UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

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 GENETICS 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 pursuance 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 November 11, 2019, was 9,130,984.

ATOSSA GENETICS INC.
FORM 10-Q
QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ATOSSA GENETICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

Assets	**As of September 30, 2019 (Unaudited)**	**As of December 31, 2018**
Current assets		
Cash and cash equivalents	$ 15,289,543	$ 10,380,493
Restricted cash	110,000	110,000
Prepaid expenses	430,042	509,833
Research and development tax rebate receivable	568,980	518,098
Other current assets	2,064	30,942
Total current assets	16,400,629	11,549,366
Furniture and equipment, net	39,142	54,487
Intangible assets, net	76,250	99,375
Right-of-use asset	63,284	-
Other assets	17,218	17,218
Total Assets	$ 16,596,523	$ 11,720,446
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 501,430	$ 353,328
Accrued expenses	225,472	177,074
Payroll liabilities	769,727	935,070
Stock-based compensation liability	-	1,410,025
Lease liability	49,266	-
Other current liabilities	18,415	39,939
Total current liabilities	1,564,310	2,915,436
Long term liabilities		
Lease liability long term	14,018	-
Total Liabilities	1,578,328	2,915,436
Commitments and contingencies (note 11)		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 671 and 2,379 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1	2
Additional paid-in capital- Series B convertible preferred stock	670,999	2,378,997
Common stock - $0.18 par value; 175,000,000 shares authorized, and 9,130,984 and 5,846,552 shares issued and outstanding, as of September 30, 2019 and December 31, 2018, respectively	1,643,565	1,052,372
Additional paid-in capital	104,156,643	82,204,902
Accumulated deficit	(91,453,013)	(76,831,263)
Total Stockholders' Equity	15,018,195	8,805,010
Total Liabilities and Stockholders' Equity	$ 16,596,523	$ 11,720,446

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

ATOSSA GENETICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses				
Research and development	$ 1,684,215	$ 1,421,851	$ 5,747,399	$ 3,360,563
General and administrative	1,613,983	1,888,119	8,901,197	5,966,504
Total operating expenses	3,298,198	3,309,970	14,648,596	9,327,067
Operating loss	(3,298,198)	(3,309,970)	(14,648,596)	(9,327,067)
Other income	12,284	104	26,846	242
Loss before income taxes	(3,285,914)	(3,309,866)	(14,621,750)	(9,326,825)
Income taxes	-	-	-	-
Net loss	$ (3,285,914)	$ (3,309,866)	$ (14,621,750)	$ (9,326,825)
Deemed dividends attributable to preferred stock	-	-	-	(11,479,308)
Net loss applicable to common shareholders	$ (3,285,914)	$ (3,309,866)	$ (14,621,750)	$ (20,806,133)
Loss per common share - basic and diluted	$ (0.36)	$ (0.64)	$ (1.77)	$ (5.71)
Weighted average shares outstanding - basic and diluted	9,130,057	5,183,492	8,283,302	3,645,682

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

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

	Series B Convertible Preferred Stock			Common Stock				Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balance at December 31, 2017	-	$ -	$ -	2,651,952	$ 477,342	$ 71,887,674	$ (65,426,329)	$ 6,938,687
Amortization of commitment shares	-	-	-	-	-	(19,852)	-	(19,852)
Compensation cost for stock options granted	-	-	-	-	-	215,139	-	215,139
Net loss	-	-	-	-	-	-	(1,874,382)	(1,874,382)
Balance at March 31, 2018	-	$ -	$ -	2,651,952	$ 477,342	$ 72,082,961	$ (67,300,711)	$ 5,259,592
Issuance of Series B convertible preferred stock and warrants, net of issuance costs of $1,333,449	13,624	14	6,926,778	-	-	5,363,759	-	12,290,551
Allocation of Series B convertible preferred stock to beneficial conversion feature	-	-	(4,782,100)	-	-	4,782,100	-	-
Deemed dividend on Series B convertible preferred stock	-	-	11,479,308	-	-	(11,479,308)	-	-
Conversion of Series B convertible preferred stock to common stock	(7,822)	(8)	(7,821,992)	2,222,147	399,987	7,422,013	-	-
Amortization of commitment shares	-	-	-	-	-	(19,851)	-	(19,851)
Compensation cost for stock options granted	-	-	-	-	-	179,050	-	179,050
Net loss	-	-	-	-	-	-	(4,142,577)	(4,142,577)
Balance at June 30, 2018	5,802	$ 6	$ 5,801,994	4,874,099	$ 877,329	$ 78,330,724	$ (71,443,288)	$ 13,566,765
Conversion of Series B convertible preferred stock to common stock	(2,285)	(2)	(2,284,998)	649,156	116,846	2,168,154	-	-
Amortization of commitment shares	-	-	-	-	-	(19,853)	-	(19,853)
Compensation cost for stock options granted	-	-	-	-	-	332,063	-	332,063
Net loss	-	-	-	-	-	-	(3,309,866)	(3,309,866)
Balance at September 30, 2018	3,517	$ 4	$ 3,516,996	5,523,255	$ 994,175	$ 80,811,088	$ (74,753,154)	$ 10,569,109

	Series B Convertible Preferred Stock			Common Stock				Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	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
Conversion of Series B convertible preferred stock to common stock	(26)	-	(26,000)	7,392	1,330	24,670	-	-
Compensation cost for stock options granted	-	-	-	-	-	5,318,796	-	5,318,796
Net loss	-	-	-	-	-	-	(7,262,529)	(7,262,529)
Balance at June 30, 2019	676	$ 1	$ 675,999	9,129,563	$ 1,643,309	$ 103,400,247	$ (88,167,099)	$ 17,552,457
Conversion of Series B convertible preferred stock to common stock	(5)	-	(5,000)	1,421	256	4,744	-	-
Compensation cost for stock options granted	-	-	-	-	-	751,652	-	751,652
Net loss	-	-	-	-	-	-	(3,285,914)	(3,285,914)
Balance at September 30, 2019	671	$ 1	$ 670,999	9,130,984	$ 1,643,565	$ 104,156,643	$ (91,453,013)	$ 15,018,195

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

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

	For the Nine Months Ended September 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (14,621,750)	$ (9,326,825)
Adjustments to reconcile net loss to net cash used in operating activities		
Compensation cost for stock options granted	6,346,281	726,252
Disposal of assets	5,806	-
Depreciation and amortization	40,289	28,690
Change in fair value of stock-based compensation liability	1,741,919	2,180,659
Changes in operating assets and liabilities:		
Prepaid expenses	79,791	(39,387)
Research and development tax rebate receivable	(50,882)	(122,218)
Other assets	28,878	(114,353)
Accounts payable	148,102	215,803
Payroll liabilities	(165,343)	(78,717)
Accrued expenses	48,398	(38,432)
Other current liabilities	(21,524)	50,543
Net cash used in operating activities	(6,420,035)	(6,517,985)
CASH FLOWS FROM INVESTING ACTIVITY		
Purchase of furniture and equipment	(7,625)	(54,448)
Net cash used in investing activities	(7,625)	(54,448)
CASH FLOWS FROM FINANCING ACTIVITY		
Proceeds from issuance of Series B convertible preferred stock and warrants, net of issuance costs	-	12,290,551
Proceeds from exercise of warrants	11,336,710	-
Net cash provided by financing activities	11,336,710	12,290,551
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	4,909,050	5,718,118
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	10,490,493	7,272,469
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 15,399,543	$ 12,990,587
SUPPLEMENTAL DISCLOSURES		
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 15,289,543	$ 12,935,587
Restricted cash	110,000	55,000
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 15,399,543	$ 12,990,587
NONCASH INVESTING AND FINANCING ACTIVITIES		
Reclassification of stock-based liability awards to equity upon cancellation	$ 3,151,944	$ -
Amortization of commitment shares	$ -	$ 59,556

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

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

NOTE 1: NATURE OF OPERATIONS

Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was 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 focused on development of its pharmaceutical and drug delivery programs.

NOTE 2: GOING CONCERN

The Company has incurred net losses and negative operating cash flows since inception. For the nine months ended September 30, 2019, the Company recorded a net loss of approximately $14.6 million and used approximately $6.4 million of cash in operating activities. As of September 30, 2019, the Company had approximately $15.3 million in cash and cash equivalents and working capital of approximately $14.8 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 be insufficient to finance the Company's operations for a year from the date of these condensed consolidated financial statements 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. 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 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, 2018.

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 and nine months ended September 30, 2019, are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

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.

Recently Adopted Accounting Pronouncements:

In the first quarter of 2019, we adopted Accounting Standards Update ("ASU") No. 2016-02, *Lease Accounting* Topic 842*: ("*Topic 842*")* and recognized on our Condensed Consolidated Balance Sheet $101,000 of lease liabilities with corresponding right-of-use assets for operating leases. The new lease standard requires a lessee to measure its operating lease liabilities at the present value of the remaining minimum lease payments with a discounted cash flow model using the interest rate implicit in the lease. If the implicit interest rate cannot be readily determined, the lessee must use its incremental borrowing rate ("IBR"). If the lessee does not have an IBR, the lessee must use a rate that approximates the rate of interest that the lessee would have to pay to borrow on a collateralized basis over a similar term in an amount equal to the lease payments in a similar economic environment. The implicit interest rate was readily determinable for our copier lease; however, we used an IBR to measure our adoption date operating lease liability related to our office space which represents our estimated borrowing rate on a secured loan collateralized by similar assets for a similar term. The adoption did not have a material impact on the Company's consolidated financial statements. As permitted under the standard, we elected prospective application of the new guidance and prior periods continue to be presented in accordance with Accounting Standards Codification ("ASC") Topic 840. Refer to our 2018 Annual Report on Form 10-K for disclosures required by Topic 840. The new standard provides a number of optional practical expedients in transition. We elected the practical expedients to not reassess our prior conclusions about lease identification under the new standard, to not reassess lease classification, to not separate lease and non lease components and to not reassess initial direct costs. We did not elect the practical expedient allowing the use-of-hindsight which would require us to reassess the lease term of our leases based on all facts and circumstances through the effective date and did not elect the practical expedient pertaining to land easements as this is not applicable to our current contract portfolio. See Note 11, *Commitments and Contingencies*, of the notes to our unaudited condensed consolidated financial statements for additional discussion of our leases and the amounts recognized in these unaudited condensed consolidated financial statements.

On January 1, 2019, we adopted ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made.* This ASU affects not-for-profit entities and business entities that receive or make contributions of cash. The

ASU clarifies and improves the scope and accounting guidance to assist entities in evaluating if those transactions should be accounted for as contributions under the scope of Topic 958 or as an exchange transaction subject to other guidance. The adoption did not have any impact on the financial statements.

Recent Accounting Pronouncements:

In August 2018, the Financial Accounting Standards Board ("FASB") issued 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 amendments are effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. Furthermore, an entity is permitted to early adopt any removed or modified disclosures upon issuance of the update and delay adoption of the additional disclosures until their effective date. We do not expect this amendment to have a material impact on our consolidated financial statements.

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2019	December 31, 2018
Prepaid insurance	$ 49,982	$ 160,576
Prepaid research and development	210,796	218,090
Professional services	124,917	110,094
Financial exchange fees	10,500	-
Prepaid rent	8,550	-
Retainer and security deposits	14,218	16,718
Other	11,079	4,355
Total prepaid expenses	$ 430,042	$ 509,833

NOTE 5: 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 research and development activities ("R&D") 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 and the nine months ended September 30, 2019 the Company incurred qualified R&D expenses of approximately $449,000 and $916,000 respectively, and $148,000 and $764,000, respectively, for the three and nine months ended September 30, 2018. The Company recorded a rebate receivable of approximately $398,000 and $333,000 for the nine months ended September 30, 2019 and 2018, respectively, and a corresponding credit to R&D expenses. At September 30, 2019, we had a total R&D rebate receivable of approximately $569,000 that includes approximately $171,000 receivable remaining from the year ended December 31, 2018.

NOTE 6: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	September 30, 2019	December 31, 2018
Accrued bonuses	$ 526,890	$ 697,995
Accrued vacation	170,105	160,740
Accrued payroll	72,732	76,335
Total payroll liabilities	$ 769,727	$ 935,070

NOTE 7: 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 September 30, 2019.

2018 Subscription Rights Offering of Units Consisting of Series B Convertible Preferred Stock and Warrants

On May 30, 2018, the Company completed a rights offering pursuant to which the Company sold an aggregate of 13,624 units consisting of an aggregate of 13,624 shares of Series B convertible preferred stock and 3,869,216 warrants, with each warrant exercisable for one share of common stock at an exercise price of $4.05 per share (the "2018 Warrants"), resulting in net proceeds to the Company of approximately $12.3 million, after deducting expenses relating to the rights offering, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants.

Warrants

As of September 30, 2019, warrants to purchase a total of 1,070,028 shares of common stock were outstanding. The warrants have an exercise price of $4.05 and expire on May 30, 2022.

In March 2019, the Company received approximately $11.3 million from exercises of the 2018 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. No warrants were exercised for the three months ended September 30, 2019.

Conversion of Series B Convertible Preferred Stock

During the three and nine months ended September 30, 2019, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 5 and 1,708 shares of preferred stock, respectively, into 1,421 and 485,244 shares, respectively, 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 8: NET LOSS PER SHARE

The Company accounts for and discloses net loss per common share in accordance with ASC Topic 260, *Earnings 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator				
Net loss	$ (3,285,914)	$ (3,309,866)	$ (14,621,750)	$ (9,326,825)
Deemed dividend attributable to preferred stock	-	-	-	(11,479,308)
Net loss attributable to common shareholders	$ (3,285,914)	$ (3,309,866)	$ (14,621,750)	$ (20,806,133)
Denominator				
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	9,130,057	5,183,492	8,283,302	3,645,682
Net loss per share of common stock, basic and diluted:	$ (0.36)	$ (0.64)	$ (1.77)	$ (5.71)

The following table sets forth the number of weighted average potential common shares excluded from the calculation of net loss per diluted share for the three and nine months ended September 30, 2019 and 2018 because including them would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Options to purchase common stock	4,348,383	783,794	2,572,413	388,377
Series B convertible preferred stock	191,543	1,338,916	281,015	751,332
Warrants to purchase common stock	1,070,028	4,716,935	1,828,085	2,644,946
	5,609,954	6,839,645	4,681,513	3,784,655

NOTE 9: 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 September 30, 2019 and December 31, 2018, due to the Company's continuing operating losses.

NOTE 10: 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 September 30, 2019 and December 31, 2018, the Company had $14,671,000 and $10,052,000 in excess of the FDIC insured limit, respectively.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Commitments

As discussed in Note 3, we adopted the requirements of ASU No. 2016-02, *Lease Accounting:* Topic 842, and all related amendments on January 1, 2019. Prior to January 1, 2019, we accounted for leases in accordance with ASC Topic 840, *Leases*. In accordance with Topic 842, we evaluate all contractual agreements at inception to determine if they contain a lease. We measure lease liabilities 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.

Our 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 and nine months ended September 30, 2019, was approximately $14,700 and $44,100 and variable lease payments of taxes and insurance were immaterial. As of September 30, 2019, the weighted average remaining lease term was approximately 1.2 years and the weighted average discount rate of our operating leases was 12%.

As of September 30, 2019, the future minimum lease payments are approximately $15,000, $44,000 and $12,000 for 2019, 2020 and 2021, respectively. These payments are reported in the condensed consolidated balance sheets at September 30, 2019, net of approximately $13,000 of imputed interest. The cash paid for amounts included in the measurement of operating lease liabilities for the three and nine months ended September 30, 2019 was approximately $13,900 and $42,700, 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 12: STOCK BASED COMPENSATION

Stock Option and Incentive Plan

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. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. 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
Total additional shares	374,782

The Company did not grant options to purchase shares of common stock during the three months ended September 30, 2019 or 2018. The Company granted options to purchase 3,565,000 shares of common stock during the nine months ended September 30, 2019 and 611,688 for the nine months ended

September 30, 2018, respectively. No options were exercised during the three and nine months ended September 30, 2019 or 2018. There are 271,430 shares available for grant under the 2010 Plan as of September 30, 2019.

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 $751,652 and $6,346,281 for the three and nine months ended September 30, 2019, respectively, and $332,063 and $726,252 for the three and nine months ended September 30, 2018 respectively, (excluding the liability options discussed below). Compensation cost is recognized in the following captions in the condensed consolidated statements of operations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
General and administrative	$ 510,398	$ 259,347	$ 4,136,727	$ 565,771
Research and development	241,254	72,716	2,209,554	160,481
Total stock compensation expense	$ 751,652	$ 332,063	$ 6,346,281	$ 726,252

The fair value of the stock options granted for the nine months ended September 30, 2019 and 2018 was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Period ended September 30,	
	2019	2018
Risk free interest rate	2.16%-2.20%	2.47%-2.71%
Expected term	5.00-5.94 years	5.24-5.57 years
Dividend yield	-	-
Expected volatility	107%-126%	109%-126%

Options issued and outstanding as of September 30, 2019, under the 2010 Plan and their activities during the nine 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, 2019	783,383	$ 12.14	-	$ -
Granted	3,565,000	1.51	-	3,667,300
Forfeited	-	-	-	-
Expired	-	-	-	-
Outstanding as of September 30, 2019	4,348,383	3.43	9.29	$ 1,860,000
Exercisable as of September 30, 2019	3,208,302	3.91	9.30	$ 1,511,250
Vested and expected to vest	4,348,383	$ 3.43	9.29	$ 1,860,000

At September 30, 2019, there were 1,140,081 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately $2,396,633. This expense is expected to be recognized over a weighted-average period of .92 years.

2018 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 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 cancelled.

The Liability Options were exercisable for shares of common stock at an exercise price of $2.38 per share, which was the fair value on the date of grant. The options had an exercise period of ten years from their date of issuance. If at the time the options were exercised the Company could not deliver shares of common stock to the optionee including, for example, if there were insufficient shares available under the Plan at the time of exercise, then in lieu of the optionee paying the exercise price and the Company issuing shares of stock, the option would only be exercised on a cash "net basis" so that the Company would pay cash in an amount equal to the excess of the fair value of the common stock over the option exercise price. If there were not sufficient shares available under the Plan, the Company would have been obligated to settle these options in cash if they were exercised. Because these options contained provisions that would require the Company to settle the options in cash in an event outside the Company's control, they were accounted for as liabilities.

The Liability Options were subject to vesting requirements. Twenty-five percent of the options were vested as of the grant date, 50% of the options would have vested quarterly over two years, and the remaining 25% would have vested upon achievement of certain milestones related to clinical trial progress. As of January 13, 2019, all of the Liability Options that vested upon achievement of clinical trial milestones were vested. On January 13, 2019, the Liability Options were cancelled and at the time of cancellation, there were 1,125,000 unvested Liability Options outstanding.

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 was 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 for the three months ended March 31, 2019 and the nine months ended September 30, 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 (vi) 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 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.

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:

- whether we can obtain approval from the U.S. Food and Drug Administration, or FDA, and foreign regulatory health bodies, to commence our clinical studies 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;
- the success, cost and timing of our product and drug development activities and clinical trials, including whether the ongoing clinical study using our intraductal technologies to administer fulvestrant and our study using our oral Endoxifen in the window of opportunity prior to surgery will enroll a sufficient number of subjects or be completed in a timely fashion or at all;
- our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;
- our ability to successfully develop and ultimately commercialize new therapeutics that are currently in development or that we might identify in the future and within the currently anticipated time frames ;
- 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 and technologies;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;
- the accuracy of our estimates of the size and characteristics of the markets that our products may address;
- whether the final study results will vary from preliminary study results that we may announce;
- our expectations as to future financial performance, expense levels and capital sources;
- our ability to attract and retain key personnel; and
- our ability to raise capital.

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

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing novel proprietary therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our lead 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. We are developing an oral and topical dosage form of Endoxifen intended to potentially treat a number of conditions, including: mammographic breast density (or, MBD); breast cancer in the "window of opportunity" between diagnosis of breast cancer and surgery; gynecomastia, which is male breast enlargement; and the recurrence of breast cancer in patients who cannot benefit from tamoxifen due to metabolism or other reasons, meaning that they are "refractory" to tamoxifen. We are also developing our patented intraductal delivery technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), directly to the site of breast cancer.

In 2017, we successfully completed our initial Phase 1 placebo-controlled clinical study 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 to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 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 September 2018, we completed a Phase 1 placebo-controlled clinical study of our proprietary topical Endoxifen in 24 healthy men. All of our objectives of safety, tolerability and pharmacokinetics were successfully met.

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 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 (studies by others have shown that MBD is an independent risk factor for breast cancer development). The preliminary analysis showed significant and rapid reduction in MBD at the 20mg daily dose level. In our Phase 2 study, MBD was reduced by an average of 14.3 percent 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 percent but was not statistically significant. These results are based on MBD measurements at the time of enrollment in the study and again at the time dosing ended, which was a mean of 55 and 88 days for the 20mg and 10mg groups, respectively. Approximately 70 percent of participants receiving 20mg topical Endoxifen experienced a reduction in MBD, and of those, the mean reduction in MBD was 27 percent. There were no significant differences in systemic endocrine or vascular side effects (for example, hot flashes) in the placebo versus active groups. Systemic side effects were measured using a modified validated symptom questionnaire. Approximately 72 participants eventually developed skin rashes and local irritation and did not complete a full six months of dosing. The results indicate a study with approximately 50-100 subjects per dosage group would be appropriate to demonstrate efficacy for regulatory approval purposes.

Based on the positive results from our topical Endoxifen Phase 2 study to reduce MBD, we are now planning a Phase 2 study of our oral Endoxifen to reduce MBD, which we plan to initiate as early as the fourth quarter of 2019 by contracting with a clinical research organization.

A Phase 2 study of our proprietary oral Endoxifen continues to be conducted in Australia for patients in the window of opportunity between diagnosis of breast cancer and surgery.

We are currently conducting a Phase 2 study, using our intraductal technology to deliver fulvestrant directly to the site of the tumor via the breast ducts. Our program to use our intraductal technology to deliver CAR-T and other immunotherapies is in the pre-clinical phase. We are migrating this study from Montefiore Medical Center to Johns Hopkins.

In July 2019, we reported that we have begun the development of a proprietary modified-release tablet form of our oral Endoxifen, which we intend will be the form of the oral drug for future clinical development and ultimately commercialization. On September 30, 2019, we reported preliminary results from our Phase 1 study of our proprietary modified-release table form of oral Endoxifen. All safety and tolerability objectives were successfully met. These results demonstrate the suitability of the tablet form of oral Endoxifen for further clinical development.

Research and Development Phase

We are in the research and development phase and are not currently marketing any products or services. 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.

Significant changes to our accounting policies as a result of adopting ASC Topic 842 are discussed in Note 3 of the notes to our unaudited condensed consolidated financial statements. There were no other changes in our significant accounting policies and estimates during the three and nine months ended September 30, 2019, 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, 2018. 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

We follow the provisions of ASC 718, *Compensation – Stock Compensation*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense based on the grant date's fair value was estimated in accordance with the provisions of ASC 718 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 plain vanilla stock option grants was based upon the simplified method provided for under ASC 718-10, which averages the contractual term of the options of ten years with the average vesting term of one to four years. The expected life assumption for options granted in the money or options with performance conditions was estimated based on historical exercises of options and warrants, expected employment dates, and corporate goals and strategies. 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.

Results of Operations

Comparison of the three and nine months ended September 30, 2019 and 2018

Revenue and Cost of Revenue: For the three and nine months ended September 30, 2019 and 2018, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were approximately $3,298,000 and $14,649,000 for the three and nine months ended September 30, 2019, respectively, consisting of research and development (R&D) expenses of approximately $1,684,000 and $5,747,000 respectively, and general and administrative (G&A) expense of approximately $1,614,000 and $8,901,000, respectively. Total operating expenses were approximately $3,310,000 and $9,327,000 for the three and nine months ended September 30, 2018, respectively, consisting of research and development expenses of approximately $1,422,000 and $3,361,000, respectively, and general and administrative expenses of approximately $1,888,000 and $5,967,000, respectively. Total operating expense for the three months ended September 30, 2019 were consistent with the same period in 2018. Total operating expenses for the nine months ended September 30, 2019 as compared to the same period in 2018 increased approximately $5,322,000 or 57%, of which approximately $1,742,000 is attributable to non-cash compensation expenses resulting from cancellation of the 2018 Liability Options in the first quarter 2019 and an increase of approximately $2,759,000 due to the grant of options to executives.

Research and Development Expenses:
R&D expenses for the three months ended September 30, 2019, were approximately $1,684,000, an increase of approximately $262,000 or 18% from total R&D expenses for the three months ended September 30, 2018 of approximately $1,422,000. R&D expenses for the nine months ended September 30, 2019, were approximately $5,747,000, an increase of approximately $2,386,000 or 71% from total R&D expenses for the nine months ended September 30, 2018 of approximately $3,361,000. The increase in R&D expense is attributed to non-cash stock-based compensation, salaries and clinical trial expenses associated with our Endoxifen program. Stock-based compensation expense, which is a non-cash charge, increased approximately $668,000 in the first quarter of 2019 resulting from the cancellation of the 2018 Liability Options. There were no Liability Option cancellations in the comparable period of 2018. Stock-based compensation expense also increased approximately $1.0 million due to the grant of options to the CEO that were 75% vested. Clinical trial expense also increased approximately $535,000 in the nine month period ended September 30, 2019 over the same period in 2018. We expect our R&D expenses to increase throughout 2019 as we commence additional Phase 2 clinical studies of oral Endoxifen, continue development and manufacturing our tablet modified-release form of oral Endoxifen, continue our clinical trial of fulvestrant administered via our intraductal technology at a new institution 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 $1,614,000 for the three months ended September 30, 2019, a decrease of approximately $274,000, or 15% from the total G&A expenses for the three months ended September 30, 2018, of approximately $1,888,000. G&A expenses were approximately $8,901,000 for the nine months ended September 30, 2019, an increase of approximately $2,934,000, or 49% from the total G&A expenses for the nine months ended September 30, 2018, of approximately $5,967,000. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expenses for the nine months ended September 30, 2019, is mainly attributed to an increase in stock-based compensation expense, which is a non-cash charge, due to the cancellation of the 2018 Liability Options of approximately $1,074,000 during the first quarter of 2019. There were no Liability Option cancellations in the comparable period of 2018. During the nine months ended September 30, 2019, stock-based compensation expense increased approximately $1.75 million due to the grant of options to the CEO and CFO that were 75% vested. Additionally, payroll expenses have increased resulting from salary increases over the prior year.

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 or nine months ended September 30, 2019 and 2018, due to uncertainty regarding utilization of our net operating carryforwards and due to our history of losses.

Liquidity and Capital Resources

The Company has incurred net losses and negative operating cash flows since inception. For the nine months ended September 30, 2019, the Company recorded a net loss of approximately $14.6 million and used approximately $6.4 million of cash in operating activities. As of September 30, 2019, the Company had approximately $15.3 million in cash and cash equivalents and working capital of approximately $14.8 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 be insufficient to finance the Company's operations for a year from the date of these condensed consolidated financial statement 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. 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 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.

Cash Flows

As of September 30, 2019, we had cash, cash equivalents and restricted cash of approximately $15.4 million.

Net Cash Flows from Operating Activities: Net cash used in operating activities was approximately $6,420,000 for the nine months ended September 30, 2019, a decrease of approximately $98,000, or 2%, compared to net cash used in operating activities for the nine months ended September 30, 2018 of approximately $6,518,000.

Net Cash Flows from Investing Activities: Net cash used in investing activities was approximately $8,000 for the nine months ended September 30, 2019, a decrease of approximately $46,000, compared to net cash used in operating activities for the nine months ended September 30, 2018 of approximately $54,000. The decrease is because during the nine months ended September 30, 2018, we purchased fixed asset equipment for specific R&D activities whereas there were no purchases of R&D equipment during the same period in 2019.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was approximately $11,337,000 for the nine months ended September 30, 2019, which represents proceeds from the exercise of warrants issued in the May 2018 financing. In the second quarter of 2018, we completed a rights offering with net proceeds of $12.3 million.

Funding Requirements

We expect to incur ongoing operating losses for the foreseeable future as we continue to develop our planned therapeutic programs including related clinical studies and other programs in the pipeline. We expect that our current available funding will be insufficient to fund our planned operations for a year from the date of this report. If we meet certain requirements, we may sell securities that are registered on our Form S-3 registration statement, and by raising capital through sales of securities to third parties and existing stockholders. 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.

Additional funding may not be available to us on acceptable terms or at all. 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:

In the first quarter of 2019, we adopted Accounting Standards Update ("ASU") No. 2016-02, *Lease Accounting* Topic 842*: ("*Topic 842*")* and recognized on our Condensed Consolidated Balance Sheet $101,000 of lease liabilities with corresponding right-of-use assets for operating leases. The new lease standard requires a lessee to measure its operating lease liabilities at the present value of the remaining minimum lease payments with a discounted cash flow model using the interest rate implicit in the lease. If the implicit interest rate cannot be readily determined, the lessee must use its incremental borrowing rate ("IBR"). If the lessee does not have an IBR, the lessee must use a rate that approximates the rate of interest that the lessee would have to pay to borrow on a collateralized basis over a similar term in an amount equal to the lease payments in a similar economic environment. The implicit interest rate was readily determinable for our copier lease; however, we used an IBR to measure our adoption date operating lease liability related to our office space which represents our estimated borrowing rate on a secured loan collateralized by similar assets for a similar term. The adoption did not have a material impact on the Company's consolidated financial statements. As permitted under the standard, we elected prospective application of the new guidance and prior periods continue to be presented in accordance with Accounting Standards Codification ("ASC") Topic 840. Refer to our 2018 Annual Report on Form 10-K for disclosures required by Topic 840. The new standard provides a number of optional practical expedients in transition. We elected the practical expedients to not reassess our prior conclusions about lease identification under the new standard, to not reassess lease classification, to not separate lease and non lease components and to not reassess initial direct costs. We did not elect the practical expedient allowing the use-of-hindsight which would require us to reassess the lease term of our leases based on all facts and circumstances through the effective date and did not elect the practical expedient pertaining to land easements as this is not applicable to our current contract portfolio. See Note 11, *Commitments and Contingencies*, of the notes to our unaudited condensed consolidated financial statements for additional discussion of our leases and the amounts recognized in these unaudited condensed consolidated financial statements.

On January 1, 2019, we adopted ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made.* This ASU affects not-for-profit entities and business entities that receive or make contributions of cash. The ASU clarifies and improves the scope and accounting guidance to assist entities in evaluating if those transactions should be accounted for as contributions under the scope of Topic 958 or as an exchange transaction subject to other guidance. The adoption did not have any impact on the financial statements.

Recent Accounting Pronouncements:

In August 2018, the FASB issued 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 amendments are effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. Furthermore, an entity is permitted to early adopt any removed or modified disclosures upon issuance of the update and delay adoption of the additional disclosures until their effective date. We do not expect this amendment to have a material impact on our 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 principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. 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 principal executive officer and principal financial officer concluded that, as of September 30, 2019, the Company's disclosure controls and procedures were not 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 September 30, 2019, that has materially affected, or is reasonably likely to materially affect our disclosure controls and procedures

For the quarter ended June 30, 2018, we identified a material weakness in the internal controls over the calculation of the deemed dividend on Series B convertible preferred stock (the "deemed dividend") for the three and six months June 30, 2018. Because of this error, an incorrect deemed dividend was included in net loss applicable to common stockholders which caused an incorrect calculation of loss per common share, basic and diluted. Management misinterpreted the technical guidance contained in *ASC 470- Debt* in calculating the deemed dividend. An appropriately detailed knowledge of *ASC 470 - Debt* was not present to prevent or detect this error. We incorrectly stated the amount of the deemed dividend as $4,782,100, rather than $11,479,308, for the three and six months ended June 30, 2018. We also incorrectly stated the loss per common share - basic and diluted, for the three and six months ended June 30, 2018 as $(2.90) and $(3.77) respectively, rather than the correct amount of $(5.08) and $(6.11), respectively. The condensed consolidated financial statements for the three and six months period ended June 30, 3018 were restated to correct the error.

Management's remediation plan is to enhance the procedures performed to independently review technical accounting memorandums for accuracy and completeness including when appropriate with an outside independent accounting firm in future periods. Through the date of this filing, the Company has taken certain actions designed to improve its internal control and remediate the aforementioned material weakness. These actions include but are not limited to (a) expanded consultations with third party specialists on complex accounting matters and regulatory filings, (b) enhanced documentation to support a more precise review process, and (c) enhanced monitoring of the review process. These actions are ongoing and the Company is also continuing to evaluate additional controls and procedures that may be required to remediate the material weakness.

The Company believes that the actions being taken to improve the design and operating effectiveness of its internal controls will effectively remediate the material weakness; however, the material weakness in the Company's internal control over financial reporting will not be considered remediated until the internal controls that are remediated operate for a sufficient period of time and management concludes, through testing, that these internal controls are operating effectively.

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

There have been no material changes to the risk factors described in our Annual Report on Form 10-K, as filed with the SEC on March 25, 2019.

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
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: November 13, 2019

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

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

Exhibit 31.1

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

I, Steven C. Quay, certify that:

1. I have reviewed this Quarterly Report of Atossa Genetics 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: November 13, 2019

/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 Genetics 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: November 13, 2019

/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 Genetics Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019 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: November 13, 2019

/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 Genetics Inc. (the "Company") on Form 10-Q for the period ending September 30, 2019 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: November 13, 2019

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