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, 2020

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	NASDAQ

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 at May 8, 2020, was 9,208,458.

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

	As of March 31, 2020 (Unaudited)	As of December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 9,351,141	$ 12,581,136
Restricted cash	110,000	110,000
Prepaid expenses	1,337,120	862,344
Research and development tax rebate receivable	734,340	739,656
Other current assets	134,519	26,130
Total current assets	11,667,120	14,319,266
Furniture and equipment, net	29,734	34,350
Intangible assets, net	60,833	68,542
Right-of-use asset	37,397	50,479
Other assets	17,218	17,218
Total Assets	$ 11,812,302	$ 14,489,855
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 356,252	$ 293,171
Accrued expenses	52,474	77,888
Payroll liabilities	466,383	899,420
Lease liability	29,385	39,371
Other current liabilities	3,458	12,892
Total current liabilities	907,952	1,322,742
Long term liabilities		
Lease liability long term	8,013	11,108
Total Liabilities	915,965	1,333,850
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 671 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	670,999	670,999
Common stock - $0.18 par value; 175,000,000 shares authorized, and 9,130,984 shares issued and outstanding, as of March 31, 2020 and December 31, 2019, respectively	1,643,565	1,643,565
Additional paid-in capital	105,600,232	104,912,480
Accumulated deficit	(97,018,460)	(94,071,040)
Total Stockholders' Equity	10,896,337	13,156,005
Total Liabilities and Stockholders' Equity	$ 11,812,302	$ 14,489,855

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

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended March 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 938,620	$ 1,451,236
General and administrative	1,998,389	2,613,093
Total operating expenses	2,937,009	4,064,329
Operating loss	(2,937,009)	(4,064,329)
Other expense	(10,411)	(8,978)
Loss before income taxes	(2,947,420)	(4,073,307)
Income taxes	-	-
Net loss	$ (2,947,420)	$ (4,073,307)
Loss per common share - basic and diluted	$ (0.32)	$ (0.62)
Weighted average shares outstanding - basic and diluted	9,130,984	6,565,514

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

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

	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, 2018	2,379	$ 2	$ 2,378,997	5,846,552	$ 1,052,372	$ 82,204,902	$ (76,831,263)	$ 8,805,010
Issuance of common stock upon warrant exercise	-	-	-	2,799,188	503,854	10,832,856	-	11,336,710
Conversion of Series B convertible preferred stock to common stock	(1,677)	(1)	(1,676,998)	476,431	85,753	1,591,246	-	-
Compensation cost for stock options granted	-	-	-	-	-	275,833	-	275,833
Reclassification of stock-based compensation liability upon option cancellation	-	-	-	-	-	3,151,944	-	3,151,944
Net loss	-	-	-	-	-	-	(4,073,307)	(4,073,307)
Balance at March 31, 2019	702	$ 1	$ 701,999	9,122,171	$ 1,641,979	$ 98,056,781	$ (80,904,570)	$ 19,496,190

	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, 2019	671	$ 1	$ 670,999	9,130,984	$ 1,643,565	$ 104,912,480	$ (94,071,040)	$ 13,156,005
Compensation cost for stock options granted	-	-	-	-	-	687,752	-	687,752
Net loss	-	-	-	-	-	-	(2,947,420)	(2,947,420)
Balance at March 31, 2020	671	$ 1	$ 670,999	9,130,984	$ 1,643,565	$ 105,600,232	$ (97,018,460)	$ 10,896,337

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

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

	For the Three Months Ended March 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (2,947,420)	$ (4,073,307)
Adjustments to reconcile net loss to net cash used in operating activities		
Compensation cost for stock options granted	687,752	275,833
Depreciation and amortization	12,326	13,983
Change in fair value of stock-based compensation liability	-	1,741,919
Changes in operating assets and liabilities:		
Prepaid expenses	(474,776)	(325,635)
Research and development tax rebate receivable	5,316	280,242
Other assets	(108,389)	2,985
Accounts payable	63,081	110,642
Accrued expenses	(25,414)	(102,230)
Payroll liabilities	(433,037)	(43,312)
Other current liabilities	(9,434)	(30,076)
Net cash used in operating activities	(3,229,995)	(2,148,956)
CASH FLOWS FROM INVESTING ACTIVITY		
Net cash used in investing activities	-	-
CASH FLOWS FROM FINANCING ACTIVITY		
Proceeds from exercise of warrants	-	11,336,710
Net cash provided by financing activities	-	11,336,710
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(3,229,995)	9,187,754
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	12,691,136	10,490,493
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 9,461,141	$ 19,678,247
SUPPLEMENTAL DISCLOSURES		
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 9,351,141	$ 19,568,247
Restricted cash	110,000	110,000
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 9,461,141	$ 19,678,247
NONCASH INVESTING AND FINANCING ACTIVITIES		
Reclassification of stock-based liability awards to equity upon cancellation	$ -	$ 3,151,944

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

NOTE 1: NATURE OF OPERATIONS

On January 6, 2020, we changed our corporate name from Atossa Genetics Inc. to Atossa Therapeutics, Inc.

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

Impact of the Novel Coronavirus

The continued spread of the COVID-19 pandemic is affecting the United States and global economies and 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 and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. Food and Drug Administration 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 the Company's 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 Endoxifen. 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. The Company does not yet know the full extent of potential delays or impacts on its 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.

In response to the Coronavirus pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes provisions related to refundable payroll tax credits, deferment of employer side social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act had no material impact on the Company's income tax provision for the three months ended March 31, 2020. The Company continues to examine the elements of the CARES Act and the impact it may have on its financial position, results of operations and cash flows.

NOTE 2: GOING CONCERN

The Company has incurred net losses and negative operating cash flows since inception. For the three months ended March 31, 2020, the Company recorded a net loss of approximately $2.9 million and used approximately $3.2 million of cash in operating activities. As of March 31, 2020, the Company had approximately $9.4 million in cash and cash equivalents and working capital of approximately $10.8 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and is currently expending funds in research and development activities that are expected to continue to require funding. Management believes the currently available funding will only be sufficient to finance the Company's operations for four to seven months from the date these condensed consolidated financial statements are filed with the SEC depending on the timing and extent of the Company's clinical trials.

The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. As the Company is currently not generating revenues, continued timely expenditures on trials is important to bring its product(s) to market as soon as able. Management's plans to obtain such resources for the Company include obtaining capital from the sale of its equity securities, entering into strategic partnership arrangements, potential exercise of outstanding warrants, and short-term borrowings from banks, stockholders or other related parties, if needed. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such capital will be obtained on acceptable terms. The continued spread of COVID-19 and uncertain market conditions may limit the Company's ability to access capital. If the Company is unable to obtain adequate capital, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned commercial activities. These conditions, in the aggregate, raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

The accompanying unaudited 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, 2019. The year-end condensed balance sheet presented was derived from audited financial statements, but does not include all disclosures required by GAAP.

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, 2020, are not necessarily indicative of the results that may be expected for the year ending December 31, 2020.

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.

Research and Development Expense:

Research and development ("R&D") costs are generally expensed as incurred. R&D expenses include, for example, manufacturing expenses for our drugs under development, expenses associated with clinical trials and associated salaries and benefits. R&D expenses also include an estimated allocation of the CEO's salary and related benefits including non-cash stock-based compensation expense based on time devoted to R&D.

Recently Adopted Accounting Pronouncements:

On January 1, 2020, the Company adopted Accounting Standard Update ("ASU") No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, to improve the effectiveness of disclosures. The amendments remove, modify, and add certain disclosure requirements in Topic 820, “Fair Value Measurement.” The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The adoption had no impact on the Company's condensed consolidated financial statements.

NOTE 4: RESTRICTED CASH

The Company's restricted cash balance of $110,000 as of March 31, 2020 and December 31, 2019, respectively, 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, 2020	As of December 31, 2019
Prepaid research and development	$ 712,387	$ 507,733
Prepaid insurance	280,098	222,476
Professional services	278,298	108,850
Financial exchange fees	32,250	-
Retainer and security deposits	14,218	14,218
Prepaid rent	17,952	4,275
Other	1,917	4,792
Total prepaid expenses	$ 1,337,120	$ 862,344

NOTE 6: RESEARCH AND DEVELOPMENT TAX 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 clinical trials. Australia offers an R&D cash rebate of $0.435 per dollar spent on qualified R&D activities incurred in the country. For the three months ended March 31, 2020 and 2019, the Company recorded a rebate receivable of approximately $133,400 and $34,700, respectively. At March 31, 2020 and December 31, 2019, we had a total R&D rebate receivable of $734,340 and $739,656, respectively.

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	As of March 31, 2020	As of December 31, 2019
Accrued bonuses	$ 203,779	$ 646,064
Accrued vacation	179,533	170,820
Accrued payroll	83,071	82,536
Total payroll liabilities	$ 466,383	$ 899,420

NOTE 8: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 185,000,000 shares of stock consisting of 175,000,000 shares of common stock, par value $0.18 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. The Company has designated 750,000 shares of Series A junior participating preferred stock, par value $0.001 per share, 4,000 shares of Series A convertible preferred stock, par value $0.001 per share, and 25,000 shares of Series B 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 and no shares of Series A convertible preferred stock are issued and outstanding as of March 31, 2020 and December 31, 2019.

Equity Distribution Agreement

On February 7, 2020, Atossa Therapeutics, Inc. entered into an equity distribution agreement with Oppenheimer & Co. Inc., acting as sales agent relating to the "at-the-market" (ATM) offering and sale by Atossa of common shares, par value $0.18 per share, having an aggregate gross sales price of up to $5,000,000. Sales of the shares, if any, will be made at Atossa's sole discretion and by means of ordinary brokers' transactions through the facilities of the Nasdaq Capital Market at market prices, in block transactions or as otherwise agreed between Atossa and Oppenheimer. The Distribution Agreement provides that Oppenheimer will be entitled to a commission of 3.0% of the gross offering proceeds of the shares sold pursuant to the Distribution Agreement and reimbursement for certain specified expenses. Atossa has no obligation to offer or sell any shares under the Agreement, and may at any time suspend offers and sales under the Distribution Agreement. Oppenheimer & Co. Inc. may also suspend or terminate the offering of common stock being made through them upon proper notice to the Company. As of May 8, 2020, there have been 68,098 shares sold under the equity distribution agreement with net proceeds of $150,253.

Warrants

As of March 31, 2020, 1,070,028 warrants to purchase shares of common stock were outstanding. The warrants have an exercise price of $4.05 and expire on May 30, 2022.

There were no warrant exercises during the three months ended March 31, 2020. For the three months ended March 31, 2019, the Company received approximately $11.3 million from exercises of the warrants. As a result of the warrant exercises, the Company cancelled approximately 2.8 million warrants and issued approximately 2.8 million shares of common stock.

Conversion of Series B Convertible Preferred Stock

There were no conversions of Series B convertible preferred stock during the three months ended March 31, 2020. During the three months ended March 31, 2019, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 1,677 shares into 476,431 shares of the Company's common stock based on the conversion ratio of approximately 284 shares of common stock for each share of Series B convertible preferred stock.

NOTE 9: NET LOSS PER SHARE

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

	Three Months Ended March 31,	
	2020	**2019**
Numerator		
Net loss attributable to common shareholders	$ (2,947,420)	$ (4,073,307)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	9,130,984	6,565,514
Net loss per share of common stock, basic and diluted:	$ (0.32)	$ (0.62)

The following table sets forth the 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,	
	2020	**2019**
Options to purchase common stock	4,308,383	783,383
Series B convertible preferred stock	190,617	458,994
Warrants to purchase common stock	1,070,028	3,369,468
	5,569,028	4,611,845

NOTE 10: 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, 2020 and December 31, 2019, due to the Company's continuing operating losses.

NOTE 11: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. At March 31, 2020 and December 31, 2019, the Company had $8,967,650 and $12,316,429 in excess of the FDIC insured limit, respectively.

NOTE 12: 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.

The Company's operating lease assets consist of an office lease and a copier system lease. Our office lease expires in August of 2020 and our copier system lease expires in October of 2021. None of our leases contain options to extend. Total operating lease expense for the three months ended March 31, 2020 and 2019, was approximately $13,300 and $12,900, respectively, and variable lease payments of taxes and insurance were immaterial. As of March 31, 2020, the weighted average remaining lease term was approximately 9 months and the weighted average discount rate of our operating leases was 12%.

As of March 31, 2020, the future minimum lease payments are approximately $29,500 and $12,400 for 2020 and 2021, respectively. These payments are reported in the condensed consolidated balance sheets at March 31, 2020 and 2019, net of imputed interest of approximately $4,500 and $12,900, respectively. The cash paid for amounts included in the measurement of operating lease liabilities for the three months ended March 31, 2020 and 2019, was approximately $14,700 and $14,600, respectively.

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 13: 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 ("the 2020 Plan") to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. No awards may be granted under the 2020 Plan after the date that is 10 years from the date of stockholder approval.

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan ("the 2010 Plan") to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. An aggregate of 5,556 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan and on May 18, 2016, an additional 11,111 shares were reserved for issuance under the 2010 Plan. On May 9, 2018, the stockholders approved an additional 125,000 shares for issuance under the 2010 Plan. On April 12, 2018, the stockholders approved an additional 500,000 shares for issuance under the 2010 Plan. On May 16, 2019 the stockholders approved an additional 3,600,000 shares.

The following table presents the automatic additions to the 2010 Plan since inception pursuant to the "evergreen" terms of the 2010 Plan:

January 1,	Number of shares
2012	2,502
2013	2,871
2014	4,128
2015	5,463
2016	7,257
2017	12,623
2018	106,076
2019	233,862
2020	365,239
Total additional shares	740,021

The Company did not grant options to purchase shares of common stock during the three months ended March 31, 2020 or 2019. No options were exercised during the three months ended March 31, 2020 or 2019. There are 676,669 shares available for grant under the 2010 Plan as of March 31, 2020.

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 $687,752 and $275,833 (excluding Liability Options discussed below) for the three months ended March 31, 2020 and 2019, respectively.

	Three Months Ended March 31,	
	2020	2019
General and administrative	$ 483,000	$ 224,676
Research and development	204,752	51,157
Total stock compensation expense	$ 687,752	$ 275,833

Options issued and outstanding as of March 31, 2020, under the 2010 Plan and their activities during the three months then 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, 2020	4,308,383	$ 3.44		-
Granted	-	-		-
Forfeited	-	-		-
Expired	-	-		-
Outstanding as of March 31, 2020	4,308,383	3.44	8.80	$ -
Exercisable as of March 31, 2020	3,832,000	3.58	8.80	$ -
Vested and expected to vest	4,308,383	$ 3.44	8.80	$ -

At March 31, 2020, there were 476,383 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately $953,046. This expense is expected to be recognized over a weighted-average period of 0.59 years.

Liability Options

On June 27, 2018, the Company granted 2,300,000 options to the Chief Executive Officer (CEO) and 700,000 to the Chief Financial Officer (CFO) (the "Liability Options"). Each option was exercisable for an equivalent number of shares of the Company's common stock. The Liability Options were granted pursuant to an option award agreement and were granted outside the Company's 2010 Plan; however, they were subject to the terms and conditions of the 2010 Plan. On January 13, 2019, the Liability Options were canceled.

Compensation costs associated with the Liability Options were initially recognized, based on the grant-date fair values of these options, over the requisite or vesting period for time-based options or when it is probable the performance criteria were achieved for options that vest based on performance. Compensation cost was remeasured each period based on the market value of our underlying stock until award vesting or settlement.

At the time of cancellation, the fair value of Liability Options at January 13, 2019, was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	January 13, 2019
Risk free interest rate	2.53%
Expected term (in years)	4.50-5.00
Stock price	$ 1.36
Dividend yield	-%
Expected volatility	121.0-123.0%

As a result of the cancellation of these options in the first quarter of 2019, the Company recognized all remaining unrecognized compensation expense related to these options of $1,741,919, which was included in the following captions in the condensed consolidated statements of operations:

	Period Ended March 31, 2019
General and administrative	$ 1,074,183
Research and development	667,736
Total stock compensation expense	$ 1,741,919

Also on January 13, 2019, at the same time the Liability Options were cancelled, the Company awarded a new option to the CEO to purchase 2,300,000 shares of common stock and a new option to the CFO to purchase 800,000 shares of common stock (the “2019 Options”). The 2019 Options: (i) have an exercise price equal to the fair market value of common stock on the date of board of director approval which was $1.36 per share, (ii) do not contain a net cash exercise provision, (iii) are awarded pursuant to the terms and conditions of the 2010 Plan as amended by the Board of Directors on January 13, 2019, to include shares issuable upon exercise of the 2019 Options and other changes to the 2010 Plan so that the 2019 Options do not conflict with the 2010 Plan (the “Amended Plan”), (iv) vest and are exercisable in accordance with the vesting schedule related to the 2018 Liability Options; provided, however, that the 2019 Options are not exercisable unless and until the Company’s stockholders approve the Amended Plan to increase the authorized number of shares available for grant under the Plan and (v) are subject to and conditioned upon the 2019 Option Agreements with the optionees and the employment agreements with the optionees.

The above actions were unanimously approved by the disinterested members of the Board of Directors. The above actions were intended to eliminate the Company’s potential liability associated with the net cash exercise provision of the Liability Options, and to allow the stockholders of the Company the opportunity to vote on the Amended Plan, which includes shares issuable upon exercise of the 2019 Options. On May 16, 2019, the stockholders approved the Amended Plan and thereby approved the issuance of the 2019 Options.

Accounting Treatment

Awards offered under a plan that are subject to shareholder approval are not considered granted under GAAP until the approval is obtained, unless such approval is essentially a formality (or perfunctory). For example, if management and board members control sufficient votes to approve the plan, the vote may be considered perfunctory. As management and the Company’s Board of Directors did not control enough votes to approve the 2019 Options, the 2019 Options were not deemed granted under Accounting Standards Codification ("ASC") 718. Cancellation of an award that is not accompanied by the concurrent grant are accounted for as a repurchase for no consideration. Accordingly, any previously unrecognized compensation cost is recognized at the cancellation date. On January 13, 2019, as noted above, upon cancellation of the Liability Options the Company recognized $1,741,919 of unrecognized compensation cost related to the 2018 Liability Options. Additionally, the fair value of the stock-based compensation liability of $3,151,944 was reclassified to additional-paid in capital on the cancellation date. Shareholder approval was obtained on May 16, 2019, which was determined to be the grant date for the 2019 Options, and the Company remeasured and recorded the 2019 Options as a new grant under ASC 718 during the quarter ended June 30, 2019. The Company recorded $4,959,277 in the second quarter of 2019 for the 2019 Options granted to the executives.

NOTE 14: SUBSEQUENT EVENT

On April 9, 2020, the Company granted the following stock options (the “2020 Performance Options”) to executives of the Company: (i) to the Chairman of the Board, President and Chief Executive Officer, an option to purchase 1,500,000 shares of Company common stock, 195,000 of which were granted under the Company’s 2010 Plan and 1,305,000 of which were granted under the Company’s 2020 Plan; and (ii) to the Chief Financial Officer, General Counsel and Secretary, an option to purchase 590,000 shares of Company common stock, 195,000 of which were granted under the 2010 Plan and 395,000 of which were granted under the 2020 Plan.

The 2020 Performance Options have an exercise price equal to fair market value of the Company’s common stock on the date of grant which was $1.48 per share. The 2020 Performance Options vest quarterly over two years; however, vesting shall accelerate with respect to 50% of any unvested options granted under the 2020 Plan upon U.S. Federal Drug Administration ("FDA") approval of certain therapies. The 2020 Performance Options are subject to the option agreements and employment agreements with the executives. Notwithstanding the foregoing, options granted under the 2020 Plan are not exercisable unless and until the Company’s stockholders approve the 2020 Plan and they automatically expire and terminate if stockholder approval is not obtained within one year of grant.

The above actions were unanimously approved by the Compensation Committee of the Board of Directors.

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 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 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 trial, 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 oral and topical Endoxifen (an active metabolite of Tamoxifen) and our intraductal technologies to administer therapeutics, including our study using fulvestrant and immunotherapies;
- the success, cost and timing of our product and drug development activities and clinical trials, including whether the ongoing clinical trial using our intraductal technologies to administer fulvestrant and our study using our oral Endoxifen will enroll a sufficient number of subjects or be completed in a timely fashion or at all;
- whether we will successfully initiate and complete our clinical trial of topical Endoxifen to reduce mammographic breast density and whether the study will meet its objective;
- 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, including regulatory approvals to commence studies:
- 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 seeking to discover and develop innovative medicines in areas of significant unmet medical need with a focus on coronavirus ("COVID-19") and breast cancer. We are developing a proprietary formulation of two drugs called AT-H201 for the treatment of COVID-19 patients on mechanical ventilators. In April 2020, we contracted to commence a clinical trial of AT-H201, called the COVID-19 HOPE Trial, at NYC Health + Hospitals/Metropolitan in New York City. The COVID-19 HOPE Trial will evaluate AT-H201 in COVID-19 patients on ventilators with the goal of reducing the amount of time on ventilators. AT-H201 is not an antiviral drug, but is intended to improve compromised lung function for COVID-19 patients who are on a mechanical ventilator. Subject to FDA and IRB and input and approval, thirty-nine patients will be enrolled in the active treatment group and compared to the outcomes of 66 patients in a matched retrospective control group.

Our lead breast health program is the development of Endoxifen, an active metabolite of tamoxifen which is an FDA-approved drug, to treat and prevent breast cancer in high risk women. Our primary goal is to develop our proprietary oral Endoxifen to reduce mammographic breast density ("MBD"), which 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 2019, we contracted with Stockholm South General Hospital to conduct a double-blinded, placebo-controlled Phase 2 study of our oral Endoxifen in approximately 1,000 pre-menopausal women with MBD who will be dosed over six months. We are also developing oral Endoxifen to potentially treat breast cancer in the “window of opportunity” between diagnosis of breast cancer and surgery and we are currently conducting a Phase 2 study in Australia in this setting. We have successfully completed a Phase 1 study in men, for whom we are evaluating Endoxifen for the treatment and/or reduction of gynecomastia, which is male breast enlargement. We are also developing our proprietary intraductal delivery technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), close to the site of breast cancer in the breast ducts. A Phase 2 study is being conducted by Johns Hopkins University using our intraductal technology to deliver fulvestrant.

In 2017, we successfully completed our initial Phase 1 placebo-controlled clinical trial of our proprietary oral and topical formulations of Endoxifen in 48 healthy women, supporting the continued development of this drug. There were no clinically significant safety signals and no clinically significant adverse events, and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study who took daily doses of oral Endoxifen to reach steady-state serum levels of Endoxifen was approximately seven days. Published literature indicates that it can take approximately 50 to 200 days for patients to reach steady-state Endoxifen levels from daily doses of oral tamoxifen.

In December 2018, we began providing our oral Endoxifen to a pre-menopausal, estrogen-receptor positive (ER+), lacking CYP2D6 function, breast cancer patient under an FDA-approved "expanded access, single patient" program. The purpose of this therapeutic approach was to reduce activity of the cancer cells prior to surgery. The patient received daily doses of our oral Endoxifen for approximately three weeks prior to surgery. There were no safety or tolerability issues and her surgery was successfully completed. The cancer cell biological activity was reduced, based on the estrogen receptor activity of the tumor cells and a 50% reduction in Ki-67. The FDA has also permitted use of our Endoxifen for this patient following her surgery, under the FDA expanded access Investigational New Drug ("IND") program, as part of her long-term breast cancer treatment regimen. The use of our proprietary oral Endoxifen is restricted solely to this patient.

In June 2019, we reported preliminary analysis from our Phase 2 study of proprietary daily topical Endoxifen to reduce MBD, showing significant (p=0.02) and rapid reduction in MBD at the 20mg daily dose level. MBD was reduced by an average of 14.3% in the group applying 20mg daily topical Endoxifen, which was statistically significant (p=0.02). In the lower dose group (10mg), MBD was reduced by an average of 9.0%, but was not statistically significant. Approximately 70% of participants receiving 20mg topical Endoxifen experienced a reduction in MBD, and of those, the mean reduction in MBD was 27%. We plan to reevaluate our development strategy for the topical form of Endoxifen, as well as the opportunity to treat gynecomastia with Endoxifen, once we complete the Phase 2 study of oral Endoxifen to reduce MBD.

In May 2020, we reported interim results from our Phase 2 study of oral Endoxifen in the window of opportunity. A statistically significant (p=0.031) reduction of about 74% in tumor cell proliferation, as measured by Ki-67, over the 22 days of dosing was achieved in the initial patients. Ki-67 is a recognized standard measurement of breast cancer cell proliferation.The purpose of this study is to determine if Atossa’s oral Endoxifen reduces breast cancer tumor cell proliferation as measured by several biomarkers, including Ki-67. The open-label study was designed to permit an interim analysis of the Ki-67 change. The requirement was to achieve a meaningful Ki-67 change in at least two of eight patients. Six out of six (100%) patients experienced a significant reduction in Ki-67. A summary of these results includes:

- Ki-67 was reduced by more than 50% in every patient in the window of opportunity between initial biopsy and surgery, with an overall relative reduction of 74%.
- All six patients had a Ki-67 below 25% after treatment. In a paper entitled, “Prognostic value of different cut-off levels of Ki-67 in breast cancer: a systematic review and meta-analysis of 64,196 patients,” Ki-67 was an independent prognostic value for predicting overall survival in ER+ breast cancer patients. Ki-67 levels below 25% were associated with the lowest risk of death in this systematic review and meta-analysis.
- Treatment ranged from 16-40 days with an average of 22 days.
- There were no safety or tolerability issues, including vasomotor symptoms such as hot flashes and night sweats, which are often a tolerability challenge for patients on tamoxifen.

Also in May 2020, we reported a regulatory update. The FDA recently provided written input on our clinical path for oral Endoxifen to reduce MBD. The input was provided pursuant to a pre- IND meeting request which was scheduled for April 30, 2020. The input received from the FDA was very useful and will inform our clinical trial strategy and study design both in the U.S. and in Stockholm, Sweden where we are planning a Phase 2 study to reduce MBD. The upcoming study in Stockholm is subject to approval by the European Medical Product Authority ("MPA") and the re-opening of mammography clinics in Stockholm following the COVID-19 closures.

We recently applied to the FDA for approval to commence the COVID-19 HOPE Trial. The FDA has requested, among other things, that we submit additional pre-clinical and other information on AT-H201 before approving the study. We are in the process of gathering the data and information requested and plan to provide it to the FDA as soon as possible. There can be no assurance that we will be able to provide the information requested by the FDA nor that the FDA will approve the COVID-19 HOPE Trial.

Research and Development Phase

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

Commercial Lease Agreements

On November 1, 2018, the Company entered into an operating lease to pay $3,660 monthly rent for a term of 22 months with WW 107 Spring Street LLC to lease office space at 107 Spring Street, Seattle, Washington.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

There were no changes in our significant accounting policies and estimates during the three months ended March 31, 2020, from those set forth in "Note 3, *Summary of Accounting Policies*" in our Annual Report on Form 10-K for the year ended December 31, 2019. We believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Share-Based Payments

Stock compensation expense is based on the grant date's fair value and is recognized as an expense over the requisite service period with forfeitures recognized 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 our stock options, the expected life of the options, an expectation regarding future dividends on our common stock, and estimation of an appropriate risk-free interest rate. Our expected common stock price volatility assumption is based upon the volatility of our stock price. The expected life assumption for stock option grants was based upon the simplified method provided for under Accounting Standards Codification 718-10, which averages 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.

Research and Development Expense

Research and development ("R&D") costs are generally expensed as incurred. Our research and development expenses include, for example, manufacturing expenses for our drugs under development, expenses associated with clinical trials and associated salaries and benefits. R&D expenses also include an estimated allocation of the CEO's salary and related benefits including non-cash stock based compensation expense based on time devoted to R&D.

Results of Operations

Comparison of the three months ended March 31, 2020 and 2019

Revenue and Cost of Revenue: For the three months ended March 31, 2020 and 2019, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were approximately $2,937,000 for the three months ended March 31, 2020, which is a decrease of approximately $1,127,000 or 28%, from the three months ended March 31, 2019. Operating expenses consisted of R&D expenses of approximately $939,000 and general and administrative ("G&A") expenses of approximately $1,998,000. Operating expenses for 2019 consisted of R&D expenses of approximately $1,451,000, and G&A expenses of approximately $2,613,000. The basis for decreased operating expenses in 2020 is explained below.

Research and Development Expenses: R&D expenses for the three months ended March 31, 2020, were approximately $939,000, a decrease of approximately $512,000 or 35% from total R&D expenses for the three months ended March 31, 2019 of approximately $1,451,000. R&D expense consists primarily of clinical trial expenses associated with our Endoxifen program, salaries and non-cash stock based compensation expense. The decrease in R&D expense is attributed to the decrease in non-cash stock-based compensation expense of approximately $514,000. We expect our R&D expenses to increase throughout 2020 as we commence studies of AT-H201 including the COVID-19 HOPE Trial, additional Phase 2 clinical trials of Endoxifen, continue the clinical trial of Fulvestrant administered via our intraductal technology and continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal technologies.

General and Administrative Expenses: G&A expenses were approximately $1,998,000 for the three months ended March 31, 2020, a decrease of approximately $615,000, or 24% from total G&A expenses for the three months ended March 31, 2019, of approximately $2,613,000. G&A expenses consist primarily of salaries and related benefit costs, non-cash stock based compensation, facilities, professional services, insurance, and public company related expenses. The decrease in G&A expenses for the quarter ended March 31, 2020, is mainly attributed to the decrease in non-cash stock-based compensation expense of approximately $816,000, offset by an increase in salaries, legal and professional fees of approximately $200,000, as compared to the same period in 2019.

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, 2020 and 2019, 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, 2020, we recorded a net loss of approximately $2.9 million and used approximately $3.2 million of cash in operating activities. As of March 31, 2020, we had approximately $9.4 million in cash and cash equivalents and working capital of approximately $10.8 million. Management believes the currently available funding will only be sufficient to finance our operations for four to seven months from the date these condensed consolidated financial statements are filed with the SEC depending on the timing and extent of our clinical trials.

Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. As we are not currently generating revenues, continued timely expenditures on trials is important to bring our product(s) to market as soon as able. Management's plans to obtain such resources for the Company include obtaining capital from the sale of its equity securities, entering into strategic partnership arrangements, potential exercise of outstanding warrants, and short-term borrowings from banks, stockholders or other related parties, if needed. We can give no assurances that any additional capital that the Company is able to obtain, if any, will be sufficient to meet our needs, or that any such capital will be obtained on acceptable terms. The continued spread of COVID-19 and uncertain market conditions may limit our ability to access capital. If we are unable to obtain adequate capital, we may be required to reduce the scope, delay, or eliminate some or all of its planned commercial activities. These conditions, in the aggregate, raise substantial doubt as to our ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern.

Cash Flows

As of March 31, 2020, we had cash, cash equivalents and restricted cash of approximately $9.5 million.

Net Cash Flows from Operating Activities: Net cash used in operating activities was approximately $3,230,000 for the three months ended March 31, 2020, an increase of approximately $1,081,000, or 50%, compared to net cash used in operating activities for the three months ended March 31, 2019 of approximately $2,149,000. The increase in the 2020 period as compared to 2019 resulted primarily from increased spending on payroll and prepaid R&D activities.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was approximately $11,337,000 for the three months ended March 31, 2019, which represents proceeds from the exercise of warrants issued in the May 2018 financing. There were no comparable warrant exercises or financing activities for the three months ended March 31, 2020.

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 trials and other programs in the pipeline. We expect that our existing resources will only be sufficient to fund our planned operations for the next four to seven months from the date of filing this quarterly report with the SEC. If we meet certain requirements, we may sell securities that are registered on our Form S-3 registration statement (File No. 333-220572), and by raising capital through sales of securities to third parties and existing stockholders, including for example, pursuant to our $5 million ATM financing program we entered into in February 2020 with Oppenheimer & Co.

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 developments. 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.

Off-Balance Sheet Arrangements

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

Recently Adopted Accounting Pronouncements:

On January 1, 2020, we adopted Accounting Standard Update ("ASU") No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, to improve the effectiveness of disclosures. The amendments remove, modify, and add certain disclosure requirements in Topic 820, "Fair Value Measurement." The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The adoption had no impact on our condensed consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. 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, 2020. 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 ("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 Securities and Exchange Commission's rules and forms.

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 principal executive and principal 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. Our chief executive officer and chief financial officer concluded that, as of March 31, 2020, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2020, that has materially affected, or is reasonably likely to materially affect, our disclosure controls and procedures.

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 of our 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 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.

We were incorporated in Delaware in April 2009. Initially, our operations were focused on establishing our CLIA-certified laboratory, commercializing our ForeCYTE and FullCYTE Breast Aspirators and manufacturing our intraductal microcatheters. In December 2015, we sold our laboratory, ceased generating revenue, ceased developing and commercializing our medical devices, kits, and tests, and refocused our business on the development of novel therapeutics and delivery methods 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 COVID-19 patients who were relying on mechanical ventilation. However, this is a departure from our historical focus on breast cancer and we have no operating history as a company in developing COVID-19 therapies and antiviral drugs. 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:

- our ability to innovate our novel drug candidate for COVID-19;
- commence, execute and obtain successful results from our clinical studies;
- obtain regulatory approvals in the U.S. and elsewhere for our pharmaceuticals and intraductal microcatheters we are developing;
- work with contract manufacturers to produce our pharmaceuticals under development and our intraductal microcatheter 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 may not continue as a going concern.

We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. The auditor's opinion on our audited financial statements for the year ended December 31, 2019 includes an explanatory paragraph stating that our recurring losses from operations and accumulated deficit raise substantial doubt about our ability 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.

If we do not raise additional capital, we anticipate liquidity issues in the next four to seven months.

For the Quarter ended March 31, 2020, we incurred a net loss of $2,947,420 and we had an accumulated deficit of $97,018,460. As of the date of filing this Quarterly report with the SEC, we expect that our existing resources will be sufficient to fund our planned operations for at least the next four to seven months. We have not yet established an ongoing source of revenue sufficient to cover our 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. We currently have no other products and services approved for commercialization. We may not receive or maintain regulatory clearance for our products and other sources of capital may not be available when we need them or on acceptable terms. If we are unable to raise in a timely fashion the amount of capital we anticipate needing, we would be forced to curtail or 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.

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 device and pharmaceutical candidates, pursuing acquisition, licensing, development and commercialization efforts, and our ability to continue operations, generate revenues, and achieve or sustain profitability will be substantially harmed.

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.

Failure to raise additional capital as needed could adversely affect us and our ability to develop our products.

We expect to spend substantial amounts of capital to:

- develop our pharmaceutical and microcatheter-based intraductal therapeutics delivery programs, including our COVID-19 program;
- perform clinical studies for the pharmaceuticals and microcatheter-based delivery methods we are developing;
- continue our research and development activities to advance our product pipeline; and
- obtain clinical supplies of the pharmaceuticals and microcatheters for the programs we are developing.

We have not identified other sources for additional funding and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products or our research and development activities. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations.

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, 2020 was $2,947,420. 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.

Our business may be affected by legal proceedings.

We have been in the past, and may become in the future, involved in legal proceedings. For example, on October 10, 2013, a securities class action complaint was filed against us, certain of our directors and officers and the underwriters from our initial public offering. This action was purportedly brought on behalf of a class of persons and entities who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, and sought damages of an unspecified amount. On March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for $3.5 million, completely funded by defendants' insurers, and on July 20, 2018 the Court approved the settlement. This case is considered closed.

You should carefully review and consider the various disclosures we make in our reports filed with the SEC regarding legal matters that may affect our business. Civil and criminal litigation is inherently unpredictable and outcomes can result in excessive verdicts, fines, penalties and/or injunctive relief that can affect how we operate our business. Monitoring and defending against legal actions, whether or not meritorious, and considering stockholder demands, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, legal fees and costs incurred in connection with such activities may be significant. We cannot predict with certainty the outcome of any legal proceeding in which we become involved, and it is difficult to estimate the possible costs to us stemming from these matters. Settlements and decisions adverse to our interests in legal actions could result in the payment of substantial amounts and could have a material adverse effect on our cash flow, results of operations, and financial position.

Raising funds by issuing equity or debt securities could dilute the value of the Common Stock and impose restrictions on our working capital.

If we raise additional capital by issuing equity securities or through the exercise of warrants currently outstanding or that we may issue in the future, the value of the then outstanding common stock may be reduced. If the additional equity securities are issued at a per share price less than the per share value of the outstanding shares, then all of the outstanding shares would suffer a dilution in value with the issuance of such additional shares. Further, the issuance of debt securities in order to obtain additional funds may impose restrictions on our operations and may impair our working capital as we service any such debt obligations.

The 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 and microcatheters-based intraductal therapeutics delivery technique 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 and tests, 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 medical devices, 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.

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 and other breast conditions is expensive, difficult, and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

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

In addition, from time to time we expect to report interim, top-line or “preliminary” data for clinical trials, including for example the interim results reported in May 2020 for our window of opportunity Phase 2 study. 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.")

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 our COVID-19 HOPE Trial. If we cannot provide the requested data and information the FDA may not authorize us to commence this study.

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 AT-H201 drug to treat COVID-19 patients who are extremely 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 our COVID-19 HOPE Trial who are on ventilators. COVID patients on ventilators are very sick and many do not recover either because of COVID-19 or other illnesses. As a result, it is likely that we will observe severe adverse outcomes of some patients in our COVID 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.

In the event that we seek and the FDA does not grant accelerated approval or priority review for a drug candidate, we would experience a longer time to commercialization in the U.S., if commercialized at all, and our development costs may increase and our competitive position may be harmed.

We may in the future decide to seek accelerated approval pathway for our products. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint under an accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. There can be no assurance that the FDA will agree that any endpoint we suggest with respect to any of our drug candidates is an appropriate surrogate endpoint. Furthermore, there can be no assurance that any application will be accepted or that approval will be granted. Even if a product candidate is granted accelerated approval, such accelerated approval is contingent on the sponsor's agreement to conduct one or more post-approval confirmatory trials. Such confirmatory trial(s) must be completed with due diligence and, in some cases, the FDA may require that the trial(s) be designed and/or initiated prior to approval. Moreover, the FDA may withdraw approval of a product candidate or indication approved under the accelerated approval pathway for a variety of reasons, including if the trial(s) required to verify the predicted clinical benefit of a product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug, or if the sponsor fails to conduct any required post-approval trial(s) with due diligence.

In the event of priority review, the FDA has a goal (but is not required) to take action on an application within a total of eight months (6 months to take action following a 60 day period to determine if the application is acceptable) instead of the 12- months (10 months to take action following a 60 day period to determine if the application is acceptable) allocated for a standard review. The FDA grants priority review only if it determines that a product treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared to a standard application. The FDA has broad discretion whether to grant priority review, and, while the FDA has granted priority review to other oncology product candidates, our drug candidates may not receive similar designation. Moreover, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted eight-month cycle or thereafter.

A failure to obtain accelerated approval or priority review would result in a longer time to commercialization of the applicable product in the U.S., if commercialized at all, could increase the cost of development and could harm our competitive position in the marketplace.

Even if our products are successful in clinical trials and receive regulatory approvals, we may not be able to successfully commercialize them.

The development and ongoing clinical trials for our drug candidates may not be successful and, even if they are, the resulting products may never be successfully developed into commercial products. Even if we are successful in our clinical trials and in obtaining other regulatory approvals, the respective products may not reach or remain in the market for a number of reasons including:

- they may be found ineffective or cause harmful side effects;
- they may be difficult to manufacture on a scale necessary for commercialization;
- they may experience excessive product loss due to contamination, equipment failure, inadequate transportation or storage, improper installation or operation of equipment, vendor or operator error, inconsistency in yields or variability in product characteristics;
- they may be uneconomical to produce;
- we may fail to obtain reimbursement approvals or pricing that is cost effective for patients as compared to other available forms of treatment or that covers the cost of production and other expenses;
- they may not compete effectively with existing or future alternatives, for example our AT-H201 drug may not effectively compete with a vaccine if and when a vaccine is developed and commercialized;
- we may be unable to develop commercial operations and to sell marketing rights;
- they may fail to achieve market acceptance; or
- we may be precluded from commercialization of a product due to proprietary rights of third parties.

If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement and access to drugs, which could adversely affect our future revenues and profitability.

To the extent our products are developed, commercialized, and successfully introduced to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. Globally, governmental and other third-party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue.

In the U.S., we are subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “PPACA” or the “Affordable Care Act”), instituted comprehensive health care reform, and includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions), and impose new and/or increased taxes. The future of the Affordable Care Act and its constituent parts are uncertain at this time.

In almost all markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe and in other countries is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides, and that treatment with the product works at least as well as currently available treatments.

The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers, and collaborative partners, as well as the availability of capital.

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 Johns Hopkins University for the clinical study they are conducting for us using microcatheters to intraductally deliver fulvestrant and we will be 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 timely.

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 Johns Hopkins University, 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 in our COVID-19 HOPE Trial;
- failure of microcatheters to inject a sufficient amount of drug, CAR-T or other immunotherapy into the desired location, which could lead to ineffective treatment; 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 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 February 29, 2020, we own 6 U.S. and 40 (7 U.S. and 33 international) 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 and intraductal delivery of therapeutics, for example using microcatheters.

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. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation under the Leahy-Smith America Invents Act, or the America Invents Act, including changes from a “first-to-invent” system to a “first to file” system, changes to examination of U.S. patent applications and changes to the processes for challenging issued patents. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted 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 some 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. In any event, the America Invents Act and any other 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 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. For example, we may seek to develop our intraductal treatment program by licensing pharmaceuticals, CAR-T cell technology or immunotherapy from a third-party. 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 interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions. Recently, the America Invents Act introduced new procedures including *inter partes* review and post-grant review. The implementation of these procedures brings 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 interference 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 HOPE Trial. Presently, we are responding to comments and information requests from the FDA relating to our proposed COVID-19 HOPE Trial and there can be no assurance that the FDA will permit us to proceed with the trial.

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.

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.

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, including during the 30 days prior to filing this report.

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.

Any actual 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, including for example, sales of stock pursuant to our At-the-Market financing program we entered into in February 2020. 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. During the one year prior to May 6, 2020, our stock price has ranged from $0.76 to $3.25. 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.

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock was delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. Our common stock has generally traded below $5.00 per share, including during the period covered by this report. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" (i.e., generally, any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions) and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market.

The ownership of our common stock is 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 be 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, if required, 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.

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Capital Market, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results.

In addition, complying with public disclosure rules makes our business more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

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.

We do not expect to pay dividends in the future, which means that investors may not be able to realize the value of their shares except through a sale.

We have never, and do not anticipate that we will, declare or pay a cash dividend. We expect to retain future earnings, if any, for our business and do not anticipate paying dividends on common stock at any time in the foreseeable future. Because we do not anticipate paying dividends in the future, the only opportunity for our stockholders to realize the creation of value in our common stock will likely be through a sale of those shares.

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

We may elect to raise additional funds from time to time through public or private equity offerings, debt financings, corporate collaboration, and licensing arrangements, or other financing alternatives, as well as sales of common stock through a purchase agreement. Additional equity or debt financing or corporate collaboration and licensing 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 pursuing acquisition, licensing, development and commercialization efforts and our ability to generate revenues and achieve or sustain profitability will be substantially harmed.

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 that we raise may contain terms, such as liquidation preferences, and other rights 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.

Risks related to our February 2020 "at-the-market" (ATM) Financing Program

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds we receive in the offering, and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents, including the net proceeds we receive in the ATM financing, to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use to fund our operations, we may invest our cash and cash equivalents, including the net proceeds from this offering, in a manner that does not produce income or that loses value.

Sales of our common stock in the offering, or the perception that such sales may occur, could cause the market price of our common stock to fall.

We may issue and sell shares of our common stock for aggregate gross proceeds of up to $5.0 million from time to time in connection with the offering. The actual number of shares of common stock that may be issued and sold in this offering, as well as the timing of any such sales, will depend on a number of factors, including, among others, the prices at which any shares are actually sold this offering (which may be influenced by market conditions, the trading price of our common stock and other factors) and our determinations as to the appropriate timing, sources and amounts of funding we need. The issuance and sale from time to time of these new shares of common stock, or the mere fact that we are able to issue and sell these shares in this offering, could cause the market price of our common stock to decline.

The ATM Program may not be available when needed and it is not possible to predict the actual number of shares of common stock, if any, that we will sell under the ATM Program, or the gross proceeds resulting from those sales.

Our ability to utilize the ATM Program is subject to a number of conditions, including, for example, that we periodically deliver legal opinions, comfort letters and other documents to Oppenheimer and that the registration statement covering the shares subject to the ATM Program remains effective. In addition, the Company or Oppenheimer may suspend or terminate the offering of common stock being made through Oppenheimer upon proper notice to the other party. Because of these terms, conditions and other requirements, the ATM Program may not be available to us when needed. Subject to certain limitations in the agreement related to the ATM program and compliance with applicable law, we have the discretion to deliver a placement notice to Oppenheimer at any time throughout the term of the agreement. The number of shares that are sold through Oppenheimer after delivering a placement notice will fluctuate based on a number of factors, including the market price of our shares during the sales period, the limits we set with Oppenheimer in any applicable placement notice, and the demand for our shares during the sales period. Because the price per share of each share sold will fluctuate during this offering and because of the other conditions and requirements that must be satisfied when we seek to sell shares, if any, under the ATM Program it is not currently possible to predict the number of shares that will be sold or the gross proceeds to be raised in connection with those sales.

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. In December 2019, a novel strain of COVID-19 emerged in Wuhan, Hubei Province, China. While initially the outbreak was largely concentrated in China and caused significant disruptions to its economy, it is now considered by the World Health Organization as a pandemic and has spread to many other countries and infections have been reported globally, with a significant number of cases in the Seattle area, which is where we have our headquarters, and in New York City, which is where we plan to conduct a clinical study of AT-H201 in COVID-19 patients. The extent to which the coronavirus pandemic impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of the COVID-19 could have an adverse impact on our business and our financial results. In particular, 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, IRB) meetings and approvals could be delayed;
- our drug supply chain could be interrupted;
- 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.

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.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit No.	Description	Incorporated by Reference Herein Form	Date
1.1	Equity Distribution Agreement, dated as of February 7, 2020, by and between Atossa Therapeutics, Inc. and Oppenheimer & Co. Inc.	Current Report on Form 8-K, as Exhibit 1.1.	February 7, 2020
3.1	Certificate of Amendment to the Certificate of Incorporation of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.1	January 6, 2020
3.2	Amended and Restated Bylaws of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.2	January 6, 2020
4.1	Form of 2020 ISO Option Award Agreement	Filed herewith	
4.2	Form of 2020 Option Award Agreement	Current Report on Form 8-K, as Exhibit 4.1	April 13, 2020
4.3	Atossa Therapeutics, Inc. 2020 Stock Incentive Plan	On Form DEF 14A, as Appendix A	April 13, 2020
31.1	Certification pursuant to Rule 13a-14(a) under the securities Exchange Act of 1934 of Steven C. Quay	Filed herewith	
31.2	Certification pursuant to Rule 13a-14(a) under the securities Exchange Act of 1934 of Kyle Guse	Filed herewith	
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay	Filed herewith	
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse	Filed herewith	
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T	Filed herewith	

SIGNATURES

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

Date: May 13, 2020

/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 4.1

INCENTIVE STOCK OPTION AGREEMENT
UNDER THE ATOSSA THERAPEUTICS, INC.
2020 STOCK INCENTIVE PLAN

Name of Optionee: _____

No. of Option Shares: _____

Option Exercise Price per Share: $_____
[FMV on Grant Date (110% of FMV if a 10% owner)]

Grant Date: _____

Expiration Date: _____
[up to 10 years (5 if a 10% owner)]

Pursuant to the Atossa Therapeutics, Inc. 2020 Stock Incentive Plan as amended through the date hereof (the "Plan"), Atossa Therapeutics, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.18 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated:

Incremental Number of Option Shares Exercisable*	Exercisability Date
_____ (___%)	_____
_____ (___%)	_____
_____ (___%)	_____
_____ (___%)	_____

* Max. of $100,000 per yr.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written or electronic notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such issuance and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock

Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Employment. If the Optionee's employment by the Company or a Subsidiary (as defined in the Plan) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's employment terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date shall become fully exercisable and may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier.

(b) Termination Due to Disability. If the Optionee's employment terminates by reason of the Optionee's disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date shall become fully exercisable and may thereafter be exercised by the Optionee for a period of 12 months from the date of termination or until the Expiration Date, if earlier.

(c) Termination for Cause. If the Optionee's employment terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect. For purposes hereof, "Cause" shall mean, unless otherwise provided in an employment agreement between the Company and the Optionee, a determination by the Administrator that the Optionee shall be dismissed as a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the conviction of, indictment for or plea of nolo contendere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliberate non-performance (other than by reason of disability) by the Optionee of the Optionee's duties to the Company.

(d) Other Termination. If the Optionee's employment terminates for any reason other than the Optionee's death, the Optionee's disability, or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's employment shall be conclusive and binding on the Optionee and his or her representatives or legatees.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

6. Status of the Stock Option. This Stock Option is intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), but the Company does not represent or warrant that this Stock Option qualifies as such. The Optionee should consult with his or her own tax advisors regarding the tax effects of this Stock Option and the requirements necessary to obtain favorable income tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements. To the extent any portion of this Stock Option does not so qualify as an "incentive stock option," such portion shall be deemed to be a non-qualified stock option. If the Optionee intends to dispose or does dispose (whether by sale, gift, transfer or otherwise) of any Option Shares within the one-year period beginning on the date after the transfer of such shares to him or her, or within the two-year period beginning on the day after the grant of this Stock Option, he or she will so notify the Company within 30 days after such disposition.

7. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the minimum required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due.

8. No Obligation to Continue Employment. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee in employment and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the employment of the Optionee at any time.

9. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

10. Amendment. Pursuant to Section 18 of the Plan, the Administrator may at any time amend or cancel any outstanding portion of this Stock Option, but no such action may be taken that adversely affects the Optionee's rights under this Agreement without the Optionee's consent.

Atossa Therapeutics, Inc.

By: _____
Name: _____
Title: _____

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned.

Dated: _____

_____

Optionee's Signature

Optionee's name and address:

_____

_____

_____

[OPTIONEE SIGNATURE PAGE TO STOCK OPTION AGREEMENT]

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 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, statements of stockholders' equity 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 13, 2020

/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 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 13, 2020

/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 ending March 31, 2020 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 13, 2020

/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 ending March 31, 2020 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 13, 2020

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