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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, 2022

OR

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

For the transition period from _____ to _____

Commission file number: 001-35610

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

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

Registrant's telephone number, including area code: (206) 325-6086

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒

The number of shares of the registrant's common stock, $0.18 par value per share, outstanding as of May 6, 2022, was 126,624,110.

ATOSSA THERAPEUTICS, INC.
FORM 10-Q
QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

Assets	**As of March 31, 2022 (Unaudited)**	**As of December 31, 2021**
Current assets		
Cash and cash equivalents	$ 131,486	$ 136,377
Restricted cash	110	110
Prepaid expenses	3,874	2,488
Research and development rebate receivable	668	1,072
Other current assets	710	1,193
Total current assets	136,848	141,240
Other assets	630	22
Total Assets	$ 137,478	$ 141,262
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,596	$ 1,717
Accrued expenses	120	204
Payroll liabilities	593	1,184
Other current liabilities	13	21
Total current liabilities	2,322	3,126
Total Liabilities	2,322	3,126
Commitments and contingencies (Note 13)		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of March 31, 2022 and December 31, 2021	-	-
Additional paid-in capital - Series B convertible preferred stock	582	582
Common stock - $0.18 par value; 175,000 shares authorized; 126,624 shares issued and outstanding as of March 31, 2022 and December 31, 2021	22,792	22,792
Additional paid-in capital - common stock	245,802	243,996
Accumulated deficit	(134,020)	(129,234)
Total Stockholders' Equity	135,156	138,136
Total Liabilities and Stockholders' Equity	$ 137,478	$ 141,262

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

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

	For the Three Months Ended March 31,	
	2022	**2021**
Operating expenses		
Research and development	$ 1,499	$ 1,379
General and administrative	3,248	2,152
Total operating expenses	4,747	3,531
Operating loss	(4,747)	(3,531)
Other expense, net	(39)	(7)
Loss before income taxes	(4,786)	(3,538)
Income taxes	-	-
Net loss	$ (4,786)	$ (3,538)
Loss per common share - basic and diluted	$ (0.04)	$ (0.04)
Weighted average shares outstanding - basic and diluted	126,624	92,587

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

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

	Series B Convertible Preferred Stock			Common Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2020	1	$ -	$ 621	47,550	$ 8,559	$ 129,887	$ (111,899)	$ 27,168
Cumulative effect of adopted accounting standard	-	-	-	-	-	9,732	3,271	13,003
Issuance of common stock and warrants, net of issuance costs of $5,493	-	-	-	41,211	7,418	62,250	-	69,668
Issuance of common stock upon warrant exercise	-	-	-	32,063	5,771	26,989	-	32,760
Conversion of Series B convertible preferred stock to common stock	-	-	(1)	-	-	1	-	-
Compensation cost for stock options granted	-	-	-	-	-	640	-	640
Net loss	-	-	-	-	-	-	(3,538)	(3,538)
Balance at March 31, 2021	1	$ -	$ 620	120,824	$ 21,748	$ 229,499	$ (112,166)	$ 139,701

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

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

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

	For the Three Months Ended March 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (4,786)	$ (3,538)
Adjustments to reconcile net loss to net cash used in operating activities		
Compensation cost for stock options granted	1,806	640
Depreciation and amortization	2	9
Changes in operating assets and liabilities:		
Prepaid expenses	(1,386)	(737)
Research and development rebate receivable	404	(85)
Other assets	(114)	582
Accounts payable	(121)	(866)
Accrued expenses	(84)	58
Payroll liabilities	(591)	(474)
Other current liabilities	(8)	3
Net cash used in operating activities	(4,878)	(4,408)
CASH FLOWS FROM INVESTING ACTIVITY		
Purchase of furniture and equipment	(13)	-
Net cash used in investing activities	(13)	-
CASH FLOWS FROM FINANCING ACTIVITY		
Proceeds from issuance of common stock, net of issuance costs	-	69,668
Proceeds from exercise of warrants	-	32,760
Net cash provided by financing activities	-	102,428
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(4,891)	98,020
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	136,487	39,664
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 131,596	$ 137,684
SUPPLEMENTAL DISCLOSURES		
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 131,486	$ 137,574
Restricted cash	110	110
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 131,596	$ 137,684
NONCASH INVESTING AND FINANCING ACTIVITIES		
Reclassification of the warrant liability to equity upon adoption of accounting standard	$ -	$ 13,003
Conversion of Series B convertible preferred stock to common stock	$ -	$ 1

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

ATOSSA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 1: NATURE OF OPERATIONS

Atossa Therapeutics, Inc. (the Company) was incorporated on April 30, 2009 in the State of Delaware to develop and market medical devices, laboratory tests and therapeutics to address breast health conditions. The Company is currently focused on development of its pharmaceuticals for the treatment of the novel coronavirus (COVID-19), breast cancer and other breast conditions. The Company's fiscal year ends on December 31.

Impact of the Novel Coronavirus

The ongoing COVID-19 pandemic may affect the Company's operations and those of third parties on which the Company relies, including causing possible disruptions in the supply of the Company's Endoxifen, AT-H201,AT-301 and the pace of enrollment in our clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. FDA and other health authorities including similar entities/agencies in Sweden and Australia, which could result in delays in meetings, reviews and approvals. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole, however, we have not experienced a significant delay in the enrollment or the drug supply for our ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. Although there have been times when the number of reported COVID-19 cases has surged, there have also been times when the number of reported cases of COVID-19 has declined in many countries. If the number of COVID-19 cases decline, it may be difficult to enroll participants in our COVID-19 clinical studies.

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, 2022, the Company recorded a net loss of $4,786 and used $4,878 of cash in operating activities. As of March 31, 2022, the Company had $131,486 in cash and cash equivalents and working capital of $134,526. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and believes it will need to continue to raise substantial additional capital to accomplish its business plan over the next several years. Management believes its currently available funding, including the funds received from warrant exercises and the issuance of common stock and warrants with net proceeds of $113,486 during 2021, will be sufficient to finance the Company's operations for at least one year from the date these condensed consolidated financial statements are issued. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of public or private equity offerings, debt financings or other sources, including potential corporate collaborations, licenses and other similar arrangements. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future. If the Company is unable to secure additional funding, it may be forced to curtail or suspend its business plans.

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. They do not include all information and notes required by GAAP for complete financial statements. However, except as disclosed herein, there has been no material change in the information disclosed in the Notes to Consolidated Financial Statements included in the Annual Report on Form 10-K of the Company for the year ended December 31, 2021. The year-end condensed consolidated balance sheet presented was derived from audited consolidated financial statements, but does not include all disclosures required by GAAP. All amounts have been presented in thousands, except for par value and other per share data.

In the opinion of management, all adjustments (including normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2022, are not necessarily indicative of the results that may be expected for the year ending December 31, 2022.

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. Actual results could differ from those estimates.

Segments

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

Research and Development

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

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

Fair Value Measurements

The Company records financial assets and liabilities measured on a recurring and non-recurring basis as well as all non-financial assets and liabilities subject to fair value measurement at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. These fair value principles prioritize valuation inputs across three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's assumptions used to measure assets and liabilities at fair value. An asset or liability's classification within the various levels is determined based on the lowest level input that is significant to the fair value measurement. Also refer to Note 8.

Stock-based Payments

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

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

Recently Adopted Accounting Pronouncements

On May 3, 2021, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* — a consensus of the FASB Emerging Issues Task Force. The ASU provides a principles-based framework to determine whether an issuer should recognize the modification or exchange as an adjustment to equity or an expense. As there were no modifications or exchanges of freestanding equity-classified warrants during the quarter ended March 31, 2022, the standard did not have an impact on the condensed consolidated financial statements.

On January 1, 2022, the Company adopted ASU 2021-10 *Annual Disclosure Requirements for Business Entities Receiving Government Assistance. (Topic 832*), *– Disclosures by Business Entities about Government Assistance*, which requires business entities to disclose information about transactions with a government that are accounted for by applying a grant or contribution model by analogy. For transactions within scope, the new standard requires the disclosure of information about the nature of the transaction, including significant terms and conditions, as well as the amounts and specific financial statement line items affected by the transaction. The disclosure of the Company's research and development rebate receivable is detailed in Note 6.

NOTE 4: RESTRICTED CASH

The Company's restricted cash balance of $110 as of March 31, 2022 and December 31, 2021, consists entirely of cash pledged as security for the Company’s issued commercial credit cards.

NOTE 5: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	As of March 31, 2022	As of December 31, 2021
Prepaid research and development	$ 2,927	$ 1,853
Prepaid insurance	613	461
Professional services	293	124
Other	41	50
Total prepaid expenses	$ 3,874	$ 2,488

NOTE 6: RESEARCH AND DEVELOPMENT REBATE RECEIVABLE

On May 23, 2017, Atossa 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 our Phase 1 and Phase 2 Endoxifen and COVID-19 clinical trials. Australia offers an R&D cash rebate of $0.435 per dollar spent on qualified R&D activities incurred in the country. The Australian R&D tax incentive program is a self-assessment process, and as such, the Australian Government has the right to review the Company’s qualifying programs and related expenditures for a period of four years. If such a review were to occur, and as a result of the review and failure of a related appeal a qualified program and related expenditures were disqualified, the respective R&D rebates could be recalled with penalties and interest. The Company uses the grant accounting model by analogy to International Accounting Standards (IAS) 20 to account for the cash rebates received by the Australian government. During the three months ended March 31, 2022 and 2021, the Company incurred qualified R&D expenses in Australia of $354 and $270, respectively. During the quarter ended March 31, 2022 and year ended December 31, 2021, the Company collected R&D cash rebates of $563 and $0, respectively. At March 31, 2022 and December 31, 2021, we had a total research and development rebate receivable of $668 and $1,072, respectively. The rebate reduced the Research and Development expense line item on the Condensed Consolidated Statements of Operations by $140 and $107 for the three months ended March 31, 2022 and 2021, respectively.

The Company had realized (losses) and gains on foreign currency exchange, related to the research and development rebate receivable balance, during the three months ended March 31, 2022 and March 31, 2021, of $28 and $6, respectively, which is included in Other expense, net in the Condensed Consolidated Statements of Operations.

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	March 31, 2022	December 31, 2021
Accrued bonuses	$ 241	$ 894
Accrued vacation	229	183
Accrued payroll	123	107
Total payroll liabilities	$ 593	$ 1,184

NOTE 8: FAIR VALUE OF FINANCIAL INSTRUMENTS

Pursuant to the accounting guidance for fair value measurement and its subsequent updates, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date. The accounting guidance establishes a hierarchy for inputs used in measuring fair value that minimizes the use of unobservable inputs by requiring the use of observable market data when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on active market data. Unobservable inputs are inputs that reflect the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances.

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

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

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

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

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

March 31, 2022	**Estimated Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Money market account	$ 51,797	$ 51,797	$ -	$ -

December 31, 2021	**Estimated Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Money market account	$ 51,796	$ 51,796	$ -	$ -

Warrants issued in December of 2020 contained provisions that may have required the Company to settle the warrants in cash in an event outside the Company's control and were therefore accounted for as liabilities, with changes in the fair values included in net loss for the respective periods. Because some of the inputs to the valuation model were either not observable or were not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability was classified as Level 3 in the fair value hierarchy. On January 1, 2021, the Company early adopted ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Topic 470) and Derivative Hedging - Contracts in an Entity's Own Equity (Topic 815)*. Upon adoption, the Company recorded a cumulative adjustment to beginning Stockholders' Equity in the amount of $13,003 to reclassify the common stock warrant liability to accumulated deficit and additional paid-in capital.

The following table summarizes the changes in the Company's Level 3 warrant liability for the three months ended March 31, 2021:

Warrant liability	
Beginning balance	$ 13,003
Reclassification of equity upon adoption of accounting standard	(13,003)
Issuance of warrants	-
Change in fair value	-
Ending balance	$ -

NOTE 9: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 185,000 shares of stock consisting of 175,000 shares of common stock, par value $0.18 per share, and 10,000 shares of preferred stock, par value $0.001 per share. The Company has designated 750 shares of Series A junior participating preferred stock, par value $0.001 per share, 4 shares of Series A convertible preferred stock, par value $0.001 per share, 25 shares of Series B convertible preferred stock, par value $0.001 and 20 shares of Series C convertible preferred stock, par value $0.001 per share, through the filings of certificates of designation with the Delaware Secretary of State. No shares of Series A junior participating preferred stock, no shares of Series A convertible preferred stock and no shares of Series C convertible preferred stock are outstanding as of March 31, 2022 and December 31, 2021.

2021 Financing Transactions

On January 6, 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 23,850 shares of Company common stock, par value $0.18 per share and warrants to purchase 17,888 shares of common stock. The combined purchase price for one share of common stock and a warrant to purchase 0.75 shares of common stock was $1.055. Subject to certain ownership limitations, the warrants are exercisable upon issuance. The warrants will expire on the 4.5-year anniversary of the date of issuance and have an exercise price of $1.055 per share. The common stock and warrants have been registered under the Securities Act of 1933, as amended. The offering closed on January 8, 2021 with net proceeds to the Company from the offering of $23,300 after deducting fees and expenses.

On March 22, 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 17,361 shares of our common stock, par value $0.18 per share. Concurrently with the offering, and pursuant to the purchase agreement, the Company also commenced a private placement whereby it issued and sold warrants exercisable for an aggregate of up to 13,021 shares of common stock. The combined purchase price for one share of common stock and a purchase warrant to purchase 0.75 shares of common stock is $2.88. Subject to certain ownership limitations, the warrants are exercisable upon issuance. The warrants will expire on the 4.5-year anniversary of the date of issuance. Subsequent to the issuance of the warrants, the Company filed a registration statement on Form S-3 (File No. 333-255411) to cover the sale of an aggregate of 13,021 shares of common stock issuable upon exercise of the warrants which was declared effective by the SEC on April 29, 2021. The net proceeds to the Company from the offering and the private placement are $46,400, after deducting fees and expenses.

Series B Convertible Preferred Stock

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

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

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

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

Liquidation Preference. Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series B convertible preferred stock will be entitled to receive out of our 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. We are 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.

Warrants

The terms and conditions of the warrants are as follows:

Exercisability. Each warrant is exercisable at any time and will expire between 4 and 4.5-years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise, except in the case of a cashless exercise as discussed below.

The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of our assets, or other similar transaction, the holders of warrants shall, at the option of the Company, be required to exercise the

warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

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

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

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

Warrants Outstanding

As of March 31, 2022, warrants to purchase 22,277 shares of common stock were outstanding including:

	Outstanding Warrants to Purchase Shares		Exercise Price Per Share	Expiration date
May 2018 warrants	762	$	4.05	May 30, 2022
December 2020 warrants	6,490	$	1.00	December 11 2024-June 21, 2025
January 2021 warrants	4,500	$	1.055	July 8, 2025
March 2021 warrants	10,525	$	2.88	September 22, 2025
	22,277			

Warrant Activity

There were no warrant exercises during the three months ended March 31, 2022. During the three months ended March 31, 2021, the Company received $32,760 from the exercises of warrants. The warrant exercises resulted in the reduction of 32,063 warrants, and the issuance of 32,063 shares of common stock.

Conversion of Convertible Preferred Stock

During the three months ended March 31, 2022, there were no conversions of Series B convertible preferred stock. During the three months ended March 31, 2021, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 0.001 share, respectively, into 0.285 shares of the Company's common stock.

NOTE 10: NET LOSS PER SHARE

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

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

The Company's warrants and 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. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended March 31, 2022, and 2021.

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

	Three Months Ended March 31,	
	2022	**2021**
Numerator		
Net loss attributable to common shareholders	$ (4,786)	$ (3,538)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	126,624	92,587
Net loss per share of common stock, basic and diluted	$ (0.04)	$ (0.04)

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

	Three Months Ended March 31,	
	2022	**2021**
Options to purchase common stock	11,089	7,067
Series B convertible preferred stock	165	177
Warrants to purchase common stock	22,277	25,078
	33,531	32,322

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. No income tax liabilities existed as of March 31, 2022 and December 31, 2021, due to the Company's continuing operating losses.

NOTE 12: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits which include a money market account. Accounts at each institution are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250. As of March 31, 2022 and December 31, 2021, the Company had $131,279 and $136,185, respectively, including restricted cash, in excess of the FDIC insured limit, respectively.

NOTE 13: COMMITMENTS AND CONTINGENCIES

Lease Commitments

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

Our office lease expired February 28, 2022. In March 2022, the Company entered into a new operating lease for office space to pay monthly rent of $1 for a term of 12 months. The Company had lease expense under short term leases of $8 and $5 during the three months ended March 31, 2022, and 2021, respectively. As of March 31, 2022, and December 31, 2021, the right of use asset and lease liability balances were $0.

Litigation and Contingencies

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

NOTE 14: STOCK BASED COMPENSATION

Stock Option and Incentive Plan

On March 24, 2020, the Board of Directors approved the adoption of the 2020 Stock Incentive Plan (2020 Plan) to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. No awards may be granted under the 2020 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 3,000 shares were initially reserved for issuance in connection with awards granted under the 2020 Plan. On May 14, 2021, the stockholders approved an additional 15,000 shares available for issuance under the 2020 Plan. There are 9,214 options available for grant under the 2020 Plan as of March 31, 2022.

The Company granted options to purchase 2,722 and 0 shares of common stock to employees during the three months ended March 31, 2022 and 2021, respectively. The weighted average grant date fair value of options granted during the three months ended March 31, 2022 was $1.07. There were no options exercised during the three months ended March 31, 2022 and 2021.

The fair value of stock options granted for the three months ended March 31, 2022, was calculated using the Black-Scholes option-pricing model applying the following assumptions:

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

Compensation costs associated with the Company's stock options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized stock-based compensation expense of $1,806 and $640 for the three months ended March 31, 2022 and 2021, respectively, which was included in the following captions in the consolidated statements of operations:

	Three Months Ended March 31,	
	2022	2021
General and administrative	$ 1,184	$ 450
Research and development	622	190
Total stock compensation expense	$ 1,806	$ 640

Options issued and outstanding as of March 31, 2022, and their activities during the three months ended are as follows:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years	Aggregate Intrinsic Value
Outstanding as of January 1, 2022	10,027	$ 2.82		$ 1,006
Granted	2,722	1.25		
Exercised	-	-		
Forfeited	-	-		
Expired	-	-		
Outstanding as of March 31, 2022	12,749	2.48	8.42	$ -
Exercisable as of March 31, 2022	7,279	2.82	7.67	
Vested and expected to vest	12,749	$ 2.48	8.42	$ -

At March 31, 2022, there were 5,470 unvested options outstanding and the related unrecognized total compensation cost associated with these options was $8,279. This expense is expected to be recognized over a weighted-average period of 1.48 years.

Defined Contribution Plan

The Company has a defined contribution plan to which employees of the Company may defer compensation for income tax purposes. Participants are eligible to receive employer matching contributions of 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, 2022 and 2021, were $34 and $33, respectively.

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

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

Forward-Looking Statements

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

- The impact of the ongoing coronavirus pandemic and the degree to which the pandemic negatively impacts our supply chain, clinical trial enrollment and timing, nonclinical study timing, and our ability to access capital markets;
- whether we can obtain approval from the U.S. Food and Drug Administration (FDA), and foreign regulatory bodies, to commence our clinical trials, including our planned COVID-19 and Endoxifen trials, and to sell, market and distribute our therapeutics under development;
- our ability to successfully initiate and complete clinical trials of our pharmaceutical candidates under development, including our COVID-19 therapies and Endoxifen (an active metabolite of Tamoxifen), and whether those trials will meet their objectives;
- the success, cost and timing of our product and drug development activities and clinical trials, including whether our studies using our COVID-19 therapies and Endoxifen will enroll a sufficient number of subjects or be completed in a timely fashion or at all;
- 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 that we might identify in the future and in the time frames currently expected;
- our ability to successfully defend litigation and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;
- our ability to establish and maintain intellectual property rights covering our products;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;
- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;
- whether the final study results will vary from preliminary study results that we may announce;
- our expectations as to future financial performance, expense levels and capital sources;
- our ability to attract and retain key personnel; and
- our ability to raise capital.

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

Company Overview

We are a clinical-stage biopharmaceutical company seeking to develop proprietary innovative medicines in areas of significant unmet medical need in oncology and infectious diseases, with a current focus on breast cancer, other breast conditions and COVID-19. Our drug under development for breast cancer and other breast conditions is Endoxifen which is being developed primarily in two settings: one to reduce tumor cell activity in breast cancer patients in the neoadjuvant setting, meaning prior to surgery; and another to reduce dense breast tissue in women. Our two COVID-19 drugs under development are AT-H201, an inhalation therapy to improve lung function of moderate to severely ill, hospitalized COVID-19 patients; and AT-301, a nasal spray for COVID-19 patients for at-home use. A key feature of the original SARS-CoV-2 virus that is retained in both the Delta and Omicron variants, is the furin cleavage site found on the spike protein which facilitates viral infection. Our COVID-19 programs under development are designed to interact with this cleavage site so they are expected to be effective against both current and future COVID-19 variants that continue to contain a furin cleavage site.

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

Summary of Leading Programs

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

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

In December 2021, we commenced a Phase 2 study of our proprietary oral Endoxifen. The study, known as the Karisma-Endoxifen study, is a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary oral Endoxifen in healthy premenopausal women with measurable breast density. The primary objective of the study is to determine the dose-response relationship of daily Endoxifen on breast density reduction. Secondary endpoints will assess safety and tolerability, and the trial includes an exploratory endpoint to assess durability of the breast density changes. The study is being conducted at the South General Hospital in Stockholm and will include approximately 240 participants who will receive daily doses of Endoxifen or placebo for six months. The study is being led by principal investigator Per Hall, M.D., Ph.D., Department of Medical Epidemiology and Biostatistics at Karolinska Institutet.

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 Endoxifen also reduces the incidence of breast cancer. We may therefore conduct additional studies of Endoxifen to assess its correlation with the risk of breast cancer and/or reduction in the incidence of new breast cancers.

Endoxifen for Neoadjuvant Treatment of Breast Cancer. We are also developing Endoxifen to treat breast cancer in the neoadjuvant setting, which is the administration of a therapy before the surgical treatment, with a current focus on breast cancers that are classified as estrogen receptor positive (ER+). Although there are numerous neoadjuvant treatments for breast cancers that are not ER+, there are few neoadjuvant treatments for ER+ breast cancer which comprises about 78% of all breast cancers. We believe there is a compelling need for therapy with our Endoxifen in this setting.

In December 2021, we completed a PIND meeting with the FDA. The purpose of the meeting was to obtain input from the FDA on pre-clinical, clinical, manufacturing and regulatory matters in the U.S. for our proprietary Endoxifen to treat breast cancer. Based in part on the feedback from the FDA, we plan to open an IND for a multi-center Phase 2 study to further advance our Endoxifen in the neoadjuvant setting. We plan to focus our development on pre-menopausal women with ER+, human epidermal growth factor receptor 2 negative (HER2-) breast cancer for whom the current treatment options typically include drugs that suppress ovarian function and essentially force the patient into menopause.

We recently completed a Phase 2 study in Australia which enrolled 7 newly diagnosed patients with ER+ and stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. In February 2021, we concluded that the study produced substantially positive results and that continuing enrollment in the study would not be necessary in advancing the program. We therefore discontinued the study based in part on results from the first six patients. In June 2021, we reported final results from the study of all 7 patients which showed that tumor cell proliferation in study participants was reduced by an average of 65%, as measured by Ki-67 expression, which is a common measure of tumor cell activity in breast cancer.

AT-301 for COVID-19. AT-301 is our proprietary drug formulation candidate intended for nasal administration in patients immediately following diagnosis of COVID-19 but who have not exhibited symptoms severe enough to require hospitalization. It is intended for at-home use to reduce symptoms of COVID-19 and to slow the infection rate so that a person's immune system can more effectively fight COVID-19.

AT-301 is being developed with a nasal spray delivery mechanism because many COVID-19 patients are infected via the nasal passage. Our nasal spray formulation AT-301 is being designed to contain ingredients that can potentially block SARS-CoV-2 viral entry in nasal epithelial cells by interfering with spike protein activation by host proteases, by masking receptor binding domains via electrostatic mechanisms, and by providing a generalized mucoadhesive epithelial barrier.

In October 2020, we completed enrollment in a Phase 1 study of AT-301 which was a double-blinded, randomized, and placebo-controlled safety study of AT-301 nasal spray in 32 healthy adult subjects. An evaluation of the data indicated that there were no serious adverse events, no discontinuations, and only one of the subjects in the study experienced adverse events that were considered related to the study drug and moderate in severity. We concluded that our AT-301 nasal spray was safe and well tolerated in this study. We received input from the FDA on this program in 2021 and based in part on that input, we are now preparing to conduct additional pre-clinical studies. Following that, we expect to apply to the FDA to commence a Phase 2 study in the United States.

We may also develop our AT-301 nasal spray to potentially help prevent COVID-19 infection — particularly for people in high-risk environments, such as people living with an infected patient, people living and working in healthcare facilities, emergency responders or teachers.

AT-H201 for COVID-19. AT-H201 is a proprietary combination of two drugs previously approved by the FDA to treat other diseases. It is intended to improve compromised lung function for moderate to severely ill, hospitalized COVID-19 patients by inhalation. We also intend to study AT-H201 on long haul COVID-19 survivors. We received input from the FDA on potential pathways to develop AT-H201 and the FDA requested that we provide, among other things, additional pre-clinical results and other information on AT-H201.

In September 2021 we began enrollment in Australia in a Phase 1/2a study of AT-H201 and in April 2022, we completed enrollment in the second of four parts of the study. The study plans to enroll 60 healthy participants and moderately ill hospitalized COVID-19 patients. An Australian human research ethics committee will review data after each part of the study before we may proceed with subsequent parts of the study. Because the final part of the study in COVID-19 infected patients may require that we use additional study sites, approval of that part of the study and additional sites will depend on COVID-19 infections and may therefore be delayed.

Impact of the Novel Coronavirus

The ongoing COVID-19 pandemic may affect our operations and those of third parties on which we rely, including causing possible disruptions in the supply of Endoxifen, AT-H201, AT-301, the pace of enrollment in our clinical trials and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. FDA and other health authorities including similar entities/agencies in Sweden and Australia, which could result in delays in meetings, reviews and approvals. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole as a result of the COVID-19 pandemic; however, we have not experienced a significant delay in the enrollment or the drug supply for our ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. Although there have been times when the number of reported COVID-19 cases has surged, there have also been times when the number of reported cases of COVID-19 has declined in many countries. If the number of COVID-19 cases decline, it may be difficult to enroll participants in our COVID-19 clinical studies.

Research and Development Phase

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

Commercial Lease Agreements

Refer to Note 13 Condensed Consolidated Financial Statements.

Critical Accounting Policies and Significant Estimates

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

While our significant accounting policies are more fully described in Note 3 to our condensed consolidated financial statements included in this Form 10-Q, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our condensed consolidated financial statements.

Research and Development

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

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

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

Stock-Based Payments

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

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

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

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021 (amounts in thousands)

Revenue and Cost of Revenue: For the three months ended March 31, 2022 and 2021, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $4,747 for the three months ended March 31, 2022, which is an increase of $1,216 or 34%, from the three months ended March 31, 2021. Operating expenses for 2022 consisted of research and development (R&D) expenses of $1,499 and general and administrative (G&A) expenses of $3,248. Operating expenses for 2021 consisted of R&D expenses of $1,379, and G&A expenses of $2,152. The basis for the increased operating expenses in 2022 is explained below.

Research and Development Expenses: R&D expenses for the three months ended March 31, 2022, were $1,499, an increase of $120 or 9% from total R&D expenses for the same period in 2021 of $1,379. The increase in R&D expense is attributed to increased spending on clinical and non-clinical trials of $584 over 2021 due to additional drug manufactuing costs. Stock-based compensation, which is a non-cash charge, also increased $433 quarter over quarter, and other R&D compensation was up $79 due to salary bonus and benefit increases quarter over quarter. The increase in R&D was offset by a refund of $1,000 from the research institution that the Company had an exclusive right to negotiate for the acquisition of the world-wide rights to two oncology R&D programs. In February 2022, the other party did not honor its obligation to negotiate with us which lead to a cancellation of the agreement and refund of the $1,000 we paid them.

General and Administrative Expenses: G&A expenses were $3,248 for the three months ended March 31, 2022, an increase of $1,096, or 51% from the total G&A expenses for the three months ended March 31, 2021, of $2,152. The increase in G&A expenses for the three months ended March 31, 2022, is primarily attributable to non-cash stock-based compensation expense of $734. Other compensation also increased $264 due to the addition of a new employee quarter over quarter as well as salary, bonus and benefit increases. Legal fees also increased $124 quarter over quarter due to increased patent activity.

Income taxes: We have incurred net operating losses from inception; we did not record an income tax benefit for our incurred losses for the three months ended March 31, 2022 and 2021, due to uncertainty regarding utilization of our net operating carryforwards and due to our history of losses.

Liquidity and Capital Resources

We have incurred net losses and negative operating cash flows since inception. For the three months ended March 31, 2022, we recorded a net loss of $4,786 and used $4,878 of cash in operating activities. As of March 31, 2022, we had $131,486 in cash and cash equivalents and working capital of $134,526. We believe we have sufficient cash to fund our projected operating requirements for at least the following twelve months.

Cash Flows

As of March 31, 2022, we had cash, cash equivalents and restricted cash of $131,596.

Net Cash Flows from Operating Activities: Net cash used in operating activities was $4,878 for the three months ended March 31, 2022, an increase of $470, or 11%, compared to net cash used in operating activities for the three months ended March 31, 2021 of $4,408. The increase in the 2022 period as compared to 2021 resulted primarily from an increase in costs associated with clinical trial activity of $584 as well as in increase in prepaid clinical expenses of $649. Offsetting the year over year increase is the February 2022 refund of $1,000 attributable to a one-time fee to a leading research institution for the exclusive right to negotiate for world-wide rights to two oncology R&D programs.

Net Cash Flows from Investing Activity: Net cash used in investing activities was $13 for the three months ended March 31, 2022, and no cash was used in investing activities for the three months ended March 31, 2021. The increase in cash used was due to purchases of office equipment during the first quarter of 2022.

Net Cash Flows from Financing Activities: There were no financing activities during the three months ended March 31, 2022. Net cash provided by financing activities was $102,428 for the three months ended March 31, 2021. During this period, we sold common stock and warrants for net proceeds of $69,668 and received proceeds of $32,760 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.

If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease 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 development. As mentioned earlier, the COVID-19 outbreak could adversely impact the timing and enrollment of our clinical trials.

Additional funding may not be available to us on acceptable terms or at all. The continued spread of COVID-19 and uncertain market conditions 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, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders would result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private 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.

Recent Accounting Pronouncements

Refer to Note 3 to the Condensed Consolidated Financial Statements for recently issued accounting pronouncements not yet adopted.

Recently Adopted Accounting Pronouncements

Refer to Note 3 to the Condensed Consolidated Financial Statements for recently adopted accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As of March 31, 2022, we had $131,486 cash and cash equivalents. Our cash equivalents are primarily held in a commercial money market account. We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our money market investments will not be subject to adverse changes in market value. In addition, we maintain substantially all of our cash and cash equivalents at one financial institution that are in excess of federally insured limits.

We engage CROs, contract manufacturers and other vendors on a global scale. We may be subject to fluctuations in foreign currency rates in connection with certain of our agreements with these parties. We do not participate in any foreign currency hedging activities, and we do not have any other derivative financial instruments. As of March 31, 2022, we have a cash account and a research and development rebate receivable denominated in Australian Dollars. Our research and development rebate receivable balance denominated in Australian dollars was 889 and our Australian dollar cash balance was 90 at March 31, 2022. We did not recognize any significant exchange rate losses during the quarter ended March 31, 2022.

We currently have no product revenues and depend on funds raised through other sources. Our sources of funding include future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price, prevailing interest rates, and on the state of the capital markets generally.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its chief executive and chief financial officers, 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, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation and Contingencies

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

ITEM 1A. RISK FACTORS

Purchasing shares of common stock is an investment in our securities and involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information contained in this quarterly report and our Annual Report, before purchasing our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the common stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to our Business

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

Since December 2015, our business has focused on the development of novel therapeutics for the treatment of breast cancer and other breast conditions. In the first quarter of 2020, we began development of a novel potential therapy for hospitalized COVID-19 patients and in the second quarter 2020 we launched a second COVID-19 program for patients who do not require hospitalization. However, this is a departure from our historical focus on breast cancer and we have no operating history as a company in developing treatments for infectious diseases. 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 growth in operations;
- respond to changes in applicable government regulations and legislation;
- access additional capital when required; 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 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. 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, we may be unable to develop and commercialize our product offerings or geographic reach and we could be forced to cease operations.

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

For the three months ended March 31, 2022, we incurred a net loss of $4,786 and we had an accumulated deficit of $134,020 since inception. As of March 31, 2022, we had cash and cash equivalents of $131,486. 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 from time to time 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 will be prevented from developing our pharmaceutical candidates, pursuing acquisitions, invest in other companies including as a sponsor or investor in special purpose acquisition companies, licensing, development and commercialization efforts, and our ability to continue operations, generate revenues, and achieve or sustain profitability will be substantially harmed. We currently have fewer than four million shares of common stock authorized that are not reserved for specific purposes. Although we have proposed to our stockholders that at our 2022 annual stockholder meeting our charter be amended to add additional authorized shares for various potential purposes, including potential capital raising transactions, to date our stockholders have not approved such a proposal and may not approve such a proposal in the future. A lack of authorized shares may limit our ability to raise capital when needed.

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

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

We intend to use our capital resources to execute on our business plan, which may include acquiring or in-licensing additional programs and may also include the internal development of additional programs that may or may not be related to oncology and infectious diseases. 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. These investments may be in special purpose acquisition companies either as a sponsor or as an equity investor. Our business plan may evolve to require more capital resources than currently contemplated either because our existing programs progress more quickly or at a greater expense than currently anticipated or because we add additional programs. You may not agree with the ways in which we expend our capital resources and we may not produce stockholder value from the ways we deploy our capital.

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 loss for the quarter ended March 31, 2022, was $4,786. We will continue to incur further losses in connection with research and development costs for development of our programs, including ongoing and additional clinical studies.

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

We may not succeed in achieving commercial market acceptance of any of our products. In order to gain market acceptance for the drugs under development, we will need to demonstrate to physicians and other healthcare professionals the benefits of these therapies including the clinical and economic application for their particular practice. 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, 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), or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products.

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

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

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. These employees may not be available in this geographic region. In addition, competition for these employees is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage organization 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 have made employment costs substantially higher. As a result, our operating expenses may go up 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 anti-cancer and other pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs to treat cancer, other breast conditions and infectious diseases is expensive, difficult, and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

- an unacceptable safety profile;
- lack of efficacy;
- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products, and completing manufacturing to support clinical studies;
- pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;
- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products;
- equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;
- inefficient cost structure of a compound, finished drug, or device compared to alternative treatments;
- obstacles resulting from proprietary rights held by others, such as patent rights for a particular compound;
- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, perceived cost/benefit of participating in the study, eligibility criteria for tests, and competition with other clinical testing programs;
- nonclinical or clinical testing requiring significantly more time than expected resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;
- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;
- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;
- delays in reaching or failing to reach agreement on acceptable terms with manufacturers or prospective clinical research organizations (CROs), and trial sites;
- availability of vaccines or approved therapeutics developed by others may reduce the demand and commercial opportunities for our COVID-19 drug candidates; and
- failure of third-parties, such as clinical research organizations, academic institutions, collaborators, cooperative groups, and/or investigator sponsors, to conduct, oversee, and monitor clinical trials and results.

In addition, from time to time we expect to report interim, top-line or "preliminary" data for clinical trials, including for example the results reported in 2021 for our neoadjuvant or "window of opportunity" Phase 2 study of Endoxifen in Australia. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Interim, top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, interim, top-line or "preliminary" results may differ from future 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 in general.

For example, some participants in the Phase 2 MBD study we conducted in Stockholm, Sweden despite showing reduced MBD as a result of using our topical Endoxifen exited the study before completing a full six months of dosing because of skin irritation and rashes.

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 the 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.) 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 preclinical 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 preclinical 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. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA, and other foreign regulatory agencies can delay, limit, or deny approval of a product for many reasons, including, but not limited to:

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

Regulatory agencies may also fail to grant approvals to commence studies for any number of reasons. For example, in May 2020, the FDA asked for additional pre-clinical data and other information for a proposed study of AT-H201. If we cannot provide the requested data and information the FDA may not authorize us to commence this study.

Another example is that Hunan Research Ethics Committee (HREC) provided approval to commence the study but has not approved the final part of the study involving COVID-19 infected patients because it is unclear if that part of the study will be conducted at the site in Australia. The addition of new sites will require additional approvals and we will have to conduct this part of the study where COVID-19 infections allow.

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, including AT-H201 to treat COVID-19 and Endoxifen for breast cancer, 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 intend to enroll patients in studies of our drug candidates for patients who may die while enrolled in our studies. For example, we are developing AT-H201for COVID patients who may be severely ill, including patients on ventilators. COVID patients on ventilators are very sick and many do not recover either because of COVID-19 or other illnesses. Patients in our Endoxifen studies may have breast cancer which could cause death. As a result, it is likely that we will observe severe adverse outcomes of some patients in our clinical trials for our drugs, 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 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 Good Laboratory Practices (GLP) or similar standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of these regulatory authorities may take action against a contract manufacturer who violates cGMP. Failure of our manufacturers to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

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

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

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

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

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

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

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

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

- the effects of the ongoing coronavirus pandemic, including access to clinical trial sites both by study participants and our clinical research organizations;
- failure to obtain on a timely basis, or at all, approval from the applicable institutional review board or ethics committee to open a clinical study;
- lower than anticipated patient enrollment for reasons such as existing conditions, eligibility criteria or if patients perceive a lack of benefit to enroll in the study for whatever reason;
- delays in reaching agreements on acceptable terms with prospective CROs; and
- failure of CROs or other third parties to effectively and timely monitor, oversee, and maintain the clinical trials.

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. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost, or otherwise, to protect against potential product liability claims could prevent or inhibit the commercialization of our products.

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

Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and to protect our existing patent position, both in the U.S. and in other countries, for therapeutics and related technologies, processes, methods, compositions, and other inventions that we believe are patentable all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of January 15, 2022, we own and are pursuing 83 (11 U.S. and 72 international applications) pending provisional and non-provisional patent applications. We continue to evaluate the full range of our technologies and file new patent applications.

Our ability to preserve our trade secrets, trademarks and other intellectual property rights is also important to our long-term success. Our success depends in part on obtaining patent protection for our products and processes, preserving trade secrets, patents, copyrights and trademarks, operating without infringing the proprietary rights of third parties, and acquiring licenses for technology or products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to establish or maintain profitability. Patents may also be issued to third parties which could interfere with our ability to bring our therapeutics to market. As the patent and 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 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. The patent positions of diagnostic companies and pharmaceutical and biotechnology companies, including our patent position, are generally highly uncertain and 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 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 such 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, deemed unenforceable, invalidated or circumvented. 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 or 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;
- the patents of others will not have an adverse effect on our business; or
- our patents and patent applications or patents and patent applications that we license from others, if any will survive legal challenges, and remain valid and enforceable.

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

Any litigation proceedings relating to our proprietary technology may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Finally, we may not be able to prevent, alone or with the support of our licensors, if any, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

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

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

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

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

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

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

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

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

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

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

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

We cannot assure you that our current or future products will not infringe on existing or future patents. We may not be aware of patents that have already 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. Third parties may also attempt to initiate reexamination, post-grant review or *inter partes* review of our patents in the USPTO. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

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

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

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

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

Risks Related to Our Industry

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

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

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

The FDA recently announced the Coronavirus Treatment Acceleration Program. That program may not, however, lead to a faster review or approval of our FDA submissions including for our COVID-19 studies.

Our inadvertent or unintentional failure to comply with the complex government regulations concerning privacy patients, 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. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could incur damages under state laws, for example, California Consumer Privacy Act, to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

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

The HIPAA privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

The collection and use of personal data including personal health data of individuals in the E.U. regardless of citizenship or residence is governed by the provisions of the General Data Protection Regulation 2016/679 (commonly known as GDPR) which came into effect on May 25, 2018 with no transition period, and which has penalties for noncompliance. GDPR supersedes the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995. GDPR regulates the protection of individuals in E.U. with regard to the processing of personal data and on the free movement of such data within E.U. and outside the E.U. and European Economic Area ("EEA") areas. GDPR imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual E.U. Member States, and the security and confidentiality of the personal data. No personal data may be processed unless this processing is done under one of six lawful bases specified by the regulation (consent, contract, public task, vital interest, legitimate interest or legal requirement). When the processing is based on consent the data subject has the right to revoke it at any time.

Failure to comply with the requirements of GDPR, and the related national data protection laws of the E.U. Member States 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.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of £17.5 million or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU 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 by the Commission during this period. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

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

We rely on information technology systems to keep financial records, manage our manufacturing operations, fulfill customer orders, capture laboratory data, maintain corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events including but not limited to natural disaster. 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 timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches — whether by employees or others — which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations. In addition, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations and the E.U. GDPR, and other regulations, the breach 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.

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

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

In addition to the 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 the new federal legislation and the expansion in government’s effect on the U.S. healthcare industry 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.

Other Risks

The continued spread of coronavirus globally could adversely impact our operations and clinical trials.

Public health pandemics, epidemics or outbreaks could adversely impact our business. The ongoing COVID-19 pandemic and related supply-chain disruptions are affecting the United States and global economies and may affect our operations and those of third parties on which we rely, including causing possible disruptions in the supply of the Company's Endoxifen, AT-H201, AT-301 and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. FDA and other health authorities including similar entities/agencies in Sweden and Australia, which could result in delays in meetings, reviews and approvals. The evolving COVID-19 pandemic could also directly or indirectly impact the pace of enrollment in our clinical trials for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices except for a health emergency. Such facilities and offices may also be required to focus limited resources on non-clinical trial activities, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial activities related to our products under development. We have not experienced any delay in drug supply for our ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on the Company's liquidity, capital resources, operations, financial position and business and those of the third parties on which we rely. We will continue to monitor future enrollment in studies for potential restrictions on site visits, mammograms or the impositions of new restrictions on trials as a result of the COVID-19 pandemic. The continued spread of the coronavirus globally could adversely impact our operations that are dependent on third-party service providers for a number of critical operational activities including, in particular,

- regulatory (FDA, MPA, TGA) meetings and approvals could be delayed;
- protocol review groups (IRB, HREC, IEC, etc.) meetings and approvals could be delayed;
- our drug supply chain could be interrupted and shipping may incur new surcharges;
- enrollment in our clinical studies could slow or be halted;
- operations in general could be disrupted with potential infection of employees and consultants and difficulties with a remote work force;
- quarantines of people and drugs needed for our studies could adversely affect operations;
- our stock price could be adversely impacted and access to capital could be more challenging; or
- our ability to access our facilities and timely prepare and file regulatory reports with the SEC.

The end of the COVID-19 pandemic may make our COVID-19 programs obsolete.

Although many public health authorities have said that COVID-19 will continue to be present in circulation for the foreseeable future, the end of the pandemic and the shift to an endemic phase would likely reduce the need for our COVID-19 product candidates and may make them obsolete or unnecessary or otherwise reduce the size of the potential market for our product candidates. It is possible that our development timeline for these programs will exceed the duration of the pandemic such that we do not realize a positive return on these investments. To the extent that the stock market has placed value in our COVID-19 programs, positive developments relating to the end of the pandemic could have a negative impact on our stock price.

Risks Related to the Securities Markets and Investment in our Securities

Our shares of common stock are listed on The Nasdaq Capital Market, but we cannot guarantee that we will be able to satisfy the continued listing standards going forward.

Although our shares of common stock are listed on The Nasdaq Capital Market, we cannot ensure that we will be able to satisfy the continued listing standards of The Nasdaq Capital Market going forward. If we cannot satisfy the continued listing standards going forward, Nasdaq may commence delisting procedures against us, which could result in our stock being removed from listing on The Nasdaq Capital Market.

If our stock price does not satisfy the $1.00 minimum bid price requirement or we otherwise fail to satisfy other continued listing requirements (and such other continued listing requirements may be enhanced during the period our stock price is below the $1.00 minimum bid requirement including a requirement that we maintain at least $5 million in stockholders' equity rather than the $2.5 million that is typically required for continued listing), we may be delisted from Nasdaq, which could adversely affect our stock price, liquidity, and our ability to raise funding. Our common stock has at times trades below the $1.00 minimum bid requirement.

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

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

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

- results of clinical studies;
- regulatory and FDA actions, including inspections and warning letters;
- actions of securities analysts who initiate or maintain coverage of us, and changes in financial estimates by any securities analysts who follow our Company, or our failure to meet these estimates or the expectations of investors;
- any ongoing litigation that we are currently involved in or litigation that we may become involved in in the future;
- additional shares of our common stock being sold into the market by us or our existing stockholders or warrant holders or the anticipation of such sales; and
- media coverage of our business and financial performance.

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

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

Our ownership may become concentrated among a small number of stockholders. These stockholders, acting together, will 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 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 you.

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, 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, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, 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 is listed, the Securities and Exchange Commission, or other regulatory authorities, which could require additional financial and management resources.

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

Our Stockholder Rights Agreement that we adopted in May 2014, our amended and restated certificate of incorporation, and amended and restated bylaws contain provisions that could delay or prevent a change in control or changes in our Board of Directors that our stockholders might consider favorable. These provisions include the establishment of a staggered Board of Directors, 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, our Shareholder Rights Plan and Delaware law might discourage, delay or prevent a change in control or changes in the Board of Directors of the Company. These provisions could also discourage proxy contests and make it more difficult for an investor 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 the Board of Directors

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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

Not applicable.

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein	
		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	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith	
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith	
101.INS	Inline XBRL Instance Document		
101.SCH	Inline XBRL Taxonomy Extension Schema Document		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document		
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)		

SIGNATURES

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

Date: May 9, 2022

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

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

Exhibit 31.1

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

I, Steven C. Quay, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officers 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 function):

(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 9, 2022

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

Exhibit 31.2

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

I, Kyle Guse, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officers 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 function):

(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 9, 2022

/s/Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Atossa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven C. Quay, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 9, 2022

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

Exhibit 32.2

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

In connection with the Quarterly Report of Atossa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kyle Guse, Chief Financial Officer, General Counsel and Secretary of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 9, 2022

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)