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, 2025
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.)**
10202 5th Avenue NE, Suite 200 Seattle, WA	**98125**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (206) 588-0256

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

As of May 1, 2025, the registrant had 129,170,004 shares of common stock, $0.18 par value per share, outstanding.

ATOSSA THERAPEUTICS, INC.
QUARTERLY REPORT
FORM 10-Q

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PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share and per share data)
(Unaudited)

	March 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 65,116	$ 71,084
Restricted cash	110	110
Prepaid materials	2,079	2,098
Prepaid expenses and other current assets	1,439	1,165
Total current assets	68,744	74,457
Other assets	2,003	1,987
Total assets	$ 70,747	$ 76,444
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,165	$ 679
Accrued expenses	1,788	919
Payroll liabilities	942	1,862
Other current liabilities	1,530	1,507
Total current liabilities	5,425	4,967
Total liabilities	5,425	4,967
Commitments and contingencies (Note 12)	—	—
Stockholders' equity		
Convertible preferred stock - $0.001 par value; 10,000,000 shares authorized; 582 shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock - $0.18 par value; 350,000,000 shares authorized; 129,170,004 shares issued and outstanding as of March 31, 2025 and December 31, 2024	23,488	23,488
Additional paid-in capital	261,819	261,256
Treasury stock, at cost; 1,320,046 shares of common stock at March 31, 2025 and December 31, 2024	(1,475)	(1,475)
Accumulated deficit	(218,510)	(211,792)
Total stockholders' equity	65,322	71,477
Total liabilities and stockholders' equity	$ 70,747	$ 76,444

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

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ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(Unaudited)

	For the Three Months Ended March 31,	
	2025	2024
Operating expenses		
Research and development	$ 4,157	$ 3,748
General and administrative	3,257	3,232
Total operating expenses	7,414	6,980
Operating loss	(7,414)	(6,980)
Interest income	720	1,138
Other expense, net	(24)	(36)
Loss before income taxes	(6,718)	(5,878)
Income tax benefit	—	—
Net loss	$ (6,718)	$ (5,878)
Net loss per share of common stock - basic and diluted	$ (0.05)	$ (0.05)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	129,170,004	125,319,778

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ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(amounts in thousands, except share data)
(Unaudited)

	Convertible Preferred Stock		Common Stock			Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Amount	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2023	582	$ —	125,304,064	$ 22,792	$ 255,987	$ (1,475)	$ (186,288)	$ 91,016
Issuance of common stock upon warrant exercise	—	—	203,750	37	167	—	—	204
Stock-based compensation	—	—	—	—	417	—	—	417
Net loss	—	—	—	—	—	—	(5,878)	(5,878)
Balance at March 31, 2024	582	$ —	125,507,814	$ 22,829	$ 256,571	$ (1,475)	$ (192,166)	$ 85,759

	Convertible Preferred Stock		Common Stock			Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Amount	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2024	582	$ —	129,170,004	$ 23,488	$ 261,256	$ (1,475)	$ (211,792)	$ 71,477
Stock-based compensation	—	—	—	—	563	—	—	563
Net loss	—	—	—	—	—	—	(6,718)	(6,718)
Balance at March 31, 2025	582	$ —	129,170,004	$ 23,488	$ 261,819	$ (1,475)	$ (218,510)	$ 65,322

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

	For the Three Months Ended March 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (6,718)	$ (5,878)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	563	417
Loss on disposal of assets	—	2
Depreciation	4	5
Changes in operating assets and liabilities:		
Prepaid materials	19	115
Prepaid expenses and other current assets	(274)	549
Other assets	(11)	—
Accounts payable	486	424
Accrued expenses	869	640
Payroll liabilities	(920)	(995)
Other current liabilities	23	23
Net cash used in operating activities	(5,959)	(4,698)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(9)	(6)
Net cash used in investing activities	(9)	(6)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of warrants	—	204
Net cash provided by financing activities	—	204
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(5,968)	(4,500)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	71,194	88,570
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 65,226	$ 84,070
RECONCILIATION OF CASH AND CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 65,116	$ 83,960
Restricted cash	110	110
Total cash, cash equivalents and restricted cash	$ 65,226	$ 84,070

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

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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 focused on developing proprietary innovative medicines in areas of significant unmet medical need in oncology, with a focus on breast cancer and other breast conditions.

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, 2025, the Company recorded a net loss of $6.7 million and used $6.0 million of cash in operating activities. As of March 31, 2025, the Company had $65.1 million in cash and cash equivalents and working capital of $63.3 million. 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 cash and cash equivalents 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 SIGNIFICANT 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 have been no material changes 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, 2024. The year-end Condensed Consolidated Balance Sheet presented in this report was derived from audited consolidated financial statements but does not include all annual disclosures required by GAAP.

In the opinion of management, all adjustments (including normal recurring accruals) considered necessary for a fair presentation have been included and have been prepared on the same basis as the annual consolidated financial statements. Operating results for the three months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025.

Use of 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. Significant estimates and assumptions reflected in these financial statements include stock-based compensation expense and prepaid or accrued clinical trial balances at the end of any reporting period. Actual results could differ materially from the Company's estimates.

Cash and Cash Equivalents

Cash and cash equivalents include unrestricted cash and all highly liquid instruments with original maturities of three months or less at the date of purchase. Cash equivalents consist primarily of amounts invested in money market accounts.

Restricted Cash

The Company's restricted cash balance as of March 31, 2025 and December 31, 2024 consisted entirely of cash pledged as security for the Company's issued commercial credit cards.

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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 equivalents, including those deposited in money market deposit accounts. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any material losses in such accounts and believes it is not exposed to significant risk. The Company has invested its excess cash primarily in money market funds.

Clinical Trial and Preclinical Study Accruals

The Company makes estimates of its accrued expenses for clinical trial and preclinical study activities as of each balance sheet date in its financial statements based on the facts and circumstances known to the Company at that time. These accruals are based upon estimates of costs incurred and fees that may be associated with services provided by clinical trial investigational sites and Contract Research Organizations (CROs), and for other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and progression through the various stages of the Company's clinical trials. In accruing for these services, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other information available to it. If the Company underestimates or overestimates the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, the Company’s estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in the Company's accruals.

Prepaid Materials

The Company capitalizes its purchase of certain raw materials, active pharmaceutical ingredients and related supplies for use in the manufacturing of drug products for use in its preclinical and clinical development programs, as it has determined that these materials have alternative future use. The Company can use these raw materials and related supplies in multiple clinical drug products, and they therefore they have future use independent of the development status of any particular drug program until they are utilized in the manufacturing process. The Company expenses the cost of materials when used. The Company periodically reviews these capitalized materials for continued alternative future use and writes down the assets to their net realizable value in the period in which an impairment is identified. Prepaid materials not expected to be used within 12 months of the balance sheet date are presented in Other assets on the Condensed Consolidated Balance Sheets.

Other Assets

Other assets consist of property and equipment, prepaid materials and clinical deposits.

Fair Value Measurements

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

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

- Level 1: Quoted market prices in active markets for identical assets or liabilities;
- Level 2: Other observable market-based inputs or unobservable inputs that are corroborated by market data; and
- Level 3: Unobservable inputs that cannot be corroborated by market data that reflects the reporting entity's own assumptions.

The carrying amounts reflected in the accompanying Condensed Consolidated Balance Sheets for cash and cash equivalents, restricted cash, and accounts payable approximate their fair values due to their short-term nature. Refer to Note 8 of these Condensed Consolidated Financial Statements.

Research and Development

Research and development (R&D) costs are expensed as incurred and consist of costs associated with research activities. R&D expenses include, for example, manufacturing expenses for the Company's 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 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 activities and also acts as the Company's Chief Medical Officer.

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Stock-based Compensation

The Company measures and recognizes compensation expense for all stock-based awards made to employees, officers, non-employee directors, and other key persons providing services to the Company, currently limited to stock options. Stock-based compensation is measured using the estimated grant date fair value and is recognized as an expense over the requisite service period, generally the vesting 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 price of the Company's common stock, the expected life of the options, an expectation regarding future dividends on the Company's common stock, and a 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 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 assumption is based upon prevailing short-term interest rates over the expected life of the options as of the grant date.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to be recovered or settled. Realization of deferred tax assets is dependent upon future taxable income. A valuation allowance is recognized if it is more likely than not that some portion or all of a deferred tax asset will not be realized based on the weight of available evidence, including expected future earnings. The Company recognizes an uncertain tax position in its financial statements when it concludes that a tax position is more likely than not to be sustained upon examination based solely on its technical merits. Only after a tax position passes the first step of recognition will measurement be required. Under the measurement step, the tax benefit is measured as the largest amount of benefit that is more likely than not to be realized upon effective settlement. This is determined on a cumulative probability basis. The full impact of any change in recognition or measurement is reflected in the period in which such change occurs. The Company records any interest or penalties related to income taxes in income tax benefit in the Condensed Consolidated Statements of Operations.

Recently Issued Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) No. 2024-03, *Disaggregation of Income Statement Expenses (Topic 220-40)*. This standard requires business entities to disclose in a tabular format, on an annual and interim basis, purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion for each income statement line item that contains those expenses. The guidance is effective for public business entities in annual reporting periods beginning after December 15, 2026, and in interim periods within annual reporting periods beginning after December 15, 2027. Entities may apply the guidance prospectively or retrospectively. The Company is currently assessing the potential impact of this ASU.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes: Improvements to Income Tax Disclosures (Topic 740).* This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. This ASU is effective for annual periods beginning after December 15, 2024. The Company is currently assessing the potential impact of this ASU.

The Company does not expect the adoption of any other recently issued accounting pronouncements to have a material impact on its financial statements.

NOTE 4: PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	As of March 31, 2025	As of December 31, 2024
Prepaid pre-clinical and clinical trial deposits	$ 285	$ 350
Prepaid insurance	461	628
Prepaid professional services	425	68
Other	268	119
Total prepaid expenses and other current assets	$ 1,439	$ 1,165

NOTE 5: ACCRUED EXPENSES

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Accrued expenses consisted of the following (in thousands):

	As of March 31, 2025	As of December 31, 2024
Accrued pre-clinical and clinical trial costs	$ 1,109	$ 700
Accrued professional services and other	679	219
Total accrued expenses	$ 1,788	$ 919

NOTE 6: PAYROLL LIABILITIES

Payroll liabilities consisted of the following (in thousands):

	As of March 31, 2025	As of December 31, 2024
Accrued bonuses	$ 320	$ 1,305
Accrued vacation	261	226
Accrued payroll and benefits	361	331
Total payroll liabilities	$ 942	$ 1,862

NOTE 7: OTHER CURRENT LIABILITIES

In 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 R&D cash rebates on qualified R&D activities incurred in the country. The Australian R&D tax incentive program is a self-assessment program, and as such, the Australian Taxation Office (ATO) has the right to review the Company's program and related expenditures for a period of four years following the tax return filing date. If a review were to occur, a qualified program and related expenditures could be disqualified by the ATO with interest and penalties. Based on the Company's evaluation of the ATO's taxpayer alert in December 2023, the Company believes that it is no longer reasonably assured that the full tax position would be sustained under audit. Accordingly, as of March 31, 2025 and December 31, 2024, a liability of $1.5 million was included in Other current liabilities in the Condensed Consolidated Balance Sheets.

NOTE 8: 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, that are measured at fair value on a recurring basis (in thousands):

March 31, 2025	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market fund	$ 62,756	$ 62,756	$ —	$ —

December 31, 2024	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market fund	$ 68,543	$ 68,543	$ —	$ —

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NOTE 9: STOCKHOLDERS' EQUITY

Common Stock

The Company is authorized to issue 350,000,000 shares of common stock, par value $0.18 per share. The Company may offer, from time to time, to sell, in an "at the market offering", shares of our common stock up to an aggregate offering price of up to $100.0 million. We did not make any sales under the at the market offering facility during the year ended December 31, 2024 or during the quarter ended March 31, 2025.

Preferred Stock

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value $0.001 per share. The Company has designated 750,000 shares of Series A junior participating preferred stock, par value $0.001 per share, 4,000 shares of Series A convertible preferred stock, par value $0.001 per share, 25,000 shares of Series B convertible preferred stock, par value $0.001 per share, and 20,000 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, 2025 and December 31, 2024.

Series B Convertible Preferred Stock

Conversion. Each share of Series B convertible preferred stock is convertible at the Company's option at any time, or at the option of the holder at any time, into the number of shares of the Company's 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 the Company's common stock outstanding immediately after giving effect to its conversion.

During the quarters ended March 31, 2025 and 2024 there were no conversions of Series B convertible preferred stock**.**

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 its common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by its 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. The Company's preferred stock contractually entitles 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.

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 warrants were issued to institutional and accredited investors as a part of certain financing transactions, which closed on December 21, 2020, January 8, 2021, and March 23, 2021. The terms and conditions of the warrants are as follows:

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Exercisability. Each warrant is exercisable at any time and will expire 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 the Company's 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 or, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of the Company's 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 the Company's 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 the Company's stockholders. The Company's warrants 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.

Warrants Outstanding

As of March 31, 2025, the following warrants to purchase shares of the Company's common stock were outstanding:

	Outstanding Warrants to Purchase Shares		Exercise Price Per Warrant	Expiration Date
December 2020 warrants	2,812,500	$	1.00	June 21, 2025
January 2021 warrants	4,500,000	$	1.055	July 8, 2025
March 2021 warrants	10,525,000	$	2.88	September 22, 2025
	17,837,500			

Warrant Activity

There were no warrant exercises during the three months ended March 31, 2025. During the three months ended March 31, 2024, the Company received approximately $0.2 million from the exercises of warrants, resulting in the issuance of 203,750 shares of common stock.

NOTE 10: NET LOSS PER SHARE

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding. Diluted net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock that would have been outstanding during the period assuming the issuance of shares of common stock for all potentially dilutive shares of common stock outstanding. Potentially dilutive shares of common stock consist of outstanding stock options, convertible preferred stock and common stock

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warrants. Because the inclusion of potential shares of common stock would be anti-dilutive for all periods presented, they have been excluded from the calculation.

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

	Three Months Ended March 31,	
	2025	2024
Options to purchase common stock	20,631,717	17,310,990
Series B convertible preferred stock	165,338	165,338
Warrants to purchase common stock	17,837,500	21,498,786
	38,634,555	38,975,114

NOTE 11: 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. Therefore, no income tax provision was recorded for the three months ended March 31, 2025 and 2024.

NOTE 12: COMMITMENTS AND CONTINGENCIES

Litigation and Contingencies

On April 3, 2025, Intas Pharmaceuticals Ltd. (Intas) filed a Petition for Post Grant Review (PGR) with the U.S. Patent and Trademark Office's (USPTO) Patent Trial and Appeal Board (PTAB) (the 391 PGR Petition) seeking to invalidate one of the Company's issued patents (U.S. Patent No. 12,071,391) titled "Methods for Making and Using Endoxifen," on the alleged grounds of anticipation, obviousness, lack of written description, and lack of enablement.

On April 3, 2025, Intas also filed a Petition for *Inter Partes* Review (IPR) with the USPTO's PTAB (the 151 IPR Petition) seeking to invalidate one of the Company's issued patents (U.S. Patent No. 11,261,151) titled "Methods for Making and Using Endoxifen" (together with U.S. Patent No. 12,071,391, the Patents) on the alleged grounds of anticipation and obviousness.

The Company intends to vigorously contest the 391 PGR Petition and the 151 IPR Petition and believes that the Patents were properly granted and include valid and enforceable claims. However, there can be no assurance that the Company will prevail in contesting either the 391 PGR Petition or the 151 IPR Petition.

From time to time, the Company is subject to other legal proceedings and claims that arise in the ordinary course of its business. The Company believes that these matters do not have a material effect, individually or in the aggregate, on its financial position, results of operations or cash flows.

Contractual Obligations

Contractual obligations represent the Company's future cash commitments and liabilities under agreements with third party clinical trial service providers. Apart from contracts with one third-party clinical trial service provider, such agreements are cancellable upon written notice by the Company. The non-cancellable contracts expire upon completion of the clinical trial and release of the final report, or the contracts may be terminated by the clinical trial service provider, by the FDA or another governmental agency. As of March 31, 2025, the Company's estimated non-cancellable commitment was $9.4 million.

NOTE 13: STOCK BASED COMPENSATION

On May 15, 2020, the stockholders of the Company approved the 2020 Stock Incentive Plan (the 2020 Plan) to provide for the grants 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 June 27, 2034. An aggregate of 30,000,000 shares of common stock is reserved for issuance in connection with awards granted under the 2020 Plan. As of March 31, 2025, 12,973,325 shares were available for future grants under the 2020 Plan.

The Company granted 134,600 and 145,834 options to purchase shares of common stock to employees and directors during the three months ended March 31, 2025 and 2024, respectively. The weighted average grant date fair value of options granted during the three months ended March 31, 2025 and 2024 was $0.58 and $1.13, respectively. No stock options were exercised during the three months ended March 31, 2025 and 2024.

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The Company recognized stock-based compensation expense in the Condensed Consolidated Statements of Operations as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 131	$ 116
General and administrative	432	301
Total stock-based compensation expense	$ 563	$ 417

The following table shows a summary of all stock option activity for the three months ended March 31, 2025:

	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, 2025	20,691,571	$ 1.60		
Granted	134,600	0.72		
Forfeited	(116,000)	1.02		
Expired	(2,627)	338.40		
Outstanding as of March 31, 2025	20,707,544	$ 1.56	6.61	$ 9,482
Exercisable as of March 31, 2025	17,848,421	$ 1.63	6.18	$ 8,182
Vested and expected to vest	20,707,544	$ 1.56	6.61	$ 9,482

As of March 31, 2025, there were 2,859,123 unvested options outstanding, and the related unrecognized total compensation cost associated with these options was $2.4 million. This expense is expected to be recognized over a weighted-average period of 1.82 years.

NOTE 14: 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, 2025 and 2024 were $75 thousand and $77 thousand, respectively.

NOTE 15: SEGMENTS

The Company operates as a single segment. Operating segments are identified as the components of an enterprise of which separate discrete financial information is available for evaluation by the Chief Operating Decision Maker (the CODM) in making decisions regarding resource allocation and in assessing performance. The measure of segment assets is reported on the balance sheets as total assets. To date, the Company's CODM has made such decisions and assessed performance at the Company-level as a single segment using information at the condensed consolidated financial statement level.

The CODM is Steven C. Quay, M.D., Ph D. Chairman, President and CEO. The CODM utilizes Net Loss from the Condensed Consolidated Statement of Operations for the measure of segment loss.

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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 our business. Actual results, outcomes and the timing of results or outcomes 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

All statements made in this Quarterly Report on Form 10-Q (this report) that are not statements of historical fact, including statements regarding guidance, industry prospects or future results of operations or financial position, are 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, outcomes and the timing of results or outcomes to differ materially from those projected or anticipated. Although we believe that our assumptions underlying our forward-looking statements are reasonable as of the date of this Quarterly Report, we cannot assure you that the forward-looking statements set out in this Quarterly Report will prove to be accurate. We may identify these forward-looking statements by the use of forward-looking words, including, but not limited to, "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate," "future," "believe," "design," "predict," or the negative versions of these words or other similar expressions. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about: :

- the impact of general macroeconomic conditions, including the impact of inflation, high interest rates, general economic slowdown or a recession, foreign exchange rate volatility, financial institution instability, changes in monetary policy, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, and increasing geopolitical instability, including the conflict in Ukraine, the conflict in the Middle East and rising tensions between China and Taiwan, on our business, our ability to access capital markets, our operating costs and our supply chain;
- the effects of natural disasters, pandemics, severe weather conditions and other events beyond our control;
- 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 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 deploy artificial intelligence "AI" in our or our collaborators' product candidates;
- 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;

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- our ability to establish and maintain intellectual property rights covering our products, including our ability to obtain patent coverage for our product candidates;
- 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, including evolving legal standards and regulations, including those concerning data protection, consumer privacy, sustainability and evolving labor standards;
- our ability to regain compliance with the continued listing requirements of the Nasdaq Capital Market (Nasdaq);
- 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.

This Quarterly Report also contains estimates and other statistical data provided by third parties and by us relating to market size and growth, and other industry data. These and other forward-looking statements made in this Quarterly Report, unless otherwise indicated, are presented as of the date of the filing of this Quarterly Report. We have discussed certain important factors, risks and uncertainties in the cautionary statements included in this Quarterly Report, particularly in the sections titled "ITEM 1A. RISK FACTORS," "ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS," and elsewhere in this Quarterly Report that we believe could cause our actual results, events or outcomes, or the timing of these results or outcomes, to differ materially from our anticipated results, events or outcomes, or the anticipated timing of these results or outcomes, including any variation between interim or preliminary and final clinical results or analysis. 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 Quarterly Report. Except as required by law, we expressly disclaim any intent to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events, future 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 focus on women's breast cancer and other breast conditions. Our lead drug candidate under development is oral (Z)-endoxifen, which we are developing for both the prevention and treatment of breast cancer and other therapeutic areas.

As of May 1, 2025, we have been granted six U.S. and ten international 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 at least November 17, 2038.

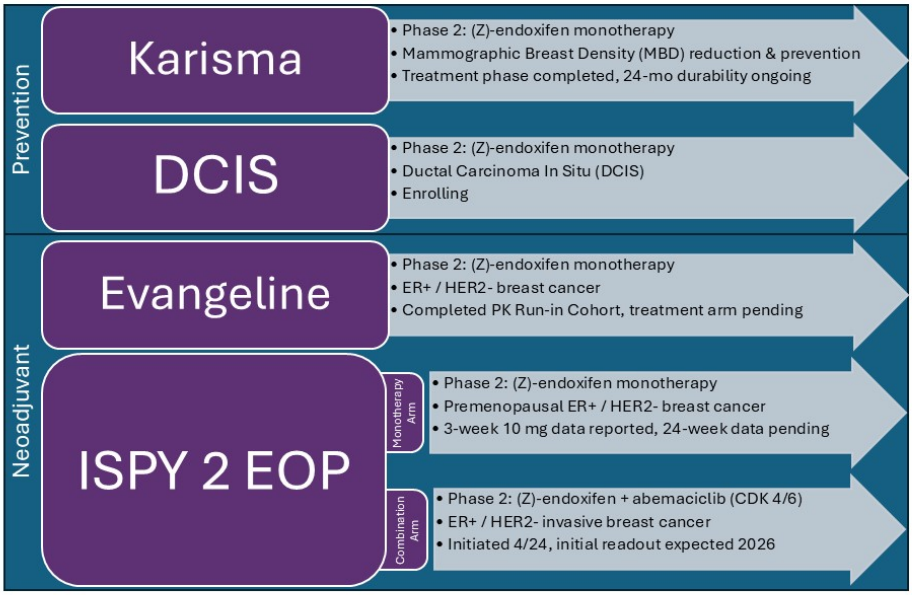
Our business strategy is to advance our programs through clinical studies, including potentially with partners, and opportunistically add programs in areas of high unmet medical need through acquisition, minority investment, collaboration or internal development.

In early 2025, we made a strategic decision to pursue a metastatic breast cancer indication for our lead program, *(Z)-endoxifen.* We believe that this approach may offer a more streamlined regulatory pathway to deliver *(Z)-endoxifen* to patients with urgent unmet medical needs as the current treatment options for metastatic breast cancer often provides limited durability of response and substantial side effects. *(Z)-endoxifen*, a potent and well-tolerated selective estrogen receptor modulator (SERM), has shown encouraging signs in previous clinical trials, which we believe supports its potential to fill this critical gap in treatment. The Company has initiated engagement with the U.S. Food and Drug Administration (FDA) to advance the metastatic indication and other indications, such as breast cancer prevention and neoadjuvant therapy, which typically require larger and longer clinical trials.

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Summary of Our Leading Programs

The following is a summary of the status of our major clinical development programs as of the date of this report:



(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. It is also referred to as a SERM. We are developing a proprietary form of (Z)-endoxifen which is administered orally for the potential treatment of breast cancer and the 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 Mammographic Breast Density. Mammographic breast density (MBD) is an emerging public health issue. Almost half of the women in the world over the age of 40 have dense breasts, and there are currently no approved treatments to reduce breast density. Elevated breast density can make a mammogram more difficult to interpret because dense breast tissue and some abnormal breast changes, such as calcifications and tumors, appear as white areas in a mammogram. Women with the highest density are four to six times more likely to develop breast cancer in their lifetime and more likely to develop cancer between mammograms compared to those with low breast density. The latter are sometimes referred to as "interval cancers," which are often larger, more advanced, and more difficult to treat.

In December 2021, we commenced a Phase 2 study of our proprietary oral (Z)-endoxifen. The study, known as the Karisma-(Z)-endoxifen study, was a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary oral (Z)-endoxifen in healthy premenopausal women with measurable mammographic breast density. The primary objective of the study was to determine the dose-response relationship of daily (Z)-endoxifen on breast density reduction. Secondary endpoints assessed safety and tolerability. The study was conducted in Stockholm, Sweden and included approximately 240 participants who received daily doses of oral (Z)-endoxifen or placebo for six months after enrollment, randomized to one of three arms: placebo, 1 mg of (Z)-endoxifen, or 2 mgs of (Z)-endoxifen. The study also included an exploratory endpoint to assess durability of the breast density changes.

The study fully enrolled in November 2023 and in September 2024, the study concluded. The data showed the potential of low-dose (Z)-endoxifen to significantly reduce MBD, a key risk factor for breast cancer, while showing a favorable safety profile.

Results showed that the 1 mg dose of (Z)-endoxifen reduced MBD by 17.3% ($p<0.01$), while the 2 mg dose achieved a reduction of 23.5% ($p<0.01$), compared to a minimal change in the placebo group of 0.27%. Plasma concentrations for (Z)-endoxifen were measured at 4.8 ng/mL and 9.7 ng/mL for the 1 mg and 2 mg arms, respectively, which showed the effectiveness of the lower dose in achieving significant reductions. Importantly, no significant differences in adverse events were observed between the 1 mg dose and the placebo. The 2 mg dose was associated with higher rates of hot flashes, night sweats and vaginal discharge.

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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 Ductal Carcinoma In Situ. Ductal carcinoma in situ (DCIS) is the presence of abnormal cells inside a milk duct in the breast. It rarely produces symptoms, or a breast lump one can feel, typically being detected through screening mammography. In some cases, DCIS may become invasive and spread to other tissues, but there is no way of determining which lesions will remain stable without treatment and which will go on to become invasive. This uncertainty can result in aggressive and unnecessary treatment approaches that can have harmful side effects without significant benefit.

In October 2023, the Quantum Leap Healthcare Collaborative (the QLHC) announced the initiation of the Phase 2 DCIS: Re-Evaluating Conditions for Active Surveillance Suitability as Treatment (the RECAST) study. (Z)-endoxifen is being investigated as part of this platform trial, which offers women with DCIS six months of neoadjuvant treatment with the intent of determining their suitability for long-term active surveillance without surgery. Approximately 100 patients are expected to be treated with (Z)-endoxifen. The study incorporates both a neoadjuvant therapy phase, with patients at high risk for progression to invasive disease proceeding to surgery, followed by an extended surveillance phase for low-risk patients. Enrollment in this study is ongoing.

(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 approximately 240,000 new cases or 78% of all breast cancers.

In October 2022, we received authorization from the FDA for our Investigational New Drug (IND) application for oral (Z)-endoxifen. The study, known as "EVANGELINE" is a Phase 2 randomized study assessing (Z)-endoxifen as neoadjuvant therapy in premenopausal women with primary ER+, HER2– breast cancer. The study will enroll approximately 190 patients across up to 25 U.S. sites, and is structured in two parts.

In Part 1, a Pharmacokinetic (PK) Run-In Cohort evaluated two dosage levels. A 40 mg per day cohort was initiated in February 2023 to assess if a plasma steady state concentration (Css) of 500 to 1000 ng/mL, which is required for optimal PKC-β inhibition, to be achieved. However, data showed that none of the patients in the 40 mg cohort reached the target Css. Subsequently, an 80 mg per day cohort was initiated and fully enrolled in July 2024. In this higher dose group, about 50% of patients receiving (Z)-endoxifen with goserelin and 38% of patients receiving (Z)-endoxifen alone attained the target plasma Css, with an average of 484 ng/mL. Importantly, tumor Css levels were found to be more than double the plasma levels, exceeding 500 ng/g in 90% of patients, and 85% of patients exhibited a 4-week Ki-67 response (≤10%), indicating substantial tumor suppression. (Z)-endoxifen was generally well tolerated, with no significant Grade 3 or 4 toxicities, though four gynecologic events (including one Grade 3 hemorrhagic ovarian cyst) were noted in the 80 mg group.

In January 2025, based on adverse events reported in 80 mg/day groups, as well as the findings reported on (Z)-endoxifen tissue and plasma Css, overall tolerability, and antitumor activity, the trial will proceed based on an amended protocol as a randomized trial that compares (Z)-endoxifen 40 mg/day plus OFS to exemestane plus OFS, using the 4-week Ki-67 reduction as the primary endpoint. Part 2 is expected to compare the two treatment arms based on baseline Ki-67 levels, and the aim is to evaluate the endocrine sensitive disease rate, pathologic complete response, and other key endpoints. The Treatment Cohort was initiated in April 2025.

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 Endocrine Optimization Pilot (I-SPY 2 EOP). The I-SPY 2 EOP is a collaborative effort among academic investigators from major cancer research centers across the U.S., QLHC, the FDA, and the Foundation for the National Institutes of Health (FNIH) Cancer Biomarkers Consortium. Twenty patients were treated with (Z)-endoxifen for up to 24 weeks prior to surgery. Enrollment was completed in January 2024.

A preliminary data analysis from this study, which included 20 women with ER+/HER2- breast cancer who received 10 mg of (Z)-endoxifen orally once daily for six cycles (each cycle = 28 days), showed that (Z)-endoxifen met the primary endpoint with 95% (19/20 patients) receiving > 75 % of planned treatment. The data also showed (Z)-endoxifen activity in rapidly reducing key biomarkers, such as Ki-67, by 69% from baseline and a 30.4% reduction in functional tumor volume (FTV) from baseline after three weeks of treatment. FTV is a quantitative measurement of tumor burden that can be used to assess treatment response for breast cancer. (Z)-endoxifen was well tolerated in this study with the most common side effects being mild, including hot flashes, insomnia, and fatigue. No dose reductions or discontinuations due to treatment related adverse events were observed in this study. Surgical Ki-67 values and 24-week imaging will be analyzed in the future.

In April 2024, we announced our participation in a new study arm of the I-SPY 2 EOP which was initiated to evaluate our proprietary (Z)-endoxifen in combination with abemaciclib (VERZENIO®), a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company, in women with ER+/HER2- breast cancer. In Iune 2024, we announced that the study had been expanded to include 80 women with newly diagnosed ER+ / HER2- invasive breast cancer. Currently enrolled and newly enrolled participants are expected to transition to or be initiated on 40 mg of (Z)-endoxifen (from 80 mg) once daily in combination with 150 mg of abemaciclib twice daily for a total of 24 weeks prior to surgery. The transition to the 40 mg dose from an 80 mg dose is the result of a protocol amendment approved in January 2025. Enrollment in this study is ongoing.

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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 Agreement

We have an operating lease for office space in Seattle, Washington with Regus International Workplace Group. The lease commencement date was June 1, 2024, and we agreed to pay monthly rent of $1 thousand per month for 12 months. On March 3, 2025 we entered into a new operating lease with a commencement date of June 1, 2025, and we agreed to pay $2 thousand per month for 12 months.

On December 20, 2024, we entered into an additional operating lease with Regus International Workplace Group for additional office space in Seattle, Washington for 12 months for additional monthly rent of $1 thousand per month.

Critical Accounting 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 (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 our 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.

There have been no material changes to our critical accounting estimates during the three months ended March 31, 2025 from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on March 25, 2025.

Results of Operations

Comparison of Three Months Ended March 31, 2025 and 2024

Revenue and Cost of Revenue. For the three months ended March 31, 2025 and 2024, we had no source of revenue and no associated cost of revenue.

Operating Expenses. Total operating expenses were $7.4 million for the three months ended March 31, 2025, which was an increase of $0.4 million, from the three months ended March 31, 2024 of $7.0 million. Factors contributing to the increased operating expenses in the three months ended March 31, 2025 are explained below.

Research & Development (R&D) Expenses. The following table provides a breakdown of major categories within R&D expenses for the three months ended March 31, 2025 and 2024, together with the dollar change and percentage change in those categories (dollars in thousands):

		For the Three Months Ended March 31,			
		2025	2024	Increase (Decrease)	% Increase (Decrease)
Research and Development Expenses					
	Clinical and pre-clinical trials	$ 2,747	$ 2,884	$ (137)	(5)%
	Compensation	880	626	254	41%
	Professional fees and other	530	238	292	123%
	Research and Development Expenses Total	$ 4,157	$ 3,748	$ 409	11%

As (Z)-endoxifen is our only product candidate for which we currently incur R&D expenses, we have not further disaggregated R&D expenses by product candidate:

- Clinical and pre-clinical trial expenses decreased $0.1 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024, due to a slight decrease in spend related to our (Z)-endoxifen trials, including drug development costs.

- The increase in R&D compensation expenses of $0.3 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024 was due to an increase in headcount.

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- The increase in R&D professional fees and other of $0.3 million was due to an increase in spending on regulatory consulting services.

General and Administrative (G&A) Expenses. The following table provides a breakdown of major categories within G&A expenses for the three months ended March 31, 2025 and 2024, together with the dollar change and percentage change in those categories (dollars in thousands):

	For the Three Months Ended March 31,			
	2025	2024	Increase (Decrease)	% Increase (Decrease)
General and Administrative Expenses				
Compensation	$ 1,462	$ 1,325	$ 137	10%
Professional fees and other	1,614	1,680	(66)	(4)%
Insurance	181	227	(46)	(20)%
General and Administrative Expenses Total	$ 3,257	$ 3,232	$ 25	1%

- The increase in G&A compensation expenses of $0.1 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024 was due to an increase in headcount quarter over quarter.

Interest Income. Interest income was $0.7 million for the three months ended March 31, 2025, a decrease of $0.4 million from interest income of $1.1 million for the three months ended March 31, 2024. The decrease was due to a decrease in the balance in our money market account.

Income Taxes. We did not record an income tax expense or benefit for the three months ended March 31, 2025 and 2024 due to uncertainty regarding utilization of our net operating loss carryforwards and our history of losses.

Liquidity and Capital Resources

We are authorized to issue up to 350,000,000 shares of common stock, par value $0.18 per share. On November 19, 2024, we entered into an Open Market Sale Agreement[SM] with Jefferies LLC. We may offer, from time to time, to sell, in an "at the market offering," shares of our common stock up to an aggregate offering price of up to $100.0 million. We have not made any sales under the at the market offering facility during the three months ended March 31, 2025.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	For the Three Months Ended March 31,	
	2025	2024
	(unaudited)	
Net cash used in operating activities	$ (5,959)	$ (4,698)
Net cash used in investing activities	(9)	(6)
Net cash provided by financing activities	—	204
Net decrease in cash, cash equivalents and restricted cash	$ (5,968)	$ (4,500)

We have incurred net losses and negative operating cash flows since inception. For the three months ended March 31, 2025, we recorded a net loss of $6.7 million and used $6.0 million of cash and cash equivalents. As of March 31, 2025, we had $65.1 million in cash and cash equivalents and working capital of $63.3 million. We believe we have sufficient cash on hand to fund our projected operating requirements for at least the next 12 months.

Net Cash Flows from Operating Activities. During the three months ended March 31, 2025 and 2024, net cash used in operating activities increased $1.3 million, primarily reflecting:

- a $0.8 million increase in cash used for professional fees, for prepaid investor relations as well as legal fees due to patent protection;
- an increase of $0.2 million in cash used for compensation due to an increase in full time employees;

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- a decrease of $0.1 million in cash used for clinical and preclinical trials due to timing of the Evangeline trial, for which we expect to ramp up spend later in 2025; and
- a $0.4 million decrease in cash provided by interest income due to lower amounts invested our money market account.

Net Cash Flows from Investing Activities. Net cash used in investing activities was $9 thousand for the three months ended March 31, 2025, compared to net cash used in investing activities of $6 thousand for the three months ended March 31, 2024. Current and prior period cash used in investing activities was primarily related to purchases of new computers.

Net Cash Flows from Financing Activities. No cash was provided by or used in financing activities for the three months ended March 31, 2025. Net cash provided by financing activities was $0.2 million for the three months ended March 31, 2024 and consisted of the receipt of proceeds from the exercise of warrants.

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 costs of manufacturing drugs under development, the costs associated with clinical and non-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 license of additional product candidates or technologies.

If we are unable to raise additional capital when needed on reasonable terms, if at all, 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.

Additional funding may not be available to us on acceptable terms or at all. Continued uncertain market and macroeconomic conditions, including the impact of inflation, tariffs, high interest rates, general economic slowdown or a recession, foreign exchange rate volatility, financial institution instability, changes in monetary policy, changes in trade policies and other trade restrictions or the threat of such actions, 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.

On February 21, 2025, we received a letter from Nasdaq informing us that we are not in compliance with Nasdaq Listing Rule 5550(a)(2) for continued listing on Nasdaq, because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. We have until August 20, 2025 to regain compliance with Nasdaq Listing Rule 5550(a)(2). In the event we do not regain compliance by then, we may be eligible an additional 180 calendar day compliance period, subject to certain conditions. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days.

Contractual Obligations

Our contractual obligations represent our future cash commitments and liabilities under agreements with third-party clinical trial service providers. Apart from contracts with one third-party clinical trial service provider, such agreements are cancellable upon written notice by us. The non-cancellable contracts expire upon completion of the clinical trial and release of the final report, or the contract may be terminated by the clinical trial service provider, by the FDA or another governmental agency. As of March 31, 2025, our estimated non-cancellable commitment was $9.4 million which will be paid over the term of the clinical trials.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as 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.

Recently Issued Accounting Pronouncements

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Please refer to Note 3 "Summary of Significant Accounting Policies" to the Condensed Consolidated Financial Statements.

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 Principal Executive Officer and Principal Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2025, pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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 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 our management, including our Principal Executive Officer and Principal 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, 2025, our Principal Executive Officer and Principal 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, 2025, that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are, and from time to time we may become, involved in legal proceedings or be subject to claims arising in the ordinary course of our business. For a discussion of our legal proceedings, see Note 12 "Commitments and Contingencies" to the Condensed Consolidated Financial Statements. We are not presently a party to any other legal proceedings that in the opinion of our management, if determined adversely to us, would individually or taken together 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 and uncertainties, including risks and uncertainties 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. 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 three months ended March 31, 2025, 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. These risks and uncertainties are discussed more fully below and include, but are not limited to, risks related to:

Risks Related to our Business

- We have a history of operating losses and 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.
- 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.
- 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.
- 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 as well as for clinical trial activities.
- 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.
- The deployment of artificial intelligence (AI) in our or our collaborators' product candidates could adversely affect our business, reputation or financial results.
- Our products and services may expose us to possible litigation and product liability claims.
- Business disruptions, including natural disasters, severe weather, 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.
- Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.
- We, or our wholly-owned subsidiary, could lose our ability to operate in Australia, or our subsidiary may be unable to benefit from the past or future R&D tax rebates available under current Australian regulations.

Risks Related to our Intellectual Property

- We may not be able to protect our proprietary technology.

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- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies.
- Changes in U.S. patent law could diminish the value of patents in general.
- 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 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.
- Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact 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.
- Significant disruptions in our information technology systems or breaches of data security could adversely affect our business.
- 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.
- 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 regain compliance with the continued listing standards or 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.
- The trading price of our common stock has been and is likely to continue to be volatile.
- We have never paid dividends and we do not anticipate paying dividends in the future.
- The ownership of our common stock may become concentrated among a small number of stockholders.
- We may be unable to implement and maintain effective internal control over financial reporting.
- The requirements of being a public company may strain our resources, result in litigation, and divert management's attention.
- 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.

In evaluating our business, you should carefully consider the following discussion of material risks, events and uncertainties that make an investment in us speculative or risky in addition to the other information included in this Quarterly Report. A manifestation of any of the following risks and uncertainties could, in circumstances we may or may not be able to accurately predict, materially and adversely affect our business and operations, growth, reputation, prospects, operating and financial results, financial condition, cash flows, liquidity and stock price. Some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future. The risks and uncertainties described below are not the only ones we face. Our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our business. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

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Risks Related to our Business

We 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 or due to increased supply chain costs. 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 high interest rates, the inflationary environment, recessionary fears, foreign exchange rate volatility, instability in financial institutions, changes in monetary policy, changes in trade policies, including tariffs and other trade restrictions or the threat of such actions, and rising geopolitical instability we may be unable to develop and commercialize our product offerings or increase our geographic reach and we could be forced to cease operations.

For example, in recent months, the United States has announced tariffs on imports from most countries, including significant tariffs on imports from Canada, Mexico and China, leading to increasing trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. There is substantial uncertainty about the duration of existing tariffs or pauses in tariffs, tariff levels and whether additional tariffs or other retaliatory actions may be imposed, modified or suspended. These actions and the related rising political tensions could negatively impact global macroeconomic conditions and the stability of global financial markets, which could have a material adverse effect on our business, financial condition and results of operations, including through increased supply chain costs.

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, 2025, we incurred a net loss of $6.7 million, and we had an accumulated deficit of $218.5 million since inception. As of March 31, 2025, we had cash and cash equivalents of $65.1 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.

For example, our ability to raise capital in the public capital markets, including through “at the market” offerings pursuant to our Open Market Sale Agreement℠ (the Sale Agreement) with Jefferies LLC (Jefferies), may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Although

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alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

If we raise additional funds by selling or issuing equity securities or equity-linked securities, including through our Sale Agreement, our stockholders will experience dilution and it may have an adverse effect on the price of our common stock. 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 do not agree or that do not 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 and as a sponsor or as an equity investor in special purpose acquisition companies, and we may not be able to realize the expected business or financial benefits of these investments. For example, in the fourth quarter of 2024, Dynamic Cell Therapies, Inc. (DCT), a U.S. private company previously focused on Chimeric Antigen Receptor (CAR) T-cell therapies, laid off all employees and ceased operations, and we incurred a $1.7 million and $3.0 million impairment charge for the years ended December 31, 2024 and 2023, respectively.

In addition, 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, 2025, was $6.7 million. We will continue to incur further losses in connection with 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 Chairman, President, Chief Executive Officer and founder, who provides much of the necessary experience to execute our business plan.

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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 have in the past and could in the future cause us to fail to realize the anticipated benefits of such acquisitions and transactions, and result in higher than expected costs, the recording of asset impairment or restructuring charges and other actions which could negatively impact our business, financial condition, results of operations and our ability to execute on our strategic plan. For example, we incurred a $1.7 million and $3.0 million impairment charge for the years ended December 31, 2024 and 2023, respectively, in connection with our investment in DCT.

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 high 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;

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- 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, patient insurance approvals of trial participation, 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 Contract Research Organizations (CROs) and trial sites; and
- failure of third parties, such as CROs, 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 2024 for our EVANGELINE study, a Phase 2 randomized study of (Z)-endoxifen as a neoadjuvant treatment for pre-menopausal women with ER+ / human epidermal growth factor receptor 2 negative (HER2-) breast cancer. Such data is 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:

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- 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 applicable requirements under current Good Laboratory Practices (GLP), cGMP, Good Clinical Practices (GCP) 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 GCP and data privacy standards such as defined under the Health Insurance Portability and Accountability Act (HIPAA), General Data Protection Regulation (GDPR) and UK 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

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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 UK 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.

In addition, our employees and personnel or our vendors or partners may use AI, including generative AI, technologies to perform their work or in their operations, and the disclosure and use of personal information in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI, controlling for data bias and antidiscrimination. Any use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits.

We also rely on a third-party information technology vendor to oversee our information technology systems, including our mechanisms, controls, technologies, systems, and other processes designed to help prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting our data and to help maintain a stable information technology environment. As a result, our cybersecurity systems and processes are dependent upon the performance of our information technology vendor.

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. We and our third-party service providers may be subject to inspections by FDA and other regulatory authorities. Any such failure by us or by our third party service providers to comply with applicable legal or regulatory requirements 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, administrative detention, 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 warning or untitled letters, import alerts, 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:

- supply chain disruptions, or lack of availability or increased costs of materials for our product candidates, including as a result of changes in trade policies, including tariffs or other trade restrictions or the threat of such actions;
- outbreaks of disease, pandemics or epidemics, which could limit access to clinical trial sites, divert healthcare resources and limit the availability of medical facilities for our clinical trials;
- failure to obtain on a timely basis, or at all, approval from the applicable Regulatory Agencies, 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 or vendors;
- failure of CROs or other third parties to effectively and timely monitor, oversee, and maintain the clinical trials;
- the imposition of partial or full clinical holds by FDA, or the pausing or termination of our clinical trials by institutional review boards or ethics committees;
- 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 clinical trials;
- availability of materials provided by third parties necessary to manufacture our product candidates; and

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- 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.

The deployment of AI in our or our collaborators' product candidates could adversely affect our business, reputation or financial results.

We or our collaborators may integrate AI, including generative AI, and machine learning in our drug discovery efforts and efforts to develop our product candidates. As a new and rapidly evolving technology, the use of AI is subject to numerous risks and uncertainties, including operational, technical, legal, compliance, privacy, data security, ethical, competitive and reputational risks. Machine learning and predictive analytics may produce flawed, biased, incomplete, overbroad or inaccurate results, which could negatively impact the development of our or our collaborators' product candidates and expose us to competitive and reputational harm. Developing, testing and deploying resource-intensive AI systems, or supporting our collaborator's development of such systems, including our sponsorship of the Phase 2 SMART study that seeks to validate an AI-driven breast cancer risk assessment model, requires significant investment and may increase our costs, and there is no guarantee that our investment in such systems will lead to discovery of new product candidates or eventual regulatory approval or commercialization of any product candidates or accelerate or reduce costs associated with the drug discovery, development or approval timeline. Our inability to successfully deploy AI in the discovery or development of our or our collaborators' product candidates, or the public's lack of acceptance of such products, could adversely affect our business, reputation and financial results.

Business disruptions, including natural disasters, severe weather 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 and wildfires, 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, 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.

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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.

If we, or our wholly-owned subsidiary, lose our ability to operate in Australia, or if our subsidiary is unable to benefit from the past or future R&D tax rebates available under current Australian regulations, our business and results of operations could be harmed.

Through our wholly-owned subsidiary in Australia, Atossa Genetics AUS Pty Ltd., we conduct certain R&D activities, including some of our clinical trials. Current Australian tax regulations provide for a R&D cash rebate on qualified R&D activities incurred in the country. The Australian R&D tax incentive program is a self-assessment program, and as such, the Australian Taxation Office (ATO) has the right to review our program and our related expenditures for a period of four years following the tax return filing date. If we are ineligible or unable to receive the anticipated cash rebate, if past rebates are determined to be ineligible upon an audit by the ATO, or if the Australian government significantly reduces or eliminates the rebate, our business and results of operations would be adversely affected.

Based on our evaluation of the ATO's taxpayer alert published in the fourth quarter of 2023, we believe that it is no longer reasonably assured that our full tax position would be sustained under an audit. Accordingly, we recorded a change in estimate that represents our estimate of the amount (inclusive of potential penalties) that no longer meets the reasonably assured threshold. We recorded an estimated accrued current liability of $1.5 million in our Condensed Consolidated Balance Sheets as of March 31, 2025 and December 31, 2024. We may in the future be required to record additional changes in estimates, which could further increase our expenses and adversely affect our business and results of operations.

Additionally, due to the geographic distance from our headquarters, we may not be able to successfully monitor or conduct our clinical trials and R&D activities in Australia and develop or commercialize our drug candidates. We can provide no assurance that the results of any clinical trials that we conduct in Australia will be accepted by the FDA or other foreign authority. Furthermore, if we lose our ability to operate our subsidiary in Australia, our business and results of operations may be adversely affected.

If the estimates we make, or the assumptions on which we rely, in preparing our condensed consolidated financial statements prove inaccurate, our actual results may vary from those reflected in our accruals.

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various

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other assumptions that we believe to be reasonable under the circumstances. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct.

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 May 1, 2025, we own and are pursuing 128 pending provisional and non-provisional patent applications (29 U.S. patent applications and 99 international patent applications, including one allowed U.S. application and two allowed international applications) and 19 issued patents (7 U.S. patents and 12 international patents). We continue to evaluate the full range of our technologies and file new patent applications consistent with our evolving business goals.

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), *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014), and *Amgen Inc. v. Sanofi,* 598 U.S. 594 (2023), and the Federal Circuit Court decisions *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019). 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 or drug candidate 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.

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If third parties successfully challenge the validity of one or more of our patent applications, we may lose certain patent rights, even if previously granted by a patent office. For example, on August 18, 2023, Intas Pharmaceuticals Ltd. filed a Petition for Post Grant Review with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO), seeking to invalidate all claims related to one of our issued patents (U.S. Patent No. 11,572,334) titled "Methods for Making and Using Endoxifen", and on January 29, 2025, the PTAB issued a final written decision finding all claims of U.S. Patent No. 11,572,334 were unpatentable.

On April 3, 2025, Intas Pharmaceuticals Ltd. filed a Petition for Post Grant Review with the USPTO's PTAB (the 391 PGR Petition) relating to one of our issued patents (U.S. Patent No. 12,071,391) titled "Methods for Making and Using Endoxifen," and also filed a Petition for *Inter Partes* Review (IPR) with the USPTO's PTAB (the 151 IPR Petition) relating to another of our issued patents (U.S. Patent No. 11,261,151) titled "Methods for Making and Using Endoxifen" (together with U.S. Patent No. 12,071,391, the Patents). We intend to vigorously contest the 391 PGR Petition and the 151 IPR Petition and believe that the Patents were properly granted and include valid and enforceable claims. However, there can be no assurance that we will prevail in contesting either the 391 PGR Petition or the 151 IPR Petition.

Any litigation proceedings relating to our proprietary technology may result in unsuccessful outcomes for us and, even if such proceedings result in successful outcomes for us, the proceedings 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.

The 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 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. For example, we are currently contesting the 391 PGR Petition and the 151 IPR Petition. See Note 12 to the Condensed Consolidated Financial Statements. 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

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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. For example, the Indian Pharmaceutical Alliance filed the Opposition against our pending Indian Patent Application. 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. For example, we are currently contesting the 391 PGR Petition, the 151 IPR Petition and also are involved in the Indian Pharmaceutical Alliance Pre-Grant Opposition. 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. Any such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our drug product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art and that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. 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.

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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

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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.

Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget funding levels or a reduction in the FDA's workforce and its ability to hire and retain key personnel, disruptions caused by government shutdowns, public health crises, the FDA's ability to accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. There have been mass layoffs of federal employees since the start of the current presidential administration in January 2025, the full impact of which is unclear at this time. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, the presidential administration has made and is expected to continue to make changes in the leadership of various U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA.

We are unable to predict the extent to which the presidential administration may impose or seek to impose leadership or policy changes at the FDA or changes to rules and policies impacting our business and operations. It is unclear how these executive actions or other potential actions by the federal government will impact the FDA or other regulatory authorities that oversee our business. Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA's ability to perform its responsibilities, which could result in delays in our clinical trial timelines. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or approval of our product candidates, which could have a material adverse effect on 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.

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. State health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, govern the privacy and security of health-related information and may apply even when HIPAA does not and impose additional requirements. Therefore, we are required to comply with both HIPAA privacy regulations and state privacy laws, which vary from state to state, impose a range of obligations, and are often more restrictive than HIPAA. 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 violating the privacy of their medical information by healthcare providers such as us.

In addition to HIPAA, failing to take appropriate steps to keep consumers' personal information secure may result in the Federal Trade Commission (FTC) bringing a claim that a company has engaged in unfair or deceptive acts or practices in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act (FTCA). The FTC requires companies to have reasonable and appropriate security measures, based on factors such as data sensitivity and volume, complexity of the business and available resources. Health information is considered sensitive data that merits stronger safeguards. There are also state consumer

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protection laws, which may be modeled on the FTCA, that can provide state-law causes of action for allegedly unfair or deceptive acts or practices, among other things.

While we may not be presently subject to any comprehensive state privacy laws (e.g., the California Consumer Privacy Act as amended by the California Privacy Rights Act) as a covered entity due to applicability and exemption considerations, the legal landscape is rapidly changing. If we were to become subject to these laws, we would be required to comply with the demanding obligations they impose with respect to personal information. Furthermore, if our service providers or partners are subject to such laws, we may have contractual obligations relating to these requirements.

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 requirements related to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, 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, in addition to the GDPR, companies have to comply with the 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 personal 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. In addition, transfers of personal data from the UK to other countries, including the EEA, are subject to specific transfer rules under the UK regime. Personal data may freely flow from the UK to the EEA, since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. These UK international transfer rules broadly mirror the E.U. GDPR rules. With regard to the transfer of personal data from the UK to the U.S., from October 12, 2023, businesses in the UK can start to transfer personal data to U.S. organizations certified to the "UK Extension to the EU-US Data Privacy Framework" (UK Extension) under the UK GDPR, without the need for further safeguards. On March 21, 2022, the international data transfer agreement (IDTA) and the international data transfer addendum to the European Commission's standard contractual clauses (SCCs) for international data transfers (Addendum), and a document setting out transitional provisions, came into force and replaced the prior EU SCCs for purposes of the UK regime. The relationship between the UK and other jurisdictions 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 personal 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.

Significant disruptions in our information technology systems or breaches of data security could adversely affect our business.

We rely on information technology systems to keep financial records, 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 data (including 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 data (including sensitive personal data) 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. Sensitive data could also be leaked, disclosed, or revealed as a result of or in connection with our employee’s, personnel’s, vendors’ or partners’ use of AI technologies. In addition, because we collect, store and transmit confidential

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information in digital form, we, and third parties who we work with, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. Any data breaches 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 (including data breach notification statutes and the California Consumer Privacy Act), 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.

Additionally, we are or may become subject to contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

Although we utilize various procedures and controls to help mitigate our exposure to these risks, cyber attacks and other cyber events are evolving, unpredictable and increasing in sophistication, including through the use of increasingly sophisticated and evolving AI technologies. Moreover, the information technology systems of our third-party partners, including suppliers, manufacturers, service providers and others on which we rely, may be subject to similar risks. We have cybersecurity insurance coverage in the event we become subject to certain 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 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 (the 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.

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We also compete with a substantial number of other companies that are working to develop novel drugs using emerging AI technologies that compete directly or indirectly with us. Companies implementing generative AI, for example, have been devoting resources to create large and high-quality training datasets in order to accelerate drug discovery processes. This includes using AI tools to create novel drug molecules, streamline disease target identification, and construct AI-based prediction models for clinical trial outcomes. As a result of these dynamics, we may not be able to secure the technologies we desire or to otherwise effectively compete. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and/or technologies.

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 regain compliance with the continued listing standards or satisfy the continued listing standards going forward, which could make it more difficult for our stockholders to sell their shares.

Our shares of common stock are listed on the Nasdaq Capital Market (Nasdaq), and as such, we are required to satisfy the continued listing standards of Nasdaq to maintain our listing. However, we cannot assure you that we will be able to regain compliance with the continued listing standards of Nasdaq, including its minimum closing bid price requirement, or satisfy the continued listing standards of Nasdaq going forward.

On February 21, 2025, we received a letter from Nasdaq informing us that we are not in compliance with Nasdaq Listing Rule 5550(a)(2) for continued listing on Nasdaq, because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. We have until August 20, 2025 to regain compliance with Nasdaq Listing Rule 5550(a)(2). In the event we do not regain compliance by then, we may be eligible an additional 180 calendar day compliance period, subject to certain conditions. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days.

The Nasdaq notice has no immediate effect on the listing or trading of our common stock on Nasdaq. However, if we are unable to regain compliance with Nasdaq Listing Rule 5550(a)(2) or if we are unable to comply with other continued listing standards of Nasdaq, going forward, Nasdaq may commence delisting procedures against us, which could result in our stock being removed from listing on Nasdaq, and we could face significant material adverse consequences, including:

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- stock price volatility;
- limited availability of market quotations for our common stock;
- reduced 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
- decreased 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, including through “at the market” offerings pursuant to our Sale Agreement with Jefferies, sales by holders of our warrants to purchase our common stock or sales by 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 on Form 10-Q, 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, high interest rates, the inflationary environment, general economic slowdown or a recession, foreign exchange rate volatility, financial institution instability, changes in monetary policy, changes in trade policies including tariffs and other trade restrictions or the threat of such actions, and rising geopolitical instability, including the ongoing conflict in Ukraine, the conflict in the Middle East, and rising tensions between China and Taiwan;
- 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 regulations;
- 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, severe weather, pandemics, or responses to these events;
- public statements made by third parties, including trial participants and clinical investigators, regarding our current or future clinical trials that may harm our reputation;
- 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;

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- 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.

We have never paid dividends and we do not anticipate paying dividends in the future.

We have never declared or paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth, development, operation and expansion of our business, and we do not anticipate declaring or paying any dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain for the foreseeable future.

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.

The requirements of being a public company may strain our resources, result in litigation, and divert management's attention.

As a public company, we are subject to certain reporting requirements, listing requirements, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could materially and adversely affect our business and operating results. In addition, a change in our filer status could trigger a requirement to begin complying with Section 404(b) of the Sarbanes-Oxley Act of 2002, and our independent registered public accounting firm would have to evaluate and report on the effectiveness of internal control over financial reporting, increasing our costs. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will also increase our costs and expenses.

By disclosing information in this and in future filings required of a public company, our business and financial condition will become more visible, which has resulted in, and may in the future result in, threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

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.

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 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, and Delaware law, might

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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.

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes.

Our Amended and Restated Certificate of Incorporation, as amended, provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain actions. The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage lawsuits. In addition, there is uncertainty as to whether a court would enforce such a provision. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our Amended and Restated Certificate of Incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially and adversely affect our business.

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

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

(c) Trading Plans

During the quarter ended March 31, 2025, no director or Section 16 officer adopted, modified, or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

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ITEM 6. EXHIBITS

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein or Filed or Furnished Herewith	
		Form	**Date**
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(1)	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith	
32.2(1)	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 With Embedded Linkbase Documents		
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)		

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

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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 13, 2025

/s/Steven C. Quay

Chairman, President and Chief Executive Officer (On behalf of the registrant)

/s/Heather Rees

Chief Financial Officer (as Principal Financial and Accounting Officer)

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Exhibit 31.1

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-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 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 13, 2025

/s/ Steven C. Quay
Steven C. Quay, M.D., Ph D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-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, Heather Rees, 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 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 13, 2025

/s/ Heather Rees
Heather Rees
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Atossa Therapeutics, Inc. (the "Company") for the period ended March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven C. Quay, Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: May 13, 2025

/s/ Steven C. Quay
Steven C. Quay, M.D., Ph D.
Chairman, 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 on Form 10-Q of Atossa Therapeutics, Inc. (the "Company") for the period ended March 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Heather Rees, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: May 13, 2025

/s/ Heather Rees
Heather Rees
Chief Financial Officer
(Principal Financial and Accounting Officer)

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