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 March 31, 2023

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: 001-35610

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

Delaware	**26-4753208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
107 Spring Street **Seattle, WA** (Address of principal executive offices)	**98104** (Zip Code)

Registrant's telephone number, including area code: (206) 588-0256
Former name or former address, if changed since last report: N/A
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.18 par value	ATOS	The Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "a 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 ☒

The number of shares of the registrant's common stock, $0.18 par value per share, outstanding as of May 10, 2023, was 126,624,110.

ATOSSA THERAPEUTICS, INC.
QUARTERLY REPORT
FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except for par value)

	As of March 31, 2023 (unaudited)	As of December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 103,868	$ 110,890
Restricted cash	110	110
Prepaid expenses	5,295	4,031
Research and development tax rebate receivable	738	743
Other current assets	858	2,423
Total current assets	110,869	118,197
Investment in equity securities	4,700	4,700
Other assets	631	635
Total assets	$ 116,200	$ 123,532
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,444	$ 2,965
Accrued expenses	613	1,059
Payroll liabilities	822	1,525
Other current liabilities	65	19
Total current liabilities	2,944	5,568
Total liabilities	2,944	5,568
Commitments and contingencies (Note 14)		
Stockholders' equity		
Series B convertible preferred stock - $0.001 par value; 10,000 shares authorized; 1 shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Additional paid-in capital - Series B convertible preferred stock	582	582
Common stock - $0.18 par value; 175,000 shares authorized; 126,624 shares issued and outstanding as of March 31, 2023 and December 31, 2022	22,792	22,792
Additional paid-in capital - common stock	252,357	250,784
Accumulated deficit	(162,475)	(156,194)
Total stockholders' equity	113,256	117,964
Total liabilities and stockholders' equity	$ 116,200	$ 123,532

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)
(amounts in thousands, except for per share amounts)

	For the Three Months Ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 3,508	$ 1,499
General and administrative	3,590	3,248
Total operating expenses	7,098	4,747
Operating loss	(7,098)	(4,747)
Interest income	850	1
Other expense, net	(33)	(40)
Loss before income taxes	(6,281)	(4,786)
Income taxes	-	-
Net loss	(6,281)	(4,786)
Loss per share of common stock - basic and diluted	$ (0.05)	$ (0.04)
Weighted average shares outstanding - basic and diluted	126,624	126,624

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)
(amounts in thousands)

	Series B Convertible Preferred Stock			Common Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	1	$ -	$ 582	126,624	$ 22,792	$ 243,996	$ (129,234)	$ 138,136
Compensation cost for stock options granted	-	-	-	-	-	1,806	-	1,806
Net loss	-	-	-	-	-	-	(4,786)	(4,786)
Balance at March 31, 2022	1	$ -	$ 582	126,624	$ 22,792	$ 245,802	$ (134,020)	$ 135,156

	Series B Convertible Preferred Stock			Common Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	1	$ -	$ 582	126,624	$ 22,792	$ 250,784	$ (156,194)	$ 117,964
Compensation cost for stock options granted	-	-	-	-	-	1,573	-	1,573
Net loss	-	-	-	-	-	-	(6,281)	(6,281)
Balance at March 31, 2023	1	$ -	$ 582	126,624	$ 22,792	$ 252,357	$ (162,475)	$ 113,256

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(amounts in thousands)

	For the Three Months Ended March 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (6,281)	$ (4,786)
Adjustments to reconcile net loss to net cash used in operating activities		
Compensation cost for stock options granted	1,573	1,806
Depreciation and amortization	3	2
Changes in operating assets and liabilities:		
Prepaid expenses	(1,264)	(1,386)
Research and development tax rebate receivable	5	404
Other current assets	1,565	(114)
Other assets	1	-
Accounts payable	(1,521)	(121)
Accrued expenses	(446)	(84)
Payroll liabilities	(703)	(591)
Other current liabilities	46	(8)
Net cash used in operating activities	(7,022)	(4,878)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture and equipment	-	(13)
Net cash used in investing activities	-	(13)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net cash provided by financing activities	-	-
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(7,022)	(4,891)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	111,000	136,487
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 103,978	$ 131,596
SUPPLEMENTAL DISCLOSURES		
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 103,868	$ 131,486
Restricted cash	110	110
Total cash, cash equivalents and restricted cash shown in the Condensed Consolidated Statements of Cash Flows	$ 103,978	$ 131,596

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)
(amounts in thousands, except for per share amounts)

NOTE 1: NATURE OF OPERATIONS

Atossa Therapeutics, Inc. (the Company) was incorporated on April 30, 2009, in the State of Delaware to develop and market medical devices, laboratory tests and therapeutics to address breast health conditions. The Company is currently focused on developing proprietary innovative medicines in areas of significant unmet medical need in oncology, with a current focus on breast cancer and other breast conditions. The Company's fiscal year ends on December 31.

NOTE 2: LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred net losses and negative operating cash flows since inception. For the three months ended March 31, 2023, the Company recorded a net loss of $6,281 and used $7,022 of cash in operating activities. As of March 31, 2023, the Company had $103,868 in unrestricted cash and cash equivalents and working capital of $107,925. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs, and it believes it will need to continue to raise substantial additional capital to accomplish its business plan over the next several years. Management believes its currently available funding will be sufficient to finance the Company’s operations for at least one year from the date these Condensed Consolidated Financial Statements are issued. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of public or private equity offerings, debt financings or other sources, including potential corporate collaborations, licenses and other similar arrangements. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future. If the Company is unable to secure additional funding, it may be forced to curtail or suspend its business plans.

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. They do not include all information and notes required by GAAP for complete financial statements. However, except as disclosed herein, there has been no material change in the information disclosed in the Notes to Consolidated Financial Statements included in the Annual Report on Form 10-K of the Company for the year ended December 31, 2022. The year-end condensed consolidated balance sheet presented in this report was derived from audited consolidated financial statements but does not include all disclosures required by GAAP. All amounts in the condensed consolidated financial statements and the notes thereto have been presented in thousands, except for par value and other per share data.

In the opinion of management, all adjustments (including normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2023, are not necessarily indicative of the results that may be expected for the year ending December 31, 2023.

Reclassification

Interest income has been reclassified from prior period amounts to conform to the current year presentation.

Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Segments

The Company operates as a single segment. Operating segments are identified as the components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and in assessing performance. To date, our chief operating decision maker has made such decisions and assessed performance at the Company-level as a single segment.

Cash and Cash Equivalents

Cash and cash equivalents include unrestricted cash and all highly liquid instruments with maturities of three months or less at the date of purchase.

Investments in Equity Securities

The Company currently has one investment in non-marketable securities. This investment does not have a readily determinable fair value, so the Company has elected to measure the investment at cost in accordance with Accounting Standards Codification *ASC 321 – Equity*. At each reporting period, the Company will perform an assessment to determine if it still qualifies for this measurement alternative. The Company considers qualitative impairment factors in determining if there are any signs of impairment.

The assumptions and estimates used to estimate the fair value of investments may include, but not be limited to, the following information from the respective investee:

- Unaudited financial statements;
- Projected technological developments;
- Current fundraising transactions;
- Current ability to raise additional financing when needed;
- Changes in the economic environment which may have a material impact on the operating results; and
- Timing of a deemed liquidation event occurring.

Please also refer to Note 4.

Fair Value Measurements

The Company records financial assets and liabilities measured on a recurring and non-recurring basis, as well as all non-financial assets and liabilities subject to fair value measurement at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

The accounting guidance establishes a hierarchy for inputs used in measuring fair value that minimizes the use of unobservable inputs by requiring the use of observable market data when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on active market data. Unobservable inputs are inputs that reflect the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances.

The fair value hierarchy is broken down into the three input levels summarized below:

● *Level 1* —Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by us at the reporting date. Examples of assets and liabilities utilizing Level 1 inputs are certain money market funds, U.S. Treasuries and trading securities with quoted prices on active markets.

● *Level 2* —Valuations based on inputs other than the quoted prices in active markets that are observable either directly or indirectly in active markets. Examples of assets and liabilities utilizing Level 2 inputs are U.S. government agency bonds, corporate bonds, commercial paper, certificates of deposit and over-the- counter derivatives.

● *Level 3* —Valuations based on unobservable inputs in which there are little or no market data, which require the Company to develop its own assumptions

Please also refer to Note 9.

Research and Development

Research and development (R&D) costs are generally expensed as incurred. R&D expenses include, for example, manufacturing expense for the Company's drugs under development, expenses associated with preclinical studies, clinical trials and associated salaries, bonuses, stock-based compensation and benefits. The Company has entered into various research and development contracts with research institutions, clinical research organizations, clinical manufacturing organizations and other companies. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying condensed consolidated balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid expense or accrued expense balances at the end of any reporting period. Actual results could differ from the Company’s estimates.

R&D expenses also include an allocation of the CEO's salary and related benefits including bonus and non-cash stock-based compensation expense based on an estimate of his total hours spent on R&D activities. The Company's CEO is involved in the development of the Company's drug candidates and oversight of the related clinical trial activity.

Stock-based Payments

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, officers, non-employee directors, and other key persons providing services to the Company, currently limited to stock options. Stock compensation expense is based on the estimated grant date fair value and is recognized as an expense over the requisite service period. The Company has made a policy election to recognize forfeitures when they occur.

The fair value of each stock option grant is estimated using the Black-Scholes option-pricing model, which requires assumptions regarding the expected volatility of the stock options, the expected life of the options, an expectation regarding future dividends on the Company’s common stock, and estimation of an appropriate risk-free interest rate. The Company’s expected common stock price volatility assumption is based upon the historical volatility of its stock price. The Company has elected the simplified method for the expected life assumption for stock option grants, which averages the contractual term of the options of 10 years with the vesting term, typically one to four years, as the Company does not have sufficient history of option exercise experience. The dividend yield assumption of zero is based upon the fact that the Company has never paid cash dividends and presently has no intention of paying cash dividends in the future. The risk-free interest rate used for each grant was based upon prevailing short-term interest rates over the expected life of the options as of grant date.

Foreign Currency Translation and Transactions

The majority of the Company's operations occur in entities that have the U.S. dollar as their functional currency. The one non-U.S. dollar denominated functional currency subsidiary has assets and liabilities translated into U.S. dollars at rates of exchange in effect at the end of the period. Expense amounts are translated using the average exchange rates for the period. Net unrealized gains and losses resulting from foreign currency translation are recorded in Other expense, net in the Condensed Consolidated Statements of Operations. The Company had realized losses on foreign currency exchange during the three months ended March 31, 2023 and March 31, 2022 of $29 and $28, respectively, which is included in Other expense, net in the Condensed Consolidated Statements of Operations.

NOTE 4: INVESTMENT IN EQUITY SECURITIES

On December 23, 2022, the Company completed its investment in Dynamic Cell Therapies, Inc. (DCT) a U.S. private company that is in the pre-clinical stage of developing novel Chimeric Antigen Receptor (CAR) T-cell therapies based on technology licensed from a leading U.S. cancer treatment and research institution. In total, the Company paid $4,700 to DCT and received Series Seed Preferred Shares representing approximately 19% of the post-investment outstanding shares of DCT. The investment in DCT has been accounted for as an investment in equity securities on the Condensed Consolidated Balance Sheet.

The Company considered qualitative impairment factors in determining if there were any signs of impairment of this investment on the balance sheet dates. Specifically, the Company considered the additional adverse changes in the general market condition of the industry in which DCT operates and continued concerns about the investee's ability to continue as a going concern, due to negative cash flows from operations during the first quarter of 2023. Based on these impairment indicators, the Company performed a quantitative fair value measurement as of March 31, 2023. The resulting quantitative valuation concluded that the investment was not impaired, thus, no impairment has been recorded as of March 31, 2023.

NOTE 5: RESTRICTED CASH

The Company's restricted cash balance of $110 as of March 31, 2023 and December 31, 2022, consists entirely of cash pledged as security for the Company's issued commercial credit cards.

NOTE 6: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	March 31, 2023	December 31, 2022
Prepaid research and development	$ 4,619	$ 3,480
Prepaid insurance	520	387
Professional services	138	130
Other	18	34
Total prepaid expenses	$ 5,295	$ 4,031

NOTE 7: RESEARCH AND DEVELOPMENT REBATE RECEIVABLE

On May 23, 2017, the Company formed a wholly-owned subsidiary in Australia called Atossa Genetics AUS Pty Ltd. The purpose of this subsidiary is to perform R&D activities, including some of the Company's clinical trials. Australia offers an R&D cash rebate of $0.435 per dollar spent on qualified R&D activities incurred in the country. For entities with over 80% of revenue from passive sources, the rate increases to $0.485 per dollar. The Australian R&D tax incentive program is a self-assessment process, and as such, the Australian Government has the right to review the Company's qualifying programs and related expenditures for a period of four years. If such a review were to occur, and as a result of the review and failure of a related appeal, a qualified program and related expenditures could be disqualified, and the respective R&D rebates of $2,028 collected could be recalled with penalties and interest. The Company uses the grant accounting model by analogy to International Accounting Standards (IAS) 20 to account for the cash rebates received from the Australian government.

During the three months ended March 31, 2023 and 2022, the Company incurred qualified R&D expenses in Australia of $52 and $354, respectively. There were no collections of R&D cash rebates during the three months ended March 31, 2023. The Company collected R&D cash rebates of $563, during the three months ended March 31, 2022. At March 31, 2023 and December 31, 2022 the Company had total R&D rebate receivables of $738 and $743, respectively. The Company records the R&D rebate credit in the period when it incurs the associated R&D cost. As such, the rebate reduced the Research and development expense line item in the Condensed Consolidated Statements of Operations by $15 and $140 for the three months ended March 31, 2023 and, 2022, respectively.

NOTE 8: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	As of March 31, 2023	As of December 31, 2022
Accrued bonuses	$ 297	$ 1,060
Accrued vacation	278	224
Accrued payroll	247	241
Total payroll liabilities	$ 822	$ 1,525

NOTE 9: FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables present the Company's fair value hierarchy for all its financial assets and liabilities, by major security type, measured at fair value on a recurring basis:

March 31, 2023	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market accounts	$ 93,520	$ 93,520	$ -	$ -

December 31, 2022	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market account	$ 102,681	$ 102,681	$ -	$ -

NOTE 10: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 185,000 shares of stock consisting of 175,000 shares of common stock, par value $0.18 per share, and 10,000 shares of preferred stock, par value $0.001 per share. The Company has designated 750 shares of Series A junior participating preferred stock, par value $0.001 per share, 4 shares of Series A convertible preferred stock, par value $0.001 per share, 25 shares of Series B convertible preferred stock, par value $0.001 and 20 shares of Series C convertible preferred stock, par value $0.001 per share, through the filings of certificates of designation with the Delaware Secretary of State. No shares of Series A junior participating preferred stock, Series A convertible preferred stock or Series C convertible preferred stock were outstanding as of March 31, 2023 and December 31, 2022.

On May 19, 2014, the Company adopted a stockholder rights agreement which provides that all stockholders of record on May 26, 2014 received a non-taxable distribution of one preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of 15% or more of the Company's common stock (or, in the case of a person who beneficially owned 15% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of the Company's common stock then outstanding (excluding compensatory arrangements)), or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a number of shares of the Company's common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is $15.00, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive $30.00 worth of the Company's common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled to purchase a similar amount of stock of the acquiring entity.

Series B Convertible Preferred Stock

Conversion. Each share of Series B convertible preferred stock is convertible at the Company's option at any time on or after the first anniversary of the closing of this offering, or at the option of the holder at any time, into the number of shares of our common stock determined by dividing the $1,000 stated value per share of the Series B convertible preferred stock by a conversion price of $3.52 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series B convertible preferred stock will not have the right to convert any portion of the Series B convertible preferred stock to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

Fundamental Transactions. In the event the Company effects certain mergers, consolidations, sales of substantially all of its assets, tender or exchange offers, reclassifications or share exchanges in which its common stock is effectively converted into or exchanged for other securities, cash or property, the Company consummates a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by our issued and outstanding common stock, then, upon any subsequent conversion of the Series B convertible preferred stock, the holders of the Series B convertible preferred stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series B convertible preferred stock.

Dividends. Holders of Series B convertible preferred stock shall be entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock.

Voting Rights. Except as otherwise provided in the certificate of designation or as otherwise required by law, the Series B convertible preferred stock has no voting rights.

Liquidation Preference. Upon the Company's liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series B convertible preferred stock will be entitled to receive out of the Company's assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Series B convertible preferred stock were fully converted (disregarding for such purpose any conversion limitations under the certificate of designation) to common stock, which amounts shall be paid pari passu with all holders of common stock.

Redemption Rights. The Company is not obligated to redeem or repurchase any shares of Series B convertible preferred stock. Shares of Series B convertible preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous provisions.

2021 and 2020 Warrants

The terms and conditions of the warrants are as follows:

Exercisability. Each warrant is exercisable at any time and will expire between 4 and 4.5-years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to the Company a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise, except in the case of a cashless exercise as discussed below. The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split of, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of our assets, or other similar transaction, the holders of warrants shall, at the option of the Company, be required to exercise the warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

Cashless Exercise. If at any time there is no effective registration statement registering, or the prospectus contained therein is not available for issuance of, the shares issuable upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of the Company's common stock purchasable upon such exercise.

Exercise Price. Each warrant represents the right to purchase one share of common stock. In addition, the exercise price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications, and for certain dilutive issuances. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of the warrant to the extent that, after giving effect to the exercise, the holder, together with its affiliates, and any other person acting as a group together with the holder or any of its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to its exercise. The holder, upon notice to the Company, may increase or decrease the beneficial ownership limitation provisions of the warrant, provided that in no event shall the limitation exceed 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise of the warrant.

Transferability. Subject to applicable laws and restrictions, a holder may transfer a warrant upon surrender of the warrant to us with a completed and signed assignment in the form attached to the warrant. The transferring holder will be responsible for any tax liability that may arise as a result of the transfer.

Exchange Listing. The Company does not intend to apply to list the warrants on any securities exchange or recognized trading system.

Rights as Stockholder. Except as set forth in the warrant, the holder of a warrant, solely in such holder’s capacity as a holder of a warrant, will not be entitled to vote, to receive dividends or to any of the other rights of our stockholders.

Warrants Outstanding

As of March 31, 2023, warrants to purchase 21,515 shares of common stock were outstanding, including:

	Outstanding Warrants to Purchase Shares	Exercise Price Per Share	Expiration Date
December 2020 warrants	6,490	$ 1.00	December 11, 2024-June 21, 2025
January 2021 warrants	4,500	$ 1.055	July 8, 2025
March 2021 warrants	10,525	$ 2.88	September 22, 2025
	21,515		

Warrant Activity

There were no warrant exercises during the three months ended March 31, 2023 and 2022.

Conversion of Convertible Preferred Stock

During the three months ended March 31, 2023 and 2022, there were no conversions of Series B convertible preferred stock.

NOTE 11: NET LOSS PER SHARE

The Company follows the two-class method when computing net loss per share as the Company has issued warrants and preferred stock that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of potential future exercises of outstanding stock options and common stock warrants. Because the inclusion of potential common shares would be anti-dilutive for all periods presented, they have been excluded from the calculation.

The Company's common stock warrants and preferred stock contractually entitle the holders of such securities to participate in dividends but do not contractually require the holders of such securities to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the three months ended March 31, 2023 and 2022.

The following table summarizes the Company's calculation of net loss per common share:

	Three Months Ended March 31,	
	2023	**2022**
Numerator		
Net loss attributable to common stockholders	$ (6,281)	$ (4,786)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	126,624	126,624
Net loss per share of common stock, basic and diluted	$ (0.05)	$ (0.04)

The following table sets forth the weighted average number of potential common shares excluded from the calculation of net loss per diluted share, because including them would be anti-dilutive:

	Three Months Ended March 31,	
	2023	**2022**
Options to purchase common stock	14,743	11,089
Series B convertible preferred stock	165	165
Warrants to purchase common stock	21,515	22,277
	36,423	33,531

NOTE 12: INCOME TAXES

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of March 31, 2023 and December 31, 2022 due to the Company's continuing operating losses.

NOTE 13: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of deposits of cash and cash and cash equivalents including those deposited in money market deposit accounts. Accounts at each institution that contain specified types of deposits are insured by the Federal Deposit Insurance Corporation (FDIC) for up to $250. As of March 31, 2023 and December 31, 2022, the Company had deposits of $103,712 and $110,647, respectively, of cash and cash equivalents in excess of the FDIC insured limit.

NOTE 14: COMMITMENTS AND CONTINGENCIES

Lease Commitments

The Company evaluates all contractual agreements at inception to determine if they contain a lease. Lease liabilities are measured at the present value of lease payments not yet paid, using a discounted cash flow model that requires the use of a discount rate, or incremental borrowing rate. Leases with a term of 12 months or less are considered short-term operating leases and no asset or liability is recognized.

The Company's operating lease consists of an office lease. On November 22, 2022, the Company entered into a new short-term operating lease for office space to pay monthly rent of $2 for a term of 12 months commencing January 1, 2023. The Company had lease expense under a short-term lease of $4 and $8 during the three months ended March 31, 2023 and 2022, respectively.

Litigation and Contingencies

The Company is subject to legal proceedings and claims that arise in the normal course of business. The Company believes that these matters are either without merit or of a kind that should not have a material effect, individually or in aggregate, on its financial position, results of operations or cash flows.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third party clinical research organizations (CROs) and clinical manufacturing organizations (CMOs). With the exception of one CRO contract, such agreements are cancellable upon written notice by the Company. The one non-cancellable contract expires upon completion of the study and release of the final report, or the contract may be terminated by the CRO, or by the FDA or other governmental agency. As of March 31, 2023, the Company's non-cancellable commitment related to this contract are estimated to be $1,146 and $13 in 2024. As of March 31, 2023, we have incurred $111 under this contract.

NOTE 15: STOCK-BASED COMPENSATION

On March 24, 2020, the Board of Directors approved the adoption of the 2020 Stock Incentive Plan (the 2020 Plan) to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. No awards may be granted under the 2020 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 3,000 shares of common stock were initially reserved for issuance in connection with awards granted under the 2020 Plan. On May 14, 2021, the stockholders approved an additional 15,000 shares available for issuance under the 2020 Plan. There were 5,790 shares available for future grants under the 2020 Plan as of March 31, 2023.

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan (the 2010 Plan) to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive stock options could be granted under the 2010 Plan until September 2020. Shares may no longer be granted under this plan.

The Company granted 2,461 and 2,722 options to purchase shares of common stock under the 2020 Plan to employees and directors during the three months ended March 31, 2023 and 2022, respectively. The weighted average grant date fair value of options granted during the three months ended March 31, 2023 and 2022 was $.061 and $1.07, respectively. There were no stock options exercised during the three months ended March 31, 2023 and 2022.

The fair value of stock options granted were calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	3.87% - 4.25%	1.86% - 2.53%
Expected term (in years)	5.50 - 6.11	5.51 - 6.11
Dividend yield	-	-
Expected volatility	103% - 118%	117% - 128%

The Company recognized stock-based compensation expense, which was included under the following captions in the Condensed Consolidated Statements of Operations:

	Three Months Ended March 31,	
	2023	2022
General and administrative	$ 1,054	$ 1,184
Research and development	519	622
Total stock-based compensation expense	$ 1,573	$ 1,806

Options issued and outstanding as of March 31, 2023 and related activities during the three months ended March 31,2023 were as follows:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years	Aggregate Intrinsic Value
Outstanding as of January 1, 2023	13,906	$ 2.35		-
Granted	2,461	$ 0.72		
Exercised	-	-		
Forfeited	-	-		
Expired	(3)	$ 793.83		
Outstanding as of March 31, 2023	16,364	$ 1.95	7.93	$ 44
Exercisable as of March 31, 2023	11,227	$ 2.32	7.28	
Vested and expected to vest	11,227	$ 1.95	7.93	$ 44

On March 31, 2023, there were 5,137 unvested options outstanding, and the related unrecognized total compensation cost associated with these options was $4,085. This expense is expected to be recognized over a weighted-average period of 1.31 years from March 31, 2023.

Defined Contribution Plan

The Company has a defined contribution plan to which employees of the Company may defer contributions for income tax purposes. Participants are eligible to receive employer matching contributions up to 6% of deferrals. Employees may also be eligible for a discretionary match over 6%. Defined contribution plan employer matching contributions for the three months ended March 31, 2023 and 2022, were $56 and $34, respectively.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the Condensed Consolidated Financial Statements and the related notes included elsewhere in this report. This discussion contains forward-looking statements, which are based on assumptions about the future of the Company's business. The actual results could differ materially from those contained in the forward-looking statements. Please read "Forward-Looking Statements" included below for additional information regarding forward-looking statements.

Forward-Looking Statements

This report contains, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties which could cause actual results to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this report, we cannot assure you that the forward-looking statements set out in this report will prove to be accurate. We may identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate," "believe," "future," or the negative versions of these words or other comparable words. All statements other than statements of historical fact, including statements regarding guidance, industry prospects, or future results of operations or financial position, made in this report are forward-looking. Forward-looking statements contained in this report include, but are not limited to, statements about:

- the impact of the ongoing COVID-19 pandemic and the degree to which the pandemic negatively impacts our supply chain, clinical trial enrollment and timing and our ability to access capital markets;
- the impact of inflation, rising interest rates, general economic slowdown or a recession, foreign exchange rate volatility, financial institution instability, changes in monetary policy and increasing geopolitical instability on our business, our ability to access capital markets, our operating costs and our supply chain;
- whether we can obtain approval from the U.S. Food and Drug Administration (FDA), and foreign regulatory bodies, to continue our clinical trials, including our planned (Z)-endoxifen trials, and to sell, market and distribute our therapeutics under development;
- our ability to identify and partner with organizations to commercialize any of our products once they are approved for marketing;
- our ability to successfully initiate and complete clinical trials of our products under development, including our proprietary (Z)-endoxifen (an active metabolite of Tamoxifen);
- the success, costs and timing of our development activities, such as clinical trials, including whether our studies using our (Z)-endoxifen therapies will enroll a sufficient number of subjects in a timely fashion or be completed in a timely fashion or at all;
- whether we will successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives;
- our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;
- our ability to successfully develop and commercialize new therapeutics currently in development, or new therapeutics that we might identify in the future, and within the time frames we currently expect;
- our ability to successfully defend litigation and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;
- our ability to establish and maintain intellectual property rights covering our products;
- our increased risk of theft or misappropriation of our intellectual property and other proprietary technology outside of the U.S.;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;
- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;
- whether final study results will vary from preliminary study results that we may announce;
- our expectations as to future financial performance, expense levels and capital sources;
- our ability to attract and retain key personnel; and
- our ability to raise capital.

These and other forward-looking statements made in this report are presented as of the date of the filing of this report. We have discussed certain important factors, risks and uncertainties in the section titled “ITEM 1A. RISK FACTORS,” that we believe could cause our actual results, events or outcomes to differ materially from our anticipated results, events or outcomes. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this report. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

Company Overview

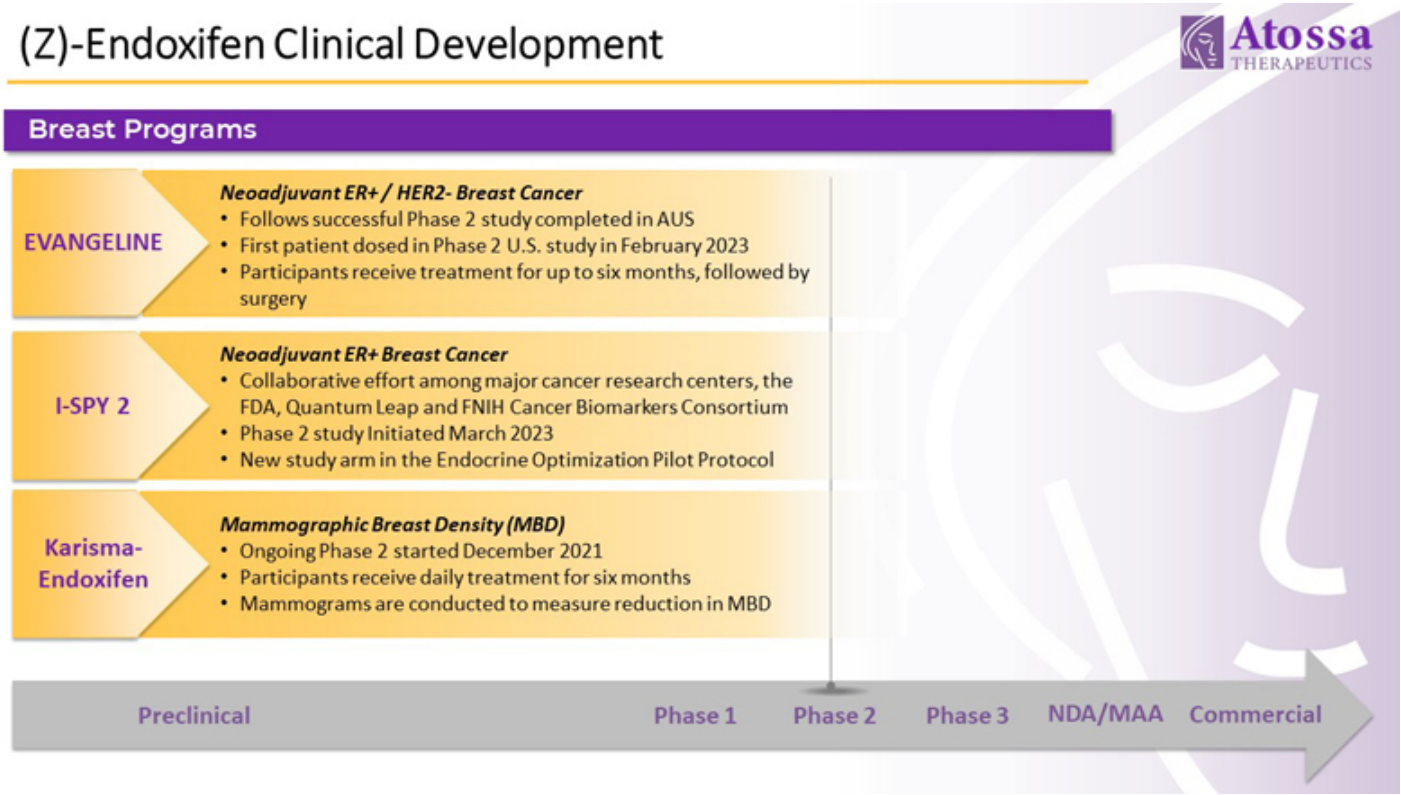
We are a clinical-stage biopharmaceutical company developing proprietary innovative medicines in areas of significant unmet medical need in oncology, with a current focus on breast cancer and other breast conditions. Our lead drug candidate under development is oral (Z)-endoxifen which we are developing in two settings: one to treat breast cancer by reducing tumor cell activity prior to surgery and another one to reduce dense breast tissue in women. More than 10 million women in the U.S. and millions more worldwide have high breast density, which reduces the ability of mammograms to detect cancer and increases the risk of breast cancer. There is no FDA-approved treatment for breast density. We believe there is also a significant unmet need for breast cancer treatments in premenopausal women prior to surgery as the typical treatment for the majority of early-stage breast cancer patients currently involves ovarian suppression, which can induce premature menopause and dramatically impact a patient’s quality of life.

We have been granted two U.S. patents covering our proprietary (Z)-endoxifen and we have numerous applications pending in the U.S. and in other major countries. We have patent protection covering our proprietary (Z)-endoxifen through November 17, 2038.

Our business strategy is to advance our programs through clinical studies, including with partners, and opportunistically add programs in areas of high unmet medical need through acquisition, minority investment, collaboration or internal development.

Summary of Leading Programs

The following is a summary of the current status of our major clinical development programs:



*(Z)-endoxifen. (Z)-*endoxifen is an active metabolite of tamoxifen, which is an FDA-approved drug to treat and prevent breast cancer in high-risk women. We are developing a proprietary form of (Z)-endoxifen which is administered orally for the potential treatment of breast cancer and reduction of breast density. We have completed four Phase 1 clinical studies (including a study in men) and two Phase 2 clinical studies with our proprietary (Z)-endoxifen (including oral and topical formulations). We have also completed significant pre-clinical development and have developed clinical manufacturing capabilities through qualified third-parties.

(Z)-endoxifen for Women with Breast Density. Mammographic breast density (MBD) is an emerging public health issue affecting over 10 million women in the U.S. alone. Studies conducted by others have shown that MBD increases the risk of developing breast cancer and that reducing MBD may reduce the incidence of breast cancer.

In December 2021, we commenced a Phase 2 study of our proprietary oral (Z)-endoxifen. The study, known as the Karisma-(Z)-endoxifen study, is a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary oral (Z)-endoxifen in healthy premenopausal women with measurable breast density. The primary objective of the study is to determine the dose-response relationship of daily (Z)-endoxifen on breast density reduction. Secondary endpoints will assess safety and tolerability. The study also includes an exploratory endpoint to assess durability of the breast density changes. The study is being conducted in Stockholm, Sweden and will include approximately 240 participants, at full enrollment, who will receive daily doses of oral (Z)-endoxifen or placebo for six months after they enroll.

Based on input from the FDA and Swedish Medical Products Agency, reduction in MBD may not be an approvable indication unless we can demonstrate that our (Z)-endoxifen also reduces the incidence of breast cancer. We may therefore conduct additional studies of (Z)-endoxifen to assess its correlation with the risk of breast cancer and/or reduction in the incidence of new breast cancers.

(Z)-endoxifen for Neoadjuvant Treatment of Breast Cancer. We are also developing (Z)-endoxifen to treat estrogen receptor positive (ER+)/human epidermal growth factor receptor 2 negative (HER2-) breast cancer in the neoadjuvant setting, which is the administration of a therapy before the main treatment, which is usually surgery. Although there are neoadjuvant treatments for breast cancers that are not ER+, there are few neoadjuvant treatments for ER+ breast cancer which comprises about 78% of all breast cancers and the treatments that are available typically for premenopausal women involve ovarian suppression which can induce premature menopause and significantly impact quality of life. We believe there is a compelling need for therapy with our (Z)-endoxifen in this setting.

In October 2022, we received authorization from the U.S. FDA for our Investigational New Drug (IND) application for oral (Z)-endoxifen. The study, “A Randomized Phase 2 Noninferiority Trial of (Z)-endoxifen and Exemestane + Goserelin as Neoadjuvant Treatment in Premenopausal Women with ER+/HER2- Breast Cancer,” also known as “EVANGELINE,” is an open-label, randomized, Phase 2 study designed to investigate (Z)-endoxifen for the neoadjuvant treatment of premenopausal women ages 18 and older with early stage (Grade 1 or 2) ER+/HER2- breast cancer. Participants will receive neoadjuvant treatment for up to six months, followed by surgery. The study is expected to enroll approximately 175 patients at up to 25 sites. EVANGELINE is a two part study consisting of a PK Run-in Cohort and a Treatment Cohort. The primary objective of the Treatment Cohort is to evaluate the endocrine sensitive disease (ESD) rate, measured by Ki-67 (a proliferation marker prognostic for disease free survival), after four weeks of treatment with (Z)-endoxifen compared to treatment with current standard of care, exemestane plus goserelin. Exemestane is an aromatase inhibitor designed to block the synthesis of estrogen and slow the growth of ER+ cancers. Goserelin is a medication given to block the ovaries from making estrogen, also called ovarian function suppression (OFS). In premenopausal women, OFS is associated with significant morbidity and inadequate compliance, which compromises efficacy and increases the risk of mortality. In February 2023, we enrolled the first patient in this study.

In March 2023, a second Phase 2 trial investigating oral (Z)-endoxifen as a neoadjuvant treatment for women diagnosed with locally advanced ER+ breast cancer was initiated. This trial is a study arm in the ongoing I-SPY 2 clinical trial. The I-SPY 2 TRIAL is a collaborative effort among academic investigators from major cancer research centers across the United States, Quantum Leap Healthcare Collaborative, the U.S. FDA, and the Foundation for the National Institutes of Health (FNIH) Cancer Biomarkers Consortium. Approximately 20 patients will be treated with (Z)-endoxifen for up to 24 weeks prior to surgery.

Inhaled HNAC(AT-H201). AT-H201 was under development as a potential treatment for COVID-19; however, due to the rapidly shifting treatment landscape and introduction of effective vaccines and treatments, in late 2022 we shifted our focus to the treatment of patients with compromised lung function due to the damaging effects of cancer treatment. We are scheduled to conclude our study in healthy volunteers with AT-H201 in early 2023, but we do not expect to advance the program further in 2023 as we focus on our (Z)-endoxifen programs.

Recent Investment in CAR-T Company

On December 23, 2022, we closed our previously announced investment in Dynamic Cell Therapies, Inc. (DCT), a privately-held, venture capital-backed, developer of CAR-T therapies. DCT is in the pre-clinical phase of developing controllable CAR-T cells to address difficult-to-treat cancers. Its platform technology of dynamic control of engineered T-cells is designed to improve the safety, efficacy, and durability of CAR-T cell therapies. While its initial focus is hematologic malignancies, it's possible that its innovative approach could also have broad applicability in solid tumors and autoimmune diseases. Our investment in DCT, which totaled $4.7 million, resulted in our owning approximately 19% of the outstanding capital stock of DCT.

Research and Development Phase

We are in the research and development phase and are not currently marketing any products. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical programs.

Commercial Lease Agreements

On November 22, 2022, the Company entered into an operating lease with WW 107 Spring Street LLC to lease office space in Seattle Washington. The Company agreed to pay $1,560 in monthly rent for a term of 12 months beginning January 1, 2023.

Critical Accounting Policies and Significant Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, (U.S. GAAP). The preparation of these Condensed Consolidated Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on our historical experience, known trends and events, and on various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our Condensed Consolidated Financial Statements.

Investments in Equity Securities

Our investment in DCT Series Seed Preferred Stock does not have a readily determinable fair value, so we have elected to measure the investment at cost less any impairment. As part of preparing our Condensed Consolidated Financial Statements, we considered qualitative impairment factors in determining if an impairment analysis is required. Specifically, we considered the adverse change in the general market condition of the industry in which DCT operates and concerns about the investee's ability to continue as a going concern, due to negative cash flows from operations. Based on these impairment indicators, we performed a fair value measurement using a Black-Scholes options pricing model. The model requires assumptions regarding the expected average volatility of comparable companies, the expected term of our investment, and an estimation of an appropriate risk-free interest rate over the term of our investment. The expected stock price volatility assumption is based upon the average historic volatility of eighteen comparable public clinical stage immunotherapy or CAR-T companies. The expected term of our investment is four years. The risk-free interest rate used is based upon prevailing short-term interest rates over the expected term of the investment.

The resulting valuation concluded that the investment was not impaired, thus, no impairment has been recorded. The assumptions and estimates used to estimate the fair value of the investment include the following information from DCT:

- Unaudited financial statements;
- Projected technological developments of DCT;
- Current fundraising transactions;
- Current ability of DCT to raise additional financing when needed;
- Changes in the economic environment which may have a material impact on the operating results of DCT; and
- Timing of a deemed liquidation event occurring.

While assumptions used to calculate and account for the investment in non-marketable equity securities represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgement. As a result, if underlying assumptions and estimates change, our investment may be impaired in future periods.

Research and Development Expenses

As part of the process of preparing our Condensed Consolidated Financial Statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and work orders, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the associated cost incurred for the services, including, in some cases, when we have not yet been invoiced or otherwise notified of actual costs. R&D costs are generally expensed as incurred. R&D expenses include, for example, manufacturing expense for our drugs under development, expenses associated with preclinical studies, clinical trials and associated salaries, bonuses, stock-based compensation and benefits. R&D expenses also include an allocation of the CEO's salary and related benefits including bonus and non-cash stock-based compensation expense based on an estimate of his total hours spent on research and development activities.

We have entered into various research and development contracts with clinical research institutions, (CRO's), clinical manufacturing organizations (CMOs) and other companies. The majority of our service providers invoice us monthly for services performed, however, payments under some of these contracts may be required in advance of the services being performed, for example when a contract requires an initial payment at the outset of the contract. Payments made in advance of performance of services are reflected in the accompanying condensed consolidated balance sheets as prepaid expenses.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs and other companies that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. We make estimates of our accrued expenses as of each balance sheet date in the Condensed Consolidated Financial Statements based on facts and circumstances known to us at that time. However, additional information may become available to us, which may allow us to make a more accurate estimate in future periods. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Stock-Based Payments

We measure all stock option awards granted to employees, non-employee directors and consultants based on the fair value on the date of grant, and we recognize compensation expense over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions. We account for forfeitures as they occur.

The fair value of each option grant is estimated using the Black-Scholes option-pricing model, which requires assumptions regarding the expected volatility of the price of our common stock, the expected life of the options, an expectation regarding future dividends on our common stock, estimation of an appropriate risk-free interest rate and expected term. Our expected common stock price volatility assumption is based upon the historic volatility of our stock price. The expected life assumption for stock option grants is based on an average of the contractual term of the options of 10 years with the average vesting term of one to four years. The dividend yield assumption of zero is based upon the fact that we have never paid cash dividends and presently have no intention of paying cash dividends in the future. The risk-free interest rate used for each grant is based upon prevailing short-term interest rates over the expected lives of the options.

While assumptions used to calculate and account for stock-based compensation awards represent management’s best estimates, these estimates involve inherent uncertainties and the application of management’s judgement. As a result, if revisions are made to our underlying assumptions and estimates, our stock-based compensation expense could vary significantly from period to period.

Results of Operations

Comparison of the three months ended March 31, 2023 and 2022 *(dollar amounts in thousands unless otherwise noted)*

Revenue and Cost of Revenue:

For the three months ended March 31, 2023 and 2022, we had no source of sustainable revenue and no associated cost of revenue.

Operating Expenses:

The following table provides a breakdown of major categories within Research and Development (R&D) and General and Administrative (G&A) expenses for the three months ended March 31, 2023 and 2022, together with the dollar and percentage change in those categories:

	March 31, 2023	March 31, 2022	Change	% Change
Research and Development				
Clinical trials	$ 2,336	$ 1,288	$ 1,048	81%
Compensation	1,034	1,094	(60)	-5%
Professional fees	101	115	(14)	-12%
Exclusivity agreements	-	(1,000)	1,000	-100%
Other	37	2	35	*
Research and Development Total	$ 3,508	$ 1,499	$ 2,009	134%
General and Administrative				
Compensation	$ 2,084	$ 2,005	$ 79	4%
Legal and professional fees	926	669	257	38%
Insurance and other	580	574	6	1%
General and Administrative Total	$ 3,590	$ 3,248	$ 342	11%

* Percentage is not meaningful.

Total operating expenses were $7,098 for the three months ended March 31, 2023, which was an increase of $2,351, or 50%, from the three months ended March 31, 2022. Operating expenses for the three months ended March 31, 2023 consisted of R&D expenses of $3,508 and G&A expenses of $3,590. Operating expenses for the three months ended March 31, 2022 consisted of R&D expenses of $1,499 and G&A expenses of $3,248. Factors contributing to the increased operating expenses for the three months ended March 31, 2023 are explained below.

Research and Development Expenses: R&D expenses for the three months ended March 31, 2023, were $3,508, an increase of $2,009, from total R&D expenses for the three months ended March 31, 2022 of $1,499. Key changes were as follows:

- The increase in R&D expense was attributed primarily to increased spending on clinical and non-clinical trials of $1,048 compared to the prior year period due to (Z)-endoxifen trial costs and increased spending on active pharmaceutical ingredients (API) and drug product formulation and development.

- The decrease in R&D compensation expense for the three months ended March 31, 2023 compared to the prior year quarter, was in part attributable to the increase in compensation expense of $43, or 9%, compared to the prior year period due to an increase in headcount, salaries and bonus accruals that was partially offset by a decrease in non-cash stock-based compensation. Non-cash stock-based compensation decreased by $103, or 17%, compared to the prior year quarter due to the weighted average fair value of options amortizing in 2023 being lower quarter over quarter.

- In the first quarter of 2022, the Company received a refund of $1,000 from the research institution with which the Company had an exclusive right to negotiate for the acquisition of the worldwide rights to two oncology R&D programs. No exclusivity payments were made or refunded during the three months ended March 31, 2023.

G&A Expenses: G&A expenses for the three months ended March 31, 2023, were $3,590, an increase of $342, from total G&A expenses for quarter ended March 31, 2022 of $3,248. Key changes were as follows:

- The increase in G&A compensation expense for the three months ended March 31, 2023 compared to the prior year quarter, was in part attributable to the increase in compensation expense of $209, or 26%, compared to the prior year quarter due to an increase in headcount, salaries and bonus accruals that was partially offset by a decrease in non-cash stock-based compensation. Non-cash stock-based compensation decreased by $130, or 11%, compared to the prior year period as the weighted average fair value of options amortizing in 2023 was lower quarter over quarter.

- Legal and professional fees increased by $257 for the three months ended March 31, 2023, compared to the prior year period due primarily to higher patent activity for (Z)-endoxifen and our immunotherapy research.

Interest Income: Interest income was $850 for the three months ended March 31, 2023 an increase of $849, from interest income of $1 for the three months ended March 31, 2022. The increase was due to the higher average balance of invested cash in a money market account and higher average interest rates for the three months ended March 31, 2023 compared to the prior year period.

Income Taxes: We have incurred net operating losses since inception. We did not record an income tax benefit for incurred losses for the quarters ended March 31, 2023 and 2022, due to uncertainty regarding utilization of our net operating loss carryforwards and due to our history of losses.

Liquidity and Capital Resources

We have incurred net losses and negative operating cash flows since inception. For the three months ended March 31, 2023, we have recorded a net loss of $6,281 and used $7,022 of cash in operating activities. As of March 31, 2023, we had $103,868 in unrestricted cash and cash equivalents and working capital of $107,925. We believe we have sufficient cash and cash equivalents to fund our projected operating requirements for at least the next 12 months.

Cash Flows

As of March 31, 2023, we had cash, cash equivalents and restricted cash of $103,978.

Net Cash Flows from Operating Activities: Net cash used in operating activities was $7,022 for the three months ended March 31, 2023, an increase of $2,144, or 44%, compared to net cash used in operating activities for the three months ended March 31, 2022 of $4,878. The increase compared to the prior year period was primarily due to an increase in cash used in clinical trial activity of $1,048.

Net Cash Flows from Investing Activities: Net cash used in investing activities was $0 for the three months ended March 31, 2023, compared to net cash used in investing activities of $13 for the three months ended March 31, 2022. The decrease compared to the prior year period was primarily due to cash used for purchases of new computers.

Net Cash Flows from Financing Activities: There was no cash used for financing activities during the three months ended March 31, 2023 and 2022.

Funding Requirements

We expect to incur ongoing operating losses for the foreseeable future as we continue to develop our planned therapeutic programs, including related clinical studies and other programs in the pipeline. Our future funding requirements will depend on many factors, including:

- the cost of manufacturing drugs under development, the costs associated with clinical trials and associated salaries and benefits;
- the extent to which we enter into contracts or invest in third parties in order to further develop our drug candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending other intellectual property-related claims; and
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;

If we are unable to raise additional capital when needed, we could be forced to curtail or cease our operations. Our future capital uses and requirements will depend on the time and expenses needed to begin and continue clinical trials for our new drug developments. As discussed above, the coronavirus pandemic could adversely impact the timing and enrollment of our clinical trials.

Additional funding may not be available to us on acceptable terms or at all. The continued coronavirus pandemic and uncertain market and macroeconomic conditions, including due to inflationary pressures, rising interest rates, general economic slowdown or a recession, foreign exchange rate volatility, financial institution instability, changes in monetary policy and increasing geopolitical instability may limit our ability to access capital. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, we may raise additional funds by issuing equity securities or by equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. Further, we may elect to raise additional funds even before we need them if we believe the conditions for raising capital are favorable.

Although we submitted a proposal to our stockholders to amend our amended and restated certificate of incorporation to increase the number of authorized shares of our common stock for various potential purposes, including potential capital raising transactions, our stockholders did not approve the proposal at our 2021 and 2022 annual meetings of stockholders nor did they approve it at a special meeting of stockholders held in September 2021. A lack of authorized shares may limit our ability to raise capital when needed.

We may not be able to satisfy the continued listing standards of The Nasdaq Capital Market (Nasdaq), including its $1.00 minimum bid price requirement. If we cannot satisfy the continued listing standards of Nasdaq, Nasdaq may commence delisting procedures against us, which could result in our common stock being removed from listing on Nasdaq. On October 5, 2022, we received a letter from Nasdaq stating that we were not in compliance with Listing Rule 5550(a)(2) because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. We had until April 3, 2023 to regain compliance or obtain an extension. We applied for such an extension, and on April 4, 2023, we were informed that our deadline for compliance was extended by 180 days, or until October 2, 2023. To regain compliance, the closing bid price of the Company's common stock must be $1.00 per share or more for a minimum of 10 consecutive business days at any time prior to the expiration of the compliance period. The Company intends to actively monitor the closing bid price of its common stock and is committed to regaining compliance with the minimum closing bid price requirement prior to the expiration of the compliance period.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement. If we are unable to regain compliance with Nasdaq Listing Rule 5550(a)(2), and if our stock price continues to trade below the $1.00 minimum bid price requirement, or if we otherwise fail to satisfy other Nasdaq listing requirements, we may be delisted from Nasdaq, and we could face significant material adverse consequences, including adverse effects on our stock price, liquidity, and our ability to raise funding.

Contractual obligations represent future cash commitments and liabilities under agreements with third party clinical research organizations (CROs) and clinical manufacturing organizations (CMOs). With the exception of one CRO contract, such agreements are cancellable upon written notice by the Company. The one non-cancellable contract expires upon completion of the study and release of the final report, or the contract may be terminated by the CRO, or by the FDA or other governmental agency. At March 31, 2023, the Company's non-cancellable commitment related to this contract are estimated to be $1,146 and $13 in 2024. As of March 31, 2023, we have incurred $111 under this contract.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2023, pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act.

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports that are filed or furnished under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (SEC). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or furnished under the Exchange Act is accumulated and communicated to the Company’s management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended March 31, 2023, 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

We are not currently a party to any material legal proceedings. From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. However, we believe that there are no claims or actions pending against us currently, the ultimate disposition of which would have a material adverse effect on our condensed consolidated results of operations, financial condition or cash flows.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, clinical and commercialization activities, the manufacturing of our product candidates, intellectual property, third-party relationships, competitive environment, product and environmental liabilities, and our common stock. These risks are discussed more fully below and include, but are not limited to, risks related to:

Risks Relating to our Business

- We only have a history of operating losses, and, as such, an investor cannot assess our profitability or performance based on past results.
- We have not established sources of ongoing revenue to cover operating costs and allow us to continue as a going concern.
- We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.
- We may expend our capital resources in ways that you don't agree or that don't produce stockholder value.
- We have a history of operating losses, and we expect to continue to incur losses in the future.
- Any products we may develop may never achieve significant commercial market acceptance.
- We may be unable to establish sales, marketing and commercial supply capabilities.
- The loss of the services of our Chief Executive Officer could adversely affect our business.
- Our acquisitions of, collaborations with, licenses with and investments in, other businesses may not yield expected benefits and our inability to successfully integrate these transactions may negatively impact our business, financial condition, and results of operations.
- We may experience difficulty in locating, attracting and retaining experienced and qualified personnel, which could adversely affect our business.
- Compounds and methods that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and interim, top-line or preliminary clinical trial data reports may ultimately differ from actual results once data are more fully evaluated.
- We may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our products.
- We are developing our products for patients who are severely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if such deaths are not shown to be related to our drugs.
- We are dependent on third-party service providers for a number of critical operational activities including, in particular, for the manufacture and testing of our products and associated supply chain operations, as well as for clinical trial activities. Any failure or delay in these undertakings by third parties could harm our business.
- We may encounter delays in our clinical trials or may not be able to conduct our trials in a timely manner.
- Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization.
- Our products and services may expose us to possible litigation and product liability claims.
- Business disruptions, including natural disasters and pandemics, could seriously harm our future revenue and financial condition and increase our costs and expenses.
- We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.
- Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.

Risks Related to our Intellectual Property

- If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.
- Obtaining and maintaining our 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 for non-compliance with these requirements.
- Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

- We may not be able to protect our intellectual property rights throughout the world.
- Our current patent portfolio may not include all patent rights needed for the full development and commercialization of our products. We cannot be sure that patent rights we may need in the future will be available for license on commercially reasonable terms, or at all.
- Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.
- We cannot assure you that our current or future products will not infringe on existing or future patents. We may not be aware of patents that have already been issued that a third-party might assert are infringed by one of our current or future products.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

Risks Related to Our Industry

- Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.
- Our inadvertent or unintentional failure to comply with the complex government regulations concerning patients' privacy, data subjects, and of medical records could subject us to fines and adversely affect our reputation.
- If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.
- The failure to comply with complex federal and state laws and regulations related to submission of claims for services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.
- We face significant competition from other biotechnology and pharmaceutical companies.
- Our employees and third-party partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- Our business involves risk associated with handling hazardous and other dangerous materials.

Risks Related to the Securities Markets and Investment in our Securities.

- Our shares of common stock are listed on the Nasdaq Capital Market, but we cannot guarantee that we will be able to satisfy the continued listing standards going forward.
- The sale of a substantial number of shares of our common stock into the market may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of a substantial number of shares of common stock could cause the price of our common stock to decline.
- The trading price of our common stock has been and is likely to continue to be volatile.
- The ownership of our common stock may become concentrated among a small number of stockholders, and if our principal stockholders, directors and officers choose to act together, they may be able to significantly influence management and operations, which may prevent us from taking actions that may be favorable to stockholders.
- If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock may be negatively affected.
- Our Stockholder Rights Agreement, the anti-takeover provisions in our governing documents and Delaware law could delay or prevent a change in control which could reduce the market price of our common stock and could prevent or frustrate attempts by our stockholders to replace or remove our current management and the current Board of Directors.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our common stock and trading volume could decline.

Purchasing shares of common stock is an investment in our securities and involves a high degree of risk and uncertainty. You should carefully consider the following information about these risks and uncertainties, together with the other information contained in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, before purchasing our securities. If any of the following risks and uncertainties actually occur, our business, financial condition and results of operations may suffer. In that case, the market price of our common stock could decline, and you may lose part or all of your investment in our Company. Additional risks and uncertainties of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to our Business

We only have a history of operating losses, and, as such, an investor cannot assess our profitability or performance based on past results.

Since December 2015, our business has primarily focused on the development of novel therapeutics for the treatment of breast cancer and other breast conditions. Because of our limited operating history, particularly in the area of pharmaceutical development, our revenue and income potential is uncertain and cannot be based on prior results. Any evaluation of our business and prospects must be considered in light of these factors and the risks and uncertainties often encountered by companies in the development stage. Some of these risks and uncertainties include our ability to:

- commence, execute and obtain successful results from our clinical studies;
- obtain regulatory approvals in the U.S. and elsewhere for our pharmaceuticals we are developing;
- work with contract manufacturers to produce our pharmaceuticals under development in clinical and commercial quantities on acceptable terms and in accordance with required standards;
- respond effectively to competition;
- manage our growth in operations;
- respond to changes in applicable government regulations and legislation;
- access additional capital when required;
- execute and successfully integrate strategic transactions, including potential acquisitions or investments; and
- attract and retain key personnel.

We have not established sources of ongoing revenue to cover operating costs and allow us to continue as a going concern.

Although we believe we have sufficient capital resources to fund our operations for at least the next 12 months based on our current business plan, our business plan may change and may require greater expenditures of capital than currently anticipated, in particular, due to expenditures relating to strategic transactions. We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital on reasonable terms, if at all, including due to macroeconomic factors, such as the inflationary environment and recessionary fears, we may be unable to develop and commercialize our product offerings or increase our geographic reach and we could be forced to cease operations.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

For the quarter ended March 31, 2023, we incurred a net loss of approximately $6.3 million, and we have an accumulated deficit of approximately $162.5 million since inception. As of March 31, 2023, we had cash and cash equivalents of approximately $103.9 million. Because we have no current sources of revenue, we expect that we will need to raise capital again in the future to continue to fund our operations. When we elect to raise additional funds or when additional funds are required, we may raise such funds through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. These financing arrangements may not be available on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from developing our pharmaceutical candidates, pursuing acquisitions, and investing in other companies, including as a sponsor or investor in special purpose acquisition companies, licensing, development and commercialization efforts, and our ability to continue our operations, generate revenues, and achieve or sustain profitability may be substantially harmed. We currently have fewer than five million shares of common stock authorized that are not reserved for specific purposes. Although we proposed to our stockholders, at our 2021 and 2022 annual stockholders' meetings and at a special meeting of stockholders held in September 2021, that our amended and restated certificate of incorporation, as amended, be further amended to add additional authorized shares for various potential purposes, including potential capital raising transactions, our stockholders did not approve such proposals and may not approve a similar proposal in the future. A lack of authorized shares may limit our ability to raise capital when needed.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity, including securities convertible into or exercisable for equity securities, that we raise may contain terms, such as liquidation, conversion and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third-parties, it may be necessary for us to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected, and we may be unable to continue our operations.

We may expend our capital resources in ways that you don't agree or that don't produce stockholder value.

We intend to use our capital resources to execute on our business plan, which may include acquiring or in-licensing programs and may also include the internal development of additional programs that may or may not be related to oncology. We may also use our capital resources to invest directly or indirectly in business opportunities in healthcare or other industries, including through purchases of equity in other companies, such as our investment in Dynamic Cell Therapies, Inc. (DCT). These investments may be in special purpose acquisition companies, including either as a sponsor or as an equity investor. Our business plan may evolve to require more capital resources than currently contemplated either because our existing programs progress more quickly or at a greater cost than currently anticipated or because we may add additional programs. Stockholders may not agree with the ways in which we expend our capital resources and our capital deployment activities may not lead to increases in stockholder value.

We have a history of operating losses, and we expect to continue to incur losses in the future.

We have a limited operating history and have incurred net losses each year. Our net operating loss for the three months ended March 31, 2023, was approximately $6.3 million. We will continue to incur further losses in connection with research and development costs for development of our programs, including ongoing and additional clinical studies.

Any products we may develop may never achieve significant commercial market acceptance.

We may not succeed in achieving commercial market acceptance of any of our products. In order to gain market acceptance for the drugs under development, we will need to demonstrate to physicians and other healthcare professionals the benefits of these therapies, including the clinical and economic application for their particular practice, the efficacy and safety and potential advantages compared to alternative therapies. Many physicians and healthcare professionals may be hesitant to introduce new services or techniques into their practice for many reasons, including lack of time and resources, the learning curve associated with the adoption of such new services or techniques into already established procedures, the product's cost, convenience and ease of administration, the then-current standard of care, the strength of marketing and distribution support and the uncertainty of the applicability or reliability of the results of a new product. In addition, the availability of full or even partial payment for our products, whether by third-party payors (e.g., insurance companies), by government payors or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products.

We may be unable to establish sales, marketing and commercial supply capabilities.

We do not currently have, nor have we ever had, commercial pharmaceutical sales and marketing capabilities. If any of our product candidates become approved, we would need to build these capabilities in order to commercialize our approved product candidates. The process of establishing commercial capabilities will be expensive and time consuming, and may not be successful. Even if we are successful in building these capabilities, we may not be successful in commercializing any of our product candidates.

The loss of the services of our Chief Executive Officer could adversely affect our business.

Our success is dependent in large part upon our ability to execute our business plan, manufacture our pharmaceutical drugs and attract and retain highly skilled professional personnel. In particular, due to the relatively early stage of our business, our future success is highly dependent on the services of Steven C. Quay, our Chief Executive Officer and founder, who provides much of the necessary experience to execute our business plan.

Our acquisitions of, collaborations with, licenses with and investments in, other businesses may not yield expected benefits and our inability to successfully integrate these transactions may negatively impact our business, financial condition, and results of operations.

We anticipate that we will make acquisitions of, collaborations with, licenses with or investments in businesses in the future. We may not realize the anticipated benefits, or any benefits, from these transactions. If we fail to properly evaluate, complete and execute acquisitions, our business may be seriously harmed and our stock price may decline. For us to realize the benefits of future transactions, we must successfully integrate the acquired businesses with ours. Some of the challenges to successful integration include:

- unanticipated costs or liabilities resulting from our acquisitions;
- inability to retain key employees from acquired businesses;
- difficulties integrating acquired operations, personnel, and technologies;
- diversion of management attention from existing business operations and strategy;
- diversion of resources that are needed in other parts of our business;
- potential write-offs of acquired assets;
- inability to maintain relationship partners of the acquired business;
- potential financial and credit risks associated with the acquired business;
- the need to implement controls, procedures, and policies at the acquired company;
- the need to comply with additional laws and regulations applicable to the acquired business; and
- the indirect tax of any such acquisitions.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and other transactions could cause us to fail to realize the anticipated benefits of such acquisitions and transactions and negatively impact our business, financial condition, and results of operations.

We may experience difficulty in locating, attracting and retaining experienced and qualified personnel, which could adversely affect our business.

We will need to attract, retain, and motivate experienced clinical development and other personnel, particularly in the greater Seattle area as we expand our pharmaceutical development activities. Personnel with the required skills and experience may be scarce or may not be available at all in this geographic region. In addition, competition for these skilled personnel is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage Company such as ours. If we are unable to attract and retain qualified personnel, our development activities may be adversely affected. Even if we are successful in identifying and attracting qualified employees, recent market changes, including the labor shortage, and rising inflation have increased employee-related costs substantially. As a result, our operating expenses may continue to increase in the current market environment.

Compounds and methods that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and interim, top-line or preliminary clinical trial data reports may ultimately differ from actual results once data are more fully evaluated.

Successful development of pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs is expensive, difficult, and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

- an unacceptable safety profile;
- lack of efficacy;
- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products, and completing manufacturing to support clinical studies;
- pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;
- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products;
- equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;
- inefficient cost structure of a compound, finished drug, or device compared to alternative treatments;
- obstacles resulting from proprietary rights held by others, such as patent rights for a particular compound;
- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, perceived cost/benefit of participating in the study, eligibility criteria for tests, and competition with other clinical testing programs;
- nonclinical or clinical testing requiring significantly more time than expected resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;
- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;
- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;
- delays in reaching or failing to reach agreement on acceptable terms with manufacturers or prospective clinical research organizations (CROs), and trial sites; and
- failure of third-parties, such as clinical research organizations, academic institutions, collaborators, cooperative groups, and/or investigator sponsors, to conduct, oversee, and monitor clinical trials and results.

In addition, from time to time we expect to report interim, top-line or “preliminary” data for clinical trials, including for example the results reported in 2021 for our neoadjuvant or “window of opportunity” Phase 2 study of (Z)-endoxifen. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Interim, top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, interim, top-line or “preliminary” results may differ from future/final results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In addition, third-parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations 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 compound and our business generally.

If the development of our products is delayed or fails, or if top-line or preliminary clinical trial data reported differ from actual results, our development costs may increase and our ability to commercialize our products may be harmed, which could harm our business, financial condition, operating results or prospects.

We may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our products.

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the Europe Medicines Agency (EMA) in the European Union (E.U.), the United Kingdom’s Medicines and Healthcare products Regulatory Agency and the Therapeutic Goods Administration (TGA) in Australia.

Our product candidates are currently in research or development, and we have not received marketing approval for our products. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and pre-clinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. As a result, the regulatory pathway for these products may be more complex and obtaining regulatory approvals may be more difficult.

Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. The number, size, design, and focus of pre-clinical and clinical trials that will be required for approval by the FDA, the EMA, or any other foreign regulatory agency varies depending on the compound, the disease or condition that the products are designed to address and the regulations applicable to any particular products. Pre-clinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA, and other foreign regulatory agencies can delay, limit, or deny approval of a product for many reasons, including, but not limited to:

- a product may not be shown to be safe or effective;
- the clinical and other benefits of a product may not outweigh its safety risks;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- regulatory agencies may not approve the manufacturing process or determine that the manufacturing is not in accordance with current good manufacturing practices;
- a product may fail to comply with regulatory requirements; or
- regulatory agencies might change their approval policies or adopt new regulations.

If our products are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

We are developing our products for patients who are severely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if such deaths are not shown to be related to our drugs.

We have enrolled patients in studies of our drug candidates who may die while enrolled in our studies. Patients in our clinical trials may also experience adverse outcomes following treatment with our drug candidates, including patient death. These adverse outcomes, even if unrelated to our drugs, could expose us to lawsuits and liabilities and could diminish our ability to obtain regulatory approval and/or achieve commercial acceptance for the related drug and our business could be materially harmed.

We are dependent on third-party service providers for a number of critical operational activities including, in particular, for the manufacture and testing of our products and associated supply chain operations, as well as for clinical trial activities. Any failure or delay in these undertakings by third parties could harm our business.

Our business is dependent on the performance by third-parties of their responsibilities under contractual relationships. In particular, we heavily rely on third-parties for the manufacture and testing of our products. We do not have an internal analytical laboratory or manufacturing facilities to allow the testing or production of products in compliance with Good Manufacturing Practices (cGMP). As a result, we rely on third-parties to supply us in a timely manner with manufactured product candidates. We may not be able to adequately manage and oversee the manufacturers we choose; they may not perform as agreed or they may terminate their agreements with us. In particular, we depend on third-party manufacturers to conduct their operations in compliance with current Good Laboratory Practices (GLP) or similar standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of these regulatory authorities may take action against a contract manufacturer who violates cGMP. Failure of our manufacturers to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

We may not be able to obtain sufficient quantities of our products if we are unable to secure manufacturers when needed, or if our designated manufacturers do not have the capacity or otherwise fail to manufacture compounds according to our schedule and specifications or fail to comply with cGMP regulations. Furthermore, in order to ultimately obtain and maintain applicable regulatory approvals, any manufacturers we utilize are required to consistently produce the respective products in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so, which is referred to as process validation. In order to obtain and maintain regulatory approval of a compound, the applicable regulatory authority must consider the result of the applicable process validation to be satisfactory and must otherwise approve of the manufacturing process. Even if our compound manufacturing processes obtain regulatory approval and sufficient supply is available to complete clinical trials necessary for regulatory approval, there are no guarantees we will be able to supply the quantities necessary to affect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any product shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

We also rely on third-party service providers for certain warehousing and transportation. With regard to the distribution of our drugs, we depend on third-party distributors to act in accordance with Good Distribution Practice (GDP), and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with Good Clinical Practices (GCP) and data privacy standards such as defined under the Health Insurance Portability and Accountability Act (HIPAA), and General Data Protection Regulation (GDPR) and in accordance with our timelines, expectations and requirements. We are substantially dependent on the organizations conducting our clinical trials. To the extent any such third-parties are delayed in achieving or fail to meet our clinical trial enrollment expectations, fail to conduct our trials in accordance with GCP, patient and data privacy standards such as HIPAA or study protocol or otherwise take actions outside of our control or without our consent, our business may be harmed. Furthermore, we conduct clinical trials in foreign countries, subjecting us to additional risks and challenges, including, patient and data privacy standards such as GDPR and in particular, as a result of the engagement of foreign medical institutions and foreign CROs, who may be less experienced with regard to regulatory matters applicable to us and may have different standards of medical care.

With regard to certain of the foregoing clinical trial operations and stages in the manufacturing and distribution chain of our compounds, we rely on vendors. In most cases we use a primary vendor and have identified, in some cases, secondary vendors. In particular, our current business structure contemplates, at least in the foreseeable future, use of a primary commercial supplier for the (Z)-endoxifen drug substance. The use of primary vendors for core operational activities, such as, manufacturing, and the resulting lack of diversification, exposes us to the risk of a material interruption in service related to these primary, outside vendors. As a result, our exposure to this concentration risk could harm our business.

Although we monitor the compliance of our third-party service providers performing the aforementioned services, we cannot be certain that such service providers will consistently comply with applicable regulatory requirements or that they will otherwise timely satisfy their obligations to us. Any such failure and/or any failure by us to monitor their services or to plan for and manage our short- and long-term requirements underlying such services could result in shortage of the required compound, delays in or cessation of clinical trials, failure to obtain or revocation of product approvals or authorizations, product recalls, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization, and/or distribution of products, operating restrictions, injunctions, suspension of licenses, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution), and/or unanticipated related expenditures to resolve shortcomings.

Such consequences could have a significant impact on our business, financial condition, operating results, or prospects.

We may encounter delays in our clinical trials or may not be able to conduct our trials in a timely manner.

Clinical trials are expensive and subject to regulatory approvals. Potential trial delays may arise from, but are not limited to:

- the effects of the ongoing coronavirus pandemic, including access to clinical trial sites both by study participants and our clinical research organizations, diversion of healthcare resources to address COVID-19, which could limit the availability of medical facilities for our clinical trials, and supply chain disruptions which could have a material adverse effect on the availability or cost of materials for our product candidates;
- failure to obtain on a timely basis, or at all, approval from the applicable institutional review board or ethics committee to open a clinical study;
- lower than anticipated patient enrollment or delays in patient enrollment, including due to the size and nature of the patient population, existing conditions, patient eligibility criteria defined in the protocol, proximity of patients to trial sites, the design of the trial, our ability to recruit clinical trial investigators with the appropriate competencies and expertise, competing clinical trials for similar or alternate therapeutic treatments, clinicians' and patients' perception of a lack of benefit to enroll in the study for whatever reason, our ability to obtain and maintain patient consents and patients dropping out of the trial;
- delays in reaching agreements on acceptable terms with prospective CRO/vendors;
- failure of CROs or other third-parties to effectively and timely monitor, oversee, and maintain the clinical trials.
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in a clinical trials;
- availability of materials provided by third parties necessary to manufacture our product candidates; and
- changes in regulatory requirements, or additional regulatory requirements.

Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If the FDA concludes that our clinical trials have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the U.S. for the indications sought. In addition, it could cause us to abandon the product candidate and might delay development of other product candidates. Any delay or termination of our clinical trials would delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials could experience adverse side effects that are not currently part of a product candidate's profile.

Our products and services may expose us to possible litigation and product liability claims.

Our business may expose us to potential product liability risks inherent in the testing, marketing, and processing personalized medical products, particularly those products and services we offered prior to shifting our focus on pharmaceutical development. Product liability risks may arise from, but are not limited to:

- death of severely ill patients participating in our studies; and
- adverse events related to drugs and therapies we are developing.

A successful product liability claim, or the costs and time commitment involved in defending against a product liability claim, could have a material adverse effect on our business. Regardless of the merit or outcome of a claim, it may result in decreased demand for our product candidates, reputational harm, withdrawal of clinical trial participants, investigations by regulators, withdrawal of prior governmental approvals, substantial monetary awards to patients, loss of revenue and the inability to commercialize our product candidates. Although we currently carry clinical trial insurance and product liability insurance which we believe to be reasonable, it may not be adequate to cover all liability that we may incur. An inability to renew our policies or to obtain sufficient insurance at an acceptable cost and on commercially desirable or reasonable terms, if at all, including due to a successful product liability claim, could prevent or inhibit the commercialization of our products.

Business disruptions, including natural disasters and pandemics, could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations are based primarily in Seattle, Washington. These operations could be subject to power shortages, telecommunications failures, water shortages, floods, earthquakes, fires, extreme weather conditions, pandemics or epidemics and other natural or man-made disasters or business interruptions, for which we maintain customary insurance policies that we believe are appropriate. In addition, outbreaks of viruses, infectious diseases or pandemics (including, COVID-19), terrorist acts or acts of war, or geopolitical tensions, could cause damage or cause disruptions to us, our employees, facilities, contractors and collaborators, which could have a material adverse effect on our business, financial condition and results of operations. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to manufacture clinical supplies of our product candidates could be disrupted if our suppliers are affected by any of the above events. We may have limited recourse against third parties if the non-compliance is due to factors outside of the manufacturer’s control.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash is held at banking institutions in non-interest-bearing and interest-bearing accounts in amounts that exceed the Federal Deposit Insurance Corporation (FDIC) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. Although we did not have cash, cash equivalents or investments at SVB and the Federal Reserve subsequently announced that account holders would be made whole, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards (NOLs), and research and development tax credits (R&D credits) as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), respectively. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the U.S. Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 of the Code imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carry forwards and Section 383 of the Code imposes an annual limitation on the amount of tax a corporation may offset with business credit (including R&D credits) carryforwards.

We have experienced ownership changes in the past, and there can be no assurance that we will not experience ownership changes in the future. As a result, our NOLs and business credits (including R&D credits) may be subject to limitations, and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs or R&D credits were freely usable.

Risks Related to our Intellectual Property

If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.

Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and to protect our existing patent position, both in the U.S. and in other countries, for therapeutics and related technologies, processes, methods, compositions, and other inventions that we believe are patentable, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of January 31, 2023, we own and are pursuing 75 pending provisional and non-provisional patent applications (19 U.S., including one allowed U.S. application, and 56 international applications, including two allowed international applications) and two issued patents. We continue to evaluate the full range of our technologies and file new patent applications.

Our ability to preserve our trade secrets, trademarks and other intellectual property rights is also important to our long-term success. Our success depends in part on obtaining patent protection for our products and processes, preserving trade secrets, patents, copyrights and trademarks, operating without infringing the proprietary rights of third-parties, and acquiring licenses for technology or products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to establish or maintain profitability. Patents may also be issued to third-parties, which could interfere with our ability to bring our therapeutics to market. As the patent landscape for products for breast disorders, including breast cancers, grows more crowded and becomes more complex we may find it more difficult to obtain patent protection for our products, including those related to (Z)-endoxifen.

The laws of some foreign countries do not protect our proprietary rights to the same extent as U.S. laws, and we may encounter significant problems in protecting our proprietary rights in these countries. Even in the U.S., the patent positions of diagnostic companies and pharmaceutical and biotechnology companies, including our patent position, are generally highly uncertain, particularly after the Supreme Court decisions *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012), *Association for Molecular Pathology v. Myriad Therapeutics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014), and the Federal Circuit Court decisions *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019) and *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021). Our patent positions also involve complex legal and factual questions, for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology companies' patents has emerged to date in the U.S. Furthermore, in the biotechnology and pharmaceutical fields, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for diagnostics, personalized medicine, and analysis and comparison of DNA and, therefore, any patents issued to us may be challenged and potentially invalidated or found ineligible. We will be able to protect our proprietary rights from unauthorized use by third- parties only to the extent that our proprietary technologies and any future tests and products are covered by valid and enforceable patents or are effectively maintained as trade secrets. In addition, our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our products, technology or tests.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or others were the first to make the inventions covered by each of our patent applications;
- we or others were the first to file patent applications for our claimed inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our patent applications will result in issued patents;
- other parties will not challenge any patents issued to us;
- any of our patents will be valid or enforceable;
- any patents issued to us and collaborators will provide a basis for commercially viable therapeutics, will provide us with any competitive advantages or will not be challenged by third-parties; or
- the patents of others will not have an adverse effect on our business.

If a third-party files a patent application with claims to a drug we have discovered or developed, a derivation proceeding may be initiated regarding competing patent applications. If a derivation proceeding is initiated, we may not prevail in the derivation proceeding. If the other party prevails in the derivation proceeding, we may be precluded from commercializing our products, or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

Any litigation proceedings relating to our proprietary technology may fail and, even if successful, may result in substantial costs and distract our 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Finally, we may not be able to prevent, alone or with the support of our licensors, if any, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Obtaining and maintaining our 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 for non-compliance with these requirements.

United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside firms and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on our intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. For the past several years, the U.S. has conducted proceedings involving post-issuance patent review procedures, such as *inter partes* review (IPR), and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board (PTAB), of the USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of a U.S. patent on the grounds that it was anticipated or made obvious by prior art consisting of patents or printed publications. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. Any potential future changes to the U.S. patent system 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 have a material adverse effect on our business, financial condition, results of operations and growth prospects. Further, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In particular, on March 20, 2012, the U.S. Supreme Court issued the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decision, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter. The full impact of the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decision on diagnostic and certain method claims is uncertain. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the U.S. or other countries may be applied retroactively to affect the validity, enforceability, or term of our patent. For example, the U.S. Supreme Court has modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license.

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the U.S. Consequently, we may not be able to prevent third-parties from practicing our inventions in all countries outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement of such patent protection is not as strong as that in the U.S. These products may compete with our products and services, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with our products.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products and services in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Our current patent portfolio may not include all patent rights needed for the full development and commercialization of our products. We cannot be sure that patent rights we may need in the future will be available for license on commercially reasonable terms, or at all.

We may be unable to obtain any licenses or other rights to patents, technology, or know-how from third-parties necessary to conduct our business and such licenses, if available at all, may not be available on commercially reasonable terms. Others may seek licenses from us for other technology we use or intend to use. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our proposed products, which would harm our business. We may not be able to secure such a license on acceptable terms. Litigation or patent derivation proceedings may need to be brought against third-parties, as discussed below, to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of the proprietary rights of such third-parties.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third-parties, including the intellectual property rights of competitors. There is a substantial amount of litigation, both within and outside the U.S., involving patents and other intellectual property rights in the medical device and pharmaceutical fields, as well as administrative proceedings for challenging patents, including *inter partes* review, post-grant review, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions. These procedures bring uncertainty to the possibility of challenges to our patents in the future, including those patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third-parties, exist in the fields in which we are developing our products. As the medical device, biotechnology, and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our products may give rise to claims of infringement of the patent rights of others.

We cannot assure you that our current or future products will not infringe on existing or future patents. We may not be aware of patents that have already been issued that a third-party might assert are infringed by one of our current or future products.

Third-parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our products may infringe, or which such third-parties claim are infringed by our products and services.

Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our products. Defense of these claims, regardless of their merit, would involve substantial expenses and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third-party, we may have to (i) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third-party's patents; (ii) obtain one or more licenses from the third-party; (iii) pay royalties to the third-party; or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our products, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

In addition to infringement claims against us, if third-parties have prepared and filed patent applications in the U.S. that also claim technology related to our products, we may have to participate in derivation proceedings in the USPTO to determine the priority of invention. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other diagnostic, medical device or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to enter into confidentiality agreements. However, we cannot be certain that all such confidentiality agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third-parties for misappropriating the trade secret.

Risks Related to Our Industry

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Similar changes and revisions can also occur in foreign countries.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which, may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Our inadvertent or unintentional failure to comply with the complex government regulations concerning patients' privacy, data subjects, and of medical records could subject us to fines and adversely affect our reputation.

Federal privacy regulations, among other things, restrict our ability to use or disclose protected health information in the form of patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations as defined under HIPAA, except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. Applicable privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although HIPAA and its implementing regulations do not expressly provide for a private right of damages, we could incur damages under state laws, for example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act to private parties for the wrongful use or disclosure of confidential health information or other personal information.

We intend to implement policies and practices that we believe will make us compliant with applicable privacy regulations. However, the documentation and process requirements of applicable privacy regulations are complex and subject to interpretation. Failure to comply with applicable privacy regulations could subject us to sanctions or penalties, loss of business, and negative publicity.

The HIPAA privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws, which vary from state to state, are sometimes contradictory with one another, and are often more restrictive than HIPAA. Additionally, the documentation and process requirements of such laws are complex and subject to interpretation. The failure to comply with applicable privacy laws could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

The collection and processing of personal data, including personal health data related to individuals in the E.U. regardless of citizenship or residence is governed by the provisions of the General Data Protection Regulation 2016/679 (GDPR) which provides for significant penalties for noncompliance. GDPR supersedes the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995. The GDPR regulates (i) the processing of personal data carried out in the context of the activities of a company established in the E.U.; and (ii) the processing of personal data carried out by a company not established in the E.U. where such processing relates to (a) the offering of goods or services to data subjects who are in the E.U. or (b) the monitoring of the behavior of data subjects who are in the E.U. The GDPR imposes a number of requirements, including an obligation to rely on a legal basis (such as the consent of individuals to whom the personal data relates), the information that must be provided to the individuals, notification obligations to the competent national data protection authorities, and the security and confidentiality of the personal data. E.U. Member States may also impose additional requirements in relation to health, genetic and biometric data through their national implementing legislation.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of £17.5 million or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from E.U. member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review (and may be modified or revoked) by the Commission during this period. The relationship between the UK and the E.U. in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

Failure to comply with the requirements of GDPR and/or UK GDPR, and the related national data protection laws of the E.U. Member States or the UK may result in fines and other administrative penalties, litigation, government enforcement actions (which could include civil and/or criminal penalties), and harm our business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may have contractual rights that may limit our ability to use this information. Claims that we have violated patient’s or any individual’s rights or breached our contractual obligations, even if ultimately we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity and harm our business.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, manage our manufacturing operations, fulfill customer orders, capture laboratory data, maintain corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events, including, but not limited to, natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error and complications encountered as existing systems are maintained, repaired, replace or upgraded. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could negatively impact our ability to serve our customers, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable time frame. In addition, our information technology systems are potentially vulnerable to data security breaches — whether by employees or others — which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property or could lead to the public exposure of personal information (including sensitive personal information) of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations. In addition, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations the E.U. GDPR and the UK GDPR, and other regulations, the violation of which could result in significant penalties. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Although we utilize various procedures and controls to mitigate our exposure to these risks, cyber attacks and other cyber events are evolving, unpredictable and increasing in sophistication. Moreover, we have no control over the information technology systems of our third-party partners, including suppliers, manufacturers, service providers and others with which our systems may connect and communicate. As a result, the occurrence of a cyber incident could go unnoticed for a period of time. We have cybersecurity insurance coverage in the event we become subject to various cyber attacks, however, we cannot ensure that it will be sufficient to cover any particular losses we may experience. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations.

The failure to comply with complex federal and state laws and regulations related to submission of claims for services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.

We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for services, including those that relate to coverage of services under Medicare, Medicaid, and other governmental healthcare programs, the amounts that may be billed for services, and to whom claims for services may be submitted, such as billing Medicare as the secondary, rather than the primary, payor. The failure to comply with applicable laws and regulations, for example, enrollment in the Medicare Provider Enrollment, Chain and Ownership System, could result in our inability to receive payment for our services or attempts by third-party payors, such as Medicare and Medicaid, to recover payments from us that we have already received. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including civil money penalties of up to $10,000 for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare and Medicaid. Government authorities may also assert that violations of laws and regulations related to submission of claims violate the federal False Claims Act or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. The Company will be generally dependent on independent physicians to determine when its services are medically necessary for a particular patient. Nevertheless, we could be adversely affected if it were determined that the services we provided were not medically necessary and not reimbursable, particularly if it were asserted that we contributed to the physician's referrals of unnecessary services. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by us if it were found that we knowingly participated in the arrangement that resulted in submission of the improper claims.

In addition to the Patient Protection and Affordable Care Act ("PPACA"), the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy could adversely affect our business.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the U.S. in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by any new federal legislation and the expansion in government's effect on the U.S. healthcare industry, including the Inflation Reduction Act enacted in August 2022, may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

We face significant competition from other biotechnology and pharmaceutical companies.

Our product candidates face, and will continue to face, intense competition from large pharmaceutical and biotechnology companies, as well as academic and research institutions. We compete in an industry that is characterized by (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products that compete with our product candidates and they may develop and commercialize additional products that will compete with our product candidates. Because competing companies and institutions may have greater financial resources than us, they may be able to provide broader services and product lines, make greater investments in research and development or carry on broader R&D initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking preclinical and clinical testing of product candidates, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products.

Even if we obtain regulatory approval for our products, we may not be the first to market and that may affect the price or demand for our potential products. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication, or fewer side effects, than our potential products or may offer comparable performance at a lower cost. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our potential products thereby reducing or eliminating our commercial opportunity. We may not be able to implement our business plan if the acceptance of our potential products is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our potential products, or if physicians switch to other new products or choose to reserve our potential products. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product, which may prevent us from obtaining approval from the FDA for such potential products for the same indication for a period of time. If our potential products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

Our employees and third-party partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employees' or our third-party partners' fraud or other misconduct. Misconduct by our employees or partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee and third-party misconduct could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our business and our reputation. It is not always possible to identify and deter such misconduct, 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. 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 material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Our business involves risk associated with handling hazardous and other dangerous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, animal tissue, and biological waste. The risk of accidental contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of our manufacturing processes or cessation of operations.

Risks Related to the Securities Markets and Investment in our Securities.

Our shares of common stock are listed on the Nasdaq Capital Market, but we cannot guarantee that we will be able to satisfy the continued listing standards going forward, which could make it more difficult for our stockholders to sell their shares.

Although our shares of common stock are listed on the Nasdaq Capital Market (Nasdaq), we cannot ensure that we will be able to satisfy the continued listing standards of Nasdaq going forward, including its $1.00 minimum bid price requirement. If we cannot satisfy the continued listing standards going forward, Nasdaq may commence delisting procedures against us, which could result in our stock being removed from listing on Nasdaq. On October 5, 2022, we received a letter from Nasdaq stating we were not in compliance with Listing Rule 5550(a)(2) because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. The Company had until April 3, 2023 to regain compliance or obtain an extension of the deadline to comply. The Company applied for such an extension and on April 4, 2023, the Company was informed that the deadline for compliance was extended by 180 days, or until October 2, 2023. To regain compliance, the closing bid price of the Company's common stock must be $1.00 per share or more for a minimum of 10 consecutive business days at any time prior to the expiration of the compliance period. The Company intends to actively monitor the closing bid price of its common stock and is committed to regaining compliance with the minimum closing bid price requirement prior to the expiration of the compliance period.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement. If we are unable to regain compliance with Nasdaq Listing Rule 5550(a)(2), and if our stock price continues not to satisfy the $1.00 minimum bid price requirement or we otherwise fail to satisfy other continued listing requirements, we may be delisted from Nasdaq, and we could face significant material adverse consequences, including;

- stock price volatility;
- limited availability of market quotations for our common stock;
- reduce liquidity with respect to our common stock;
- a determination that our shares are "penny stock," which will require brokers trading in our shares to adhere to more stringent requirements, and which may limit demand for our common stock among certain investors;
- limited news and analyst coverage on the Company; and
- decrease ability to issue additional securities or obtain additional financing in the future.

The sale of a substantial number of shares of our common stock into the market may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of a substantial number of shares of common stock could cause the price of our common stock to decline.

We have offered and sold a considerable amount of our common stock in past financings. Any additional or anticipated sales of shares by us, holders of our warrants to purchase common stock or other stockholders may cause the trading price of our common stock to decline. Additional issuances of shares by us may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by us, our warrant holders or other stockholders or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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

Our stock price is highly volatile. In addition to the factors discussed in this Quarterly Report, the trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control including:

- price and volume fluctuations in the overall stock market;
- changes in operating results and performance and stock market valuations of other biopharmaceutical companies generally;
- macroeconomic industry, geopolitical and market conditions, including, but not limited to, rising interest rates, the inflationary environment, recessionary fears and rising geopolitical tensions;
- financial or operational projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in government regulation;
- our inclusion or removal from certain stock indices;
- developments in patent or other proprietary rights;
- new products by our competitors;
- announcements of changes in our senior management or directors;
- other events, including those resulting from war, incidents of terrorism, natural disasters, pandemics, including COVID-19, or responses to these events;
- changes in accounting principles;
- results of clinical studies;
- regulatory and FDA actions, including inspections and warning letters;
- coverage of us, and changes in financial estimates by any securities analysts who follow our Company, or our failure to meet these estimates or the expectations of investors;
- any ongoing litigation that we are currently involved in or litigation that we may become involved in the future;
- additional shares of our common stock being sold into the market by us or our existing stockholders or warrant holders or the anticipation of such sales; and
- media coverage of our business and financial performance.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many healthcare companies. Stock prices of many healthcare companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. As a result, an investment in our common stock may decrease in value.

The ownership of our common stock may become concentrated among a small number of stockholders, and if our principal stockholders, directors and officers choose to act together, they may be able to significantly influence management and operations, which may prevent us from taking actions that may be favorable to stockholders.

Our ownership may become concentrated among a small number of stockholders. These stockholders, acting together, could have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could also have the effect of delaying, deferring, or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to stockholders.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock may be negatively affected.

We are required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. If we identify material weaknesses in our internal control over financial reporting, or if we are unable to comply with the requirements of the Sarbanes-Oxley Act in a timely manner or assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Our Stockholder Rights Agreement, the anti-takeover provisions in our governing documents and Delaware law could delay or prevent a change in control which could reduce the market price of our common stock and could prevent or frustrate attempts by our stockholders to replace or remove our current management and the current Board of Directors.

Our Stockholder Rights Agreement, which we adopted in May 2014, our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws contain provisions that could delay or prevent a change in control or changes in our Board of Directors (our Board) that our stockholders might consider favorable. These provisions include a staggered Board, which divides the Board into three classes, with directors in each class serving staggered three-year terms. The existence of a staggered board can make it more difficult for a third-party to effect a takeover of our Company if the incumbent Board does not support the transaction. These and other provisions in our corporate documents, including our Shareholder Rights Plan and Delaware law might discourage, delay or prevent a change in control or changes in our Board. These provisions could also discourage proxy contests and make it more difficult for activist investors and other stockholders to elect directors not nominated by our Board. Furthermore, the existence of these provisions, together with certain provisions of Delaware law, might hinder or delay an attempted takeover other than through negotiations with our Board.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our common stock and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Multiple securities and industry analysts currently cover us. If one or more of the analysts downgrade our common stock or publish inaccurate or unfavorable research about our business, the price of our common stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which could cause the price of our common stock and trading volume to decline.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEMS 6. EXHIBITS

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein	
		Form	**Date**
3.1	Amended & Restated Bylaws	Current Report on Form 8-K, as Exhibit 3.2	April 26, 2023
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith	
31.2	Certification Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith	
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith	
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith	
101.INS	Inline XBRL Instance Document		
101.SCH	Inline XBRL Taxonomy Extension Schema Document		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document		
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)		

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.

Date: May 15, 2023

/s/ Steven C. Quay
President and Chief Executive Officer
(On behalf of the Registrant)

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(As Principal Financial and Accounting Officer)

Exhibit 31.1

**CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Steven C. Quay, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 15, 2023

/s/Steven C. Quay
Steven C. Quay
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kyle Guse, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 15, 2023

/s/Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(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 Atossa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven C. Quay, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 15, 2023

/s/ Steven C. Quay
Steven C. Quay
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Atossa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kyle Guse, Chief Financial Officer, General Counsel and Secretary of the Company, certify, pursuant to 18 U.S.C. Section1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 15, 2023

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal Financial and Accounting Officer)