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, 2022

OR

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

For the transition period from to

Commission File Number: 001-40708

ELIEM THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-2273741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
23515 NE Novelty Hill Road, Suite B221 #125 Redmond, WA	**98053**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (425) 276-2300

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ELYM**	**The Nasdaq Stock Market LLC (The Nasdaq Global Market)**

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of November 10, 2022, the registrant had 26,567,681 shares of common stock, $0.0001 par value per share, outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

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

Assets	**September 30, 2022**	**December 31, 2021**
Current assets:		
Cash and cash equivalents	$ 35,944	$ 46,922
Short-term marketable securities	86,675	89,558
Prepaid expenses and other current assets	10,552	11,772
Total current assets	$ 133,171	$ 148,252
Operating lease right-of-use assets	585	—
Long-term marketable securities	6,961	24,919
Other long-term assets	141	70
Total assets	$ 140,858	$ 173,241
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	1,494	1,404
Accrued expenses	4,434	4,627
Operating lease liabilities	352	—
Total current liabilities	$ 6,280	$ 6,031
Other long-term liabilities	—	7
Operating lease liabilities, net of current portion	219	—
Total liabilities	$ 6,499	$ 6,038
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 250,000,000 shares authorized; 26,567,681 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	248,035	242,939
Accumulated other comprehensive loss	(581)	(123)
Accumulated deficit	(113,098)	(75,616)
Total stockholders' equity	$ 134,359	$ 167,203
Total liabilities and stockholders' equity	$ 140,858	$ 173,241

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 4,258	$ 5,989	$ 21,287	$ 16,443
General and administrative	4,490	3,394	14,294	8,526
Total operating expenses	8,748	9,383	35,581	24,969
Loss from operations	(8,748)	(9,383)	(35,581)	(24,969)
Other income (expense):				
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	—	(11,718)
Foreign currency loss	(1,317)	(252)	(2,516)	(268)
Other income, net	383	20	615	20
Total other income (expense)	(934)	(232)	(1,901)	(11,966)
Net loss	$ (9,682)	$ (9,615)	$ (37,482)	$ (36,935)
Accretion of redeemable convertible preferred stock to redemption value and cumulative preferred stock dividends	—	(1,322)	—	(4,548)
Net loss attributable to common stockholders	$ (9,682)	$ (10,937)	$ (37,482)	$ (41,483)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (0.70)	$ (1.43)	$ (5.49)
Weighted-average number of shares outstanding used to compute net loss per share attributable to common stockholders, basic and diluted	26,336,029	15,585,611	26,290,868	7,554,300
Comprehensive loss:				
Net loss	$ (9,682)	$ (9,615)	$ (37,482)	$ (36,935)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net of tax of $0	23	(18)	(458)	(18)
Comprehensive loss	$ (9,659)	$ (9,633)	$ (37,940)	$ (36,953)

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

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

	Redeemable Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance as of December 31, 2021	—	$ —	26,235,317	$ 3	$ 242,939	$ (75,616)	$ (123)	$ 167,203
Vesting of restricted stock awards	—	—	9,451	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,541	—	—	1,541
Other comprehensive loss	—	—	—	—	—	—	(398)	(398)
Net loss	—	—	—	—	—	(13,204)	—	(13,204)
Balance as of March 31, 2022	—	$ —	26,244,768	$ 3	$ 244,480	$ (88,820)	$ (521)	$ 155,142
Vesting of restricted stock awards	—	—	82,633	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,772	—	—	1,772
Other comprehensive loss	—	—	—	—	—	—	(83)	(83)
Net loss	—	—	—	—	—	(14,596)	—	(14,596)
Balance as of June 30, 2022	—	$ —	26,327,401	$ 3	$ 246,252	$ (103,416)	$ (604)	$ 142,235
Vesting of restricted stock awards	—	—	20,970	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,783	—	—	1,783
Other comprehensive income	—	—	—	—	—	—	23	23
Net loss	—	—	—	—	—	(9,682)	—	(9,682)
Balance as of September 30, 2022	—	$ —	26,348,371	$ 3	$ 248,035	$ (113,098)	$ (581)	$ 134,359

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

Eliem Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share amounts)
(unaudited)

	Redeemable Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
Balance as of December 31, 2020	7,140,157	$ 46,551	3,418,751	$ 1	$ 3,152	$ (28,136)	$ —	$ (24,983)
Series A-1 Preferred Stock Issuance (net of issuance costs of $22)	4,358,972	33,978	—	—	—	—	—	—
Reclassification of redeemable convertible preferred stock tranche liability upon settlement	—	12,269	—	—	—	—	—	—
Exercise of stock options and vesting of restricted stock awards	—	—	64,047	—	105	—	—	105
Stock-based compensation	—	—	—	—	297	—	—	297
Net loss	—	—	—	—	—	(18,601)	—	(18,601)
Balance as of March 31, 2021	11,499,129	$ 92,798	3,482,798	$ 1	$ 3,554	$ (46,737)	$ —	$ (43,182)
Series B Preferred Stock Issuance (net of issuance costs of $39)	3,846,150	59,961	—	—	—	—	—	—
Exercise of stock options and vesting of restricted stock awards	—	—	7,158	—	6	—	—	6
Stock-based compensation	—	—	—	—	1,050	—	—	1,050
Net loss	—	—	—	—	—	(8,719)	—	(8,719)
Balance as of June 30, 2021	15,345,279	$ 152,759	3,489,956	$ 1	$ 4,610	$ (55,456)	$ —	$ (50,845)
Proceeds from issuance of common stock in initial public offering (net of issuance costs of $8,856)	—	$ —	7,360,000	1	83,143	—	—	83,144
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(15,345,279)	$ (152,759)	15,345,279	1	152,758	—	—	152,759
Vesting of restricted stock awards	—	—	4,027	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,236	—	—	1,236
Other comprehensive loss	—	—	—	—	—	—	(18)	(18)
Net loss	—	—	—	—	—	(9,615)	—	(9,615)
Balance as of September 30, 2021	—	—	26,199,262	$ 3	$ 241,747	$ (65,071)	$ (18)	$ 176,661

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

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (37,482)	$ (36,935)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,096	2,583
Non-cash operating lease expense	329	—
Change in fair value of redeemable convertible preferred stock tranche liability	—	11,718
Amortization of premiums and accretion of discounts on investments	223	83
Foreign currency loss (gain) from remeasurement	2,220	(245)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,219	(11,103)
Long-term assets	(72)	2,633
Accounts payable	91	1,287
Accrued liabilities	(188)	1,791
Operating lease liabilities	(356)	—
Net cash used in operating activities	$ (28,920)	$ (28,188)
Cash flows from investing activities:		
Purchase of marketable securities	(81,249)	(106,919)
Proceeds from maturities of marketable securities	101,411	—
Net cash provided by investing activities	$ 20,162	$ (106,919)
Cash flows from financing activities:		
Proceeds from issuance of common stock sold in initial public offering, net issuance costs	—	83,144
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	93,939
Proceeds from the exercise of stock options	—	111
Net cash provided by financing activities	$ —	$ 177,194
Effect of exchange rate changes on cash and cash equivalents	(2,220)	245
Net change in cash and cash equivalents	$ (10,978)	$ 42,332
Cash and cash equivalents at beginning of period	46,922	20,487
Cash and cash equivalents at end of period	$ 35,944	$ 62,819
Supplemental disclosure of cash operating activities:		
Conversion of redeemable convertible preferred stock to common stock	$ —	$ 152,759
Cash paid for leases included in operating cash outflows	$ 345	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for lease liabilities	$ 915	$ —

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

1. Description of Organization and Summary of Significant Accounting Policies

Organization

Eliem Therapeutics, Inc. (the Company) is a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in neuropsychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems. Headquartered in Redmond, Washington, the Company was incorporated on October 18, 2018 as a Delaware corporation.

Basis of Presentation and Principles of Consolidation

The accompanying interim condensed consolidated financial statements of the Company and its wholly owned subsidiary have been prepared in conformity with accounting principles generally accepted in the United States (U.S. GAAP). All intercompany transactions and balances have been eliminated in consolidation.

The accompanying condensed consolidated balance sheet as of September 30, 2022, and condensed consolidated statements of operations and comprehensive loss, condensed consolidated statements of cash flows, and condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2022 and 2021, are unaudited. The consolidated balance sheet as of December 31, 2021 was derived from the audited financial statements as of and for the year ended December 31, 2021, but does not include all disclosures required by U.S. GAAP. The unaudited interim condensed financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2021, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2022, the condensed results of its operations as of the three and nine months ended September 30, 2022 and 2021, and its cash flows for the nine months ended September 30, 2022 and 2021. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2022 and 2021 are also unaudited. The condensed results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the full year ending December 31, 2022 or any other period. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 7, 2022.

Initial Public Offering

On August 12, 2021, the Company completed its initial public offering (IPO) of 7,360,000 shares of common stock, including the underwriters' full exercise of their over-allotment option at the IPO price of $12.50 per share. Gross proceeds from the IPO were $92.0 million, and the net proceeds were $83.1 million, after deducting underwriting discounts of $6.4 million and $2.5 million of offering costs payable by the Company. At the closing of the IPO, all of the Company's then outstanding redeemable convertible preferred stock was automatically converted into an aggregate of 15,345,279 shares of common stock. The related carrying value of the redeemable convertible preferred stock of $152.8 million was reclassified to common stock and additional paid-in capital.

Liquidity

Since inception, the Company has experienced recurring losses from operations and generated negative cash flows from operations. The Company has an accumulated deficit of $113.1 million as of September 30, 2022 and expects to incur additional losses from operations in the future. The Company estimates the available cash, cash equivalents, and short- and long-term marketable securities of $129.6 million as of September 30, 2022 will be sufficient to meet its projected operating requirements for at least the next twelve months from the filing date of these unaudited condensed consolidated financial statements.

The Company will need to obtain substantial additional funding to develop and commercialize the Company's clinical programs as currently contemplated. The Company expects to finance future cash needs through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. In addition, the Company expects to continue to rely on capital markets, and to a lesser extent, United Kingdom (U.K.) research and development tax credits and incentives for funding. There are no assurances that the Company will be able to raise sufficient amounts of funding in the future on acceptable terms, or at all.

Use of Estimates

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

The three months ended as of September 30, 2022 included a reversal of $1.5 million of clinical expenses due to actual results differing from prior quarter estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and short- and long-term marketable securities. The Company's cash is held by two financial institutions in the United States (U.S.) and two financial institutions in the U.K. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's deposits held in the U.S. and U.K. may exceed the Federal Depository Insurance Corporation and Financial Services Compensation Scheme, respectively, insured limits. The Company has investments in money market funds, U.S. government debt securities, commercial paper, and corporate bonds with high-quality accredited financial institutions.

Risks and Uncertainties

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

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

Moreover, the ongoing COVID-19 pandemic, which is impacting worldwide economic activity, poses risk that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time which may increase costs and could delay the start-up and conduct of the Company's clinical trials, and negatively impact manufacturing and testing activities performed by third parties. Any significant delays may impact the use and sufficiency of the Company's existing cash reserves, and the Company may be required to raise additional capital earlier than it had previously planned. The Company may be unable to raise additional capital if and when needed, which may result in delays or suspension of its development plans. The extent to which the pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Segments

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

Fair Value Measurement

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

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

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

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

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

The Company's fair value measurements as of September 30, 2022 and December 31, 2021 were as follows (in thousands):

	September 30, 2022			
	Level 1	**Level 2**	**Level 3**	**Balance**
Assets:				
Cash equivalents:				
Money market funds	$ 22,751	$ —	$ —	$ 22,751
Marketable securities:				
U.S. government debt securities	35,304	—	—	35,304
Commercial paper	—	30,318	—	30,318
Corporate bonds	—	28,014	—	28,014
Total marketable securities	35,304	58,332	—	93,636
Total assets	$ 58,055	$ 58,332	$ —	$ 116,387

	December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Balance**
Assets:				
Cash equivalents:				
Money market funds	$ 30,557	$ —	$ —	$ 30,557
Marketable securities:				
U.S. government debt securities	3,979	—	—	3,979
Commercial paper	—	54,363	—	54,363
Corporate bonds	—	56,135	—	56,135
Total marketable securities	3,979	110,498	—	114,477
Total assets	$ 34,536	$ 110,498	$ —	$ 145,034

Summary of Significant Accounting Policies

Leases

The Company adopted ASU No. 2016-02, Leases (Topic 842) on January 1, 2022, as discussed below in the section titled "Recently Adopted Accounting Standards". Under Accounting Standards Codification (ASC) Topic 842, Leases, the Company determines if an arrangement is a lease at inception.

The Company leases office space in the U.S. and the U.K. under non-cancelable operating leases. Operating lease right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized based on the present value of lease payments over the lease term at the commencement date of the lease. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less any lease incentive received. The Company uses the rate implicit in the lease in determining the present value of lease payments and, if that rate is not readily determinable, the Company uses its incremental borrowing rate commensurate with the lease term based on the information available at the date of lease commencement. The incremental borrowing rate reflects the rate of interest that a lessee would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company does not have material short-term lease costs. Lease expense for lease payments is recognized on a straight-line basis over the lease term. For real estate leases, the Company does not separate lease and non-lease components. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company's non-lease components are primarily related to property taxes, insurance, and common area maintenance, which vary based on future outcomes, and are recognized as rent expense when incurred.

There have been no other significant changes in the Company's accounting policies during the nine months ended September 30, 2022.

Recently Adopted Accounting Pronouncements

On January 1, 2022, the Company adopted ASU No. 2016-02, Leases (Topic 842) using the modified retrospective transition method (which permitted the Company to not restate the comparative period presented) and elected the package of practical expedients to not reassess whether any expired or existing contracts are or contain leases, carry forward its historical lease classification and not reassess initial direct costs for existing leases. The Company elected to not separate non-lease components from the associated lease components and to not recognize ROU assets and lease liabilities for leases with a term of twelve months or less. Upon adoption of ASC 842, the Company recorded operating ROU assets of $0.9 million, operating lease liabilities of $0.9 million, and derecognized deferred rent and other lease liabilities of $12,000. There was no material impact to the Company's statements of operations and comprehensive loss upon adoption. Results and disclosures for the three and nine months ended September 30, 2022 are presented under ASC 842. Prior period amounts before January 1, 2022 have not been adjusted and continue to be reported in accordance with the Company's historical accounting under previous lease guidance, ASC 840: Leases (Topic 840).

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The standard changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today's "incurred loss" approach with an "expected loss" model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2022 and interim periods therein. The Company estimates that adoption will not have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The standard simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and also improves consistent application by clarifying and amending existing guidance. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. The Company estimates that adoption will not have a material impact on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting For Convertible Instruments and Contracts in an Entity's Own Equity. The standard simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The standard also simplifies the diluted net income per share calculation in certain areas. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2023, including interim periods therein. Early adoption is permitted for fiscal years beginning after December 15, 2020 and interim periods therein. The Company is currently evaluating the impact that this new guidance will have on its consolidated financial statements.

There were no other significant updates to the recently issued accounting standards other than as disclosed herewith for the nine months ended September 30, 2022. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

Reclassifications

The Company reclassified certain prior period balances on its condensed consolidated balance sheet, statements of operations and comprehensive loss, and statement of cash flows to conform to the current period presentation. These balances related to amounts incurred from related party transactions with Carnot Pharma, LLC. The services related to these transactions have been completed and the Company's services agreement with Carnot Pharma, LLC has been terminated. These reclassifications had no effect on total liabilities, loss from operations, or net cash used in operating activities.

2. Investments

Investments consists of available-for-sale securities as follows (in thousands):

	September 30, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:				
Commercial paper	$ 30,318	$ —	$ —	$ 30,318
U.S. government debt securities	35,531	—	(227)	35,304
Corporate bonds	21,367	—	(314)	21,053
Total short-term marketable securities	$ 87,216	$ —	$ (541)	$ 86,675
Long-term marketable securities:				
U.S. government debt securities	$ —	$ —	$ —	$ —
Corporate bonds	7,001	—	(40)	6,961
Total long-term marketable securities	$ 7,001	$ —	$ (40)	$ 6,961

	December 31, 2021			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:				
Commercial paper	$ 54,363	$ —	$ (1)	$ 54,362
Corporate bonds	35,231	—	(35)	35,196
Total short-term marketable securities	$ 89,594	$ —	$ (36)	$ 89,558
Long-term marketable securities:				
U.S. government debt securities	$ 3,996	$ —	$ (17)	$ 3,979
Corporate bonds	21,010	—	(70)	20,940
Total long-term marketable securities	$ 25,006	$ —	$ (87)	$ 24,919

All the commercial paper, U.S. government debt securities, and corporate bonds designated as short-term marketable securities have a contractual maturity date that is equal to or less than one year from the respective balance sheet date. Those that are designated as long-term marketable securities have a contractual maturity date that is more than one year from the respective balance sheet date.

Accrued interest receivable is excluded from the amortized cost and estimated fair value of the Company's marketable securities. Accrued interest receivable of $0.2 million and $0.5 million is presented separately within the prepaid expenses and other current assets line items in the Company's unaudited condensed consolidated balance sheet as of September 30, 2022 and December 31, 2021, respectively.

Investments in a continual unrealized loss position for less than 12 months consist of the following (in thousands):

	September 30, 2022	December 31, 2021
	Fair Value	Fair Value
Corporate bonds	$ 15,425	$ 60,114
U.S. government debt securities	26,508	—
Commercial paper	—	3,995
Total available-for-sale securities	$ 41,933	$ 64,109

Investments in a continual unrealized loss position for greater than 12 months consist of the following (in thousands):

	September 30, 2022	December 31, 2021
	Fair Value	Fair Value
Corporate bonds	$ 12,589	$ —
U.S. government debt securities	3,910	—
Total available-for-sale securities	$ 16,499	$ —

As of September 30, 2022, the Company did not intend, nor was the Company more likely than not to be required, to sell its available-for-sale investments before the recovery of the amortized cost basis, which may be maturity. Therefore, the Company believes it is more likely than not that its marketable securities in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. Based on the Company's assessment, it concluded that none of the available-for-sale investments held as of September 30, 2022 were considered to be impaired, as such, no impairment loss related to other-than-temporary declines in market value was recorded for the three and nine months ended September 30, 2022. There was no realized gain or loss on available-for-sale securities in the periods presented.

3. Certain Balance Sheet Accounts

Prepaid Expenses and Other Current Assets

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

	September 30, 2022	December 31, 2021
Recoverable research and development tax credits	$ 5,066	$ 6,523
Prepaid research and development expenses	3,033	2,906
Prepaid expenses	1,898	1,491
Other assets	555	852
Total prepaid expenses and other current assets	$ 10,552	$ 11,772

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued payroll expenses	$ 2,149	$ 2,220
Accrued research and development expenses	1,897	2,159
Other accrued expenses	388	248
Total accrued expenses	$ 4,434	$ 4,627

4. Redeemable Convertible Preferred Stock

Upon completion of the IPO on August 12, 2021, all of the Company's then outstanding shares of redeemable convertible preferred stock were converted into an aggregate of 15,345,279 shares of common stock. As of September 30, 2022 and December 31, 2021, the Company had no redeemable convertible preferred stock outstanding.

Prior to conversion, the holders of the Series A, Series A-1, and Series B redeemable convertible preferred stock had various rights, preferences, privileges, and restrictions, with respect to voting, dividends, liquidation, and conversion, which are further described in Note 5 *Redeemable Convertible Preferred Stock* to the consolidated financial statements in the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2022.

In March 2021, Series A-1 preferred stockholders exercised their tranche rights in connection with milestone achievements related to Phase 1 clinical trial results of ETX-155. As a result, the Company issued an additional 4,358,972 shares of Series A-1 redeemable convertible preferred shares for gross proceeds of $34.0 million. Upon exercise of the tranche rights, the Company reclassified the $12.3 million in preferred stock tranche liability to Series A-1 redeemable convertible preferred stock on the consolidated balance sheet.

In May 2021, the Company issued 3,846,150 shares of Series B redeemable convertible preferred stock for gross proceeds of $60.0 million.

As of September 30, 2022 and 2021, the Company had no dividends in arrears as all shares of redeemable convertible preferred stock converted to common stock upon the completion of the IPO.

5. Redeemable Convertible Preferred Stock Tranche Liability

Upon issuance in October 2020, the purchasers of Series A-1 redeemable convertible preferred stock also received tranche rights (Series A-1 Tranche Rights), which provided them the right to purchase additional shares of Series A-1 redeemable convertible preferred stock in an additional future tranche. This tranche was for the purchase of Series A-1 and was valued based upon the Company achieving certain future milestones and utilized a valuation model that reflected both potential outcomes of success or failure to meet the milestone.

The Series A-1 redeemable convertible preferred tranche liability was valued at $0.86 per share upon issuance. There was no change in value from the date of issuance and December 31, 2020.

The Company estimated the fair value of the Series A-1 Tranche Rights using a probability-weighted present value model that considered the probability of triggering the Series A-1 Tranche Rights through achievement of the clinical development milestones specified in the Series A-1 Purchase Agreement. These estimates were based, in part, on subjective assumptions. Changes to these assumptions could have had a significant impact on the reported fair value of the Series A-1 Tranche Rights.

The following reflects the significant quantitative inputs used in the valuation of the redeemable convertible preferred stock tranche liability:

	Series A-1 Tranche Call Option
Estimated fair value of redeemable convertible preferred stock	$6.94 - $11.10
Discount rate	0.10%
Dividend yield	0%
Expected term (years)	0.25 - 0.45
Expected volatility	N/A
Probability of milestone achievement	80% - 100%
Strike price	$ 7.80
Fair value of each tranche feature	$0.86 - $3.32

The Series A-1 redeemable convertible preferred tranche liability was settled on March 9, 2021 with the achievement of milestones set forth in the Series A-1 stock purchase agreement. The fair value of the liability was remeasured prior to settlement, resulting in the Company recognizing a loss in the condensed consolidated statement of operations and comprehensive loss of $11.7 million during the nine months ended September 30, 2021. Immediately thereafter, the balance of the redeemable convertible preferred stock tranche liability of $12.3 million was reclassified to Series A-1 redeemable convertible preferred stock.

A rollforward of the redeemable convertible preferred stock tranche liability is as follows (in thousands):

Balance at December 31, 2020	$ 551
Change in fair value	11,718
Settlement upon issuance of Series A-1 redeemable convertible preferred stock	(12,269)
Balance at September 30, 2021	$ —

6. Commitments and Contingencies

Facility Leases

The Company leases office space in the U.S. and U.K. under non-cancelable operating leases.

In May 2021, the Company entered into an agreement for office space in Cambridge, U.K. The term of this lease is for a period of 24 months, which commenced on July 1, 2021.

In November 2021, the Company entered into an agreement to lease approximately 5,000 square feet of office space in Bellevue, Washington. The term of this lease is for a period of 39 months, which commenced on November 1, 2021. The lease contains rent escalation clauses and an option to extend the term of the lease for an additional 3-year period at a market rate determined according to the lease. At the inception of the lease and as of September 30, 2022, the Company was not reasonably certain that it will exercise its option to extend the lease, therefore, the period covered by this option is not included within the lease term.

As of September 30, 2022, the remaining weighted-average lease term was 1.8 years and the weighted-average incremental borrowing rate used to determine the operating lease liability was 7.5%.

For each of the three months ended September 30, 2022 and 2021, the Company incurred $0.1 million in rent expense. For the nine months ended September 30, 2022 and 2021, the Company incurred $0.4 million and $0.1 million in rent expense, respectively.

As of September 30, 2022, the annual future minimum lease payments due under the Company's non-cancelable operating leases are as follows:

	Amount (In thousands)
2022 (remaining 3 months)	$ 112
2023	309
2024	172
2025	15
Total undiscounted lease payments	$ 608
Present value adjustment	(37)
Total operating lease liabilities	$ 571

Legal Proceedings

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

Indemnification

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

7. Stock-Based Compensation

2019 Plan

In 2019, the Company adopted the 2019 Equity Incentive Plan (the 2019 Plan). The 2019 Plan provides for the Company to grant qualified stock options, non-qualified stock options, and restricted stock awards to employees, non-employee directors and consultants of the Company under terms and provisions established by the Company's board of directors. Under the terms of the 2019 Plan, options are granted at an exercise price no less than fair value of the Company's common stock on the grant date, except in certain cases related to employees outside of the U.S. However, for any employee who is a 10% or greater stockholder, options are granted at an exercise price no less than 110% of the fair value of the Company's common stock on the grant date. Option awards granted typically have 10-year terms measured from the option grant date. However, if any employee is a 10% or greater stockholder, the awards have 5-year terms measured from the option grant date. While no shares are available for future issuance under the 2019 Plan, it continues to govern outstanding equity awards granted thereunder.

2021 Plan and ESPP

The compensation committee of the Company's board of directors adopted and the Company's stockholders approved the 2021 Equity Incentive Plan (2021 Plan) and the 2021 Employee Stock Purchase Plan (the ESPP), which became effective immediately prior to the effectiveness of the Company's IPO. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company's employees, officers, directors and consultants are eligible to receive awards under the 2021 Plan. Under the terms of the 2021 Plan, options are granted at an exercise price no less than fair value of the Company's common stock on the grant date, except in certain cases related to significant corporate transactions. Option awards granted typically have 10-year terms measured from the option grant date. As of September 30, 2022, the total number of shares authorized for issuance under the 2021 Plan was 3,887,174. In addition, the number of shares of common stock reserved for issuance under the 2021 Plan will automatically increase on January 1 of each year, beginning on January 1, 2022, and continuing through and including January 1, 2031, by 5% of the total number of shares of common stock outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by the Company's board of directors prior to the applicable January 1st.

The ESPP allows employees, including executive officers, to contribute up to 15% of their earnings, subject to certain limitations, for the purchase of the Company's common stock at a price per share equal to the lower of (a) 85% of the fair market value of a share of common stock on the first day of the offering period, or (b) 85% of the fair market value of a share of common stock on the last day of the offering period. As of September 30, 2022, there were 521,555 shares of common stock reserved for future issuance under the ESPP. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year or (2) a number of shares determined by the Company's board of directors. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP.

As of September 30, 2022, no shares have been granted or purchased under the ESPP.

Stock Options

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

The activity for stock options is as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contract Terms (in years)	Aggregate Intrinsic Values (in thousands)
Balance as of December 31, 2021	2,922,135	$ 3.62	9.14	$ 21,144
Options granted	1,673,932	7.80		
Options cancelled and forfeited	(62,646)	4.18		
Options exercised	—	—		—
Balance as of September 30, 2022	4,533,421	$ 5.16	8.71	$ 4,285
Vested and expected to vest, September 30, 2022[(1)]	4,488,421	$ 5.13	8.71	$ 4,285
Options exercisable as of September 30, 2022	1,499,959	$ 3.25	8.27	$ 2,338

[(1)] Excludes 45,000 stock options awards outstanding for the period ended September 30, 2022, subject to only performance conditions that have been assessed and deemed not probable.

The aggregate intrinsic value disclosed in the above table is based on the difference between the exercise price of stock options and the fair value of the Company's common stock as of the respective period-end dates. The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2022, was $5.31 per share.

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

- *Fair Value of Common Stock* — Prior to the completion of the Company's IPO, the fair value of the Company's common stock was determined by using straight-line interpolation between the value of common stock derived from valuations performed by independent third party specialists, further described in Note 2 to the consolidated financial statements *Summary of Significant Accounting Policies – Fair Value of Common Stock* in the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2022. After the completion of the Company's IPO, the fair value of each share of common stock is based on the closing price of the Company's common stock on the date of grant as reported on the Nasdaq Global Market.
- *Volatility* — The expected stock price volatilities are estimated based on the historical and implied volatilities of comparable publicly traded companies as the Company does not have sufficient history of trading its common stock.
- *Risk-free Interest Rate* — The risk-free interest rates are based on US Treasury yields in effect at the grant date for notes with comparable terms as the awards.
- *Expected Term* — The expected term represents the period that the Company's stock options are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).
- *Dividend Yield* — The expected dividend yield assumption is based on the Company's current expectations about its anticipated dividend policy.

The fair value of the Company's stock option awards was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions for the nine months ended September 30, 2022:

Expected term (in years)	5.50 - 6.50
Expected volatility	77.33% - 80.54%
Risk-free interest rate	1.69% - 3.03%
Expected dividend yield	0.00%

Restricted Stock

The Company has restricted stock awards with service conditions that vest 25% on the first anniversary of the grant date and monthly thereafter. The restricted stock awards are subject to repurchase by the Company at the original purchase price in the event that the award recipient's employment or relationship is terminated prior to the shares vesting.

In 2018, the Company granted restricted stock awards with performance conditions that vested upon the Company's initiation of a registrational clinical trial to study the efficacy of ETX-810. The probability of achieving performance conditions is assessed each reporting period. As of December 31, 2021, 21,750 of these awards were still outstanding, and the Company recognized no stock-based compensation expense relating to these awards, as the performance condition was assessed and deemed not probable. In January 2022, the Company's board of directors approved a modification to the vesting terms of these awards, such that the awards will vest in full on October 24, 2022. The incremental stock-based compensation expense related to the modification of these awards is $0.2 million, which is being recognized prospectively from the modification date through the vesting date.

The activity for restricted stock awards is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2021[(1)]	332,364	$ 7.30
Granted	—	—
Vested	(113,054)	7.95
Forfeited	—	—
Unvested at September 30, 2022	219,310	$ 7.46

[(1)] Includes 21,750 restricted stock awards granted in 2018 and still outstanding at December 31, 2021, subject to only performance conditions.

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expense	$ 657	$ 297	$ 1,872	$ 626
General and administrative expense	1,126	939	3,224	1,957
Total stock-based compensation expense	$ 1,783	$ 1,236	$ 5,096	$ 2,583

As of September 30, 2022, there was $16.1 million of total unrecognized compensation cost related to unvested stock options and unvested restricted stock awards granted and $1.6 million of unrecognized compensation cost related to unvested restricted stock awards granted, which is expected to be recognized over a weighted average period of 2.74 years and 2.53 years, respectively.

8. Net Loss Per Share Attributable to Common Stockholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (9,682)	$ (9,615)	$ (37,482)	$ (36,935)
Accretion of redeemable convertible preferred stock to redemption value and cumulative preferred stock dividends	—	(1,322)	—	(4,548)
Net loss attributable to common stockholders	(9,682)	(10,937)	(37,482)	(41,483)
Weighted-average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	26,336,029	15,585,611	26,290,868	7,554,300
Net loss per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (0.70)	$ (1.43)	$ (5.49)

All outstanding shares of redeemable convertible preferred stock were converted on a 1-for-1 basis to shares of common stock on August 12, 2021, the date of the Company's IPO (see Note 1). The cumulative preferred stock dividend was therefore eliminated upon conversion of the redeemable convertible preferred stock.

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

	Three and Nine Months Ended September 30,	
	2022	2021
Common stock options	4,533,421	2,737,315
Unvested restricted stock awards	219,310	348,639
Total potentially dilutive shares	4,752,731	3,085,954

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the SEC on March 7, 2022. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us" and "our" refer to Eliem Therapeutics, Inc. and its wholly owned subsidiary.

Forward-Looking Statements

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning in connection with any discussion of future operating or financial performance. These statements are only predictions.

All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. In evaluating these statements, you should specifically consider various factors, including the risks outlined under the caption "Risk Factors" set forth in Item 1A of Part II of this Quarterly Report on Form 10-Q, as well as those contained from time to time in our other filings with the SEC. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems. These disorders often occur when neurons are overly excited or inhibited, leading to an imbalance, and our focus is on restoring homeostasis. We are developing a pipeline of clinically differentiated product candidates focused on validated mechanisms of action with broad therapeutic potential to deliver improved therapeutics for patients with these disorders.

Our lead clinical-stage candidate is ETX-155, a novel $GABA_A$ receptor positive allosteric modulator ($GABA_A$ PAM) that is being developed for the treatment of major depressive disorder (MDD) and focal onset seizures (FOS), the most common type of seizure in people with epilepsy. In July 2022, following the observation of lower-than-expected drug exposure levels in the three subjects evaluated in a Phase 1b photosensitive epilepsy (PSE) trial, we initiated a Phase 1, single and repeat dose, clinical trial in healthy subjects to confirm the pharmacokinetic profile of ETX-155 in advance of a planned Phase 2a clinical trial in subjects with MDD. The drug exposure levels from the recently executed single dose part of the Phase 1 pharmacokinetic trial (N=42) were compared with the population pharmacokinetic model built with data from healthy subjects evaluated in the original, previously disclosed Phase 1 trials (N=70). Results demonstrated that at the 60-milligram single dose, there was no meaningful difference between exposures obtained with different batches, and that the low exposures observed in the Phase 1b PSE single dose trial are within the range of previously reported moderate variability. In addition, and upon extensive investigation, no irregularities or differences were observed with chemistry, manufacturing, and controls (CMC) associated with the drug product and the drug substance batches used in the PSE trial or with other newly produced drug substance and product.

We recently completed dosing in the Phase 1 pharmacokinetic trial. Given the encouraging overall clinical profile of the 60-milligram dose relative to the marginal additional exposure benefit of the 75-milligram dose observed in the trial, we have decided to use the 60-milligram dose in our planned Phase 2a MDD trial. We are positioned to initiate the Phase 2a MDD trial in the first quarter of 2023 and topline data would be expected in the second half of 2024.

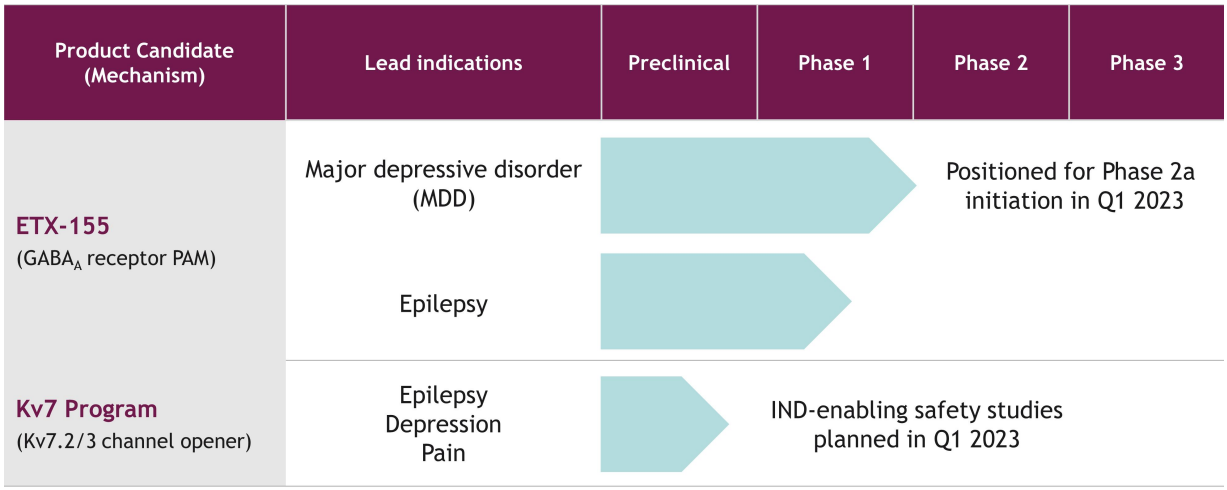
We have also determined we will not reinitiate the PSE proof-of-concept trial but will continue to pursue development of ETX-155 in FOS, given existing clinical validation of the $GABA_A$ PAM mechanism in this indication. To support Phase 2 studies in this indication, we are developing a new modified release formulation to maintain drug levels above a targeted threshold, and we will continue work on this new formulation in 2023.

Our preclinical stage program is a Kv7.2/3 channel opener. Our preclinical program targets the Kv7.2/3 potassium channel (Kv7), a target that has clinical validation in pain and epilepsy. We have filed foundational intellectual property claims on our novel Kv7 compounds. In addition, while pursuing further lead evaluation, we have initiated IND enabling studies and the scaling up of two pre-candidates. We expect to initiate IND-enabling safety studies in the first quarter of 2023, with Phase 1 studies planned to initiate in the first half of 2024. Our novel Kv7 compounds have demonstrated high potency and differentiated selectivity in electrophysiology assays, and in vivo anticonvulsant activity in the maximal electroshock seizure (MES) rat model.

We have discontinued early preclinical development of a novel, non-sedating anxiolytic for the potential treatment of GAD because none of the compounds investigated achieved the required profile.

Pipeline

Below is a summary of our wholly owned pipeline:



We have incurred significant operating losses since inception, as we have devoted substantially all of our resources to organizing and staffing our company, identifying potential product candidates, business planning, raising capital, undertaking research, executing preclinical studies and clinical development trials, and providing general and administrative support for business activities. We incurred net losses of $9.7 million and $9.6 million for the three months ended September 30, 2022 and 2021, respectively, and $37.5 million and $36.9 million for the nine months ended September 30, 2022 and 2021, respectively. We had an accumulated deficit of $113.1 million and $75.6 million as of September 30, 2022 and December 31, 2021, respectively.

Since our inception, we have funded our operations with an aggregate of $208.3 million in net proceeds from the sale and issuance of shares of our redeemable convertible preferred stock and our initial public offering of our common stock. We had cash, cash equivalents, and short- and long-term marketable securities of $129.6 million and $161.4 million as of September 30, 2022 and December 31, 2021, respectively. Based on our current operating plan, we estimate that our cash, cash equivalents and short- and long-term marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We anticipate that our expenses and operating losses will increase substantially over the foreseeable future. The expected increase in expenses will be largely driven by our ongoing activities as we:

- continue to develop and conduct clinical trials, including for ETX-155 for indications we are currently evaluating and any potential additional indications;

- initiate and continue research and development, including preclinical, clinical and discovery efforts for any future product candidates;
- seek regulatory approvals for ETX-155, or any other product candidates that successfully complete clinical development;
- add operational, financial and management information systems and personnel, including personnel to support our product candidate development and help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, manufacturing, quality control, scientific, commercial and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval; and
- add equipment and physical infrastructure to support our research and development and growing staff; acquire or in-license other product candidates and technologies.

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

We will require substantial additional funding to support our continuing operations and further the development of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or other strategic arrangements. To a lesser extent, we also expect to continue to rely on U.K. research and development tax credits and incentives for funding. Adequate funding may not be available when needed or on terms acceptable to us, or at all. If we are unable to raise additional capital as needed, we may have to significantly delay, scale back or discontinue development of our product candidates. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, resulting from increased volatility in the trading prices for shares in the biopharmaceutical industry, the ongoing pandemic, or otherwise. In addition, our ability to continue to benefit from research and development tax credits and incentives will depend on our ability to continue meet the applicable requirements for them. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

Impact of the COVID-19 Pandemic on Our Operations

We have been carefully monitoring the COVID-19 pandemic as it continues to progress and its potential impact on our business. As a result of COVID-19, we have taken precautionary measures in order to minimize the risk of the virus to our employees, such as allowing our workforce to work remotely. To date, we have been able to continue our key business activities and advance our clinical programs. We have experienced delays in availability and shipping of preclinical and clinical supplies and delays in vendor services caused by understaffing or illness. However, to date, these delays have not materially impacted our business. However, in the future, it is possible that delays such as these or other disruptions such as delays related to enrolling participants in our clinical trials could impact our clinical development timelines. While the broader implications of the COVID-19 pandemic on our results of operations and overall financial performance remain uncertain, it has, to date, not had a material adverse impact on our results of operations or our ability to raise funds to sustain operations. The economic effects of the pandemic and resulting societal changes are currently not predictable, and the future financial impacts could vary from those foreseen.

Components of Operating Results

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Our research and development expenses consist primarily of direct and indirect costs incurred in connection with our discovery efforts, preclinical studies, and clinical trial activities related to our pipeline, including our lead product candidate ETX-155 and our discontinued product candidate ETX-810.

Our direct research and development costs include:

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

Our indirect research and development costs include:

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

Total direct costs and indirect costs are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Direct costs	$ 3,158	$ 5,448	$ 20,682	$ 17,816
Indirect costs	2,175	2,295	6,211	3,232
Research and development tax credits	(1,075)	(1,754)	(5,606)	(4,605)
Total research and development expenses	$ 4,258	$ 5,989	$ 21,287	$ 16,443

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. We categorize costs by stage of development clinical or preclinical. Given our stage of development and the utilization of our resources across our various programs, we have not historically tracked our research and development costs by program. Research and development expenses are presented net of refundable research and development tax credits from the U.K. government.

Research and development costs by stage of development are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Clinical	$ 2,490	$ 4,631	$ 18,588	$ 13,080
Preclinical	2,843	3,112	8,305	7,968
Research and development tax credits	(1,075)	(1,754)	(5,606)	(4,605)
Total research and development expenses	$ 4,258	$ 5,989	$ 21,287	$ 16,443

Research and development activities are central to our business model. We expect our research and development expenses generally to increase as we advance our clinical development programs. The amount and timing of our research and development expenses may vary significantly based on factors such as:

- the number and scope of clinical studies needed for regulatory approval;
- the number and scope of preclinical and IND-enabling studies;
- the phases of development of our product candidates;
- the progress and results of our research and development activities;
- the discontinuation of any of our programs;
- the length of time required to enroll eligible subjects and initiate clinical trials;
- the number of subjects that participate in the clinical trials;

- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing of our product candidates;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the hiring and retention of research and development personnel;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights; and
- the extent to which we establish collaborations, strategic partnerships or other strategic arrangements and the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative

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

We expect that our general and administrative expenses will substantially increase for the foreseeable future as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally. We have also incurred and expect to incur increased expenses associated with operating as a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing, and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other Income (Expense)

Change in Fair Value of Redeemable Convertible Preferred Tranche Liability

Our redeemable convertible preferred stock tranche liability was accounted for at fair value at inception, with changes in the fair value recorded in earnings at each reporting period through settlement. Refer to Note 5 of the interim condensed consolidated financial statements.

Foreign Currency Loss

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

Other Income, net

Our other income consists of interest income, accretion and amortization related to our investments.

Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 4,258	$ 5,989	$ 21,287	$ 16,443
General and administrative	4,490	3,394	14,294	8,526
Total operating expenses	8,748	9,383	35,581	24,969
Loss from operations	(8,748)	(9,383)	(35,581)	(24,969)
Other income (expense):				
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	—	(11,718)
Foreign currency loss	(1,317)	(252)	(2,516)	(268)
Other income, net	383	20	615	20
Total other income (expense)	(934)	(232)	(1,901)	(11,966)
Net loss	$ (9,682)	$ (9,615)	$ (37,482)	$ (36,935)

Comparison of the Three Months Ended September 30, 2022 and September 30, 2021

Operating Expenses

The following table sets forth our operating expenses (dollars in thousands):

	Three Months Ended September 30,		Change	
	2022	2021	$	%
Research and development	$ 4,258	$ 5,989	$ (1,731)	(28.9)%
General and administrative	$ 4,490	$ 3,394	$ 1,096	32.3 %

Research and Development

Research and development expenses decreased 28.9% from $6.0 million for the three months ended September 30, 2021 to $4.3 million for the three months ended September 30, 2022.

The decrease was driven by a reduction in clinical and preclinical costs of $3.3 million, primarily due to the discontinuation of ETX-810 in August 2022 and the postponement of initiating a Phase 2a clinical trials in ETX-155, as well a reversal of $1.5 million of clinical expenses due to actual results differing from prior estimates. The decrease was partially offset by an increase of $0.9 million in personnel-related expenses from increased headcount and stock-based compensation and a $0.7 million decrease in the refundable research and development tax credits from the U.K. generated due to the reduction in research and development activities.

Research and development expenses are expected to increase as our programs advance into later stages of clinical development where clinical studies may have increased numbers of subjects, longer duration and more substantial data collection and analysis.

General and Administrative

General and administrative expenses increased 32.3% from $3.4 million for the three months ended September 30, 2021 to $4.5 million for the three months ended September 30, 2022. The increase in general and administrative expenses is primarily due to a $0.6 million increase in personnel-related expenses from increased headcount and stock-based compensation, a $0.3 million increase in other general and administrative costs that included insurance costs, and an $0.2 million increase in consulting and legal fees.

Other Income (Expense)

The following table sets forth our other income (expense) (dollars in thousands):

	Three Months Ended September 30,		Change	
	2022	2021	$	%
Foreign currency loss	$ (1,317)	$ (252)	$ (1,065)	422.6%
Other income, net	$ 383	$ 20	$ 363	1,815.0%

Foreign Currency Loss

Foreign currency loss increased from a $0.3 million loss for the three months ended September 30, 2021 to a $1.3 million loss for the three months ended September 30, 2022. The increase was driven by unfavorable changes in foreign currency exchange rates between the British Pound and the U.S. Dollar that were more significant in the current period. These changes affect the remeasurement of our British Pound denominated monetary assets and liabilities, primarily our recoverable research and development tax credits.

Other Income, net

Other income, net increased from $20,000 for the three months ended September 30, 2021 to $0.4 million for the three months ended September 30, 2022, which was driven by an increase in interest income. The increase was due to higher rates of return on our investments as a result of rising interest rates in the current period.

Comparison of the Nine Months Ended September 30, 2022 and September 30, 2021

Operating Expenses

The following table sets forth our operating expenses (dollars in thousands):

	Nine Months Ended September 30,		Change	
	2022	2021	$	%
Research and development	$ 21,287	$ 16,443	$ 4,844	29.5%
General and administrative	$ 14,294	$ 8,526	$ 5,768	67.7%

Research and Development

Research and development expenses increased 29.5% from $16.4 million for the nine months ended September 30, 2021 to $21.3 million for the nine months ended September 30, 2022.

This increase was driven by a $3.0 million increase in clinical and preclinical expenses associated with Phase 1 and Phase 2 clinical trials of ETX-155 and our discontinued product candidate ETX-810 and a $2.8 million increase in personnel-related expenses from increased headcount and stock-based compensation. The increase was partially offset by a $1.0 million increase in the refundable research and development tax credits from the U.K. generated from the increased research and development activities.

Research and development expenses are expected to increase as our programs advance into later stages of clinical development where clinical studies may have increased numbers of subjects, longer duration and more substantial data collection and analysis.

General and Administrative

General and administrative expenses increased 67.7% from $8.5 million for the nine months ended September 30, 2021 to $14.3 million for the nine months ended September 30, 2022. The increase in general and administrative expenses is primarily due to a $2.9 million increase in personnel-related expenses from increased headcount and stock-based compensation, a $1.8 million increase in other general and administrative expenses that included consulting and legal fees, and an increase of $1.1 million in insurance costs.

Other Income (Expense)

The following table sets forth our other income (expense) (dollars in thousands):

	Nine Months Ended September 30,		Change	
	2022	2021	$	%
Change in fair value of redeemable convertible preferred stock tranche liability	$ —	$ (11,718)	$ 11,718	(100.0)%
Foreign currency loss	$ (2,516)	$ (268)	$ (2,248)	838.8%
Other income, net	$ 615	$ 20	$ 595	2,975.0%

Change in fair value of redeemable convertible preferred stock tranche liability

For the nine months ended September 30, 2021, we recognized an $11.7 million charge from the settlement of our Series A-1 preferred stock tranche liability immediately prior to settlement.

Foreign Currency Loss

Foreign currency loss increased from a $0.3 million loss for the nine months ended September 30, 2021 to a $2.5 million loss for the nine months ended September 30, 2022. The increase was driven by unfavorable changes in foreign currency exchange rates between the British Pound and the U.S. Dollar that were more significant in the current period. These changes affect the remeasurement of our British Pound denominated monetary assets and liabilities, primarily our recoverable research and development tax credits.

Other Income, net

Other income, net increased from $20,000 for the nine months ended September 30, 2021 to $0.6 million for the nine months ended September 30, 2022, which was driven by an increase in interest income. The increase was due to higher rates of return on our investments as a result of rising interest rates in the current period.

Liquidity and Capital Resources

Sources of Liquidity

We primarily generate cash and cash equivalents from the sale of our equity securities, including common stock and redeemable convertible preferred stock, and to a lesser extent from cash received pursuant to U.K. research and development tax credits and incentives. From our inception to September 30, 2022, we raised aggregate proceeds of $208.3 million from the issuance of shares of our redeemable convertible preferred stock and from our initial public offering of our common stock. We have not generated any revenue from product sales or otherwise. We have incurred net losses from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of September 30, 2022 and December 31, 2021, we had cash, cash equivalents, and short- and long-term marketable securities of $129.6 million and $161.4 million and an accumulated deficit of $113.1 million and $75.6 million, respectively.

Funding Requirements

We have experienced recurring net losses since inception. Our transition to profitability is dependent upon the successful development, approval and commercialization of our product candidates and achieving a level of revenue adequate to support our cost structure. We do not expect to achieve such revenue and expect to continue to incur losses for the foreseeable future. We believe our cash, cash equivalents, and short- and long-term marketable securities of $129.6 million as of September 30, 2022 will be sufficient to meet our working capital and capital expenditure needs for at least the next twelve months.

We expect that our research and development and general and administrative expenses will increase as our clinical development programs advance. As a result, we will need significant additional capital to fund our operations, which we may obtain through one or more equity offerings, debt financings or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amount of increased capital we will need to raise to support our operations and the outlays and operating expenditures necessary to complete the development of our product candidates and build additional manufacturing capacity, and we may use our available capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the progress of our current and future product candidates through preclinical and clinical development;
- potential delays in our preclinical studies and clinical trials, whether current or planned;
- continuing our research and discovery activities;
- initiating and conducting additional preclinical, clinical, or other studies for our product candidates;
- changing or adding additional contract manufacturers or suppliers;
- seeking regulatory approvals and marketing authorizations for our product candidates;
- establishing sales, marketing, and distribution infrastructure to commercialize any products for which we obtain approval;
- acquiring or in-licensing product candidates, intellectual property and technologies;
- making milestone, royalty, or other payments due under any current or future collaboration or license agreements;
- obtaining, maintaining, expanding, protecting, and enforcing our intellectual property portfolio;
- attracting, hiring and retaining qualified personnel;
- potential delays or other issues related to our operations;
- meeting the requirements and demands of being a public company;
- defending against any product liability claims or other lawsuits related to our products; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

We believe that our existing cash, cash equivalents and short- and long-term marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2025. We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, in which case, we would be required to obtain additional financing sooner than currently projected, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we are unable 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 or delay our efforts to expand our product pipeline. We may also be required to sell or license to other parties' rights to develop or commercialize our product candidates that we would prefer to retain.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	**2021**
Net cash used in operating activities	$ (28,920)	$ (28,188)
Net cash provided by investing activities	20,162	(106,919)
Net cash provided by financing activities	—	177,194

Operating activities

For the nine months ended September 30, 2022, net cash used in operating activities was $28.9 million. This consisted primarily of net loss of $37.5 million, which was partially offset by changes in our operating assets and liabilities that resulted in a net increase of $0.7 million, primarily related to research and development activities, and non-cash charges of $7.9 million that included stock-based compensation of $5.1 million and a foreign currency loss of $2.2 million resulting from remeasurement.

For the nine months ended September 30, 2021, net cash used in operating activities was $28.2 million. This consisted primarily of net loss of $36.9 million and an increase in our operating assets and liabilities of $5.4 million, primarily related to research and development activities, which was partially offset by the non-cash charges for changes in the fair value of the redeemable convertible preferred stock tranche liability of $11.7 million and stock-based compensation of $2.6 million.

Investing activities

For the nine months ended September 30, 2022, net cash provided by investing activities was $20.2 million. This consisted of $101.4 million of proceeds received from maturities of investments in marketable securities, partially offset by purchases of $81.2 million of investments in marketable securities.

Financing activities

For the nine months ended September 30, 2021, net cash provided by financing activities was $177.2 million, primarily attributable to the proceeds from the issuance of our Series A-1 and Series B redeemable convertible preferred stock, net of issuance costs, and the proceeds from the issuance of our common stock in our initial public offering, net of issuance costs.

Contractual Commitments and Obligations

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

Off Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2022 and December 31, 2021.

Critical Accounting Policies and Estimates

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

A summary of our critical accounting policies is presented in our audited financial statements and notes thereto as of and for the year ended December 31, 2021 included in our Annual Report on Form 10-K filed with the SEC on March 7, 2022. There were no material changes to our critical accounting policies during the nine months ended September 30, 2022.

Recent Accounting Pronouncements

See Note 1 in our interim condensed consolidated financial statements included herein and see Note 2 to our annual consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on March 7, 2022.

Emerging Growth Company Status

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

As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will remain an emerging growth company under the JOBS Act until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of $1.24 billion or more, (ii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years, (iii) the date on which we are deemed a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, or (iv) December 31, 2026.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

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

Based on our evaluation, the Chief Executive Officer and Chief Financial Officer, have concluded that the Company's disclosure controls and procedures (as such term is defined in Rule(s) 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were not effective as of September 30, 2022 because of the material weaknesses in our internal control over financial reporting described below.

Material Weaknesses in Internal Control Over Financial Reporting

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

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

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

- 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 consolidated financial statements. Specifically, we did not design and maintain (a) 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, (b) 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, (c) computer operations controls to ensure that critical batch jobs are monitored, and data backups are authorized and monitored, and (d) 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 a misstatement to the consolidated 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.

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

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

Remediation Efforts to Address Material Weaknesses

We have implemented, and are continuing to implement, measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to our material weaknesses. We have hired qualified personnel with appropriate expertise to perform specific functions and ensure adequate segregation of key duties and responsibilities. We continue to design and implement improved policies, processes and internal controls, including senior management review and audit committee oversight. Further, we have implemented new financial systems to improve segregation of duties and controls and reliability of system generated data.

The actions that have been taken are subject to continued review, implementation and testing by management as well as oversight by the audit committee of our board of directors. While we have implemented a variety of steps to remediate these weaknesses, we cannot assure you that we will be able to fully remediate them, which could impair our ability to accurately and timely meet our public company reporting requirements.

Changes in Internal Control over Financial Reporting

Other than in connection with the implementation of the remedial measures described above, there have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter to which this Report relates that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

RISK FACTORS

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

Risk Factor Summary

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

- We have incurred significant losses since our inception, anticipate that we will incur substantial losses for the foreseeable future, and may never achieve or maintain profitability. We had an accumulated deficit of $113.1 million and $75.6 million as of September 30, 2022 and December 31, 2021, respectively.
- We expect to rely on capital markets, and to a lesser extent, U.K. research and development tax credits and incentives, for additional funding to conduct our future clinical trials and to complete development and commercialization of our product candidates. If we are unable to access capital when needed, we would be forced to delay, reduce or eliminate our clinical development programs or commercialization efforts.
- We have never generated any revenue from product sales, and we may never generate revenue or be profitable.
- Our business substantially depends upon the successful development, regulatory approval and commercialization of ETX-155.
- Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.
- We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.
- We face significant competition from other pharmaceutical and biotechnology companies and other research organizations and our operating results will suffer if we fail to compete effectively.
- We rely, and expect to continue to rely, on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements.
- We rely, and expect to continue to rely, on third parties to manufacture our clinical and ultimately commercial product supply. Those third parties may not perform satisfactorily, including by failing to meet product specifications, required demand or cost-efficient scale levels.
- If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Risks Related to our Financial Position and Need for Additional Capital

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

We are a clinical-stage biotechnology company with a limited operating history. Our efforts are focused primarily on developing our product candidates, including our lead clinical-stage candidate ETX-155 and our novel Kv7 compounds. Since inception, we have incurred significant operating losses. Our net losses were $47.5 million, $36.9 million and $37.5 million for the year ended December 31, 2021 and the nine months ended September 30, 2021 and September 30, 2022, respectively. We had an accumulated deficit of $113.1 million and $75.6 million as of September 30, 2022 and December 31, 2021, respectively. To date, we have not received regulatory approvals for any of our product candidates or generated any revenue from the sale of products, and we do not expect to generate any revenue in the foreseeable future. We expect to continue to incur substantial expenses and operating losses over the next several years as we continue to develop our current and future product candidates. As a result, we expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- continue to develop and conduct clinical trials, including for ETX-155 for indications we are currently evaluating and any potential additional indications;
- initiate and continue research and development, including preclinical, clinical and discovery efforts for any future product candidates;
- seek regulatory approvals for ETX-155, or any other product candidates that successfully complete clinical development;
- add operational, financial and management information systems and personnel, including personnel to support our product candidate development and help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, manufacturing, quality control, scientific, commercial and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval; and
- add equipment and physical infrastructure to support our research and development and growing staff; acquire or in-license other product candidates and technologies.

We expect to rely on capital markets, and to a lesser extent, U.K. research and development tax credits and incentives, for additional funding to conduct our future clinical trials and to complete development and commercialization of our product candidates. If we are unable to access capital when needed, we would be forced to delay, reduce or eliminate our clinical development programs or commercialization efforts.

We had cash, cash equivalents, and short- and long-term marketable securities of $161.4 million and $129.6 million at December 31, 2021 and September 30, 2022, respectively.

Based upon our current operating plan and assumptions, we believe that our existing cash, cash equivalents and short- and long-term marketable securities will be sufficient to fund our operations into 2025. However, we will need additional capital to complete the clinical development of our product candidates and to commercialize any approved products. Our estimates of the sufficiency of our cash, cash equivalents and short- and long-term marketable securities are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

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

- the scope, progress, results and costs of researching and developing ETX-155 for indications we are currently evaluating and potential additional indications, as well as our preclinical product candidates and other future product candidates we may develop;

- the timing and uncertainty of, and the costs involved in, obtaining marketing approvals for ETX-155 for indications we are currently evaluating and potential additional indications and our preclinical product candidates and other future product candidates we may develop and pursue;
- the number of future product candidates that we may pursue and their development requirements;
- the number of jurisdictions in which we plan to seek regulatory approvals;
- if approved, the costs of commercialization activities for ETX-155 for any approved indications or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of ETX-155 for any approved indications or any other product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development, establish or increase our office space and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims;
- any product liability lawsuits related to our products;
- the ongoing costs of operating as a public company; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Our ability to raise additional capital may be adversely impacted by disruptions to, or continuing volatility in, the credit and financial markets in the United States and worldwide, including increased volatility in the trading prices for shares of public companies in the biopharmaceutical sector, the impact of ongoing COVID-19 pandemic, actual and perceived changes in interest rates and economic inflation, or otherwise. We also rely on U.K. research and development tax credits and incentives for funding, and our ability to continue to benefit from such credits and incentives will depend on our ability to continue meet the applicable requirements for them. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

We are in the early stages of clinical drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. For example, in our Phase 2a clinical trials completed earlier this year investigating ETX-810 for the treatment of diabetic peripheral neuropathic pain (DPNP) and lumbosacral radicular pain (LSRP), ETX-810 did not achieve statistically significant separation from placebo on either trial's primary endpoint, and as a result, we have discontinued further development of ETX-810. In addition, interim results from our Phase 1b study evaluating ETX-155 in PSE were inconclusive, with an analysis of drug exposures in the study participants indicating drug levels that were significantly lower than expected based on the pharmacokinetic profile observed in earlier Phase 1 trials of ETX-155 in healthy subjects. As a result, in April 2022 we elected to delay advancing ETX-155 into Phase 2a depression trials in order to determine the root cause of this lower-than-expected exposure. Upon a comprehensive investigation, no irregularities or differences were observed with CMC associated with the drug product and the drug substance batches used in the PSE trial or with other newly produced drug substance and product. We also initiated a Phase 1, single and repeat dose, clinical trial in healthy subjects to confirm the pharmacokinetic profile of ETX-155 in advance of a planned Phase 2a clinical trial in subjects with MDD. The drug exposure levels from the recently executed single dose part of the Phase 1 pharmacokinetic trial (N=42) were compared with the population pharmacokinetic model built with data from healthy subjects evaluated in the original, previously disclosed Phase 1 trials (N=70). Results demonstrated that at the 60-milligram dose, there was no meaningful difference between exposures obtained with different batches, and that the low exposures observed in the Phase 1b PSE single dose trial are within the range of previously reported moderate variability. We are positioned to initiate the Phase 2a MDD trial in the first quarter of 2023 using the 60-milligram dose of ETX-155. Additional unexpected results or events could cause further delays in, or changes to, the ETX-155 development program and potentially lead us to discontinue further development of the program. We have determined not to reinitiate the PSE trial and have elected to indefinitely postpone our previously planned Phase 2a clinical trial of ETX-155 in perimenopausal depression (PMD). We have not initiated clinical trials for any of our other current research programs.

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

We have never generated any revenue from product sales and we may never generate revenue or be profitable.

We have no products approved for commercial sale. To obtain revenues from the sales of our product candidates that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing therapies with significant commercial success. Our ability to generate revenue and achieve profitability depends on many factors, including:

- successfully completing preclinical and clinical development of our product candidates;
- assessing and/or developing new product candidates or potential new indications for our current product candidates;
- developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and commercial demand for our product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development;
- launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by establishing a sales, marketing and distribution infrastructure or collaborating with a partner;
- negotiating and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
- satisfying any post-marketing requirements and obtaining reimbursement for its products from private insurance or government payors;
- obtaining market acceptance of our product candidates as viable treatment options;
- building out new facilities or expanding existing facilities to support our ongoing development activity;
- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies or clinical trials in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, absent our entering into a collaboration or partnership agreement, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

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

Our business substantially depends upon the successful development of ETX-155. If we are unable to obtain regulatory approval for, and successfully commercialize, ETX-155, our business will be harmed.

We currently have no products approved for sale and are investing the majority of our efforts and financial resources in the development of our lead product candidate ETX-155 for the treatment of MDD and epilepsy. Successful continued development and potential regulatory approval of ETX-155 for indications we are currently evaluating and potential additional indications is critical to the future success of our business. We will need to raise sufficient funds for, and successfully enroll and complete, our ETX-155 clinical development program.

Before we can generate any revenue from sales of ETX-155 or any of our other programs, these programs must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates or commercialization of any products.

We have experienced, and may in the future experience, setbacks that could delay or prevent regulatory approval of our product candidates or our ability to commercialize any products, including:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, such as the failure of ETX-810 to achieve its primary endpoint in either of our Phase 2a trials in subjects with DPNP and LSRP, respectively, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program or an indication;
- product-related side effects experienced by subjects in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- delays in submitting investigational new drug applications (INDs) in the United States or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators or institutional review boards to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- if the FDA or comparable foreign authorities do not accept the earlier preclinical and clinical trial work, then we may need to conduct additional preclinical studies or clinical trials beyond that which we currently have planned and significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials; delays in contracting with clinical sites or enrolling subjects in clinical trials, including due to the COVID-19 pandemic; delays or interruptions in the supply of materials necessary for the conduct of our clinical trials;
- regulators or institutional review boards (IRBs) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (CROs) which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors for preclinical studies or clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or take actions that could cause clinical sites or clinical investigators to drop out of the trial, which may require that we add new clinical trial sites or investigators;

- due to the impact of the COVID-19 pandemic or other events beyond our control, we may experience some delays and interruptions to our preclinical studies and clinical trials, we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- greater than anticipated clinical trial costs, including as a result of delays or interruptions that could increase the overall costs to finish our clinical trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards (DSMBs), or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- inability to make improvements in formulations of our product candidates that may be desirable for late-stage clinical development and commercialization;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial, including because the FDA has not reviewed our preclinical or clinical data, to date, having been developed outside the United States;
- inability to compete with other therapies;
- poor efficacy of our product candidates during clinical trials, such as the failure of ETX-810 to meet its primary endpoint in either of our Phase 2a trials in DPNP and LSRP, respectively;
- unfavorable FDA or other regulatory agency inspection and review of clinical trial sites or manufacturing facilities;
- failure to obtain product labeling for indications we are evaluating, such as subgroups of patients with depressive disorders;
- unfavorable product labeling associated with any product approvals and any requirements for a Risk Evaluation and Mitigation Strategy (REMS) that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of an individual product outweigh its risks;
- unfavorable acceptance of our clinical trial data by the patient or medical communities or third-party payors;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays related to the impact or the spread of COVID-19 or other pandemics, including the impact of COVID-19 on the FDA's, or any similar foreign regulatory agency's, ability to continue its normal operations;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process.

For example, in both of our Phase 2a clinical trials in DPNP and LSRP, ETX-810 did not achieve statistically significant separation from placebo on the trial's primary endpoint. Based on these results, we discontinued further development of ETX-810. In addition, in April 2022, we announced that interim results from the first three subjects in our Phase 1b photosensitive epilepsy (PSE) single dose trial were inconclusive, leading us to perform a root cause analysis. As a result, we elected to delay enrollment of the Phase 2a clinical trial of ETX-155 in MDD, pending investigation of such root cause analysis and the results of a further Phase 1 pharmacokinetic trial to determine the required dose to achieve adequate exposure levels. We have completed the root cause analysis and dosing in the Phase 1 pharmacokinetic trial and, based on the results of these activities, are positioned to initiate the Phase 2a MDD trial in the first quarter of 2023.

Furthermore, even if we do receive regulatory approval for ETX-155 or any other potential product candidate we may develop for any indication, any such approval may be subject to limitations on the indications or uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure that we will successfully develop or commercialize ETX-155 or any other potential product candidate we may develop for any indication. If we or any of our future collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize ETX-155 for indications we are currently evaluating or potential additional indications, or any other potential product candidate we may develop, we may not be able to generate sufficient revenue to continue our business. In addition, our failure to demonstrate positive results in our clinical trials in any indication for which we are developing ETX-155 could adversely affect our development efforts for ETX-155 in other indications.

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

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans to the satisfaction of FDA. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, in the United States, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds to thousands of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signs of activity in earlier preclinical studies or clinical trials, as demonstrated by the failure of ETX-810 to achieve statistically significant separation from placebo on the primary endpoint in either of our Phase 2a clinical trials in DPNP and LSRP, respectively. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, preclinical models evaluating product candidates for pain are notoriously unreliable and, as such, the therapies face substantial translational risk. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or emergence of unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of ETX-155 or any of our other product candidates. The commencement and rate of completion of preclinical studies and clinical trials may be delayed by many factors, including:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials (e.g., we based our therapeutic hypothesis for ETX-810 on studies conducted in the academic setting and the results from the academic studies were not replicated in our Phase 2a clinical trials of ETX-810);
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements (GCPs) or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a third-party contract development and manufacturing organization (CDMO) and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials. Any inability to successfully initiate or complete preclinical studies or clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

Further, our current and planned clinical trials do or will contain endpoints that require subjective assessments and subject us to a substantial risk of "placebo effect" which is a well-known risk in clinical trials evaluating therapeutics for pain as well as depression. While a product candidate may show clinical activity or therapeutic benefit, a high placebo effect in a clinical trial will make it difficult to ascertain that benefit or to show statistically significant effect of the product candidate as compared to the control arm and may ultimately cause a clinical trial to fail. For example, in both of our Phase 2a clinical trials in DPNP and LSRP, respectively, ETX-810 did not achieve statistically significant separation from placebo on the trial's primary endpoint.

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

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

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

Successful completion of clinical trials is a prerequisite to submitting a marketing application to foreign regulatory authorities or the FDA, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, or regulators may be unwilling to accept preclinical or clinical data obtained in foreign jurisdictions, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could harm our business.

Cross-trial comparisons are not reliable predictors of the relative efficacy of our product candidates against comparators.

We have not conducted head-to-head clinical trials to compare our product candidates with competing products. There are risks associated with comparing the results of our clinical trials with results from other independent studies and trials, as cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of our product candidates compared to other product candidates that may be approved or that are in development. Moreover, unless we conduct head-to-head comparative studies, we will not be able to make any claims of superiority even if our products are approved.

Additionally, even though our product candidates are designed to address the same indications as existing therapies, we have not conducted head-to-head clinical trials comparing our product candidates with such existing drugs and therapies. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical and preclinical stage biotechnology companies such as ours.

Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.

As a result of the COVID-19 pandemic, or similar pandemics, and related public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;

- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

In addition, our business could be materially adversely affected by other business disruptions to us or our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CDMOs and other contractors, consultants and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, geopolitical developments, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. For example, the outbreak of war between Russia and Ukraine and the resulting sanctions by U.S. and European governments, together with any additional future sanctions or other actions by them, could have a larger impact that expands into other markets where we do business. Further, the conflict and resulting sanctions or other actions may adversely impact macroeconomic conditions and increase volatility in and affect our ability to access capital markets and external financing sources, as well as have other unforeseen adverse impacts on our business. The occurrence of any of these business disruptions could materially adversely affect our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

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

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

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

Undesirable side effects caused by ETX-155 or any other current or future product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In addition, many compounds that have initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. For example, our lead preclinical program is a Kv7.2/3 potassium channel opener. This mechanism has been validated through regulatory approvals of multiple first generation Kv7.2/3 openers for the treatment of epilepsy and pain. These molecules showed efficacy but subsequently had to be withdrawn from the market due to significant safety issues. There is no assurance that, if we are able to move our preclinical program forward, we will be able to avoid similar safety problems. Additionally, the composition of our product candidates or learnings in preclinical studies or clinical trials may result in contraindications for any product candidates for which we may obtain regulatory approval.

If unacceptable side effects arise in the development of our product candidates, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or IRBs, DSMBs or independent ethics committees at the institutions in which our trials are conducted could suspend or terminate our trials for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially adversely affect our business, financial condition and prospects.

Treatment-emergent side effects that are deemed to be drug-related could also result in potential product liability claims. Undesirable side effects in one of our clinical trials (or in a clinical trial of a competitor's product candidate with a similar mechanism of action) for our product candidates in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of our product candidates in other indications. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require the addition of labeling statements, "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way such product candidates are distributed or administered, or change the labeling of the product candidates;
- the FDA may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools, and regulatory authorities in other jurisdictions may require comparable risk mitigation plans;
- we may be subject to regulatory investigations and government enforcement actions;
- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

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

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

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- the availability and efficacy of approved drugs for the disease under investigation;
- perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- delays in or temporary suspension of the enrollment of patients in our planned clinical trials due to the COVID-19 pandemic;
- the impacts of the COVID-19 pandemic on clinical trial sites, personnel and patient travel;
- our ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine.

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

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

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

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 preliminary or topline data from our preclinical studies and clinical trials, 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 topline or preliminary results that we report may differ from future results of the same studies, 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.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim 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. 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, operating results, prospects or financial condition.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may fail to expend our limited resources on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We currently have one lead clinical-stage candidate, ETX-155. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively advancing product candidates and ensuring replenishment of our portfolio.

Due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities; for example, earlier in 2022 we discontinued further development of ETX-810, which did not achieve statistically significant separation from placebo on the primary endpoint in either of two Phase 2a clinical trials. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the biotechnology industry, in particular for disorders of the peripheral and central nervous systems, our business may be harmed. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of additional product candidates. We currently have novel preclinical candidates in the research, discovery, screening and preclinical stages of development, with two programs currently in advanced discovery stage. Identifying, developing, obtaining regulatory approval and commercializing additional product candidates for the treatment of disorders of the peripheral and central nervous systems will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited.

One of the core elements of our strategy is to develop our existing products in multiple indications, also referred to as label expansion. Even if we are successful in developing a product in one indication this does not guarantee that it will be successful in other indications or that we will be able to obtain approval in other patient populations or diseases.

Label expansion is one of the core elements of our strategy. If our current and planned trials are successful, we intend to evaluate additional potential indications for ETX-155. These include a wide-range of compelling opportunities in both psychiatry and neurology, including potentially other subgroups of depression disorders, generalized anxiety disorder, and bipolar disorder. Even if we are successful in developing a product in one indication does not guarantee that it will be successful in other indications or that we will be able to obtain approval in other patient populations or diseases.

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

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

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

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

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

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

Risks Related to Legal and Regulatory Compliance

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

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act (ACA), was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how any additional challenges or future healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments including the Infrastructure Investment and Jobs Act, will stay in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless Congress takes additional action. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Biden administration used several means to propose or implement drug pricing reform, including through executive orders and policy initiatives. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare Part B and Part D that have been approved by the FDA for at least 7 years for drugs, and 11 years for biologics; and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. Drugs and biologics are selected for negotiation two years prior to the negotiated price taking effect. Therefore, small-molecule drug manufacturers and biologic manufacturers are afforded at least 9 years and 13 years, respectively, before they must sell their product at the negotiated price under Medicare Part B and Part D, as applicable. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs for pharmaceutical and biological products. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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

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

Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Although we do not currently have any products on the market, our operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations. These laws may impact, among other things, our current business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

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

- the U.S. federal civil and criminal false claims laws, including the False Claims Act (FCA), which can be enforced through "qui tam" or "whistleblower" actions, and civil monetary penalty law, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing such an obligation to pay money to the federal government. In addition, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;
- the U.S. federal Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services (CMS) an agency within the HHS under the Open Payments Program, information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;
- U.S. federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

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

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. These privacy laws include, without limitation, the following laws and regulations: Section 5 of the Federal Trade Commission Act, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) (which imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information) and the California Consumer Privacy Act of 2018 (CCPA) (which imposes specific requirements on covered businesses relating to personal data practices). If we are or were to become subject to these laws and/or new or amended data privacy laws, the risk of enforcement actions against us could increase because we may be subject to obligations under applicable regulatory frameworks and the number of individuals or entities that could initiate actions against us may increase (including individuals via a private right of action), in addition to further complicating our compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the equivalent law in the United Kingdom (UK GDPR) impose strict requirements for processing the personal data of individuals, including sensitive data that we may process such as health data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Similar processing penalties and fines exist under the UK GDPR and the uncertainty of data protection laws in the U.K. following Brexit has increased the complexity of our compliance efforts. Further, individuals may initiate litigation related to our processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR, UK GDPR, and laws in Switzerland generally restrict the transfer of personal data to countries such as the United States that do not provide an adequate level of personal data protection. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the European Economic Area (EEA) to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal data outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA. Similar restrictions and transfer mechanisms exist under the UK GDPR. Any of these restrictions and obligations could increase the cost and complexity of doing business in foreign jurisdictions. If we cannot implement valid compliance mechanisms for cross-border personal data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe, the U.K. and elsewhere; limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws; or requiring us to increase our personal data processing capabilities and infrastructure in Europe and/or elsewhere at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparation for and compliance with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the third-party providers (such as research institutions) who share this information with us, may contractually limit our ability to use and disclose the information.

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

Further, the vote in the U.K. in favor of exiting the EU, referred to as Brexit, has created uncertainty with regard to data protection regulation in the U.K. From January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended U.K. Data Protection Act 2018, retains the GDPR in U.K. national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the U.K. and the European Union (EU), in relation to certain aspects of data protection law remains unclear, and it is unclear how U.K. data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the U.K. will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four to six-month grace period agreed in the EU and U.K. Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU member states to the U.K for a four-year period, subject to subsequent extensions.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and third-party providers to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could harm our business.

Risks Related to Commercialization of our Product Candidates

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

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force, marketing, manufacturing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing, reimbursement and manufacturing capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

We face significant competition from other pharmaceutical and biotechnology companies and other research organizations, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical, biopharmaceutical, and biotechnology companies, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective or more convenient or have fewer or less severe side effects than any products that we may develop. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we do.

We expect to face competition from existing products and products in development for each of our product candidates. In addition, there may be other earlier stage clinical programs that, if approved, would compete with our product candidates. Many of our competitors have substantially greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields.

The successful commercialization of certain of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates and attract additional collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid, the 340B drug pricing program and TRICARE, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Even if we receive marketing approval for any of our product candidates, we may not achieve market acceptance, which would limit the revenue that we can generate from sales of any of our approved product candidates.

Even if the FDA or any comparable foreign regulatory authority approves the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Market acceptance of ETX-155 and our other product candidates, if any are approved, will depend on a number of factors, including, among others:

- the ability of ETX-155 and our other product candidates to treat neuronal excitability disorders, as compared with other available drugs, treatments or therapies;
- the prevalence and severity of any adverse side effects associated with ETX-155 and our other future product candidates;
- limitations or warnings contained in the labeling approved for ETX-155 or our other future product candidates by the FDA or any comparable foreign regulatory authority;
- availability of alternative treatments;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our product candidates through marketing efforts;
- our ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the likelihood that the FDA or any comparable foreign regulatory authority may impose additional requirements that limit the promotion, advertising, distribution or sales of our product candidates.

If any one of our product candidates is approved but does not achieve an adequate level of acceptance by patients, physicians and third-party payors, we may not generate sufficient revenue to become or remain profitable and our business may be harmed.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales, marketing and market access capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We currently have no sales, marketing, reimbursement or distribution capabilities. To achieve commercial success for any approved product for which we retain sales, marketing and market access and reimbursement responsibilities, we must either develop these capabilities, which would be expensive and time consuming, or outsource these functions to other third parties, some or all of which may be occur in advance of any approval of the product candidate. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with any future collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.
Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks Related to our Dependence on Third Parties

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

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

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

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

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

Our CROs may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be harmed.

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

If the manufacturers upon whom we rely fail to produce our product candidates in the volumes that we require on a timely basis in accordance with the specifications for our product candidates, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our product candidates, and we do not currently plan to develop any capacity to do so. We currently outsource all manufacturing of our product candidates to third-party CDMOs, typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our product candidates may delay the development or commercialization of our product candidates.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our existing or future product candidates and programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of CDMOs that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the raw materials used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate or not renew these agreements.

We have a limited number of contract manufacturers for our product candidates. At times we may have only one manufacturer for a product. In addition, we do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields; quality control, including stability of the product candidate and quality assurance testing; shortages of qualified personnel; and compliance with strictly enforced federal, state, and foreign regulations. Our manufacturers may not perform as agreed, such as failing to manufacture our product candidates in accordance with the specifications for such product candidates. If our manufacturers were to encounter any of these difficulties, our ability to provide product candidates to patients in our clinical trials and for commercial use, if approved, would be jeopardized.

In addition, all manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA and comparable foreign regulatory authorities that are applicable to both finished drug products and active pharmaceutical ingredients used both for clinical and commercial supply, through its facilities inspection program. The FDA must verify our contract manufacturers' compliance with cGMP requirements and comparable foreign regulatory authorities will similarly inspect our contract manufacturers' facilities after we submit our marketing applications to the agency and comparable foreign regulatory authorities. The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with our specifications, these cGMP requirements and with other FDA, state, and foreign regulatory requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. While we are ultimately responsible for the manufacture of our product candidates, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, including imprisonment; suspension or restrictions of production; suspension, delay, or denial of product approval or supplements to approved products; clinical holds or termination of clinical studies; warning or untitled letters; regulatory authority communications warning the public about safety issues with the drug; refusal to permit the import or export of the products; product seizure, detention, or recall; civil suits under the FCA; corporate integrity agreements; consent decrees; or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Any failure or refusal to supply our product candidates or components for our current or future product candidates that we may develop could delay, prevent, or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. While currently we have no plans to do so, we may decide to collaborate for the future development and potential commercialization of our product candidates. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

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

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

Risks Related to Intellectual Property

If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of future licensors, licensees or collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others. In the last year, we have filed multiple U.S. provisional applications covering methods of treatment and formulations of ETX-155. A U.S. provisional patent application is not eligible to become an issued patent until, among other things, we file non-provisional patent application within 12 months of filing of the provisional patent application. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

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

Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our future licensors were the first to make the inventions claimed in our owned or any future licensed patents or pending patent applications, or were the first to file for patent protection of such inventions.

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

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

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

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

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

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

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property. In addition, our patents may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

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

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

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

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

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

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

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and any future licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

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

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

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

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

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

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

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

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

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

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

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third- party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business.

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

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

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

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business.

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

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

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

We rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks Related to our Business Operations, Employee Matters and Managing Growth

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is critical to our success. The permanent or temporary loss of the services of our executive officers or other key employees for any reason could impede the achievement of our research, development and commercialization objectives, impair our operations 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 for and commercialize our product candidates. Competition to hire qualified personnel in our industry 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. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

Our full-time and part-time employee base grew from 31 employees as of December 31, 2021 to 43 employees as of September 30, 2022. As our clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research, clinical operations, regulatory affairs, general and administrative and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

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

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

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

- multiple, conflicting and changing laws and regulations, including those related to Brexit related changes, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from the ongoing COVID-19 pandemic;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- currency exchange rate fluctuations and the resulting effect on our revenue and expenses and the cost and risk of entering into hedging transactions if we chose to do so in the future;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including COVID-19 and related public health guidance measures, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

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

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

As of December 31, 2021, we had net operating loss carryforwards of approximately $6.0 million for federal income tax purposes, $16.5 million for foreign income tax purposes and $7.3 million for state income tax purposes. The federal net operating loss may be used up to 80% of future taxable income while the state and foreign losses may be used to offset up to 100% of future taxable income. The federal net operating loss carryforward can be carried forward indefinitely while the state net operating loss carryforward will begin to expire in varying amounts in 2039. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act (Tax Act), as modified by the Coronavirus Aid, Relief and Economic Security Act (CARES Act), federal net operating losses incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited.

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

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

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

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

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

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers, sales agent, health care facilities, physicians or other health care providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

If we pursue any foreign acquisitions, they typically involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

Risks Related to our Common Stock

Our operating results may fluctuate significantly and may be difficult to predict.

Our quarterly and annual operating results may fluctuate significantly, due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement; future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally; exchange rate fluctuations;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our product candidates, if approved, which may vary significantly over time.

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

Our stock price has been volatile, fluctuating from a high trading price of $29.69 per share in August 2021 to a low trading price of $2.52 in May 2022 following our announcements about the ETX-810 and ETX-155 programs. The stock market in general and the market for biotechnology companies in particular have also experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may continue to be volatile in the future and may be influenced by many factors, including:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of our clinical trials or those of our competitors;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;

- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- actions by institutional or activist investors;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- the impact of the COVID-19 pandemic;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock, in particular following significant drops in stock price. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. In addition, in the current volatile market for biotechnology stocks, in particular where shares are trading below cash balances, certain biotechnology investors have advocated for increases in short-term stockholder value through proposed corporate actions such as financial restructurings, special dividends, stock repurchases or sales of assets. Any such proposals directed at us could cause us to incur substantial costs and divert management's attention and resources from our business. In addition, if any such proposals are undertaken, they could lead to the perception of a change in the direction of our business, instability, or lack of continuity which may be exploited by our competitors, result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel and business partners.

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

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

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

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

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

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

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

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.
In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

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

- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

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

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions and also reduces the public float for our common stock.

Based upon our common stock outstanding as of September 30, 2022, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own approximately 97.3% of our outstanding common stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

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

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

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

Prior to the completion of the IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the preparation of our consolidated financial statements, we identified material weaknesses in our internal control over financial reporting as of December 31, 2020 and December 31, 2021. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses are as follows:

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

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

- 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 consolidated financial statements. Specifically, we did not design and maintain (a) 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, (b) 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 personnel, (c) computer operations controls to ensure that critical batch jobs are monitored, and data backups are authorized and monitored, and (d) 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 a misstatement to the consolidated 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 have implemented, and are continuing to implement, measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to our material weaknesses. We have hired qualified personnel with appropriate expertise to perform specific functions and ensure adequate segregation of key duties and responsibilities. We continue to design and implement improved policies, processes and internal controls, including senior management review and audit committee oversight. Further, we have implemented new financial systems to improve segregation of duties and controls and reliability of system generated data.

The actions that have been taken are subject to continued review, implementation and testing by management as well as oversight by the audit committee of our board of directors. While we have implemented a variety of steps to remediate these weaknesses, we cannot assure you that we will be able to fully remediate them, which could impair our ability to accurately and timely meet our public company reporting requirements.

As a public company, we are subject to additional requirements and regulations with respect to our accounting procedures and internal controls, which make it more difficult and costly for us to produce timely and accurate financial statements.

Following the closing of the IPO, we became subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market. Section 302 of the Sarbanes-Oxley Act requires, among other things, that we report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and, beginning with our annual report for the year ending 2022, Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to the IPO, we were not required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner going forward. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company or a smaller reporting company with less than $100 million in revenue.

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of claims or causes of action under Delaware statutory or common law: any derivative claims or causes of action brought on our behalf; any claims or causes of action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Such provisions are intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters for any offering giving rise to such complaint and any other professional or entity who has prepared or certified any part of the document underlying the offering and may result in increased costs for stockholders to bring a claim.

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

General Risk Factors

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

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates. Additional capital may not be available to us, or even if it is, the cost of such capital may be high. We may be forced to obtain additional capital before reaching clinical or regulatory milestones, when our stock price or trading volume or both are low, or when the general market for life sciences companies is weak. Raising capital under any of these or similar scenarios, if we can raise any at all, may lead to significant dilution to our existing stockholders.

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

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. As a newly public company, we may have limited equity analyst coverage. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of the ongoing COVID-19 pandemic and actual or perceived changes in interest rates and economic inflation), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We incur costs and demands upon our management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our business.

As a public company listed in the United States, we incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from regular business activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

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

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets. We may rely upon third parties service providers and technologies to operate critical business systems to process confidential information and personal data in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage in attacks.

We and the third parties upon which we rely, such as CROs, may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, geopolitical developments, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. For example, concerns have been raised about a potential increase in cybersecurity attacks generally as a result of the war between Russia and Ukraine and the resulting sanctions by U.S. and European governments, together with any additional future sanctions or other actions by them. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products and services) or the third-party information technology systems that support us and our services.

Our remote workforce poses increased risks to our information technology systems and data, as more of our personnel work from home, utilizing network connections outside our premises. Future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also harm our business. These threats pose a risk to the security of our systems, the confidentiality and the availability and integrity of our data, and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business.

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

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

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient of protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year-end).

We are also a "smaller reporting company," as defined in the Exchange Act. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

We may be unable to maintain adequate insurance coverage.

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

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

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

We have and expect to continue to rely on U.K. research and development tax credits and incentives as a source of capital for our business. The U.K. government is reviewing the requirements for this program and may change the eligibility criteria to receive such tax credits. In the event that the criteria are changed and we no longer qualify for these credits, we would lose a source of capital, which could harm our business.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On August 9, 2021 our Registration Statement on Form S-1, as amended (File No. 333-257980), was declared effective in connection with our IPO, pursuant to which we sold an aggregate of 7,360,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $12.50 per share. Evercore L.L.C., Guggenheim Securities LLC, Stifel, Nicolaus & Company, Incorporated, and SVB Leerink LLC, acted as lead manager for the offering.

The IPO closed on August 12, 2021. The aggregate net proceeds from our IPO, after underwriting discounts and commissions of $6.4 million and other estimated offering expenses of $2.5 million, were $83.1 million. In connection with our IPO, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates or to our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on August 11, 2021.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-40708	3.1	8/12/2021
3.2	Amended and Restated Bylaws of the Registrant	S-1	333-257980	3.4	8/2/2021
4.1	Reference is made to Exhibits 3.1 and 3.2				
4.2	Form of common stock certificate of the Registrant	S-1	333-257980	4.1	8/2/2021
4.3	Amended and Restated Investors Rights Agreement, dated May 21, 2021, by and among the Registrant and the investors listed on Schedule A thereto	S-1	333-257980	10.1	7/16/2021
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Scheme Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.

SIGNATURES

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

Eliem Therapeutics, Inc.

Date: November 14, 2022

By: /s/ Robert Azelby
Robert Azelby
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: November 14, 2022

By: /s/ Erin M. Lavelle
Erin M. Lavelle
Chief Operating Officer and Chief Financial Officer (*Principal Financial and Accounting Officer*)

Exhibit 31.1

CERTIFICATION 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, Robert Azelby, certify that:

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

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

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

4. The registrant's other certifying officer(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)) 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 subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) 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

   (c) 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 14, 2022

By: /s/ Robert Azelby

Robert Azelby
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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, Erin M. Lavelle, certify that:

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

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

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

4. The registrant's other certifying officer(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)) 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 subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) 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

   (c) 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 14, 2022

By: /s/ Erin M. Lavelle
Erin M. Lavelle
Chief Operating Officer and Chief Financial Officer
(Principal Financial and 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

In connection with the Quarterly Report of Eliem Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 14, 2022

By: /s/ Robert Azelby

Robert Azelby
President and Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 32.2

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

In connection with the Quarterly Report of Eliem Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 14, 2022

By: /s/ Erin M. Lavelle
Erin M. Lavelle
Chief Operating Officer and Chief Financial Officer
(Principal Financial and 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 Eliem Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.