
Unvested RSUs	470,809	—
Early exercised common stock subject to future vesting	560	7,295
Total	5,319,918	3,829,164

Note 11. Related Party Transactions

During the nine months ended September 30, 2024 and 2023, the Company had no material related party transactions.

Note 12. Restructuring Charges

On August 8, 2024, the Company announced a reduction of approximately 50% of the Company's workforce, which was approved by the Board in connection with the Company's planned restructuring following discontinuation of the EBO-301 study and to further extend the Company's operating capital. In connection with the workforce reduction, the Company recognized severance and other charges of $2.2 million for each of the three and nine months ended September 30, 2024, primarily consisting of $2.6 million related to severance payments and other employee termination-related expenses, partially offset by a $0.4 million reduction in stock-based compensation expense as a result of applying modification accounting for consulting agreements entered into with certain terminated employees. The severance and other charges were recorded to restructuring charges on the condensed statements of operations and comprehensive loss. The Company expects that the workforce reduction will be substantially complete by the end of 2024. Cash payments of $2.1 million were made in the three and nine months ended September 30, 2024. As of September 30, 2024, the Company accrued $0.5 million under accrued compensation on the condensed balance sheet related to unpaid severance liabilities which are expected to be paid in the first quarter of 2025.

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

The following discussion and analysis of our financial condition as of September 30, 2024 and results of operations for the three and nine months ended September 30, 2024 and 2023 should be read in conjunction with our condensed financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q ("Form 10-Q") and our audited financial statements and the related notes thereto included as a part of our Annual Report on Form 10-K for the year ended December 31, 2023. Except as otherwise indicated herein or as the context otherwise requires, references in this Form 10-Q to "AN2" "the Company," "we," "us" and "our" refer to AN2 Therapeutics, Inc.

This discussion and analysis and other parts of this Form 10-Q contain forward-looking statements based upon current beliefs, plans, and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" in Part II, Item 1A of this Form 10-Q. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics derived from our boron chemistry platform. AN2 has a pipeline of boron-based compounds in development for Chagas disease, non-tuberculous mycobacterial ("NTM") and melioidosis, along with early-stage programs focused on targets in infectious diseases and oncology.

Since launching operations in November 2019, we have devoted substantially all of our R&D resources to developing our initial product candidate, epetraborole, which we are developing for treatment-refractory *Mycobacterium avium* complex ("MAC") lung disease, a form of NTM lung disease. On August 8, 2024, we announced topline results from the Phase 2 part of the EBO-301 Phase 2/3 study evaluating epetraborole on top of optimized background regimen ("OBR") in treatment-refractory MAC lung disease. The Phase 2 part of the study met its primary objective of demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19). Sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Epetraborole was generally well tolerated in the trial.

After announcing these results, we commenced further review of the Phase 2 data to determine the best path forward for this program. To date, we have identified nominally statistically significant outcomes in two patient-reported-outcome (PRO) analyses that suggest clinical improvement in epetraborole patients over placebo patients. The first—a prespecified secondary endpoint of the Quality of Life (Bronchiectasis) (QoL-B) PRO—indicates that patients on epetraborole showed statistically significant symptom improvement when calculated using its least squares mean (LSM) method. Of note, this is the same endpoint Insmed, Inc. recently announced as the primary endpoint in its ENCORE Phase 3 trial for treatment-naïve MAC. The second—a post-hoc LSM calculation of the MACrO2 PRO results—also showed statistically significant clinical symptom improvement in epetraborole patients vs. placebo. We believe these two findings provide potential clinical proof of concept and that improvements in two PRO measures appear to align with FDA's recommendation, reflected in a recent guidance document, that trials to support drug approvals in NTM utilize PRO-based clinical outcomes as the primary endpoint. We will continue our data analysis and plan to request an End-of-Phase-2 meeting with FDA in the first half of 2025 to discuss the potential for re-initiating a pivotal Phase 3 trial in TR-MAC.

As we continue to evaluate future development opportunities for epetraborole in NTM, we have advanced our pipeline programs. In 2025, we anticipate initiating a Phase 1 trial in Chagas disease and a Phase 2 proof-of-concept trial in melioidosis. We also anticipate progressing our earlier-stage programs in oncology and infectious disease toward producing up to three development compounds in 2025.

On August 8, 2024, we also announced a reduction of approximately 50% of our workforce, which was approved by the Board in connection with our planned restructuring following discontinuation of the EBO-301 study and to further extend our operating capital. In connection with the workforce reduction, we recognized severance and other charges of $2.2 million for each of the three and nine months ended September 30, 2024, primarily consisting of $2.6 million related to severance payments and other employee termination-related expenses, partially offset by a $0.4 million reduction in stock-based compensation expense as a result of applying modification accounting for consulting agreements entered into with certain terminated employees. We expect that the workforce reduction will be substantially complete by the end of 2024.

We have incurred significant operating losses to date. We expect that our operating expenses will increase significantly as we advance our current and future product candidates through preclinical, nonclinical, and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate, and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; hire additional personnel; and incur costs associated with operating as a public company.

We do not have any products approved for sale and have not generated any revenue since inception. Our net losses were $43.8 million and $47.8 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $198.3 million. We have funded our operations from the sale and issuance of redeemable convertible preferred stock and proceeds from our initial public offering (“IPO”), “at-the-market” equity offering program (“ATM Offering”) and an underwritten offering (the “Underwritten Offering”). From November 2019 through October 2020, we raised an aggregate of $12.0 million from the sale of Series A redeemable convertible preferred stock. In March 2021, we raised an aggregate of $80.0 million from the sale of Series B redeemable convertible preferred stock. In March and April 2022, we completed our IPO, with gross proceeds of $79.4 million and net proceeds of $70.4 million, net of underwriting discounts, commissions and offering expenses. In June 2023, we raised gross proceeds of $20.0 million from the ATM Offering and net proceeds of $19.1 million, after deducting commissions and offering expenses. In August 2023, we raised gross proceeds of $70.0 million from the Underwritten Offering and net proceeds of $65.5 million, after deducting commissions and offering expenses.

As of September 30, 2024, we had cash, cash equivalents, and investments of $93.4 million. We believe that our available cash will be sufficient to fund our planned operations under the current operating plan through at least twelve months following the date of this Form 10-Q.

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. Until such time as we can generate revenue from our product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, non-dilutive financing, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We plan to continue to use third-party service providers, including outside research laboratories, clinical research organizations (“CROs”), and contract manufacturing organizations (“CMOs”), to carry out our preclinical, nonclinical and clinical development, and to manufacture and supply the materials to be used during the development and commercialization of our product candidates. We do not currently have a sales force. If we obtain regulatory approval for any of our product candidates, we intend to hire and deploy a specialty sales force, which will increase our operating costs.

Due to ongoing developments in our business and clinical development and regulatory efforts, among other factors, our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and should not be relied upon as being indicative of our future performance. For more information on the risks and uncertainties associated with our business and our clinical development and regulatory efforts, among other factors, see “Part II Item 1A—Risk Factors.”

Components of Our Operating Results

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our initial product candidate, epetraborole, and other product candidates. These expenses include fees incurred under arrangements with third parties, including CROs, CMOs, preclinical and nonclinical testing organizations, and academic and non-profit institutions. Research and development expenses also include consulting fees, license fees, payroll and personnel-related expenses, including salaries and bonuses, payroll taxes, employee benefit costs and non-cash stock-based compensation for our research and development employees. We expense both internal and external research and development expenses as they are incurred.

We expect our research and development expenses to increase substantially in the future, as we advance our product candidates into and through clinical trials and pursue regulatory approval. The process of conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming. Clinical studies generally become larger and more costly to conduct as they advance into later stages and we are required to make estimates for expense accruals related to clinical study expenses, which involve a degree of estimation. The successful development of our product candidates is highly uncertain. The actual probability of success for our product candidates may be affected by a variety of risks and uncertainties associated with drug development, including those set forth in the section of this Form 10-Q titled “Risk Factors.” At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our current or any future product candidates. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of payroll and personnel-related expenses, including salaries and bonuses, payroll taxes, employee benefit costs, and non-cash stock-based compensation. Other general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, and professional service fees for auditing, tax, general legal services, and other external consulting and vendor services. We expect our general and administrative expenses to continue to increase in the future, including expenses related to legal, accounting, regulatory, and tax-related services associated with maintaining compliance with requirements of The Nasdaq Stock Market LLC and the Securities and Exchange Commission ("SEC"), directors and officers liability insurance premiums, and investor relations activities.

Restructuring Charges

Our restructuring charges consist primarily of employee severance payments and other employee termination-related expenses, offset by a reduction in stock-based compensation expense related to consulting agreements entered into with certain terminated employees.

Other Income, Net

Other income, net consists of interest income and investment income earned on our cash, cash equivalents, and investments.

Results of Operations

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

The following table sets forth the significant components of our results of operations:

	Three Months Ended September 30,			
	2024	2023	Change	% Change
	(in thousands, except percentages)			
Operating Expenses:				
Research and development	$ 8,287	$ 14,429	$ (6,142)	(43%)
General and administrative	3,484	3,751	(267)	(7%)
Restructuring charges	2,243	—	2,243	100%
Total operating expenses	14,014	18,180	(4,166)	(23%)
Loss from operations	(14,014)	(18,180)	4,166	(23%)
Other income, net	1,267	1,473	(206)	(14%)
Net loss	$ (12,747)	$ (16,707)	$ 3,960	(24%)

Research and Development Expenses

Research and development expenses were $8.3 million for the three months ended September 30, 2024 compared to $14.4 million for the three months ended September 30, 2023. The decrease of $6.1 million was primarily due to decreases in clinical trial costs, personnel-related expenses, preclinical and research study expenses, consulting and outside services and other costs, partially offset by increases in chemistry manufacturing and controls ("CMC") expenses. Clinical trials expenses decreased by $4.3 million primarily as a result of the termination of our EBO-301 trial. Personnel-related expenses decreased by $1.2 million primarily as a result of our restructuring activities. Preclinical and research study expenses decreased by $0.8 million primarily due to the timing of non-dilutive funding expense offsets and reprioritization of certain research programs. Other costs decreased by $0.3 million and consulting and outside services decreased by $0.1 million. These decreases were partially offset by an increase of $0.6 million in CMC costs due to increased CMC activities related to the Chagas and melioidosis programs, partially offset by lower costs due to completion of certain intermediate and registration batch manufacturing activities in 2023. During the three months ended September 30, 2024, a total reimbursement of $1.1 million of operating expenses was recognized related to our funding arrangements. During the three months ended September 30, 2023, a total of $0.4 million reimbursement of operating expenses was recognized related to our funding arrangements, primarily related to CMC activities and research studies.

The following table shows our research and development expenses by type of activity:

	Three Months Ended September 30,			
	2024	2023	Change	% Change
	(in thousands, except percentages)			
Clinical trials expenses	$ 2,685	$ 6,973	$ (4,288)	(61%)
Personnel-related expenses	2,702	3,960	(1,258)	(32%)
Consulting and outside services	1,286	1,426	(140)	(10%)
Preclinical and research study expenses	388	1,159	(771)	(67%)
Chemistry manufacturing and controls	1,102	537	565	105%
Other expenses	124	374	(250)	(67%)
Total research and development expenses	$ 8,287	$ 14,429	$ (6,142)	(43%)

General and Administrative Expenses

General and administrative expenses were $3.5 million for the three months ended September 30, 2024 compared to $3.8 million for the three months ended September 30, 2023. The decrease of $0.3 million was primarily attributable to a $0.3 million decrease in professional services expenses.

Restructuring Charges

Restructuring charges were $2.2 million for the three months ended September 30, 2024, consisting of $2.6 million in severance payments and other employee termination-related expenses, partially offset by a $0.4 million reduction in stock-based compensation expense as a result of applying modification accounting for consulting agreements entered into with certain terminated employees. There were no restructuring charges in the three months ended September 30, 2023.

Other Income, Net

Other income, net was $1.3 million for the three months ended September 30, 2024 compared to $1.5 million for the three months ended September 30, 2023. The decrease of $0.2 million was due to lower cash, cash equivalents, and investment balances in 2024 as compared to 2023.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table sets forth the significant components of our results of operations:

	Nine Months Ended September 30,			
	2024	2023	Change	% Change
	(in thousands, except percentages)			
Operating Expenses:				
Research and development	$ 35,091	$ 39,952	$ (4,861)	(12%)
General and administrative	10,856	10,868	(12)	(0%)
Restructuring charges	2,243	—	2,243	100%
Total operating expenses	48,190	50,820	(2,630)	(5%)
Loss from operations	(48,190)	(50,820)	2,630	(5%)
Other income, net	4,391	2,986	1,405	47%
Net loss	$ (43,799)	$ (47,834)	$ 4,035	(8%)

Research and Development Expenses

Research and development expenses were $35.1 million for the nine months ended September 30, 2024 compared to $40.0 million for the nine months ended September 30, 2023. The decrease of $4.9 million was primarily due to decreases in CMC expenses, clinical trial costs, preclinical and research study expenses, and other expenses, partially offset by increases in consulting and outside services and personnel-related expenses. CMC expenses decreased by $3.7 million primarily due to completion of the intermediate and registration batch manufacturing activities in 2023 and reduced development activities for epetraborole following termination of the EBO-301 trial. Clinical trials expenses decreased by $1.0 million due to completion of the Phase 2 portion and termination of the Phase 3 portion of the EBO-301 trial. Preclinical and research study expenses decreased by $0.9 million primarily due to a decrease in epetraborole-related activities and contract research, partially offset by an increase in early-stage research projects. Other expenses decreased by $0.3 million. These expenses were partially offset by an increase of $0.9 million in consulting and outside services to support our contract and early-stage research efforts and personnel-related expenses increase by $0.1 million. During the nine months ended September 30, 2024, a total reimbursement of $2.0 million of operating expenses was recognized related to our funding arrangements. During the nine months ended September 30, 2023, a total of $0.7 million reimbursement of operating expenses was recognized related to our funding arrangements, primarily related to CMC activities and research studies.

The following table shows our research and development expenses by type of activity:

	Nine Months Ended September 30,			
	2024	2023	Change	% Change
	(in thousands, except percentages)			
Clinical trials expenses	$ 13,128	$ 14,113	$ (985)	(7%)
Personnel-related expenses	12,047	11,959	88	1%
Consulting and outside services	4,141	3,226	915	28%
Preclinical and research study expenses	2,175	3,066	(891)	(29%)
Chemistry manufacturing and controls	2,789	6,449	(3,660)	(57%)
Other expenses	811	1,139	(328)	(29%)
Total research and development expenses	$ 35,091	$ 39,952	$ (4,861)	(12%)

General and Administrative Expenses

General and administrative expenses were $10.9 million for the nine months ended September 30, 2024 and 2023.

Restructuring Charges

Restructuring charges were $2.2 million for the nine months ended September 30, 2024, consisting of $2.6 million in severance payments and other employee termination-related expenses, partially offset by a $0.4 million reduction in stock-based compensation expense as a result of applying modification accounting for consulting agreements entered into with certain terminated employees. There were no restructuring charges in the nine months ended September 30, 2023.

Other Income, Net

Other income, net was $4.4 million for the nine months ended September 30, 2024 compared to $3.0 million for the nine months ended September 30, 2023. The increase of $1.4 million was due to higher interest rates and higher cash, cash equivalents, and investment balances in 2024 as compared to 2023.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses since our inception. For the nine months ended September 30, 2024 and 2023, we had net losses of $43.8 million and $47.8 million, respectively, and we expect to incur substantial additional losses in future periods. As of September 30, 2024, we had an accumulated deficit of $198.3 million. As of September 30, 2024, we had cash, cash equivalents, and investments of $93.4 million. Based on our current business plan, we believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the date of this Form 10-Q.

To date, we have funded our operations primarily through our Underwritten Offering, ATM Offering, IPO and private placements of our then existing redeemable convertible preferred stock. In August 2023, we generated approximately $65.5 million from the Underwritten Offering, after deducting commissions and offering expenses. In June 2023, we generated approximately $19.1 million in net proceeds from the ATM Offering, after deducting commissions and offering expenses. In March and April 2022, we generated aggregate net proceeds of approximately $70.4 million from our IPO, after deducting underwriting discounts and commissions and offering expenses. Prior to our IPO, we raised $91.6 million from the issuance of our redeemable convertible preferred stock. Upon the closing of our IPO, all outstanding shares of our then existing redeemable convertible preferred stock were converted into shares of our common stock.

Future Funding Requirements

We do not have any products approved for sale, and we have never generated any revenue from contracts with customers. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval for and commercialize any of our current and future product candidates and we do not know when, or if, those events will occur. Historically, we have incurred operating losses and negative cash flows as a result of ongoing efforts to develop our initial drug product candidate, epetraborole, including conducting ongoing preclinical and nonclinical studies, clinical trials, registration API and drug product materials manufacturing, and providing general and administrative support for these operations. We expect our negative cash flows to increase significantly over the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, and continue our research and development efforts. We are subject to all the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Moreover, we expect to continue to incur costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations, as we do not expect positive cash flows from operations in the foreseeable future.

Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, if ever, we expect to finance our future cash needs through public or private equity offerings or debt financings. Additional capital may not be available on reasonable terms, if at all. 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 one or more of our current or future product candidates. If we raise additional funds by issuing equity or convertible debt securities, it could result in dilution to our existing stockholders and increased fixed payment obligations. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Any of the foregoing could significantly harm our business, financial condition, results of operations, and prospects.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development, and commercialization of product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements depend on many factors, including:

- the scope, timing, rate of progress, results and costs of our preclinical and nonclinical development activities and clinical trials for our current and future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our drug product candidates;
- the timing of enrollment of our current and any future clinical trials;
- the scope and costs of development and commercial manufacturing activities;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our product candidates that we successfully commercialize;
- the cost of building a specialty sales force in anticipation of product commercialization;
- the cost of commercialization activities, including building a commercial infrastructure, marketing, sales, and distribution costs;
- our ability to maintain existing, and establish new strategic collaborations, licensing, or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;

•any securities class action, product liability or other lawsuits related to our products;

•the expenses needed to attract, hire, and retain skilled personnel;

•our implementation of operational, financial, and management systems;

•the ongoing costs associated with being a public company;

•the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio; and

•the timing, receipt, and amount of sales of any future approved products, if any.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitation on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials or we may also be required to terminate rights to our current and future product candidates. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

See the section of this Form 10-Q titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Statements of Cash Flows

The following table sets forth a summary of the primary sources and uses of cash:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (43,984)	$ (36,220)
Cash provided by (used in) investing activities	61,469	(43,698)
Cash provided by financing activities	372	85,315
Net increase in cash and cash equivalents	$ 17,857	$ 5,397

Cash Used in Operating Activities

Net cash used in operating activities was $44.0 million for the nine months ended September 30, 2024, which consisted of a net loss of $43.8 million, primarily due to the use of funds to develop our initial drug product candidate, and a net decrease of $4.0 million in our net operating assets and liabilities, partially offset by $3.8 million in non-cash charges. The net decrease in our operating assets and liabilities was primarily due to a decrease in accrued liabilities, accrued compensation, and accounts payable, and an increase in other current liabilities. The non-cash charges consisted of stock-based compensation expense of $6.5 million, partially offset by net accretion of discounts on investments of $2.7 million.

Net cash used in operating activities was $36.2 million for the nine months ended September 30, 2023, which consisted of a net loss of $47.8 million, due to the use of funds to develop our initial drug product candidate, partially offset by a net decrease of $6.9 million in our net operating assets and liabilities and $4.7 million in non-cash charges. The net decrease in our operating assets and liabilities was primarily due to an increase in accrued liabilities, accounts payable and other current liabilities. The non-cash charges consisted of stock-based compensation expense of $6.2 million, partially offset by net accretion of discounts on investments of $1.5 million.

Cash Provided by (Used In) Investing Activities

Net cash provided by investing activities was $61.5 million for the nine months ended September 30, 2024, which primarily consisted of $83.8 million in proceeds from the maturity of investments, partially offset by $22.3 million in purchases of investments.

Net cash used in investing activities was $43.7 million for the nine months ended September 30, 2023, which primarily consisted of $112.3 million in purchases of investments, partially offset by $68.6 million in proceeds from the maturity of investments.

Cash Provided by Financing Activities

Net cash provided by financing activities was $0.4 million for the nine months ended September 30, 2024, which consisted of $0.2 million in proceeds from the issuance of common stock under the employee stock purchase plan and $0.2 million from the exercise of stock options.

Net cash provided by financing activities was $85.3 million for the nine months ended September 30, 2023, which consisted of $65.8 million in net proceeds from issuance of common stock under the Underwritten Offering, $19.1 million in net proceeds from issuance of common stock under the ATM Offering, $0.4 million in proceeds from the issuance of common stock under the employee stock purchase plan and exercise of stock options.

Contractual Obligations and Commitments

In November 2019, we entered into an exclusive worldwide license agreement with Anacor for certain compounds and other intellectual property controlled by Anacor for the treatment, diagnosis, or prevention of disease. In exchange for the worldwide, sublicensable, exclusive right and licenses to develop, manufacture, and commercialize the specified compounds, we paid Anacor a $2.0 million upfront payment in November 2019 and issued Anacor shares of our Series A redeemable convertible preferred stock. We agreed to make further payments to Anacor upon achievement of various development milestones for an aggregate maximum payment of $2.0 million, various commercial and sales threshold milestones for an aggregate maximum payment of $125.0 million, and up to 50% of royalties received under certain sublicensing arrangements. Royalties are subject to certain customary reductions, including lack of patent coverage and generic product entry. We also agreed to pay Anacor sales royalties as a percentage of net sales ranging from single to mid-teens.

We enter into contracts in the normal course of business with third-party contract organizations for preclinical and nonclinical studies and clinical trials, manufacture and supply of our preclinical, nonclinical, clinical trial, and other services and products used for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Recent Accounting Pronouncements

See the section “Recently Adopted Accounting Pronouncements” in “Note 2—Basis of Presentation and Summary of Significant Accounting Policies” to the Notes to Financial Statements in Part I, Item 1 of this Quarterly Report on 10-Q.

Critical Accounting Policies, Significant Judgements, and Use of Estimates

The preparation of financial statements and related disclosures in conformity with GAAP requires us to make judgments, assumptions, and estimates that affect the amounts reported in the condensed financial statements and accompanying notes. “Note 2—Summary of Significant Accounting Policies” to the financial statements in our Annual Report on Form 10-K for the year ended December 31, 2023 describes the significant accounting policies and methods used in the preparation of the financial statements. Our critical accounting estimates, identified in Management’s Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 of our Annual Report on Form 10-K include for the year ended December 31, 2023, but are not limited to, the discussion of estimates used for research and development and stock-based compensation. Such accounting policies and estimates require significant judgments and assumptions to be used in the preparation of the condensed financial statements, and actual results could differ materially from the amounts reported.

JOBS Act Accounting Election

The JOBS Act permits an “emerging growth company” or “EGC” such as us to 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. We have elected to use this extended 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 we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, the information we provide may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

In addition, we intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an EGC until the earliest to occur of: (1) the last day of our first fiscal year in which we have total annual revenues of more than $1.235 billion; (2) the date we qualify as a “large accelerated filer,” with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three- year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our IPO.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents, and investments of $93.4 million as of September 30, 2024, which consisted primarily of money market funds and marketable securities, largely composed of investment grade, short and long-term fixed income securities, and government securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash, cash equivalents, and investments in accordance with our Board-approved investment policy.

Our investments are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements. We do not believe that inflation, interest rate changes or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Foreign Currency Risk

A small portion of our expenses are denominated in foreign currencies. Future fluctuations in the value of the U.S. Dollar may affect the price we pay for services performed outside the United States. We were not exposed to material foreign currency risk during the quarter ended September 30, 2024.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and operating costs including clinical trial, non-clinical study, and manufacturing costs. We believe that inflation has not had a material effect on our unaudited interim condensed financial statements included elsewhere in this Form 10-Q.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Form 10-Q.

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

Our CEO and CFO have concluded that as of September 30, 2024, our disclosure controls and procedures were not effective due to material weaknesses in internal control over financial reporting previously disclosed in the Annual Report on Form 10-K for the year ended December 31, 2023 and included below.

Notwithstanding the identified material weaknesses, management, including our CEO and CFO, have determined, based on the procedures we have performed, that the condensed financial statements included in this Quarterly Report on Form 10-Q were prepared in accordance with U.S. GAAP.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

During the course of preparing for our IPO in March 2022, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of its annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified were as follows, and continue to exist as of September 30, 2024:

•We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources with (i) an appropriate level of accounting knowledge, experience and training to appropriately analyze, record and disclose accounting matters timely and accurately, and (ii) an appropriate level of knowledge and experience to establish effective processes and controls. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses.

•We did not design and maintain effective controls related to the period-end financial reporting process, including designing and maintaining formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures. Additionally, we did not design and maintain controls over the preparation and review of account reconciliations and journal entries, including maintaining appropriate segregation of duties.

The above material weaknesses resulted in adjustments to accrued expenses balances, which were recorded prior to the issuance of the financial statements, as of and for the years ended December 31, 2019 and 2020. Additionally, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

- We did not design and maintain effective controls over information technology ("IT") general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate Company personnel, (iii) computer operations controls to ensure that critical batch jobs are monitored and data backups are authorized and monitored, and (iv) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These IT deficiencies did not result in adjustments to the financial statements. However, the IT deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, management has determined the IT deficiencies in the aggregate constitute a material weakness.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

The information in Part I, Note 7—Commitments and Contingencies, is incorporated herein by reference.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the risks described below together with all of the other information contained in this Form 10-Q, including our unaudited condensed financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. Unless otherwise indicated, references in these risk factors to our business being harmed will include harm to our business, reputation, financial condition, results of operations, and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risk Factors Summary

Investing in shares of our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in shares of our common stock risky include, among others:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We may not realize the expected benefits from our recent business restructuring and workforce reduction and we may incur additional costs implementing it or other difficulties.
- We require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce, or altogether cease our current and future product development programs or future commercialization efforts.
- If we do not obtain regulatory approval for and successfully commercialize our product candidates, or if we experience significant delays in doing so, we may never become profitable.
- If clinical trials of any product candidate that we may advance to clinical trials fail to demonstrate safety, tolerability and/or efficacy to the satisfaction of the U.S. Food and Drug Administration ("FDA") or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities and receipt of necessary regulatory approvals could be delayed or prevented.
- We rely on single-sourced third parties to conduct the preclinical and nonclinical studies, clinical trials, and manufacture of our clinical trial material for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies, trials, and manufacturing services or failing to comply with applicable regulatory requirements.
- Even if any of our product candidates receive regulatory approval, they 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. If we are unable to establish sales, marketing, and distribution capabilities for our product candidates, or enter into sales, marketing, and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- We operate with a small team and our future success depends on our ability to retain key executives and to attract, retain, and motivate qualified personnel.
- We have identified material weaknesses in our internal control over financial reporting. Due to our failure 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.
- Our rights to develop and commercialize certain technology and certain of our product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, including the University of Georgia and Anacor Pharmaceuticals, Inc. (a wholly owned subsidiary of Pfizer) ("Anacor"). If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to products, technology, or data from third parties, we could lose such rights.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology, or for our product candidates, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.
- Future legislation, and/or regulations and policies adopted by the FDA or comparable regulatory authorities, may increase the time and cost required for us to conduct and complete clinical trials of our product candidates.
- The trading price of our common stock may be volatile

Risks Related to Our Financial Position and Capital Needs

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We currently have no products approved for commercial sale, have not generated any revenue from the sale of products and have incurred losses in each year since our inception in 2017. In addition, we have limited experience as a company and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry.

In August 2024, we announced topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating our initial product candidate, epetraborole, in patients with treatment-refractory MAC lung disease. Although the Phase 2 part of the study met its primary objective in demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19), sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Given these results, we decided to close out the trial. Although an ongoing data review has indicated the potential to continue development in this indication, it is possible that we will determine after completion of the review or discussions with FDA to defer or discontinue development.

Our net loss was $64.7 million for the year ended December 31, 2023 and $43.8 million and $47.8 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $198.3 million. We have funded our operations to date primarily with proceeds from our underwritten offering (the "Underwritten Offering), our “at-the-market” equity offering program (“ATM Offering”), our IPO, and the sale of our redeemable convertible preferred stock. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical and nonclinical studies, manufacturing, clinical trials, and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will increase substantially as we:

•continue our ongoing and planned preclinical, nonclinical, and clinical development of our product candidates;

•initiate preclinical and nonclinical studies and clinical trials for product candidates that we may pursue in the future;

•seek to discover and develop future product candidates;

•seek regulatory approvals for any of our product candidates that successfully complete clinical trials;

•ultimately establish sales, marketing, and distribution infrastructure and scale up external manufacturing capabilities if we move into later-stage clinical trials for, and seek to commercialize, any product candidate for which we may obtain regulatory approval and intend to commercialize on our own;

•maintain, expand, and protect our intellectual property portfolio;

•hire additional clinical, scientific, chemistry, manufacturing and controls personnel;

•add operational, financial, management, and compliance information systems and personnel, including personnel to support our product development and any future commercialization efforts; and

•incur legal, accounting, information systems, and other expenses associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing drugs that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical and nonclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing, and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are further delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts, or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in November 2019, and our operations to date have been largely focused on raising capital, developing epetraborole, broadening our expertise in the development of epetraborole, undertaking preclinical and nonclinical studies, manufacturing clinical trial material, preparing for and initiating clinical trials, and general and administrative operations. As a company, we have not yet demonstrated an ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a commercial product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have and may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. For example, in August 2024, we announced topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating our initial product candidate, epetraborole, in patients with treatment-refractory MAC lung disease. Although the Phase 2 part of the study met its primary objective in demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19), sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Given these results, we decided to close out the trial and are in the process of reviewing data from the trial to determine next steps.

In addition, we will need to transition successfully at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We may not realize the expected benefits from our recent business restructuring and workforce reduction and we may incur additional costs implementing it or other difficulties.

In August 2024, we announced a business restructuring plan and implemented a workforce reduction. The objective of these initiatives is to focus the organization and our resources on product candidates and development compounds to treat Chagas diseases, NTM, melioidosis, other infectious diseases, and oncology. We believe these changes were needed to streamline our organization and reallocate our resources in light of the topline results from the Phase 2 portion of our Phase 2/3 clinical trial evaluating our initial product candidate, epetraborole, in patients with treatment-refractory MAC lung disease, and our decision to discontinue our development efforts with respect to epetraborole in that treatment-refractory patient population.

However, the changes to our business strategy and the reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended workforce reduction, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our development activities, ability to progress our product candidate development, and results of operations or financial condition. As a result of the workforce reduction, we have recognized severance and other charges of $2.2 million for each of the three and nine months ended September 30, 2024, primarily consisting of severance payments and other employee termination-related expenses.

We may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur as a result of, or in connection with, the revised business strategy and workforce reduction. In addition, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees.

We may also discover that the workforce reduction and cost cutting measures will make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Moreover, there is no assurance we will be successful in our pursuit of any of our new goals. Our failure to successfully accomplish any of the above activities and goals may have a negative impact on our business, financial condition, results of operations and growth prospects.

We require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our current and future product development programs or future commercialization efforts.

We believe that our existing cash, cash equivalents, and investments will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, we will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements will depend on many factors, including:

- the timing, progress, and results of our ongoing and future clinical trials of our product candidates;
- the costs, timing and outcome of regulatory review of any of our product candidates that may complete clinical development;
- the scope, progress, results and costs of identifying, obtaining, and conducting preclinical development, laboratory testing and clinical trials of future product candidates that we may pursue;
- the cost and timetable of manufacturing processes for development, clinical trials and potential commercial use;
- the number and development requirements of future product candidates that we may pursue;
- the amount of funding that we receive under our non-dilutive funding opportunities, including government awards that we may apply for;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any product candidates that receive regulatory approval;
- the pricing and revenue, if any, received from commercial sales of any product candidates that receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or any future commercialization efforts.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred 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 additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or any product candidates, or to grant licenses on terms that may not be favorable to us. 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 development of our product candidates or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a contractual commitment to develop epetraborole for global health initiatives, which may affect our ability to develop and commercialize epetraborole in certain countries and may impact our intellectual property rights. Our strategy for our global health initiatives depends on receiving non-dilutive funding, and we as a company have limited experience with this strategy.

Under our Global Health Agreement with Adjuvant, we have a contractual commitment to use reasonably diligent endeavors to develop epetraborole and any other mutually agreed-upon products for melioidosis, tuberculosis, and other indications for at-risk developing countries at accessible pricing and at reasonable volume, including selling epetraborole and any other mutually agreed-upon products in certain target countries at or slightly above the cost of sales, so long as we do not sell products at a loss. Under the Global Health Agreement, we made certain commitments to develop epetraborole and any other mutually agreed-upon products and to pursue regulatory strategies and product registrations. If we do not maintain compliance with these and other program-related global access commitments under the Global Health Agreement, Adjuvant may be entitled to repayment for any portion of its investment that is not used for the purposes outlined in the Global Health Agreement. Our obligations under the Global Health Agreement may affect our ability to commercialize epetraborole in certain countries.

Our strategy for developing epetraborole for global health initiatives depends on receiving non-dilutive funding from sources such as public and private agencies and foundations. We, as a company, have limited experience with non-dilutive funding, and we may not be able to obtain additional non-dilutive funding to support our needs to fund our global health initiatives. For example, we cannot be certain that there will be additional awards, contracts, grants or funding sources or solicitations available to support our development efforts, that our other grant applications and funding proposals will be successful, or that we will be able to continue satisfying the award criteria of the NIAID contract award or any grants or funding awarded to us. If we fail to receive additional non-dilutive funding, progress in our global health initiatives may be impaired or delayed.

Risks Related to the Development of Our Product Candidates

If we do not obtain regulatory approval for and successfully commercialize any of our product candidates, or if we experience significant delays in doing so, we may never become profitable.

We currently have no products approved for sale and have historically invested a significant portion of our efforts and financial resources on the development of our initial product candidate, epetraborole, as a treatment for treatment-refractory MAC lung disease. Although we have now discontinued our development efforts with respect to epetraborole in the treatment-refractory MAC population studied in the EBO-301 trial, our business remains heavily dependent on the successful development, regulatory approval, and, if approved, commercialization of our product candidates. We cannot be certain that any product candidate will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval. The research, development, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA and other comparable foreign regulatory authorities.

Before obtaining regulatory approvals for the commercial sale of any product candidates, we must demonstrate through preclinical and nonclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage during our nonclinical studies, clinical trials or drug product manufacturing process. These delays or failures could be caused by a variety of factors, including but not limited to, toxicity, safety, tolerability, efficacy, problems with clinical trial enrollment, drug product availability, stability, and impurity issues related to drug product manufacturing. For example, in August 2024, we announced topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating epetraborole in patients with treatment-refractory MAC lung disease. Although the Phase 2 part of the study met its primary objective in demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19), sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Given these results, we decided to close out the trial and commence a review of data to help inform further development. Although that ongoing data review has to date indicated the potential to continue development in this indication, it is possible that we will determine after completion of the review or discussions with FDA to defer or discontinue development of epetraborole in NTM.

Failure to obtain regulatory approval for our product candidates in the United States or other territories will prevent us from commercializing and marketing such product candidates. The success of our product candidates will depend on several additional factors, including:

- successful and timely completion of preclinical and nonclinical studies and requisite clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA or any comparable regulatory authority requirements;
- receipt of regulatory approvals from applicable regulatory authorities;
- the ability to manufacture sufficient quantity of product for development, clinical trials or potential commercialization;
- obtaining regulatory approvals with labeling for sufficiently broad patient populations and indications, without unduly restrictive distribution limitations or safety warnings, such as black box warnings or a Risk Evaluation and Mitigation Strategies (“REMS”) program;
- obtaining and maintaining patent, trademark and trade secret protection, and regulatory exclusivity for our product candidates;
- making and retaining sufficient and reliable arrangements with third parties for manufacturing capabilities;
- launching commercial sales of products, if and when approved;
- acceptance of our therapies, if and when approved, by physicians, patients and third-party payors;
- competing effectively with other therapies;

•obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;

•maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trademarks, trade secrets and know-how;

•avoiding and defending against third-party infringement, misappropriation or other violation of intellectual property claims;

•maintaining a continued acceptable safety and tolerability profile of our drugs following approval; and

•allowance to proceed with clinical trials under future investigational new drug applications ("INDs"), or under comparable applications submitted outside the United States.

If we do not achieve these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to develop our AN2 drug discovery platform, build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of Chagas disease, NTM, melioidosis, other infectious diseases, and in oncology. We may not be able to develop product candidates that are safe and effective for any proposed use. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, as a result of significant safety, tolerability and other negative characteristics or limitations that may prevent successful regulatory approval or limit market acceptance or reimbursements from third-party payors. If we do not successfully develop and commercialize any of our product candidates, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

There can be no assurance that the clinical trials we conduct will be sufficient for product approval.

Prior to marketing any product candidate in the United States, we must demonstrate that such product candidate is safe and provide substantial evidence of effectiveness for its intended uses. The FDA has generally interpreted the "substantial evidence" requirements as requiring sponsors to conduct two adequate and well-controlled Phase 3 clinical trials. However, in some circumstances, the FDA may conclude that substantial evidence of efficacy has been demonstrated through the conduct of one adequate and well-controlled clinical trial, plus confirmatory evidence (whether obtained prior to or after such trial). Regardless of the clinical development plans we decide to pursue with respect to our product candidates, there can be no assurance that the FDA will not require additional clinical trials for approval of such product candidates beyond the trials that we currently plan to conduct, even if we successfully complete the trial and believe the results are sufficiently positive.

As a company, we have limited experience designing and conducting clinical trials in the United States or other geographies and may be unable to design and execute a clinical trial to support regulatory approval. In addition, the design and results of our clinical trials may not be sufficient to support approval, since factors such as an inappropriate dosage or flaws in the design of a clinical trial may not become apparent until the clinical trial is in progress or data are available.

There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. For example, in August 2024, we announced topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating epetraborole in patients with treatment-refractory MAC lung disease. Although the Phase 2 part of the study met its primary objective in demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19), sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64). Given these results, we decided to close out the trial and commence a review of data to help inform further development. Although that ongoing data review has to date indicated the potential to continue development in this indication, it is possible that we will determine after completion of the review or discussions with FDA to defer or discontinue development of epetraborole in NTM.

If clinical trials of our product candidates fail to demonstrate safety and/or efficacy of such product candidates to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may not commercialize, market, promote, or sell any product candidate without obtaining regulatory approval from the FDA or other comparable regulatory authorities, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will be deemed effective or safe in humans and receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any of our product candidates, we must complete preclinical and nonclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical and nonclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their products. In addition, before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize any of our product candidates, including, but not limited to:

- we may be unable to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- the FDA or other comparable regulatory authorities may disagree as to the design or implementation of our clinical trials, including the selection of primary and secondary endpoints, which may result in changes to our planned clinical trial design and potential target clinical outcomes, or may result in failure to obtain approval altogether;
- regulators, institutional review boards (“IRBs”), or ethics committees may not allow or authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach 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;
- we may experience delays in identifying, recruiting and training suitable clinical investigators;

•regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

•we may make changes or amendments to a trial protocol;

•we may select endpoints that require prolonged periods of clinical observation or require extended analysis of the resulting data;

•clinical trial sites may deviate from the trial protocol or drop out of a trial;

•clinical trials for our product candidates may produce negative or inconclusive results;

•we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

•enrollment in clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, we may fail to recruit suitable patients to participate in a trial, or the number of patients required for clinical trials of our product candidates may be larger than we anticipate;

•our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

•regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

•we may lack adequate funding to complete a clinical trial, or the cost of clinical trials of our product candidates may be greater than we anticipate;

•the FDA or other comparable regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with whom we enter into agreements for clinical and commercial supplies;

•the supply or quality of our product candidates or other materials necessary to conduct clinical trials of such product candidates may be insufficient or inadequate;

•serious adverse events may occur in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;

•our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the clinical trials; and

•the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

•be delayed in obtaining regulatory approval for our product candidates;

•not obtain regulatory approval at all;

•obtain approval for indications or patient populations that are not as broad as intended or desired;

•obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, such as black box warnings or a REMS program;

•be subject to additional post-marketing testing requirements; or

•be required to remove the product from the market after obtaining regulatory approval.

We do not know whether any of our preclinical and nonclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical and nonclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We cannot predict whether or when bacteria may develop resistance to any of our antibacterial product candidates, which could affect the revenue potential of our product candidates.

We are developing certain of our product candidates to treat bacterial infections. The bacteria responsible for these infections evolve quickly and may develop antibiotic resistance caused by spontaneous mutations in the genes encoding the cellular target of the antibiotic. In some cases, resistance mechanisms can be transferred within and between bacterial species. Prescription or use of our product candidates, if approved, could depend on the type and rate of resistance of the targeted bacteria. Although we do intend to analyze the potential of emergence of resistance to our product candidates and only select those that we believe have low resistance potential, we cannot predict whether or when bacterial resistance may develop. Such bacterial resistances, if and when identified, could adversely affect the conduct or results of our clinical trials, and could adversely affect the market potential of the product candidate, if approved. The growth of drug-resistant infections in community settings or in countries with poor public health infrastructures, or the potential use of any product candidates outside of controlled hospital settings, could contribute to the rise of resistance.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential regulatory approval.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates, whether used alone on in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidates are approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and growth prospects significantly.

Additional adverse events may emerge (along with additional data further defining previously identified risks) in any ongoing or subsequent clinical trials and there may be unforeseen serious adverse events or side effects that differ from those seen in studies completed to date. It is possible that as we test our product candidates in larger, longer and more extensive clinical programs, or as use of such product candidates becomes more widespread, if they receive regulatory approval, subjects will report illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials. Many times, side effects are only detectable after investigational drugs are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates has unexpected side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business.

Even if we believe our product candidates demonstrate clinical efficacy, any unacceptable adverse side effects or toxicities, when administered in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval or limit market acceptance if ultimately approved.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidate may be harmed and our ability to generate revenue through its sale may be delayed or eliminated. Any of these occurrences may significantly harm our business.

Additionally, if any of our product candidates receive regulatory approval, regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or the adoption of a REMS program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by any product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate, or we may decide to suspend marketing or remove a product from the marketplace;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials, including one or more post-marketing research studies;
- we could be sued and held liable for harm caused to patients;
- we may be required to implement REMS, including the creation of a medication guide outlining the risks of such side effects for distribution to patients;
- we could be subject to fines, injunctions or the imposition of criminal or civil penalties;
- we may need to conduct a recall or comparable post-marketing action; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our product candidates and harm our business and results of operations.

If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on potential clinical testing and potential regulatory approval of our current and future product candidates, including the development of AN2-502998, a boron-based small molecule therapeutic candidate for the treatment of Chagas disease, epetraborole for NTM or melioidosis, and other development compounds, an element of our strategy is to discover, develop and commercialize a portfolio of product candidates to treat diseases with high unmet need. We are seeking to do so by utilizing our targeted-design AN2 drug discovery platform, which uses bacterial genomics and state-of-the-art molecular and dynamic models to design active new compounds that target known mechanisms. We focus our clinical development on pathogens, drug targets, and patients with high, unmet medical needs to leverage the development and regulatory paths available for first-in-class or best-in-class therapeutics. Research efforts to identify and develop product candidates require substantial technical, financial, and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties’ patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

•a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;

•a product candidate may not be accepted as safe, tolerable and effective by patients, the medical community or third-party payors, if applicable; and

•the FDA or other regulatory authorities may not approve or agree with the intended use of a new product candidate.

If we fail to develop and successfully commercialize our product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidates.

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

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials will depend, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate, continue or complete clinical trials of any product candidates that we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials, as required by the FDA or other comparable regulatory authorities. We have limited experience enrolling patients in our clinical trials and cannot predict how successful we will be in enrolling patients in future clinical trials.

Patient enrollment is also affected by other factors including:

•the size and nature of the targeted patient population;

•the severity of the disease under investigation;

•the proximity and availability of clinical trial sites for prospective patients;

•the eligibility criteria for participation in the clinical trial;

•the design of the clinical trial;

•the perceived risks and benefits of the product candidate under study;

•our ability to recruit clinical trial investigators with appropriate experience;

•efforts to facility timely enrollment in clinical trials;

•the availability and efficacy of drugs approved to treat the diseases under study;

•the patient referral practices of physicians;

•our ability to obtain and maintain patient consents;

•the ability to monitor patients adequately during and after treatment; and

•the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In particular, we may face delays and difficulties in enrollment in our planned trials of certain of our product candidates because Chagas disease and certain other conditions we may target include rare diseases (i.e., the size of the targeted patient population is small). Because of this, we may experience difficulties in recruiting sufficient patients into certain of our planned clinical trials.

Additionally, other pharmaceutical companies and research institutions targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. We have experienced enrollment delays in the past. Enrollment delays in these clinical trials may result in further increased development costs for our product candidates, which would reduce the capital we have available to support our current and future product candidates and may result in our need to raise additional capital earlier than planned and could cause the value of our common stock to decline and limit our ability to obtain additional financing.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Interim "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, 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 the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline or preliminary 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, our product candidates may be harmed, which could harm our business, financial condition, operating results, growth prospects.

We may conduct clinical trials for our product candidates outside of the United States, and the FDA may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We conduct and may in the future conduct one or more of our clinical trials or a portion of our clinical trials for our product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority 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 regulatory approval in the United States, 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 study 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 regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. 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 relevant jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it may result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical and nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.

We are dependent on third parties to conduct our clinical trials, nonclinical studies and preclinical studies. Specifically, we have engaged CROs and consultants to conduct our ongoing and planned preclinical and nonclinical studies and clinical trials, in each case in accordance with trial protocols and regulatory requirements. We also expect to engage CROs for any of our other product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions, and clinical investigators, to conduct those preclinical and nonclinical studies, clinical trials, and manufacture of our clinical trial material. Currently, we rely on single source third-party research institutions, laboratories, clinical research and manufacturing organizations for research and development. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, or fail to enter into alternative arrangements in a timely manner, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our 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. Moreover, we and our CROs are required to comply with regulations and comply with good laboratory practice requirements for the conduct of certain preclinical studies and GCP requirements for clinical trials, which are regulations and guidelines enforced by the FDA, for conducting, 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. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. Failure to comply with these requirements by us or by third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

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

Our reliance on single-sourced third parties to manufacture our product candidates increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating, nor are we contemplating plans to do so. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. Our strategy is to continue to outsource all manufacturing of our product candidates and approved products, if any, to third parties.

In order to conduct clinical trials of our product candidates and prepare for commercialization, we will need to identify suitable manufacturers with the capabilities to manufacture our compounds in large quantities in a manner consistent with existing regulations. Our current and future third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities at any other time. If our manufacturers are unable to successfully scale up the manufacture of our current or future product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

We do not currently have any agreements with third-party manufacturers for the long-term commercial supply of any of our product candidates. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of such product candidates or may be unable to do so on acceptable terms.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

•reliance on the third party for regulatory compliance and quality assurance;

•the possible breach of the manufacturing agreement by the third party;

•the failure of such parties to manufacture product candidates according to our specifications or on schedule;

•the possible misappropriation of our proprietary information, including our trade secrets and know-how; and

•the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The facilities used by our third-party manufacturers must be approved for the manufacture of our product candidates by the FDA, or any comparable foreign regulatory authority, pursuant to inspections that will be conducted after we submit an NDA to the FDA, or submit a comparable marketing application to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of our product candidates. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

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

If the third parties that we engage to supply any materials or manufacture product for our preclinical and nonclinical studies and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these studies and trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop such product candidates and compete effectively.

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

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives regulatory approval, it 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.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of any of our product candidates, such product candidates may not achieve market acceptance among physicians, patients and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety, tolerability, efficacy and ease of use of a once-a-day oral dose and other potential advantages compared to alternative treatments;
- the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments;
- the convenience and ease of once-a-day oral administration compared to alternative treatments (e.g., inhaled drug through nebulizer);
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- acceptance by physicians, patients, payor-formularies and treatment facilities and parties responsible for coverage and reimbursement of the product;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- our ability to manufacture the product candidates in sufficient quantities and yields;
- the strength and effectiveness of marketing and distribution support;
- the prevalence and severity of any side effects;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved REMS;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- whether the product is safe, tolerable and efficacious when used in combination therapy with the current multi-drug standard of care regimen;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products; and
- the emergence of bacterial resistance to the product.

If the market size of any product candidate that obtains regulatory approval is significantly smaller than we anticipate, it may not achieve market acceptance or commercial success. This could significantly and negatively impact our business, financial condition, results of operations and growth prospects.

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

The development and commercialization of new drug products is highly competitive. We face competition from major multi-national pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies and generic drug companies with respect to the product candidates that we intend to develop and commercialize. Potential competitors also include academic institutions, government agencies and other public and private research organizations. If our competitors obtain regulatory approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market. Our competitors may also succeed in developing, acquiring or licensing technologies and drug products that are more effective, more effectively marketed and sold, or less costly than any product candidates that we may develop, which could render our product candidate non-competitive and obsolete.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and nonclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do as an organization. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, following the announcement of topline data from the Phase 2 portion of our Phase 2/3 clinical trial evaluating epetraborole, we effected a restructuring resulting in the elimination of a significant portion of the workforce and could result in additional unplanned loss of personnel. Continued disruption caused by the transition or by the loss of ongoing services of any qualified scientific and management personnel could delay or prevent the successful development of our current and future product candidates.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA or other comparable regulatory agencies for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or any comparable regulatory agencies or our competitors establish a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. Additional drugs may become available on a generic basis over the coming years. If any of our product candidates achieve regulatory approval, we expect that they will be priced at a significant premium over competitive generic drugs.

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain regulatory approval, we will need to establish a sales and marketing organization or enter into collaboration, distribution and other marketing arrangements with one or more third parties to commercialize such product candidate. In the United States and other key markets, we intend to build a commercial organization to target areas with the greatest incidence of conditions for which we may at some point obtain regulatory approval and recruit experienced sales, marketing and distribution professionals. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We may decide to work with regional specialty pharmacies, distributors, and/or multi-national pharmaceutical companies to leverage their commercialization capabilities to commercialize any product candidate for which we may obtain regulatory approval outside of the United States.

If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise to target the areas that we intend to target. If we are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

•our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

•the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

•the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines;

•unforeseen costs and expenses associated with creating an independent sales and marketing organization; and

•unforeseen costs and limitations with regard to setting up a distribution network.

If we are unable to establish our own sales, marketing and distribution capabilities in the United States and other jurisdictions in which any of our product candidates are approved and, instead, enter into arrangements with third parties to perform these services, our revenues and profitability, if any, are likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. We may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates.

Coverage and adequate reimbursement may not be available for any of our product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs, and providers are unlikely to prescribe our drugs, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs and their administration.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

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

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

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue;
- the inability to commercialize any drugs that we may develop; and
- a decline in our share price.

Our product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our product liability insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with current or future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

There are a variety of risks associated with marketing our product candidates internationally, which could affect our business.

We may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement landscapes in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;

•unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

•economic weakness, including inflation or political instability in particular foreign economies and markets;

•compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

•foreign taxes, including withholding of payroll taxes;

•foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

•difficulties staffing and managing foreign operations;

•workforce uncertainty in countries where labor unrest is more common than in the United States;

•potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), or comparable foreign regulations;

•challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

•production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

•business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

Risks Related to Our Business, Industry and Managing Our Growth

We operate with a small team and our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, financial and business development expertise of Eric Easom, our co-founder, president, and chief executive officer, Sanjay Chanda, Ph.D., our chief development officer, Lucy Day, our chief financial officer, Josh Eizen, J.D., our chief legal and operating officer, Michael R.K. (Dickon) Alley, Ph.D., our co-founder and SVP research fellow and head of biology, Stephen Prior, Ph.D., our chief strategy officer, and Vincent Hernandez, our senior vice president research and head of chemistry, as well as the other members of our research, development, and business teams. Each may terminate employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Our limited personnel and resources may result in greater workloads for our employees compared to those at companies with which we compete for personnel, which may lead to higher levels of employee dissatisfaction and turnover. Recruiting and retaining qualified research, development, and business personnel and, if we progress the development of our product candidates, commercialization, manufacturing, and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of research and development personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Macroeconomic uncertainties have in the past and may continue to adversely impact our business, financial condition, results of operations and growth prospects.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, volatility and disruptions in global markets and supply chains and global conflicts may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. To the extent that macroeconomic uncertainties continue to harm our business, financial condition, results of operations and growth prospects, many of the other risks described in this "Risk Factors" section will be exacerbated.

We have identified material weaknesses in our internal control over financial reporting. Due to our failure 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 had been 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 financial statements, we 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 financial statements will not be prevented or detected on a timely basis. The material weaknesses are as follows:

- We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources with (i) an appropriate level of accounting knowledge, experience and training to appropriately analyze, record and disclose accounting matters timely and accurately, and (ii) an appropriate level of knowledge and experience to establish effective processes and controls. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses.

- We did not design and maintain effective controls related to the period-end financial reporting process, including designing and maintaining formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures. Additionally, we did not design and maintain controls over the preparation and review of account reconciliations and journal entries, including maintaining appropriate segregation of duties.

- We did not design and maintain effective controls related to the accounting for certain non-routine or complex transactions, including the proper application of U.S. GAAP to such transactions.

- We did not design and maintain effective controls over information technology ("IT") general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that information technology program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate Company personnel, (iii) computer operations controls to ensure that critical batch jobs are monitored and data backups are authorized and monitored, and (iv) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These IT deficiencies did not result in adjustments to the financial statements. However, the IT deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, management has determined the IT deficiencies in the aggregate constitute a material weakness.

We cannot assure you that there will not be future material weaknesses in our internal control over financial reporting in the future. The failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. These identified material weaknesses, or any additional material weaknesses, in our internal control over financial reporting may cause investors to lose confidence in the accuracy and completeness of our financial reports and/or cause the market price of our common stock to decline, and we could be subject to sanctions or investigations by Nasdaq Stock Market LLC, the SEC or other regulatory authorities. Failure to remediate material weaknesses in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If in the future, we need to expand our research, development, and business capabilities and implement sales, marketing, and distribution capabilities, we may encounter difficulties in managing such growth, which could disrupt our operations.

Although we recently effected a restructuring to reduce our workforce by approximately 50%, if the development of our product candidates progresses, we may experience growth in the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives regulatory approval, sales, marketing and distribution. To manage any such growth, we will need to implement and improve our managerial, operational, and financial systems, expand our facilities and recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such growth, we may not be able to effectively manage such an expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may also lead to significant costs and may divert our management and research and development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drug products, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and drug products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing drug development programs and initiatives in pursuing such a strategic partnership, merger, or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Risks Related to Our Intellectual Property

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

We do not own any issued patents and we in-license patents and patent applications for our product candidates, and our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by in-licensing intellectual property relating to our product candidates including patent applications in the United States and abroad related to our technology and product candidates that are important to our business. If we or our licensors do not adequately protect the intellectual property we in-license or own, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we and our licensors file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We and our current licensors and licensees, or any future licensors and licensees, may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensors and licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection, or fail to continue to prosecute patents relating to our product candidates. Therefore, these and any of our in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our licensors' patents or our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors and licensees, or any future licensors or licensees, 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 and we might not be able to prevent third parties from making, using, and selling competing products. We cannot predict whether the patent applications we and our licensors or licensees are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. If there are material defects in the form or preparation of our or our licensors' patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how, and we may not be able to prevent such competitors from commercializing such equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and has been the subject of much litigation in recent years. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, and future changes in patent laws in or outside the United States may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights.

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. 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 licensors were the first to make the inventions claimed in patents or pending patent applications that we in-license or own, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"), or become involved in opposition, derivation, reexamination, inter partes review, or interference proceedings, in the United States or elsewhere, challenging our 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 patent rights, allow third parties to commercialize our technology or product candidates, and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights.

Our licensors' pending and future patent applications and our own 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 prevent others from commercializing competitive technologies and products. Even if our or our licensors' patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our in-licensed patents or any patents we may own in the future by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated NDAs to the FDA in which they claim that patents licensed by us or may be owned by us in the future are invalid, unenforceable, and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend and/or assert our in-licensed or owned patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court, or other agency with jurisdiction may find our in-licensed patents or any owned patents, should such patents issue in the future, invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our in-licensed patents or patents we may own in the future may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any impairment of our intellectual property rights, or our failure to protect our intellectual property rights adequately, could give third parties access to our technology and product candidates and could materially and adversely impact our business, financial condition, results of operations and growth prospects.

Our rights to develop and commercialize our technology and our other product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Anacor. If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to products, technology, or data from third parties, we could lose such rights that are important to our business.

For certain product candidates, we rely on licenses to certain patent rights and other intellectual property that are important or necessary to the development of these compounds. For example, we depend on a license agreement from Anacor, a biopharmaceutical company that originally developed epetraborole and is currently a wholly-owned subsidiary of Pfizer. Additionally, we have licensed our rights under the Anacor agreement in China, Hong Kong, Taiwan and Macau to Brii Biosciences.

Anacor has relied upon, and any future licensors may have relied upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. We have sublicensed certain patents from Anacor that are owned, maintained and prosecuted by GSK. If third-party companies such as GSK fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize our product candidates that are the subject of such licensed rights could be adversely affected. Further, we rely upon Anacor's compliance with its license agreement with GSK to maintain our sublicense to such patents owned by GSK, and any termination of Anacor's license agreement with GSK could result in us losing our license to epetraborole. Further development and commercialization of our product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize our product candidates in the future.

Our license agreement with Anacor, and other intellectual property-related agreements we may enter into in the future may impose diligence and other obligations, including payment of milestones and royalties. For example, our license agreement from Anacor requires us to satisfy diligence requirements, including using commercially reasonable efforts to develop and commercialize products. If we fail to comply with our obligations to Anacor or any future licensors, those counterparties may have the right to terminate the license agreements, in which event we might not be able to develop, manufacture, or market any product candidate licensed under the agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement and further involve termination of our rights to important intellectual property or technology.

In spite of our efforts, Anacor imposes or any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Under our license agreement with Anacor, and any future license agreements, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;

•our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

•the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

•the priority of invention of patented technology.

In addition, the license agreements involving intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. 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, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be successful in obtaining necessary rights to any product candidates we may develop through acquisitions and in-licenses.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates. We may find it necessary or prudent to obtain licenses from such third-party intellectual property holders in order to avoid infringing these third-party patents. For example, many pharmaceutical companies, biotechnology companies and academic institutions compete with us and may be filing patent applications potentially relevant to our business. 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 license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. 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 abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Competitors or other third parties may infringe, misappropriate or otherwise violate our in-licensed issued patents or other intellectual property we may own. To counter such infringement, misappropriation or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against third parties could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents, trademarks, copyrights or other intellectual property. In addition, our in-licensed patents may become involved in inventorship or priority disputes. Third parties may raise challenges to the validity of certain of our in-licensed patent claims and may in the future raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in derivation, revocation, reexamination, post-grant review ("PGR"), inter partes review ("IPR"), interference proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings challenging any patents that we may own or in-license. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our potential future owned patents or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, invalidate, or render unenforceable, our potential future owned patents or licensed patent rights, allow third parties to commercialize our product candidates 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 In a patent infringement proceeding, there is a risk that a court will decide that a patent we in-license is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents are upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our in-licensed patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our in-licensed patents could limit our ability to assert our in-licensed patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, in the future, we expect to rely on trademarks to distinguish our product candidates that are approved for marketing, if any, and if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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 litigation. 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. Moreover, there can be no assurance that we will have sufficient financial or other resources to adequately file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors and other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 significantly harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary chemistry technology without infringing, misappropriating or otherwise violating the intellectual property of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of antibacterial treatment, including compounds, formulations, treatment methods, and synthetic processes that may be applied towards the synthesis of antibiotics. If any such patents of third parties cover our product candidates or technologies, we may not be free to manufacture or market our product candidates as planned.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation, or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance.

If we are found to have infringed, misappropriated, or otherwise violated any third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing, or commercializing our product candidates. Alternatively, we may be required to obtain a license from such third party in order to use technology and continue developing, manufacturing or marketing product candidates that infringe or violate such third party's intellectual property. However, we may not be able to obtain any such required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We may also be required to pay substantial ongoing royalty or license payments or fees or comply with other unfavorable terms. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if we were to prevail in such a dispute, any litigation regarding our intellectual property could be costly and time-consuming and divert the attention of our management and key personnel from our business operations. 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. During the course of litigation, there could be public announcements or the results of hearings, motions or other interim proceedings or developments. 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. Negative publicity related to a decision by us to initiate such enforcement actions against a customer or former customer, regardless of its accuracy, may adversely impact our other customer relationships or prospective customer relationships, harm our brand and business and could cause the market price of our common stock to decline. Any of the foregoing arising from uncertainty in legal proceedings could materially and adversely impact our business, financial condition, results of operations and growth prospects.

We may be subject to claims by third parties asserting that we or our employees, consultants, and advisors have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that we or such employees, consultants and advisors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, 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, such employees and contractors may breach the agreement and claim the developed intellectual property as their own. Further, we may be unsuccessful in executing such agreements with each party who, in fact, conceives, or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing and we may be forced to bring claims against third parties, or defend claims that 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. A court could prohibit us from using technologies or features that are essential to our product candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates. Any of the foregoing could have a material adverse impact on our business, financial condition, results of operations and growth prospects.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties who have prior rights to our trademarks or third parties who have prior rights to similar trademarks may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby diluting or impeding our ability to build brand identity and possibly leading to market confusion. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks and may not be able to prevent such third parties from using and marketing any such trademarks.

In addition, any proprietary name we propose to use with any product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively and our business, financial condition, results of operations and growth prospects may be adversely affected.

If we are unable to protect the confidentiality of our proprietary information, know-how and trade secrets, the value of our product candidates could be adversely affected and our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these agreements may be inadequate to protect our proprietary and intellectual property rights. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. In addition, we may not be able to obtain adequate remedies for any such breaches. Although we use reasonable efforts to protect this proprietary information and technology, we also cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information, know-how, trade secrets or other proprietary information or each individual who has developed intellectual property on our behalf. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, distracting to management, and time-consuming, and the outcome is unpredictable and varied depending on the jurisdiction. In addition, some courts inside and outside the United States, in countries in which we operate or intend to operate, are less willing, or unwilling, to protect trade secrets, know-how and other proprietary information. Any claims or litigation could cause us to incur significant expenses. Some third parties may be able to sustain the costs of complex litigation more effectively than we can because they have substantially greater resources.

Our employees, consultants, and other parties may unintentionally or willfully disclose our information or technology to competitors and there can be no assurance that the legal protections and precaution taken by us will be adequate to prevent misappropriation of our technology or that competitors will not independently develop technologies equivalent or superior to ours. Trade secrets and know-how can be difficult to protect. Our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Additionally, competitors could purchase our product candidates and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we or our licensors do not obtain patent term extension and data exclusivity for any product candidates we or our licensors may develop, our business may be materially harmed.

Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents we license or may own in the future protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our product candidates. Depending upon the timing, duration, and specifics of any FDA approval of any of our product candidates, one or more of our in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and growth prospects could be materially harmed.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or in-licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent protection for certain licensed technology outside 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, even in jurisdictions where we or our licensors do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our in-licensed inventions in all countries outside the United States, even in jurisdictions where our licensors do pursue patent protection 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 or our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our preclinical programs. Our in-licensed 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 certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our in-licensed patents, if pursued and obtained, or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our in-licensed patents at risk of being invalidated or interpreted narrowly and our in-licensed 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. 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and growth prospects may be adversely affected.

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

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

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale, import, export and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We currently do not have any products approved for sale in any jurisdiction. For example, we are not permitted to market any product candidate in the United States until we receive regulatory approval of an NDA from the FDA. We as a company only have limited experience in filing and supporting the applications necessary to gain regulatory approvals and may rely on third-party contract research organizations to assist us in this process.

Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. For instance, changes to leadership and the reorganization and rededication of critical resources at the FDA and within similar governmental health authorities across the world, may impact the ability of new products and services from being developed or commercialized in a timely manner. Regulations and requirements vary among jurisdictions, including in Japan and Europe. We have not obtained regulatory approval for any product candidate, and it is possible that our product candidates will never obtain regulatory approval.

We have not sought or obtained regulatory approval for any product candidate, and it is possible that any product candidates we may seek to develop will never obtain regulatory approval. In order to obtain approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the nonclinical or clinical data for a product candidate is promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for product candidates either prior to or post-approval, and it may otherwise object to elements of our clinical development program.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- disagreement with the design, endpoint selection, or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied may not be sufficiently broad or representative to assure safety in the full populations for which we seek approval;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication;
- disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- requirements for additional nonclinical studies or clinical trials;
- disagreement regarding the formulation, labeling, and/or the specifications we propose for our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies;
- refusals by regulators to accept a submission due to, among other reasons, the content or formatting of the submission; or
- changes in a policies, requirements, or regulations rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage complete the FDA or foreign regulatory approval processes and are successfully commercialized. The lengthy review process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval, which would significantly harm our business, financial condition, results of operations and growth prospects.

Even if we eventually receive approval of an NDA or foreign marketing application for our product candidates, the FDA, or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, often referred to as Phase 4 clinical trials, and the FDA may require the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, review, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is 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 or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus may lead to other inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may not be able to obtain or maintain orphan drug designations for any product candidates, and we may be unable to take advantage of the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a diagnosed patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Similar laws exist in Europe and Japan. The European Commission may grant a product orphan medicinal product designation if the product is intended for the treatment, prevention or diagnosis of a life-threatening or very serious condition, with a prevalence in the European Union of not more than five in 10,000 people, and where either no satisfactory method of diagnosis, prevention or treatment of the condition in question exists, or if such method exists that the medicinal product will be of significant benefit to those affected by that condition.

As part of our business strategy, we intend to seek orphan drug designation, where applicable, from the FDA and orphan medicinal product designation from the European Commission; however, we may not be able to obtain or maintain this status for our product candidates. There can be no assurance that any regulatory authority will grant any orphan drug designations.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, it is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

More than one product may be approved by the FDA for the same orphan disease or condition, as long as the products are different drugs, as determined by the FDA. As a result, if any of our product candidates is approved by the FDA and receives orphan drug exclusivity, absent other applicable exclusivities, the FDA can still approve other drugs for use in treating the same indication or disease, which could create a more competitive market for us. The failure to successfully obtain orphan drug exclusivity would adversely affect our business.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same disease or condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same disease or condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may attempt to seek accelerated approval in the United States for certain of our product candidates. If we are not able to use that pathway, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals, if we receive them at all. In addition, even if an accelerated approval pathway is available to us, it may not lead to expedited approval of our product candidates, or approval at all.

Under the FDCA and implementing regulations, the FDA may grant accelerated approval to a product candidate to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verity and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, provided FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our product candidates we intend to seek feedback from the FDA or will otherwise evaluate ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed in these territories. Any approval we are granted for our product candidates in the United States would not assure approval of such product candidates in foreign jurisdictions.

In order to market and sell our product candidates in Japan, the European Union, United Kingdom, other areas of Asia, Australia, and any other jurisdictions, we must obtain separate regulatory 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 approval from the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and data from clinical studies approved by the FDA may not be accepted by foreign regulatory agencies, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing authorization and may not receive necessary approvals to commercialize our product candidates in any market.

Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of such product candidates may limit how we manufacture and market the product candidates and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if regulatory approval of any of our product candidates is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including with respect to the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials, In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive regulatory approval for one or more product candidates, we and our contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance. 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 facilities 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. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted, or suspension or revocation of approvals;
- product seizures or detentions, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and other regulatory authorities strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet and off-label promotion. For example, any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

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

We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct, errors, or omissions by employees and independent contractors, such as principal investigators, CROs, consultants, commercial partners, and vendors, could include failures to comply with regulations of the FDA and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately, to disclose unauthorized activities to us, or to comply with requirements of government contracts (e.g., the NIAID contract). In particular, sales, marketing, and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing, and promotion, sales commission, customer incentive programs, and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities 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. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits, and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment, or restructuring of our operations, any of which could adversely affect our ability to operate.

If we successfully commercialize any of our product candidates, failure to comply with our reporting and payment obligations under U.S. governmental pricing programs could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we participate in the Medicaid Drug Rebate Program and/or Medicare Part D, if and when we successfully commercialize a product candidate, we will be required to report certain pricing information for such product candidate to the Centers for Medicare & Medicaid Services, the federal agency that administers the Medicaid and Medicare programs. We may also be required to report pricing information to the U.S. Department of Veterans Affairs. If we become subject to these reporting requirements, we will be liable for errors associated with our submission of pricing data, for failure to report pricing data in a timely manner, and for overcharging government payers, which can result in civil monetary penalties under the Medicaid statute, the federal civil False Claims Act, and other laws and regulations.

Our current and future relationships with healthcare professionals, principal investigators, consultants, customers, and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency and other healthcare laws and regulations, which could expose us to penalties.

Healthcare providers, physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain regulatory approval. In addition, we may be subject to physician payment transparency laws and regulations by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease or order, or the arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;

- 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 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 whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements 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 does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires manufacturers of certain drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMMS") information related to payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare providers (such as nurse practitioners and physicians assistants) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

•analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws requiring the licensure of pharmaceutical sales representatives.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

Changes in healthcare policies, laws, and regulations may impact our ability to obtain approval for, or commercialize our product candidates, if approved.

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality, and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives, as well as executive, judicial, and Congressional challenges to existing healthcare laws that have significantly affected, and could continue to significantly affect, the healthcare industry. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "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 creating a new manufacturer discount program. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs and review the relationship between pricing and manufacturer patient programs. For example, the IRA, among other things (i) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023. On August 29, 2023 HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

At the state level, legislatures have become increasingly active 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. Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

We are subject to privacy and data security laws, rules, regulations, policies, industry standards, and contractual obligations, and our failure to comply with them could harm our business.

We maintain a large quantity of information, including confidential business information and information related to our employees and may maintain or have responsibility for the maintenance of personal information in connection with the conduct of our clinical trials. As such, we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure, and protection of personal information that apply or could apply to our operations or the operations of our partners, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, in particular in relation to health information, which may affect our business and is expected to increase our compliance costs and exposure to liability. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

Compliance with these and any other applicable privacy and data security laws, regulations and other requirements we may be subject to in the future is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with such data protection rules. If we fail to comply with any such laws, regulations or other requirements, we may face significant fines and penalties that could adversely affect our business, financial condition, results of operations or growth prospects. Any failure or perceived failure by us or our third-party processors to comply with these data protection and privacy laws, regulations and requirements could result in significant government enforcement actions, which could include civil, criminal, and administrative penalties, orders requiring that we change our practices, claims for damages, and other liabilities, regulatory investigations and enforcement action, private litigation, significant costs (including in investigating and defending such claims, in remediation measures or changes to our operations), and adverse publicity, any of which could negatively affect our business, financial condition, results of operations and growth prospects. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements.

With laws, regulations, and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. We are currently in the process of developing and updating our policies and procedures in accordance with requirements under applicable data privacy and protection laws and regulations. We rely on our CROs to ensure compliance with data-privacy regulations that may arise in our trials. Other than our website privacy policy, we do not currently have any formal data privacy policies and procedures in place and have not completed formal assessments of whether we are in compliance with all applicable data privacy laws and regulations. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal data, at risk, and our business, financial condition, results of operations and growth prospects may be adversely affected.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector.

We may engage third parties to sell any approved product candidates outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract, and fraud litigation, reputational harm, and other consequences.

We are also subject to export control, import, and trade sanctions laws and regulations which may restrict or prohibit altogether the provision, sale, or supply of our product candidates to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. Obtaining the necessary export license or other authorization for a particular transaction may be time-consuming and may result in the delay or loss of sales opportunities. Violations of U.S. export control, import, or sanctions laws and regulations can result in significant fines or penalties and possible incarceration for responsible employees and managers.

Risks Related to Ownership of Our Common Stock

Concentration of ownership of our common stock among our existing executive officers, directors, and principal stockholders may prevent new investors from influencing significant corporate decisions and matters submitted to stockholders for approval.

Our executive officers, directors, and current beneficial owners of 5% or more of our capital stock and their respective affiliates beneficially own, in the aggregate, a significant percentage of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, or sale of all or substantially all of our assets, or other significant corporate transactions. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

•delaying, deferring, or preventing a change in control;

•entrenching our management and/or the board of directors (the "Board");

•impeding a merger, consolidation, takeover, or other business combination involving us; or

•discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, 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 our IPO and recent financings 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.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

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 cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

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

- establish a classified board of directors such that not all members of the Board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board;
- limit the manner in which stockholders can remove directors from the Board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired more than 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Additionally, in August 2024, we entered into a Rights Agreement, which was previously approved by the Board. In connection with the Rights Agreement, a dividend was declared of one preferred stock purchase right for each share of the Common Stock of the Company outstanding at the Record Date (individually, a "Right" and collectively, the "Rights"). Each Right entitles the registered holder thereof, after the Rights become exercisable and until August 15, 2025 (or the earlier redemption, exchange or termination of the Rights), to purchase from the Company one one-thousandth of a share of Series A Preferred, of the Company at a price of $6.50 per one one-thousandth of a share of Series A Preferred, subject to adjustment. The Rights will expire on August 15, 2025, subject to the Company's right to extend such date, unless earlier redeemed or exchanged by the Company or terminated. The Rights Agreement could have the effect of discouraging, delaying or preventing a change in management or control over us. While there is no plan to do so at this time, our Board may choose to extend the current Rights Agreement or adopt a new rights agreement in the future.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, including claims under the Securities Act, which could limit our stockholders' ability to obtain a favorable 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:

•any derivative action or proceeding brought on our behalf;

•any action asserting a breach of fiduciary duty;

•any action asserting a claim against us or any of our directors, officers, employees, or agents arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws;

•any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation, or our amended and restated bylaws; and

•any action asserting a claim against us or any of our directors, officers, employees, or agents that is governed by the internal-affairs doctrine.

Furthermore, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. However, these provisions would 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. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. To the extent the exclusive forum provision restricts the courts in which claims arising under the Securities Act may be brought, there is uncertainty as to whether a court would enforce such a provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents, or our other stockholders, which may discourage such lawsuits against us and such other persons, or may result in additional expense to a stockholder seeking to bring a claim against us. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, results of operations and growth prospects.

We will have broad discretion in the use of our cash, and may invest or spend our cash in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management will have broad discretion in the application of our cash, and could spend our cash in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline, and delay the development of our pipeline programs as well as commercial preparedness.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, and accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility or debt securities may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. If we do not pay cash dividends, you could receive a return on your investment in our common stock only if you are able to sell your shares in the future and the market price of our common stock has increased when you sell your shares. As a result, investors seeking cash dividends should not purchase our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2023, we had federal and state net operating loss ("NOLs") carryforwards of approximately $58.2 million and $122.6 million, respectively. Under the Tax Cuts and Jobs Act of 2017 ("the Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), our NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. There is variation in how states have responded and may continue to respond to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future. As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

General Risk Factors

The trading price of our common stock has been and may continue to be volatile.

The trading price of our common stock has been subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares at or above the price paid for the shares. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Form 10-Q, these factors include:

- the commencement, enrollment or results of our planned and future clinical trials;
- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the results of our testing and clinical trials;
- unanticipated safety, tolerability or efficacy concerns;
- the loss of any of our key research, development or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates;
- changes to our relationships with collaborators, manufacturers, or suppliers;
- announcements concerning our competitors or the pharmaceutical industry in general;

•actual or anticipated fluctuations in our operating results;

•changes in financial estimates or recommendations by securities analysts;

•potential acquisitions;

•the results of our efforts to discover, develop, acquire, or in-license additional product candidates;

•the trading volume of our common stock on The Nasdaq Global Select Market;

•sales of our common stock by us, our executive officers and directors or our stockholders or the anticipation that such sales may occur in the future;

•general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or other countries where we conduct critical business;

•stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;

•banking crises or failures; and

•investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares of our common stock at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

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 will be influenced by the research and reports that equity research analysts publish about us and our business. We currently have research coverage by a limited number of equity research analysts. Equity research analysts may elect not to continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. We will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

We are incurring significantly increased costs as a result of operating as a company whose common stock is publicly traded in the United States, and our management is devoting substantial time to new compliance initiatives.

As a public company in the United States, we are incurring significant legal, accounting, and other expenses. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq Stock Market LLC, and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations has increased our legal and financial compliance costs and has made some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur or the timing of such costs.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. Identifying material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Significant disruptions of our or our vendors' information technology systems or cybersecurity incidents could result in significant financial, legal, regulatory, business, and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process, and transmit large amounts of confidential information, including intellectual property, proprietary business information, personal information (including health information), and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and restricted availability of such information. We have also outsourced elements of our operations, including elements of our information technology infrastructure and data processing, to third parties and, as a result, we manage a number of third-party vendors who have access to our computer networks or our information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to other third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks, and exposures, the accessibility and distributed nature of our information technology systems, and the information stored on those systems, make such systems (and the information stored therein) vulnerable to risks that threaten the confidentiality, integrity and availability of these systems and information, including unintentional or malicious, internal, and external attacks on our technology environment. Vulnerabilities can be exploited by diverse threat actors and attack vectors, including through inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Cybersecurity incidents are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states, and others, and utilizing increasingly sophisticated techniques and tools – including AI – that circumvent security controls, evade detection and remove or obfuscate forensic evidence. In addition to access to, loss of or the extraction of information, such attacks could involve the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering/phishing, malicious code embedded in software, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information technology systems or information. In addition, the prevalent use of mobile devices increases the risk of cybersecurity incidents.

Significant disruptions of our or our third-party vendors' or business partners' information technology systems or other similar cybersecurity incidents could adversely affect our business operations and result in the loss, misappropriation, and unauthorized access, use or disclosure of, or the prevention of access to, information, which could result in financial, legal, regulatory, business, and reputational harm to us. In addition, any impact to the confidentiality, integrity or availability of information technology systems and the information stored therein, whether from attacks on our or third-party technology environment or from computer viruses, natural disasters, terrorism, war, telecommunication and electrical failures, or other threats, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from ongoing, completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We cannot ensure that our cybersecurity and data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties with which we work, will prevent breakdowns or breaches in our or their systems or other cybersecurity incidents, including those that cause loss, destruction, unavailability, alteration, dissemination of, or damage, or unauthorized access to, or processing of, our data, including personal information, assets, and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, financial condition, results of operations and growth prospects.

While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or cybersecurity incidents or that our security measures and processes will be fully implemented, complied with or effective. Nor can we be certain that our third-party vendors or business partners have sufficient measures or processes in place to protect their information technology systems and infrastructure. We, our third-party vendors and business partners are, from time to time, subject to attacks and cybersecurity incidents. While we have not to our knowledge experienced an incident that has had a material impact on our operations or financial results, there is no way of knowing with certainty whether we have experienced any material cybersecurity incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that their systems or information have been compromised. Any event that leads to unauthorized access, use, or disclosure of information, including personal information regarding our patients or employees, or other adverse impact to the availability, integrity or confidentiality of our information technology systems, infrastructure or information, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law and contractual equivalents, subject us to time-consuming, distracting, and expensive litigation (including class actions), regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations, and contractual obligations, including those that protect the privacy and security of personal information. It could also result in increased costs to us, including costs to investigate, mitigate and remediate vulnerabilities and incidents, and result in significant legal and financial exposure and reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality, or data security-related legal or other obligations to third parties, or any further cybersecurity incidents, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators, or current and potential partners, to lose trust in us, or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations. Moreover, cybersecurity incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Finally, we cannot guarantee that any costs and liabilities incurred in relation to an incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all. Any of the foregoing could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects.

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

We are an "emerging growth company" as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404, not being required to comply with the auditor requirements to communicate critical audit matters in the auditor's report on the financial statements, reduced disclosure obligations regarding executive compensation, 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. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We have taken advantage of reduced reporting burdens in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q. In particular, in our Annual Reports on Form 10-K, we have provided only two comparative periods of audited financial statements. We also have not provided all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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 our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not "emerging growth companies."

Recent and potential future changes to U.S. and non-U.S. tax laws could materially adversely affect our company.

Existing, new, or future changes in tax laws, regulations, and treaties, or the interpretation thereof, in addition to tax policy initiatives and reforms under consideration in the United States or internationally and other initiatives could have an adverse effect on the taxation of international businesses. Furthermore, countries where we are subject to taxes, including the United States, are independently evaluating their tax policy and we may see significant changes in legislation and regulations concerning taxation. For example, the Tax Act, the CARES Act and the recently enacted IRA made many significant changes to the U.S. tax laws. The Tax Act made broad and complex changes to the Code, including, among other things, reducing the federal corporate tax rate. Additionally, beginning in 2022, the Tax Act required the capitalization of research and experimentation expenses with amortization periods over five and fifteen years pursuant to Code Section 174 ("Section 174"), which could impact our effective tax rate and cash flow. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to any such tax legislation may affect us, and certain aspects of the previously enacted legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA, or any newly enacted federal tax legislation. Other legislative changes could also affect the taxation of holders of our common stock. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we are subject to tax and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden, and cost of tax compliance. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislative changes and the potential tax consequences of investing in or holding our common stock.

Indemnity provisions in various agreements potentially expose us to substantial liability for intellectual property infringement, data protection, and other losses.

Our agreements with third parties may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our contractual obligations. Large indemnity payments could harm our business, financial condition, results of operations and growth prospects. Although we normally contractually limit our liability with respect to such obligations, we may still incur substantial liability. Any dispute with a third party with respect to such obligations could have adverse effects on our relationship with that third party and relationships with other existing or new partners, harming our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

On March 24, 2022, our registration statement on Form S-1 (File No. 333-263295) was declared effective by the SEC for our IPO. There has been no material change in the use of proceeds from our IPO as described in our final prospectus dated March 24, 2022 pursuant to Rule 424(b)(4).

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the fiscal quarter ended September 30, 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted, modified, or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(c) of Regulation S-K.

Item 6. Exhibit

(a)Exhibits.

The exhibits listed below are filed as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-41331	3.1	June 24, 2024
3.2	Amended and Restated Bylaws.	S-1	333-263295	3.4	March 4, 2022
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock of AN2 Therapeutics, Inc. filed with the Secretary of State of the State of Delaware on August 15, 2024.	8-K	001-41331	3.1	August 19, 2024
4.1	Rights Agreement, dated as of August 15, 2024, between AN2 Therapeutics, Inc. and Equiniti Trust Company, LLC, which includes Form of Certificate of Designations of Series A Junior Participating Preferred Stock as Exhibit A, the Form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Stock as Exhibit C.	8-K	001-41331	4.1	August 19, 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 Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document**				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document**				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document**				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document**				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document**				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

** The following materials are formatted in Inline XBRL (Extensible Business Reporting Language): (i) the cover page; (ii) the Condensed Balance Sheets as of September 30, 2024 and December 31, 2023; (iii) the Condensed Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023; (iv) the Condensed Statements of Stockholders' Equity for the three and nine months ended September 30, 2024 and 2023; (vi) the Condensed Statements of Cash Flows for the nine months ended September 30, 2024 and 2023; (vii) Notes to Condensed Financial Statements tagged as blocks of text.

† The certification attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on November 13, 2024.

AN2 Therapeutics, Inc.

By: /s/ Eric Easom
Eric Easom
Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ Lucy O. Day
Lucy O. Day
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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, Eric Easom, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of AN2 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 13, 2024

By: /s/ Eric Easom
Eric Easom
Chief Executive Officer and Director
(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, Lucy O. Day, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of AN2 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 13, 2024

By: /s/ Lucy O. Day
Lucy O. Day
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Eric Easom, Chief Executive Officer of AN2 Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 13, 2024

/s/ Eric Easom
Eric Easom
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 AN2 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 PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Lucy O. Day, Chief Financial Officer of AN2 Therapeutics, Inc. (the “Company”), hereby certifies that, to the best of her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.2 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 13, 2024

/s/ Lucy O. Day
Lucy O. Day
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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 AN2 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.”