

BERKSHIRE HATHAWAY INC  
Form 10-Q  
May 08, 2009  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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, 2009

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 001-14905

**BERKSHIRE HATHAWAY INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of

47-0813844  
(I.R.S. Employer Identification Number)

incorporation or organization)

3555 Farnam Street, Omaha, Nebraska 68131

(Address of principal executive office)

(Zip Code)

(402) 346-1400

(Registrant's telephone number, including area code)

Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

(Former name, former address and former fiscal year, if changed since last report)

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 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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

Number of shares of common stock outstanding as of May 4, 2009:

Class A 1,057,428

Class B 14,828,842

**Table of Contents**

**BERKSHIRE HATHAWAY INC.**

	<b>Page No.</b>
<b><u>Part I Financial Information</u></b>	
<b>Item 1. <u>Financial Statements</u></b>	
<u>Condensed Consolidated Balance Sheets</u>	
<u>March 31, 2009 and December 31, 2008</u>	2
<u>Condensed Consolidated Statements of Earnings</u>	
<u>First Quarter 2009 and 2008</u>	3
<u>Condensed Consolidated Statements of Cash Flows</u>	
<u>First Quarter 2009 and 2008</u>	4
<u>Notes to Interim Condensed Consolidated Financial Statements</u>	5-17
<b>Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	18-30
<b>Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	30
<b>Item 4. <u>Controls and Procedures</u></b>	30
<b><u>Part II Other Information</u></b>	
<b>Item 1. <u>Legal Proceedings</u></b>	31
<b>Item 1A. <u>Risk Factors</u></b>	31
<b>Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	31
<b>Item 3. <u>Defaults Upon Senior Securities</u></b>	31
<b>Item 4. <u>Submission of Matters to a Vote of Security Holders</u></b>	31
<b>Item 5. <u>Other Information</u></b>	31
<b>Item 6. <u>Exhibits</u></b>	31
<b><u>Signature</u></b>	32

**Table of Contents****Part I Financial Information****Item 1. Financial Statements****BERKSHIRE HATHAWAY INC.****and Subsidiaries****CONDENSED CONSOLIDATED BALANCE SHEETS***(dollars in millions)*

	March 31, 2009 (Unaudited)	December 31, 2008
<b>ASSETS</b>		
<i>Insurance and Other:</i>		
Cash and cash equivalents	\$ 22,726	\$ 24,302
Investments:		
Fixed maturity securities	29,367	27,115
Equity securities	37,578	49,073
Other	25,152	21,535
Loans and receivables	15,951	14,925
Inventories	6,802	7,500
Property, plant, equipment and assets held for lease	17,133	16,703
Goodwill	27,497	27,477
Other	13,250	13,257
	195,456	201,887
<i>Utilities and Energy:</i>		
Cash and cash equivalents	1,072	280
Property, plant and equipment	28,736	28,454
Goodwill	5,258	5,280
Other	6,137	7,556
	41,203	41,570
<i>Finance and Financial Products:</i>		
Cash and cash equivalents	1,753	957
Investments in fixed maturity securities	3,778	4,517
Loans and finance receivables	13,769	13,942
Goodwill	1,024	1,024
Other	3,559	3,502
	23,883	23,942
	\$ 260,542	\$ 267,399
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<i>Insurance and Other:</i>		
Losses and loss adjustment expenses	\$ 58,457	\$ 56,620
Unearned premiums	9,137	7,861
Life and health insurance benefits	3,645	3,619
Accounts payable, accruals and other liabilities	14,235	14,987
Notes payable and other borrowings	4,329	4,349

Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

	89,803	87,436
<b>Utilities and Energy:</b>		
Accounts payable, accruals and other liabilities	5,893	6,175
Notes payable and other borrowings	19,731	19,145
	25,624	25,320
<b>Finance and Financial Products:</b>		
Accounts payable, accruals and other liabilities	2,562	2,656
Derivative contract liabilities	15,432	14,612
Notes payable and other borrowings	13,755	13,388
	31,749	30,656
Income taxes, principally deferred	6,447	10,280
Total liabilities	153,623	153,692
<b>Shareholders' equity:</b>		
Common stock and capital in excess of par value	27,090	27,141
Accumulated other comprehensive income	(930)	3,954
Retained earnings	76,638	78,172
Berkshire Hathaway shareholders' equity	102,798	109,267
Noncontrolling interests	4,121	4,440
Total shareholders' equity	106,919	113,707
	\$ 260,542	\$ 267,399

*See accompanying Notes to Interim Condensed Consolidated Financial Statements*

**Table of Contents****BERKSHIRE HATHAWAY INC.****and Subsidiaries****CONDENSED CONSOLIDATED STATEMENTS OF EARNINGS***(dollars in millions except per share amounts)*

	2009	First Quarter 2008 (Unaudited)
<b>Revenues:</b>		
<i>Insurance and Other:</i>		
Insurance premiums earned	\$ 8,183	\$ 6,209
Sales and service revenues	14,310	14,760
Interest, dividend and other investment income	1,318	1,184
Investment gains/losses	(3,558)	115
	20,253	22,268
<i>Utilities and Energy:</i>		
Operating revenues	2,969	3,356
Other	(20)	38
	2,949	3,394
<i>Finance and Financial Products:</i>		
Interest income	418	438
Investment gains/losses	92	
Derivative gains/losses	(1,517)	(1,641)
Other	589	716
	(418)	(487)
	22,784	25,175
<b>Costs and expenses:</b>		
<i>Insurance and Other:</i>		
Insurance losses and loss adjustment expenses	6,014	4,040
Life and health insurance benefits	482	490
Insurance underwriting expenses	1,348	1,397
Cost of sales and services	11,958	12,108
Selling, general and administrative expenses	1,963	1,860
Interest expense	34	33
	21,799	19,928
<i>Utilities and Energy:</i>		
Cost of sales and operating expenses	2,355	2,584
Interest expense	291	294
	2,646	2,878

Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

**Finance and Financial Products:**

Interest expense	163	149
Other	719	767
	882	916
	25,327	23,722
<b>Earnings (loss) before income taxes and equity method earnings</b>	(2,543)	1,453
Income tax expense/benefit	(1,014)	408
Earnings from equity method investments	83	
<b>Net earnings (loss)</b>	(1,446)	1,045
Less: Earnings attributable to noncontrolling interests	88	105
<b>Net earnings (loss) attributable to Berkshire Hathaway</b>	\$ (1,534)	\$ 940
Average common shares outstanding *	1,549,483	1,548,395
<b>Net earnings (loss) per share attributable to Berkshire Hathaway shareholders *</b>	\$ (990)	\$ 607

\* Average shares outstanding include average Class A common shares and average Class B common shares determined on an equivalent Class A common stock basis. Net earnings (loss) per common share attributable to Berkshire Hathaway shown above represents net earnings (loss) per equivalent Class A common share. Net earnings (loss) per Class B common share is equal to one-thirtieth (1/30) of such amount.  
See accompanying Notes to Interim Condensed Consolidated Financial Statements

**Table of Contents****BERKSHIRE HATHAWAY INC.****and Subsidiaries****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS***(dollars in millions)*

	<b>First Quarter</b>	
	<b>2009</b>	<b>2008</b>
	<b>(Unaudited)</b>	
Net cash flows from operating activities	\$ 4,642	\$ 3,353
Cash flows from investing activities:		
Purchases of fixed maturity securities	(4,897)	(10,511)
Purchases of equity securities	(624)	(1,537)
Purchases of other investments	(3,098)	
Sales of fixed maturity securities	1,655	1,566
Redemptions and maturities of fixed maturity securities	1,614	2,548
Sales of equity securities	739	104
Purchases of loans and finance receivables	(110)	(653)
Principal collections on loans and finance receivables	174	174
Acquisitions of businesses and noncontrolling interests	(530)	(4,873)
Purchases of property, plant, equipment and assets held for lease	(1,373)	(1,041)
Other	1,023	881
Net cash flows from investing activities	(5,427)	(13,342)
Cash flows from financing activities:		
Proceeds from borrowings of finance businesses	467	2,068
Proceeds from borrowings of utilities and energy businesses	992	1,046
Proceeds from other borrowings	25	58
Repayments of borrowings of finance businesses	(116)	(1,357)
Repayments of borrowings of utilities and energy businesses	(195)	(399)
Repayments of other borrowings	(228)	(88)
Change in short term borrowings	1	(155)
Other	(21)	32
Net cash flows from financing activities	925	1,205
Effects of foreign currency exchange rate changes	(128)	21
Increase (decrease) in cash and cash equivalents	12	(8,763)
Cash and cash equivalents at beginning of year *	25,539	44,329
Cash and cash equivalents at end of first quarter *	\$ 25,551	\$ 35,566
Supplemental cash flow information:		
Cash paid during the period for:		
Income taxes	\$ 225	\$ 201
Interest of finance and financial products businesses	172	145
Interest of utilities and energy businesses	282	295
Interest of insurance and other businesses	32	37



Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

Non-cash investing activity:		
Liabilities assumed in connection with acquisitions of businesses		3,848
* Cash and cash equivalents are comprised of the following:		
<i>Beginning of year</i>		
<i>Insurance and Other</i>	\$ 24,302	\$ 37,703
<i>Utilities and Energy</i>	280	1,178
<i>Finance and Financial Products</i>	957	5,448
	\$ 25,539	\$ 44,329
<i>End of first quarter</i>		
<i>Insurance and Other</i>	\$ 22,726	\$ 31,102
<i>Utilities and Energy</i>	1,072	2,187
<i>Finance and Financial Products</i>	1,753	2,277
	\$ 25,551	\$ 35,566

*See accompanying Notes to Interim Condensed Consolidated Financial Statements*

---

**Table of Contents**

**BERKSHIRE HATHAWAY INC.**

**and Subsidiaries**

**NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2009**

**Note 1. General**

The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of Berkshire Hathaway Inc. ( Berkshire or Company ) consolidated with the accounts of all its subsidiaries and affiliates in which Berkshire holds a controlling financial interest as of the financial statement date. Reference is made to Berkshire's most recently issued Annual Report on Form 10-K ( Annual Report ) that included information necessary or useful to understanding Berkshire's businesses and financial statement presentations. In particular, Berkshire's significant accounting policies and practices were presented as Note 1 to the Consolidated Financial Statements included in the Annual Report. Certain immaterial amounts in 2008 have been reclassified to conform with the current year presentation. Financial information in this Report reflects any adjustments (consisting only of normal recurring adjustments) that are, in the opinion of management, necessary to a fair statement of results for the interim periods in accordance with accounting principles generally accepted in the United States ( GAAP ).

For a number of reasons, Berkshire's results for interim periods are not normally indicative of results to be expected for the year. The timing and magnitude of catastrophe losses incurred by insurance subsidiaries and the estimation error inherent to the process of determining liabilities for unpaid losses of insurance subsidiaries can be relatively more significant to results of interim periods than to results for a full year. Variations in the amounts and timing of investment gains/losses can cause significant variations in periodic net earnings. Investment gains/losses are recorded when investments are sold, other-than-temporarily impaired or in instances as required under GAAP, when investments are marked-to-market. In addition, changes in the fair value of derivative assets/liabilities associated with derivative contracts that do not qualify for hedge accounting treatment can cause significant variations in periodic net earnings.

As of January 1, 2009, Berkshire adopted SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51 ( SFAS 160 ). SFAS 160 requires that noncontrolling interests (formerly known as minority interests ) be displayed in the consolidated balance sheet as a separate component of shareholders' equity and that the consolidated net earnings attributable to the noncontrolling interests be clearly identified and presented in the consolidated statement of earnings. In addition, changes in ownership interests where the parent retains a controlling interest are to be reported as transactions affecting shareholders' equity. Previously such transactions were reported as additional investment purchases (potentially resulting in recognition of additional other assets, including goodwill, or liabilities). During the first quarter of 2009, Berkshire acquired certain noncontrolling interests in subsidiaries that resulted in a reduction to shareholders' equity attributable to Berkshire of approximately \$118 million, representing the excess of consideration paid over the previously recorded balance sheet carrying amount of the acquired noncontrolling (minority) interests.

**Note 2. Accounting pronouncements to be adopted**

In April 2009, the FASB issued three Staff Positions ( FSP ) to amend Financial Accounting Standards ( FAS ) relating to financial instruments. Each of these pronouncements is effective for interim and annual periods ending after June 15, 2009.

FSP FAS 115-2 and FAS 124-2 Recognition and Presentation of Other-Than-Temporary Impairments amends the recognition, measurement and presentation standards for other-than-temporary impairments of debt securities. With respect to an investment in a debt security, an other-than-temporary impairment occurs if the investor (a) intends to sell, (b) will more likely than not be required to sell before amortized cost is recovered or (c) does not expect to ultimately recover the amortized cost basis even if it does not intend to sell. Under (a) and (b) the entire other-than-temporary loss is recognized in earnings. Under (c) a credit loss is recognized in earnings to the extent that the present value of expected cash flows is less than the amortized cost basis and any difference between fair value and the amortized cost basis net of the credit loss is reflected in other comprehensive income net of applicable income taxes.

FSP FAS 107-1 and APB 28-1 Interim Disclosures about Fair Value of Financial Instruments requires publicly traded companies to make fair value disclosures of financial instruments whether or not such instruments are carried in the financial statements at fair value in interim financial statements. Previously, disclosures for instruments not carried at fair value were required only in annual statements.

FSP FAS 157-4 Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly clarifies that adjustments to quoted market prices



**Table of Contents****Notes To Interim Condensed Consolidated Financial Statements (Continued)****Note 2. Accounting pronouncements to be adopted (Continued)**

may be required in illiquid or disorderly markets in order to estimate fair value in accordance with SFAS 157 and provides guidance on the circumstances indicating whether markets are illiquid or disorderly. FSP FAS 157-4 prescribes no specific methodology for making adjustments to quoted prices but rather confirms that different valuation techniques may be appropriate under the circumstances to determine the value that would be received to sell an asset or paid to transfer a liability in an orderly transaction.

Berkshire is currently evaluating the effect that these new accounting pronouncements will have on its consolidated financial statements and related disclosures.

**Note 3. Business acquisitions**

Berkshire's long-held acquisition strategy is to purchase businesses with consistent earnings, good returns on equity, able and honest management and at sensible prices. On March 18, 2008, Berkshire acquired 60% of Marmon Holdings, Inc. ( Marmon ), a private company owned by trusts for the benefit of members of the Pritzker Family of Chicago, for \$4.5 billion. In the second quarter of 2008, Berkshire acquired additional shares and currently owns 63.6% of Marmon. Under the terms of the purchase agreement, Berkshire will acquire the remaining interests in Marmon between 2011 and 2014 for consideration based on the future earnings of Marmon. Berkshire also acquired several other relatively small businesses during 2008. Consideration paid for all businesses acquired in 2008 was approximately \$6.1 billion.

Marmon consists of approximately 130 manufacturing and service businesses that operate independently within eleven diverse business sectors. These sectors are: Engineered Wire & Cable, serving energy related markets, residential and non-residential construction and other industries; Building Wire, producing copper electrical wiring for residential, commercial and industrial buildings; Transportation Services & Engineered Products, including railroad tank cars and intermodal tank containers; Highway Technologies, primarily serving the heavy-duty highway transportation industry; Distribution Services for specialty pipe and steel tubing; Flow Products, producing a variety of metal products and materials for the plumbing, HVAC/R, construction and industrial markets; Industrial Products, including metal fasteners, safety products and metal fabrication; Construction Services, providing the leasing and operation of mobile cranes primarily to the energy, mining and petrochemical markets; Water Treatment equipment for residential, commercial and industrial applications; Retail Store Fixtures, providing store fixtures and accessories for major retailers worldwide; and Food Service Equipment, providing food preparation equipment and shopping carts for restaurants and retailers worldwide. Marmon operates more than 250 manufacturing, distribution and service facilities, primarily in North America, Europe and China.

The results of operations for businesses acquired in 2008 are included in Berkshire's consolidated results from the effective date of each acquisition. The following table sets forth certain unaudited pro forma consolidated earnings data for 2008 as if each acquisition occurring during 2008 was consummated on the same terms at the beginning of the year. Pro forma data for 2009 was not materially different from the amounts reported. Amounts are in millions, except earnings per share.

	2008
Total revenues	\$ 26,587
Net earnings attributable to Berkshire Hathaway	930
Earnings per equivalent Class A common share attributable to Berkshire Hathaway shareholders	601

**Note 4. Investments in fixed maturity securities**

Data with respect to investments in fixed maturity securities follows (in millions).

		Finance and financial products	
Insurance and other		Mar. 31,	Dec.
Mar. 31,	Dec. 31,	2009	31,
2009	2008	2009	31,

Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

	<b>2008</b>			
Amortized cost	\$ 29,632	\$ 27,618	\$ 3,620	\$ 4,297
Gross unrealized gains	1,440	1,151	279	289
Gross unrealized losses	(1,705)	(1,654)	(121)	(69)
Fair value	\$ 29,367	\$ 27,115	\$ 3,778	\$ 4,517

**Table of Contents****Notes To Interim Condensed Consolidated Financial Statements (Continued)****Note 4. Investments in fixed maturity securities (Continued)**

Unrealized losses at March 31, 2009 and December 31, 2008 included \$193 million and \$176 million, respectively, related to securities that have been in an unrealized loss position for 12 months or more. Berkshire has the ability and intent to hold these securities until fair value recovers.

**Note 5. Investments in equity securities**

Investments in equity securities are summarized below (in millions).

	March 31, 2009	December 31, 2008
Cost	\$ 36,319	\$ 40,140
Gross unrealized gains	11,312	14,782
Gross unrealized losses	(10,053)	(5,849)
Fair value	\$ 37,578	\$ 49,073

Unrealized losses at March 31, 2009 included \$524 million related to securities that have been in an unrealized loss position for 12 months or more.

**Note 6. Other Investments**

A summary of other investments as of March 31, 2009 and December 31, 2008 follows (in millions).

	March 31, 2009			
	Cost	Unrealized Gain/Loss	Fair Value	Carrying Value
Fixed maturity and equity	\$ 17,119	\$ 975	\$ 18,094	\$ 17,808
Equity method	6,350	(632)	5,718	7,344
	\$ 23,469	\$ 343	\$ 23,812	\$ 25,152

	December 31, 2008			
	Cost	Unrealized Gain	Fair Value	Carrying Value
Fixed maturity and equity	\$ 14,452	\$ 36	\$ 14,488	\$ 14,675
Equity method	5,919	352	6,271	6,860
	\$ 20,371	\$ 388	\$ 20,759	\$ 21,535

Fixed maturity and equity investments in the preceding table include perpetual preferred stock and common stock warrants of The Goldman Sachs Group, Inc. ( GS ) and The General Electric Company ( GE ) and preferred stock and subordinated notes of Wm. Wrigley Jr. Company ( Wrigley ). The GS, GE and Wrigley securities were acquired in the fourth quarter of 2008. At March 31, 2009, other fixed maturity and equity investments also include a convertible perpetual instrument of Swiss Reinsurance Company Ltd. ( Swiss Re ).

## Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

Berkshire owns 50,000 shares of 10% Cumulative Perpetual Preferred Stock of GS ( GS Preferred ) and Warrants to purchase 43,478,260 shares of common stock of GS ( GS Warrants ) which were acquired for a combined cost of \$5 billion. The GS Preferred may be redeemed at any time by GS at a price of \$110,000 per share (\$5.5 billion in aggregate). The GS Warrants expire in 2013 and can be exercised for an additional aggregate cost of \$5 billion (\$115/share). Berkshire also owns 30,000 shares of 10% Cumulative Perpetual Preferred Stock of GE ( GE Preferred ) and Warrants to purchase 134,831,460 shares of common stock of GE ( GE Warrants ) which were acquired for a combined cost of \$3 billion. The GE Preferred may be redeemed beginning in October 2011 by GE at a price of \$110,000 per share (\$3.3 billion in aggregate). The GE Warrants expire in 2013 and can be exercised for an additional aggregate cost of \$3 billion (\$22.25/share).

**Table of Contents****Notes To Interim Condensed Consolidated Financial Statements (Continued)****Note 6. Other Investments (Continued)**

Berkshire owns \$4.4 billion par amount of 11.45% subordinated notes due 2018 of Wrigley ( Wrigley Notes ) and \$2.1 billion of 5% preferred stock of Wrigley ( Wrigley Preferred ). The Wrigley Notes and Wrigley Preferred were acquired in connection with Mars, Incorporated's acquisition of Wrigley.

On March 23, 2009, Berkshire acquired a 12% convertible perpetual capital instrument issued by Swiss Re at a cost of 3 billion Swiss Francs ( CHF ), which is also the face amount of the instrument. The instrument has no maturity or mandatory redemption date but can be redeemed under certain conditions at the option of Swiss Re at 140% of the face amount until March 23, 2011 and thereafter at 120% of the face amount. The instrument possesses no voting rights and is subordinated to senior securities of Swiss Re as defined in the agreement. Beginning March 23, 2012, the instrument can be converted into 120,000,000 common shares of Swiss Re (a rate of 25 CHF per share of Swiss Re common stock).

Equity method investments include Burlington Northern Santa Fe Corporation ( BNSF ) and Moody's Corporation ( Moody's ). During the fourth quarter of 2008, Berkshire's investment in each of these companies exceeded 20%. Accordingly, Berkshire adopted the equity method of accounting with respect to these investments as of December 31, 2008. As of March 31, 2009, Berkshire owned 22.6% of BNSF's and 20.4% of Moody's outstanding common stock. Prior to December 31, 2008, the BNSF and Moody's investments were accounted for as available-for-sale equity securities recorded in the financial statements at fair value. The cumulative effect of adopting the equity method with respect to the investments in BNSF and Moody's was recorded in the financial statements as of December 31, 2008. Prior years' financial statements were not restated due to immateriality.

On April 1, 2009, Berkshire acquired 3,000,000 shares of Series A Cumulative Convertible Perpetual Preferred Stock of The Dow Chemical Company ( Dow Preferred ) for a cost of \$3 billion. The Dow Preferred was issued in connection with Dow's acquisition of the Rohm and Haas Company. Under certain conditions, the Dow Preferred is convertible at the option of Berkshire or the issuer into common stock of Dow. The conversion rate is 24.201 shares of common stock per each Dow Preferred share, subject to adjustment. The Dow Preferred is entitled to dividends at a rate of 8.5% per annum.

**Note 7. Derivative contracts of finance and financial products businesses**

Derivative contracts of Berkshire's finance and financial products businesses, with limited exceptions, are not designated as hedges for financial reporting purposes. These contracts were initially entered into with the expectation that the premiums received would exceed the amounts ultimately paid to counterparties. Changes in the fair values of such contracts are reported in earnings as derivative gains/losses. A summary of derivative contracts outstanding as of March 31, 2009 and December 31, 2008 follows (in millions).

	March 31, 2009			December 31, 2008		
	Assets <sup>(3)</sup>	Liabilities	Notional Value	Assets <sup>(3)</sup>	Liabilities	Notional Value
Equity index put options	\$	\$ 10,188	\$ 35,489 <sup>(1)</sup>	\$	\$ 10,022	\$ 37,134 <sup>(1)</sup>
Credit default obligations:						
High yield indexes		3,666	7,216 <sup>(2)</sup>		3,031	7,892 <sup>(2)</sup>
States/municipalities		887	16,681 <sup>(2)</sup>		958	18,364 <sup>(2)</sup>
Individual corporate		238	3,875 <sup>(2)</sup>		105	3,900 <sup>(2)</sup>
Other	476	481		503	528	
Counterparty netting and funds held as collateral	(277)	(28)		(295)	(32)	
	\$ 199	\$ 15,432		\$ 208	\$ 14,612	

(1)



## Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

*Represents the aggregate undiscounted amount payable at the contract expiration dates assuming that the value of each index is zero at the contract expiration date. The reduction in notional value at March 31, 2009 as compared to December 31, 2008 is solely due to the impact of changes in foreign currency exchange rates on non-U.S. index contracts.*

<sup>(2)</sup> *Represents the maximum undiscounted future value of losses payable under the contracts, assuming a sufficient number of credit defaults occur. The number of losses required to exhaust contract limits under substantially all of the contracts is dependent on the loss recovery rate related to the specific obligor at the time of the default.*

<sup>(3)</sup> *Included in other assets of finance and financial products businesses.*

**Table of Contents****Notes To Interim Condensed Consolidated Financial Statements (Continued)****Note 7. Derivative contracts of finance and financial products businesses (Continued)**

A summary of derivative gains (losses) included in the Condensed Consolidated Statements of Earnings are as follows (in millions):

	First Quarter	
	2009	2008
Equity index put options	\$ (166)	\$ (1,177)
Credit default obligations	(1,351)	(475)
Other		11
	\$ (1,517)	\$ (1,641)

Berkshire has written equity index put option contracts on four major equity indexes including three indexes outside of the United States. These contracts are European style options and will be settled on the contract expiration dates, which occur between September 2019 and January 2028. Future payments, if any, under these contracts will be required if the underlying index value is below the strike price at the contract expiration dates. Premiums on these contracts were received in full at the contract inception dates and therefore Berkshire has no counterparty credit risk. At March 31, 2009, the aggregate intrinsic value (the undiscounted liability assuming the contracts are settled on their future expiration dates based on the March 31, 2009 index values) was \$13.3 billion. However, these contracts may not be terminated or fully settled before the expiration dates and therefore the ultimate amount of cash basis gains or losses on these contracts will not be known for many years.

Credit default contracts include various high yield indexes, state/municipal debt issuers and individual corporation issuers. These contracts cover the loss in value of specified debt obligations of the issuers arising from default events, which are usually for non-payment or bankruptcy. Loss amounts are subject to contract limits.

High yield indexes are comprised of specified North American corporate issuers (usually 100 in number) whose obligations are rated below investment grade. The weighted average contract duration at March 31, 2009 was approximately 2 years. State and municipality contracts are comprised of over 500 reference obligations issuers, which had a weighted average duration at March 31, 2009 of approximately 12 years. Risks related to approximately 50% of the municipality notional amount cannot be settled before the maturity dates of the underlying obligations, which range from 2019 to 2054.

Premiums on the high yield index and state/municipality contracts were received in full at the inception dates of the contracts and, as a result, Berkshire has no counterparty credit risk. Berkshire's payment obligations under certain of these contracts are on a first loss basis. Several other contracts are subject to aggregate loss deductibles that must be satisfied before Berkshire has any payment obligations.

Credit default contracts written on individual corporate issuers in North America primarily relate to investment grade obligations. Installment premiums are due from counterparties over the terms of the contracts. In most instances, premiums are due from counterparties on a quarterly basis. Most individual issuer contracts expire in 2013.

With limited exception, Berkshire's equity index put option and credit default contracts contain no collateral posting requirements with respect to changes in either the fair value or intrinsic value of the contracts and/or a downgrade of Berkshire's credit rating. Under certain conditions, a few contracts require that Berkshire post collateral. As of March 31, 2009, Berkshire's collateral posting requirement under such contracts was approximately \$1 billion.

**Note 8. Fair value measurements**

Berkshire holds investments and has financial obligations that are required to be carried at fair value in the financial statements. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. Fair value measurements assume the asset or liability is exchanged in an orderly manner; the exchange is in the principal market for that asset or liability (or in the most advantageous market when no principal market exists); and the market participants are

## Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

independent, knowledgeable, able and willing to transact an exchange. Nonperformance risk (credit risk) is considered in valuing liabilities.

Fair values for substantially all of Berkshire's financial instruments were measured using market or income approaches. Considerable judgment may be required in interpreting market data used to develop the estimates of fair value. Accordingly, the

**Table of Contents****Notes To Interim Condensed Consolidated Financial Statements (Continued)****Note 8. Fair value measurements (Continued)**

estimates presented herein are not necessarily indicative of the amounts that could be realized in an actual current market exchange. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value.

SFAS 157 establishes a hierarchy for measuring fair value consisting of Levels 1 through 3.

**Level 1** Inputs represent unadjusted quoted prices for identical assets or liabilities exchanged in active markets. Substantially all of Berkshire's equity investments are traded on an exchange in active markets and fair value is based on the closing prices as of the balance sheet date.

**Level 2** Inputs include directly or indirectly observable inputs (other than Level 1 inputs) such as quoted prices for similar assets or liabilities exchanged in active or inactive markets; quoted prices for identical assets or liabilities exchanged in inactive markets; other inputs that may be considered in fair value determinations of the assets or liabilities, such as interest rates and yield curves, volatilities, prepayment speeds, loss severities, credit risks and default rates; and inputs that are derived principally from or corroborated by observable market data by correlation or other means. Fair values for Berkshire's investments in fixed maturity securities are primarily based on market prices and market data available for instruments with similar characteristics since active markets are not common for many instruments. Pricing evaluations are based on yield curves for instruments with similar characteristics, such as credit rating, estimated duration, and yields for other instruments of the issuer or entities in the same industry sector.

**Level 3** Inputs include unobservable inputs used in the measurement of assets and liabilities. Management is required to use its own assumptions regarding unobservable inputs because there is little, if any, market activity in the assets or liabilities or related observable inputs that can be corroborated at the measurement date. Unobservable inputs require management to make certain projections and assumptions about the information that would be used by market participants in pricing assets or liabilities. Measurements of non-exchange traded derivative contracts and certain other investments carried at fair value are based primarily on valuation models, discounted cash flow models or other valuation techniques that are believed to be used by market participants. Berkshire values its equity index put option contracts based on the Black-Scholes option valuation model which Berkshire believes is widely used by market participants. Credit default contracts are primarily valued based on indications of bid or offer data as of the balance sheet date. These contracts are not exchange traded and certain of the terms of Berkshire's contracts are not standard in derivatives markets. For example, Berkshire is not required to post collateral under most of its contracts. For these reasons, Berkshire has classified these contracts as Level 3.

Financial assets and liabilities measured at fair value in the financial statements as of March 31, 2009 and December 31, 2008 are summarized below (in millions).

	Total Fair Value	Quoted Prices (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>March 31, 2009</b>				
Insurance and other:				
Investments in fixed maturity securities	\$ 29,367	\$ 4,948	\$ 23,917	\$ 502
Investments in equity securities	37,578	37,182	72	324
Other investments	11,356			11,356
Finance and financial products:				
Investments in fixed maturity securities	3,778		3,393	385
Net derivative contract liabilities	15,233		255	14,978
Utilities and energy:				
Net derivative contract (assets)/liabilities	366	14	(43)	395
<b>December 31, 2008</b>				
Insurance and other:				
Investments in fixed maturity securities	\$ 27,115	\$ 4,961	\$ 21,650	\$ 504
Investments in equity securities	49,073	48,666	79	328

Edgar Filing: BERKSHIRE HATHAWAY INC - Form 10-Q

Other investments	8,223		8,223
Finance and financial products:			
Investments in fixed maturity securities	4,517	4,382	135
Net derivative contract liabilities	14,404	288	14,116
Utilities and energy:			
Net derivative contract liabilities	405	2	403

**Table of Contents**

**Notes To Interim Condensed Consolidated Financial Statements** *(Continued)*

**Note 8. Fair value measurements** *(Continued 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;

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 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 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 GDP, and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with GCP and in accordance with our timelines, expectations and requirements. We are substantially dependent on Montefiore Medical Center for the clinical study they are conducting for us using our intraductal microcatheters to 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 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, 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 single vendors. In particular, our current business structure contemplates, at least in the foreseeable future, use of a single commercial supplier for endoxifen drug substance. In addition, in the event endoxifen is approved, we are initially preparing to have only one commercial supplier. The use of single vendors for core operational activities, such as clinical trial operations, manufacturing and distribution, and the resulting lack of diversification, expose us to the risk of a material interruption in service related to these single, 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:

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 Montefiore Medical Center, 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:

failure of our 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 United States and in other countries, for devices, therapeutics and related technologies, processes, methods, compositions, and other inventions that we believe are patentable. Our ability to preserve our trade secrets and other intellectual property is also important to our long-term success. 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 issue to third parties which could interfere with our ability to bring our therapeutics and devices to market. 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 Genetics, Inc.*, 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014). Our patent positions also involve complex legal and factual questions, 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;

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 or patents that we license from others will survive legal challenges, and remain valid and enforceable.

If a third-party files a patent application with claims to a drug or device 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, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

The U.S. Patent and Trademark Office (the “USPTO”) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm 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 medical device and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the medical device and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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* 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* 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.

*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 United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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 United States. 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 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 United States, 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 (the “*AIA*”) 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 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 United States 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.

***We use third-party suppliers to produce our intraductal microcatheters, which are currently manufactured in small quantities. If such suppliers are not capable of producing quantities sufficient for ongoing and future clinical studies as well as for commercial sale when we are ready, we may not generate significant revenue or become profitable.***

We rely on third-party suppliers for the continued manufacture and supply of the intraductal microcatheters. If our third-party suppliers cannot produce the microcatheter in quantities sufficient for our studies and commercial needs on

acceptable terms when needed, we may be unable to commercialize our microcatheters and generate revenue from their sales as planned. In addition, if at any time after commercialization of our products, we are unable to secure essential equipment or supplies in a timely, reliable and cost-effective manner, we could experience disruptions in our services that could adversely affect anticipated results.

## **Risks Related to Our Industry**

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

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

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

***Our inadvertent or unintentional failure to comply with the complex government regulations concerning privacy 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 the Health Insurance Portability and Accountability Act, or 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 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 health data in the E.U. is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. The Directive 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. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the E.U. to the U.S. In April 2016, the EU adopted the new GDPR to replace the Directive 95/46/EC, which is expected to come into effect in May 2018 with no transition period, and which has enhanced penalties for noncompliance. We are evaluating our ability and cost to comply with the new EU GDPR regulations, and as a result of that evaluation we may make changes to our business practices and may incur additional costs.

Failure to comply with the requirements of the Data Protection Directive (or GDPR when it takes effect), 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.

***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 United States 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 United States 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. On May 11, 2017, we received a letter from NASDAQ stating we are not in compliance with Rule 5550(a)(2) because our common stock failed to maintain a minimum closing bid price of \$1.00 per share for 30 consecutive business days. We had until November 7, 2017 to either regain compliance, or request additional time to regain compliance. On November 2, 2017, we requested an additional 180 days to regain compliance and that request was approved so that we now have until May 7, 2018 to regain compliance.

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.

*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. 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 February 28, 2018, our stock price has ranged from \$0.23 to \$1.65. 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. 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. For example, after our financing in December 2017, we believe that two stockholders beneficially owned approximately 20% of our outstanding voting securities. Accordingly, 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 the 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.*

The extent to which we utilize the Aspire Purchase Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock, and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the Purchase Agreement is limited. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Aspire Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than \$1.50 per share. Even if we are able to access the full \$10 million available under the Aspire Purchase Agreement, we will still need additional capital to fully implement our business, operating, and development plans.

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 through sales of common stock to Aspire Capital under the 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.

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

## **ITEM 2. PROPERTIES**

As of December 31, 2017, we leased a total of approximately 192 square feet of office space in one location in Seattle, Washington, from WW 107 Spring Street LLC. We believe that our current facilities will be adequate to meet our needs for the next 24 months. This information is incorporated in this report under “PART II, ITEM 7. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – Commercial Lease Arrangements.”

## **ITEM 3. LEGAL PROCEEDINGS**

On October 10, 2013, a putative securities class action complaint, captioned Cook v. Atossa Genetics, Inc., et al., No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleged that all defendants violated Sections 11 and 12(a)(2) of the Securities Act, and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering’s registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. The complaint sought, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecified amount.

On February 14, 2014, the district court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the “Levi Group”) as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. On October 6, 2014 the Court granted defendants’ motion dismissing all claims against Atossa and all other defendants. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and appealed the Court’s dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On August 18, 2017, the Ninth Circuit affirmed in part and reversed in part the district court’s judgment.

On September 11, 2017, the Ninth Circuit entered an order and mandate remanding the case to the United States District Court for the Western District of Washington. On October 19, 2017, plaintiffs filed an amended complaint that conforms to the ruling by the Ninth Circuit. Since the claims under Sections 11, 12(a)(2) and 15 were dismissed by the district court and not appealed, the amended complaint only alleges violations of Section 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder against the company and one officer. All other claims and defendants have been dismissed. The alleged class period in the amended complaint is December 20, 2012 through October 4, 2013. On December 8, 2017, defendants filed an answer to the amended complaint. On February 7, 2018, following a mediation, the parties notified the district court that they had reached an agreement in principle to settle the action. The parties expect to file a stipulation of settlement with the court no later than March 15, 2018. The settlement will be funded by the company's insurance carriers, and is subject to both preliminary and final approval by the district court.

Please refer to the section titled "ITEM 1 BUSINESS – Historical Operations – Afimoxifene Topical Gel (AfTG)" for discussion of the Besins Litigation, which settled in August 2016.

**ITEM 4. MINE SAFETY DISCLOSURE**

Not applicable.

**PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock, par value \$0.015 per share, began trading on the NASDAQ Capital Market under the symbol "ATOS" on November 8, 2012. The following table sets forth, for the periods indicated, the intraday high and low prices of our common stock as reported by NASDAQ.

	2017		2016	
	High	Low	High	Low
First Quarter	\$1.81	\$0.76	\$10.65	\$3.15
Second Quarter	\$0.76	\$0.45	\$6.02	\$3.75
Third Quarter	\$0.78	\$0.34	\$4.95	\$2.00
Fourth Quarter	\$1.22	\$0.23	\$2.60	\$1.30

On February 28 2018, the closing price of our common stock was \$0.66. As of February 28, 2018, there were approximately 34 shareholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC and approximately 21,000 beneficial holders. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one shareholder.

**Certain Unregistered Sales of Securities**

In the first quarter of 2016, Ensisheim Partners LLC, which is under sole ownership and control by Steven Quay, CEO, President and Chairman of the Board, and Shu-Chih Chen, Director, purchased a total of 5,333 shares of common stock directly from the Company in at-the-market transactions which were approved by the Company's audit committee at purchase prices of \$3.30 to \$7.95 per share. The issuance of the shares is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

On May 25, 2016 we entered into the Aspire Purchase Agreement, which provides that we may sell up to \$10 million in common stock to Aspire Capital over the 30-month term of the agreement, subject to the terms and conditions set out in the Purchase Agreement, and pursuant to which we issued 49,736 shares of common stock to Aspire as a commitment fee. The issuance of the commitment fee shares to Aspire Capital under the purchase agreement is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

On December 20, 2017, concurrently with the public offering that we conducted on that same date and pursuant to a purchase agreement, we commenced a private placement whereby we issued and sold Class A and Class B Warrants (the "Warrants"), exercisable for an aggregate of 10,600,000 shares of common stock, at a price of \$0.315 per share (the "Private Placement"). The Warrants will become exercisable commencing six months from issuance. The Class A Warrants will expire eight months from issuance, while the Class B Warrants will expire on the first anniversary of the date of issuance. None of the Class A Warrants, the Class B Warrants nor the shares issuable upon exercise of such Warrants have been registered with the Securities and Exchange Commission. The Private Placement closed on December 22, 2017. The issuance of the Warrants under the purchase agreement is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

**Dividends**

The Company has never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business.

**Issuer Purchases of Securities**

We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2017.

**Use of Proceeds**

Not applicable.

**ITEM 6. SELECTED FINANCIAL DATA**

Not applicable.



## **ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Overview**

*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 Annual 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 elsewhere in this report for additional information regarding forward-looking statements.*

### **Company Overview**

We are a clinical-stage pharmaceutical company focused on developing novel, proprietary therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. We are developing Endoxifen with two routes of delivery: a topical formulation, applied like a lotion, for the treatment of a condition called mammographic breast density (or, MBD), and an oral formulation for breast cancer survivors who do not benefit from taking oral tamoxifen which is the current FDA-approved standard of care. We are also developing our patented intraductal microcatheter technology to potentially target the delivery of therapies, including fulvestrant, CAR-T and immunotherapies, directly to the site of breast cancer.

In 2017, we completed a Phase 1 clinical study of our proprietary oral and topical formulations of Endoxifen. All objective were met: 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 takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen.

We are currently conducting a Phase 2 study at Montefiore Medical Center using our intraductal microcatheter technology to deliver fulvestrant. Our program to use our intraductal microcatheters to delivery CAR-T and immunotherapies is in the research and development phase.

We plan to open enrollment in two Phase 2 studies of our proprietary Endoxifen in the first half of 2018: a study in Stockholm, Sweden using our topical Endoxifen to treat MBD and a study of our oral Endoxifen in Australia to treat patients who do not benefit from taking tamoxifen. We expect to complete these studies in the second half of 2018.

Our key objectives are to advance our programs through Phase 2 trials and then evaluate further development independently or with partners.

### **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 March 4, 2011, we entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease terminated on March 31, 2017.

On August 8, 2014, we entered into a commercial lease agreement with the Legacy Group Inc., to lease office space in Seattle, Washington. The lease provided for monthly rent payments of \$16,695 from December 1, 2014 through June 30, 2015, \$17,172 from July 1, 2015 through June 30, 2016 and \$17,649 from July 1, 2016 through June 30, 2017. On October 2015, we terminated the lease with the Legacy Group and entered into another commercial lease with the same landlord for similar office space which terminated at the end of 2016. For the year ended December 31, 2016, we incurred \$301,666 of rent expense for the lease.

On August 3, 2016 we entered into a one year commercial lease agreement with WW 107 Spring Street LLC to lease office space at 107 Spring Street, Seattle, Washington for \$2,456 per month. In September 2017, we renewed the lease for an additional year for \$2,456 per month.

### **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.

While our significant accounting policies are more fully described in Note 3 to our financial statements, 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.

### ***Fair Value Measurements***

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

### ***Financial Instruments with Characteristics of Both Liabilities and Equity***

During the year ended December 31, 2017, the Company issued certain financial instruments, consisting of warrants to purchase common stock, which have characteristics of both liability and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured at fair value at subsequent reporting periods with the resulting change in fair value recorded in "change in fair value of common stock warrants" in the consolidated statements of operations. The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature. No warrants that are classified as liabilities were outstanding at December 31, 2017.

### ***Intangible Assets***

Intangible assets consist of intellectual property and software acquired. Intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. To the extent an analysis is required to be performed and estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount, we record an impairment to the extent the fair value of the asset is below its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

We have evaluated our research and development pipeline, and have concluded that it may be necessary to update FDA marketing authorizations prior to commercializing the Acueity assets that we acquired in 2012. Because of these

additional potential regulatory activities and costs related to the Acueity assets, we have re-evaluated the assets for potential impairment. We have concluded that these assets are impaired and have recorded asset impairment charges of \$461,715 for the year ended December 31, 2017 to adjust the carrying value of these intangible assets to their estimated fair values, which were deemed to be nominal, as of December 31, 2017.

We determined the fair values of the Acueity intangibles using an income approach (Level 3 of the fair value hierarchy). For purposes of the income approach, fair value was determined based on the present value of estimated future cash flows that a market participant could be expected to generate from the development of products using the patented technology we acquired in the Acueity transaction, discounted at an appropriate risk-adjusted rate reflecting the weighted average cost of capital for a potential market participant. The discount rate used in valuation for these intangible assets was approximately 48.5%. The estimated future cash flows, including an estimate of long-term future growth rates, reflect our own assumptions of what market participants would utilize to price the assets pursuant to ASC 820, *Fair Value Measurements*.

### ***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.

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 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 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.

We adopted ASU No. 2016-09, *Compensation - Stock Compensation*, effective January 1, 2017. As a result of the adoption of this guidance, we made an accounting policy election to recognize the effect of forfeitures in compensation cost when they occur.

## Results of Operations

### Comparison of Years Ended December 31, 2017 and 2016

#### *Revenue and Cost of Revenue:*

For the years ended December 31, 2017 and 2016, we have no source of sustainable revenue and no associated cost of revenue.

#### *Operating Expenses:*

Total operating expenses were \$7,649,171 for the year ended December 31, 2017, which is a decrease of \$319,419 or 4.0%, from the year ended December 31, 2016. Operating expenses for 2017 consisted of general and administrative (G&A) expenses of \$4,859,369, R&D expenses of \$2,328,087, and impairment of our Acueity intangible assets of \$461,715.

*General and Administrative Expenses:* G&A expenses were \$4,859,369 for the year ended December 31, 2017, a decrease of \$1,619,824, or 25.0% from the total G&A expenses for the year ended December 31, 2016 of \$6,479,193. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The 2017 decrease in G&A expense was primarily attributable to a reduction in payroll expenses resulting from decreased headcount, rent and exit costs incurred in 2016. At the beginning of 2016, our strategy shifted away from commercialization of medical devices towards focusing exclusively on development of our pharmaceutical and microcatheter candidates.

*Research and Development Expenses:* R&D expenses for the year ended December 31, 2017, were \$2,328,087, an increase of \$1,557,660, or 202% from R&D expenses in 2016 of \$770,427. The increase in R&D expenses is attributed to salaries, manufacturing, and clinical trial expenses associated with our Endoxifen program for which manufacturing commenced at the beginning of 2017 and the clinical studies commenced in mid-2017. We expect our R&D expenses to increase throughout 2018 as we commence Phase 2 clinical studies of Endoxifen, continue the clinical trial of fulvestrant administered via our microcatheters and as we continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal microcatheters.



*Impairment of Intangible Assets:* During the years ended December 31, 2017 and 2016, we evaluated our Acueity intangible assets for impairment and concluded that the fair values as of December 31, 2017 and 2016, were below the carrying values of \$461,715 and \$1,237,970, respectively. Therefore, we reduced the carrying value of these assets to their fair value of zero and \$519,000, as of December 31, 2017 and 2016, respectively.

*Warrant Financing Costs and Change in Fair Value of Common Stock Warrants:* The April 2017 financing included the issuance of common stock liability warrants. The Company incurred financing costs associated with these common stock liability warrants of \$192,817 upon issuance. The Company also recorded changes in the fair value of the liability warrants during the year ended December 31, 2017 of \$280,747. There were no common stock liability warrants issued during the year ended December 31, 2016.

*Other Income (Expense):* In August 2016, the Company received a termination payment of \$1,762,931 pursuant to the settlement agreement with Besins Healthcare Luxembourg SARL. There were no settlement payments received by the Company for the year ended December 31, 2017.

*Income taxes:* We have incurred net operating losses from inception; we did not record an income tax benefit for our incurred losses for the years ended December 31, 2017 and 2016 due to uncertainty regarding utilization of our net operating carryforwards and due to our history of losses.

## **Liquidity and Capital Resources**

We have a history of operating losses as we have focused our efforts on raising capital and building our products and services in our pipeline. The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2017, the Company recorded a net loss of approximately \$8.1 million, and used approximately \$6.6 million of cash in operating activities. As of December 31, 2017, the Company had approximately \$7.2 million in cash and cash equivalents and working capital of approximately \$6.7 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. 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. 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 financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying 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.



During the first quarter of 2016, we sold 405,747 shares of common stock to Aspire Capital under the November 2015 agreement with them for aggregate gross proceeds to us of \$2.2 million, or net proceeds of \$2.1 million after deducting costs of the offering. On May 25, 2016 we entered into a new common stock purchase agreement with Aspire Capital which provides that we may sell up to \$10 million in common stock to Aspire Capital over the 30 month term of the agreement, subject to the terms and conditions set out in the stock purchase agreement, none of which have been sold as of the date of filing this report with the SEC.

On August 4, 2016, we entered into a settlement agreement with Besins Healthcare pursuant to which Besins paid us a total of approximately \$1,762,931. See “Part I, Item 3 Legal Proceedings.”

In August 2016, we completed an underwritten public offering of 1,150,000 shares of common stock at a price per share of \$2.50, with gross proceeds to us of \$2.9 million, or proceeds of \$2.6 million after deducting underwriter discounts, commissions, non-accountable expense allowance and expense reimbursement.

On April 3, 2017 we completed an underwritten public offering that generated gross proceeds to the Company of approximately \$4.4 million and net proceeds of approximately \$3.9 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

The offering included 664,000 Class A Units at a public offering price of \$0.75 per Class A Unit, which consisted of 664,000 shares of common stock and warrants to purchase 664,000 shares of common stock. The offering also included 3,502 Class B Units at a public offering price of \$1,000 per Class B Unit, which consisted of 3,502 shares of Series A convertible preferred stock convertible into a total of 4,669,329 shares of common stock and warrants to purchase 4,669,329 shares of common stock. In addition, the underwriter exercised the over-allotment to purchase an additional 530,000 shares of common stock and warrants to purchase 530,000 shares of common stock, which are included in the gross proceeds of \$4.4 million. The warrants had a per share exercise price of \$0.9375, were exercisable immediately and were scheduled to expire five years from the date of issuance. All of these warrants were exercised, and all of the preferred stock was converted into common stock, in 2017.

On October 30, 2017, the Company completed an underwritten public offering that generated gross proceeds to the Company of approximately \$5.5 million and net proceeds of \$4.9 million after deducting underwriting discounts, commissions and other offering costs paid by the Company.

On December 22, 2017, the Company completed a public offering of 5,300,000 shares of Company common stock at a public offering price of \$0.27 per share. The offering generated gross proceeds to the Company of approximately \$1.4 million and net proceeds of \$1.2 million after deducting underwriting discounts, commissions, and other offering costs paid by the Company.

Concurrently with the December 22, 2017 public offering, the Company also commenced a private placement whereby it issued and sold Class A and Class B Warrants, exercisable for an aggregate of 10,600,000 shares of common stock, at an exercise price of \$0.315 per share. The public offering and the private placement involve the same purchasers. The Class A and Class B Warrants exercise price is fixed at \$0.315 per warrant, and will become exercisable commencing six months from issuance. The Class A Warrants will expire eight months from issuance, while the Class B Warrants will expire on the first anniversary of the date of issuance. Other than the different expiration dates, the Class A Warrants and Class B Warrants have identical terms. None of the Class A Warrants, the Class B Warrants nor the shares issuable upon exercise of such Warrants have been registered with the Securities and Exchange Commission; however, the Company intends to register the shares issuable upon exercise of these warrants prior to the date they become exercisable.

As of the date of filing this annual report, we expect that our existing resources will be sufficient to fund our planned operations for the next 6-8 months; however, additional capital resources will be needed to fund operations longer-term.

Our ability to continue as a going concern is dependent on our obtaining additional adequate capital to fund additional operating losses until we become profitable. If we are unable to obtain adequate capital, we could be forced to cease operations.

### **Cash Flows**

As of December 31, 2017, we had cash and cash equivalents of \$7.2 million.

*Net Cash Flows from Operating Activities:* Net cash used in operating activities was \$6,593,950 for the year ended December 31, 2017, an increase of \$1,219,361, or 22.7%, compared to net cash used in operating activities for the year ended December 31, 2016 of \$5,374,589. The increase in the 2017 period as compared to 2016 resulted primarily from increased spending on R&D activities. We spent approximately \$2.3 million on research and development for the year ended December 31, 2017, compared to \$770,000 for the same period in 2016; this increase was offset by reductions in compensation expense from reduced headcount, reduced occupancy expense, reduced consulting fees, and from severance payments in 2016 that were not incurred in 2017. The year ended December 31, 2016 also included \$1.6 million in other income due to a litigation settlement as compared to \$154 in other income for the year ended December 31, 2017.

*Net Cash Flows from Investing Activities:* Net cash used in investing activities for the year ended December 31, 2017 was zero, a decrease of \$9,213, compared to net cash used in investing activities for the year ended December 31, 2016 of \$9,213. The decrease was attributable to the reduction in purchases of fixed asset equipment in 2017 as compared to 2016.

*Net Cash Flows from Financing Activities:* Net cash provided by financing activities was \$10,783,457 for the year ended December 31, 2017, an increase of \$6,087,588, or 129.6%, compared to net cash provided by financing activities of \$4,695,869, for the year ended December 31, 2016. The increase is mainly attributed to the Company completing three financings in 2017 as opposed to two financings in 2016. During 2017, we raised \$3,871,636 from the issuance of Class A and Class B units, and \$749,233 from the exercise of warrants that were attached to those units. The remaining increase was attributable to proceeds received from the issuance of common stock in excess of the prior year financings.

## **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 existing resources will be sufficient to fund our planned operations for at least the next 6-8 months from the date of this report. In addition to our cash and cash equivalents at December 31, 2017 of approximately \$7.2 million, 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. 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.

### **Recent Accounting Pronouncements**

In February 2016, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Lease Accounting Topic 842*. This ASU requires a lessee to recognize lease assets and liabilities on the balance sheet for all arrangements with terms longer than 12 months. The new standard applies a right-of-use (ROU) model that requires a lessee to record, for all leases with a lease term of more than 12 months, an asset representing its right to use the underlying asset for the lease term and a liability to make lease payments. The lease term is the non-cancellable period of the lease, and includes both periods covered by an option to extend the lease, if the lessee is reasonably certain to exercise that option, and periods covered by an option to terminate the lease, if the lessee is reasonably certain not to exercise that termination option. For leases with a lease term of 12 months or less, a practical expedient is available whereby a lessee may elect, by class of underlying asset, not to recognize an ROU asset or lease liability. A lessee making this accounting policy election would recognize lease expense over the term of the lease, generally in a straight-line pattern. The lessor accounting remains largely consistent with existing U.S. GAAP. The new standard takes effect in 2019 for public business entities. The Company has not adopted the provisions of ASU No. 2016-02. The Company is currently evaluating the impact of adopting ASU 2016-02 on its consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation*, simplifying the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities and classification on the statements of cash flows. Under the new standard, all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) should be recognized as income tax expense or benefit on the statements of income. We adopted ASU No. 2016-09 effective January 1, 2017. As a result of the adoption of this guidance, we made an accounting policy election to recognize the effect of forfeitures in compensation cost when they occur. There was an immaterial impact on results of operations and financial position and no impact on cash flows at adoption.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, amending the presentation of restricted cash within the statement of cash flows. The new guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The ASU is effective retrospectively for reporting periods beginning after December 15, 2017, with early adoption permitted. The Company has not yet adopted the provisions

of ASU No. 2016-18 and does not expect it will have a material impact on the financial statements upon adoption.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of future equity offerings. Current accounting guidance requires financial instruments with down round features to be accounted for at fair value. Part II of the Update applies only to nonpublic companies and is therefore not applicable to the Company. The amendments in Part I of the Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. This Update is effective for public entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company has not yet determined when it will adopt the provisions of this Update and has not yet determined the impact on its consolidated financial statements upon adoption.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by this item are set forth beginning on page 60 of this report and are incorporated herein by reference.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Conclusion Regarding the Effectiveness of Disclosure 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 December 31, 2017. 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 December 31, 2017, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

A change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) has occurred during the year ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect our disclosure controls and procedures. The changes to our internal control over financial reporting were made to remediate the material weaknesses identified during the year ended December 31, 2016 and are described in Management's Report on Internal Control Over Financial Reporting.

For the year ended December 31, 2016, we identified a material weakness in that we did not design and maintain effective controls over the preparation of the 2016 impairment analysis of the Acueity patents described below in Management's Report on Internal Control Over Financial Reporting.



For the year ended December 31, 2016, we also identified a material weakness in that we did not design and maintain effective controls over the calculation of the weighted average number of shares outstanding and basic and diluted loss per share for the year ended December 31, 2016 described below in Management's Report on Internal Control Over Financial Reporting.

### **Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2017. Because we are a smaller reporting company, BDO USA LLP, our independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In 2016, we identified a material weakness in that we did not design and maintain effective controls over the preparation of the 2016 impairment analysis of the Acueity patents, primarily because we did not include potential income taxes in the discounted cash flow model we used to estimate the fair value of the Acueity patents at December 31, 2016. Management's remediation plan was to use appropriate valuation methodologies in future analyses that may be required to determine the fair value of these intangible assets and to seek the assistance of outside valuation resources in performing such analyses. Management also implemented a control whereby the Controller and CFO perform a detailed review of the assumptions used in the calculation prepared by the outside valuation resource. During the year ended December 31, 2017 we hired an outside valuation specialist to perform the impairment analysis of the Acueity patents and the Controller and CFO performed a detailed review of the analysis and the assumptions used in estimating the fair value. Management considers this material weakness remediated as the control operated effectively during the year ended December 31, 2017.

We also identified a material weakness in 2016 in that we did not design and maintain effective controls over the calculation of the weighted average number of shares outstanding and basic and diluted loss per share for the year ended December 31, 2016. During 2017, management enhanced the procedures performed to prepare the calculation of weighted average shares outstanding and loss per share in future periods, which included the use of a new template to support the calculation. The Company also hired a new Controller in 2017 which increased the level of competency and the level of precision in the design of the work performed. Management's remediation plan also included implementing a control to have the calculation independently reviewed by the CFO. Our enhanced review procedures and documentation standards were in place during the year ended December 31, 2017. Management considers this

material weakness remediated as of December 31, 2017 as the control has operated effectively for a sufficient period of time.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information regarding our executive officers is set forth in Item 1 of Part 1 of this Report under the caption “Executive Officers.”

The information required by this item is incorporated herein by reference to the sections entitled “Proposal No. 1 — Election of Directors,” “Beneficial Owners and Management,” “Section 16(a) Beneficial Ownership Reporting Compliance,” “Director Compensation,” “Corporate Governance” and “Board of Directors and Committees” in our definitive Proxy Statement for the Annual Meeting of Shareholders to be held on April 12, 2018 (the “Proxy Statement”).

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to the sections entitled “Executive Compensation,” “Director Compensation,” “Proposal No. 3 — To increase the number of shares authorized for issuance under the Atossa Genetics 2010 Stock Option and Incentive Plan,” and “Corporate Governance”, in the Proxy Statement.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS**

The information required by this item is incorporated by reference to the sections entitled “Equity Compensation Plan Information” and “Beneficial Owners and Management” in the Proxy Statement.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item is incorporated by reference to the section entitled “Certain Relationships and Related Party Transactions” and “Corporate Governance” in the Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by reference to the sections entitled “Proposal No. 2 — Ratification of Selection of Independent Registered Public Accounting Firm” in the Proxy Statement.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as a part of this 10-K:

**1. Financial Statements**

The following financial statements are included in Part II, Item 8 of this 10-K:

Report of Independent Registered Public Accounting Firm	59
Consolidated Balance Sheets	60
Consolidated Statements of Operations	61
Consolidated Statements of Stockholders' Equity	62
Consolidated Statements of Cash Flows	63
Notes to Consolidated Financial Statements	64

**2. Financial Statement Schedules**

All financial statement schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

**3.Exhibits**

See the Exhibit Index set forth on page 86 of this report.

**ITEM 16. FORM 10-K SUMMARY**

Not applicable.

57

**ATOSSA GENETICS INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Audited Consolidated Financial Statements:

<u>Report of Independent Registered Public Accounting Firm</u>	<u>59</u>
<u>Consolidated Balance Sheets</u>	<u>60</u>
<u>Consolidated Statements of Operations</u>	<u>61</u>
<u>Consolidated Statements of Stockholders' Equity</u>	<u>62</u>
<u>Consolidated Statements of Cash Flows</u>	<u>63</u>
<u>Notes to Consolidated Financial Statements</u>	<u>64</u>

## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders

Atossa Genetics Inc.

Seattle, Washington

### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Atossa Genetics Inc. (the “Company”) as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

### **Going Concern Uncertainty**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2014.

Seattle, Washington

March 8, 2018



**ATOSSA GENETICS INC.****CONSOLIDATED BALANCE SHEETS**

	As of December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	\$7,217,469	\$3,027,962
Restricted cash	55,000	55,000
Prepaid expenses	250,944	171,601
Research and development tax rebate receivable	358,277	
Other current assets	16,344	
Total current assets	7,898,034	3,254,563
Furniture and equipment, net	11,467	55,119
Intangible assets, net	75,686	640,440
Other assets	178,907	194,250
Total assets	\$8,164,094	\$4,144,372
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$334,901	\$254,320
Accrued expenses	90,105	16,964
Payroll liabilities	784,867	769,899
Other current liabilities	15,534	6,083
Total current liabilities	1,225,407	1,047,266
Commitments and contingencies (note 15)		
Stockholders' equity		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, no shares issued and outstanding		
Common stock - \$.015 par value; 75,000,000 shares authorized, 31,822,741 and 3,786,913 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	477,342	56,804
Additional paid-in capital	71,887,674	60,344,050
Accumulated deficit	(65,426,329)	(57,303,748)
Total stockholders' equity	6,938,687	3,097,106
Total liabilities and stockholders' equity	\$8,164,094	\$4,144,372

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



**ATOSSA GENETICS INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>For the Years Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Operating expenses:		
Research and development expenses	\$ 2,328,087	\$ 770,427
General and administrative expenses	4,859,369	6,479,193
Impairment of intangible assets	461,715	718,970
Total operating expenses	7,649,171	7,968,590
Operating loss	(7,649,171 )	(7,968,590 )
Change in fair value of common stock warrants	(280,747)	
Warrant financing expense	(192,817)	
Other income, net	154	1,599,705
Loss before income taxes	(8,122,581 )	(6,368,885 )
Income taxes		
Net loss	(8,122,581 )	(6,368,885 )
Deemed dividend attributable to Series A preferred stock	(2,568,132 )	
Net loss attributable to common stockholders	\$ (10,690,713 )	\$ (6,368,885 )
Loss per common share - basic and diluted	\$ (0.91 )	\$ (2.16 )
Weighted average shares outstanding, basic and diluted	11,697,273	2,947,282

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

## ATOSSA GENETICS INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series A Convertible Preferred Stock		Common Stock		Additional		Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Paid-in Capital	Accumulated Deficit	
Balance at December 31, 2015			2,177,151	\$32,657	\$54,643,940	\$(50,934,863)	\$3,741,734
Issuance of common shares (net of issuance costs of \$356,214)			1,561,080	23,417	4,672,452		4,695,869
Issuance of common shares as commitment fees			49,736	746	197,777		198,523
Amortization of commitment shares					(42,864)		(42,864)
Settlement of fractional shares			(1,054)	(16)	(3,444)		(3,460)
Compensation cost for stock options granted to executives and employees					876,189		876,189
Net loss						(6,368,885)	(6,368,885)
Balance at December 31, 2016			3,786,913	56,804	60,344,050	(57,303,748)	3,097,106
Issuance of common stock and warrants net of issuance costs of \$768,412			17,800,000	267,001	5,895,587		6,162,588
Issuance of common stock			1,194,000	17,910	811,774		829,684

in Class A units, net of issuance costs of \$65,816								
Allocation of Class A unit proceeds to warrant liability						(328,350 )		(328,350 )
Issuance of Series A convertible preferred stock in Class B units, net of issuance costs of \$267,231	3,502	4	3,234,769					3,234,773
Allocation of Series A convertible preferred stock to warrants and beneficial conversion feature			(2,568,132)			1,284,066		(1,284,066 )
Deemed dividend on Series A convertible preferred stock			2,568,132			(2,568,132 )		
Conversion of Series A convertible preferred stock to common stock	(3,502 )	(4 )	(3,234,769)	4,669,329	70,040		3,164,733	
Reclassification of warrant liability upon exercise of common stock warrants				1,490,833	22,362		1,870,798	1,893,160
Issuance of common stock upon warrant exercise for cash on liability warrant exercise				2,881,666	43,225		706,008	749,233
Amortization of commitment shares						(79,410 )		(79,410 )
Compensation cost for stock						786,550		786,550

options granted to executives and employees					
Net loss				(8,122,581 )	(8,122,581 )
Balance at December 31, 2017	31,822,741	\$477,342	\$71,887,674	\$(65,426,329)	\$6,938,687

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

## ATOSSA GENETICS INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	<b>For the Years Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (8,122,581	) \$ (6,368,885
Adjustments to reconcile net loss to net cash used in operating activities:		
Compensation cost for stock options granted	786,550	876,189
Loss on disposal of assets	17,695	163,333
Impairment of intangible assets	461,715	718,970
Change in fair value of common stock warrants	280,747	
Warrant financing expense	192,817	
Depreciation and amortization	128,994	303,482
Changes in operating assets and liabilities:		
Restricted cash		220,000
Other assets	(80,408	) 144,951
Prepaid expenses	(79,343	) 21,692
Research and development tax rebate receivable	(358,277	)
Accounts payable	80,581	(560,128
Payroll liabilities	14,968	(389,436
Accrued expenses	73,141	(446,712
Other current liabilities	9,451	(58,045
Net cash used in operating activities	(6,593,950	) (5,374,589
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of furniture and equipment		(9,213
Net cash used in investing activities		(9,213
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net proceeds from issuance of Class A and Class B Units	3,871,636	
Proceeds from warrant exercises	749,233	
Net proceeds from issuance of common stock and warrants	6,162,588	4,695,869
Net cash provided by financing activities	10,783,457	4,695,869
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	4,189,507	(687,933
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR</b>	3,027,962	3,715,895
<b>CASH AND CASH EQUIVALENTS, ENDING OF YEAR</b>	\$ 7,217,469	\$ 3,027,962
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Interest paid	\$ 330	\$
<b>NONCASH INVESTING AND FINANCING ACTIVITIES</b>		
Amortization of commitment shares	\$ 79,410	\$ 42,864

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



## **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’s consolidated financial statements are prepared using Generally Accepted Accounting Principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2017, the Company recorded a net loss of approximately \$8.1 million and used approximately \$6.6 million of cash in operating activities. As of December 31, 2017, the Company had approximately \$7.2 million in cash and cash equivalents and working capital of approximately \$6.7 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. 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. 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, it could be forced to cease operations or substantially curtail its activities. These conditions 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.

Management’s plan to continue as a going concern is as follows. In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management’s plans to obtain such resources for the Company include obtaining capital from the sale of its equity securities, potential exercise of outstanding warrants, and short-term borrowings from banks, stockholders or other related party(ies), if needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

As of the date of filing this report, we expect that our existing resources will be sufficient to fund our planned operations for the next 6-8 months; however, additional capital resources will be needed to fund operations longer-term.

The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish the plans described in the preceding paragraphs and eventually to secure other sources of financing and attain profitable operations.

### **NOTE 3: SUMMARY OF ACCOUNTING POLICIES**

#### **Basis of Presentation:**

The accompanying consolidated financial statements have been prepared pursuant to the rules of the Securities and Exchange Commission (“SEC”) and in accordance with U.S. generally accepted accounting principles (“GAAP”). The accompanying consolidated financial statements include the financial statements of Atossa Genetics Inc. and its wholly-owned subsidiaries. All significant intercompany account balances and transactions have been eliminated in consolidation. Certain amounts from prior years have been reclassified to conform to the 2017 presentation.

On August 26, 2016, the Company completed a 1-for-15 reverse stock split of the shares of the Company’s common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, every 15 shares of issued and outstanding common stock were combined into one issued and outstanding share of common stock, and the par value per share was changed to \$0.015 per share. No fractional shares were issued because of the Reverse Stock Split and any fractional shares that would otherwise have resulted from the Reverse Stock Split were paid in cash. As a result of the Reverse Stock Split, fractional shares totaling approximately 1,054 shares of common stock were rounded down and paid in cash. The number of authorized shares of common stock was not reduced as a result of the Reverse Stock Split. The Company’s common stock began trading on a reverse stock split-adjusted basis on August 26, 2016. All share and per share data included in this report has been retroactively restated to reflect the Reverse Stock Split.

#### **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 Issued Accounting Pronouncements:**

In February 2016, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Lease Accounting Topic 842*. This ASU requires a lessee to recognize lease assets and liabilities on the balance sheet for all arrangements with terms longer than 12 months. The new standard applies a right-of-use (ROU) model that requires a lessee to record, for all leases with a lease term of more than 12 months, an asset representing its

right to use the underlying asset for the lease term and a liability to make lease payments. The lease term is the non-cancellable period of the lease, and includes both periods covered by an option to extend the lease, if the lessee is reasonably certain to exercise that option, and periods covered by an option to terminate the lease, if the lessee is reasonably certain not to exercise that termination option. For leases with a lease term of 12 months or less, a practical expedient is available whereby a lessee may elect, by class of underlying asset, not to recognize an ROU asset or lease liability. A lessee making this accounting policy election would recognize lease expense over the term of the lease, generally in a straight-line pattern. The lessor accounting remains largely consistent with existing U.S. GAAP. The new standard takes effect in 2019 for public business entities. The Company has not adopted the provisions of ASU No. 2016-02 and is currently evaluating the impact of adopting ASU 2016-02 on its consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation*, simplifying the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities and classification on the statements of cash flows. Under the new standard, all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) should be recognized as income tax expense or benefit on the statements of income. We adopted ASU No. 2016-09 effective January 1, 2017. As a result of the adoption of this guidance, we made an accounting policy election to recognize the effect of forfeitures in compensation cost when they occur. There was an immaterial impact on results of operations and financial position and no impact on cash flows at adoption.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, amending the presentation of restricted cash within the statement of cash flows. The new guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The ASU is effective retrospectively for reporting periods beginning after December 15, 2017, with early adoption permitted. The Company has not yet adopted the provisions of ASU No. 2016-18 and does not expect it will have a material impact on the financial statements upon adoption.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of future equity offerings. Current accounting guidance requires financial instruments with down round features to be accounted for at fair value. Part II of the Update applies only to nonpublic companies and is therefore not applicable to the Company. The amendments in Part I of the Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. This Update is effective for public entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company has not yet determined when it will adopt the provisions of this Update and has not yet determined the impact on its consolidated financial statements upon adoption.

### ***Research and Development***

All research and development costs are expensed as incurred.

### ***Income Taxes***

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

### ***Cash and Cash Equivalents***

Cash and cash equivalents include cash and all highly liquid instruments with original maturities of three months or less.

### ***Furniture and Equipment***

Furniture and equipment are stated at cost less accumulated depreciation. Expenditures for maintenance and repairs are charged to earnings as incurred; additions, renewals and betterments are capitalized. When furniture and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation are removed from the respective accounts, and any gain or loss is included in operations.

Depreciation is computed using the straight-line method over the estimated useful lives of the assets as follows:

	Useful Life (in years)
Furniture and equipment	3 - 5

The Company applies the provisions of FASB ASC Topic 360 (“ASC 360”), *Property, Plant, and Equipment*, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The Company periodically evaluates the carrying value of long-lived assets to be held and used in accordance with ASC 360. ASC 360 requires the impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets’ carrying amounts. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair market value of the long-lived assets. Loss on long-lived assets to be disposed of is determined in a similar manner, except that fair market values are reduced for the cost of disposal. For the years ended December 31, 2017 and 2016, no impairment of property and equipment was recorded.

### *Fair Value Measurements*

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

### *Intangible Assets*

Intangible assets consist of intellectual property and software acquired. Intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. Impairment losses must be recorded when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amounts. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair market value of the assets. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

We continuously evaluate and reprioritize our research and development pipeline. Based on the most recent business strategies, we do not currently intend to develop and invest further in the Acueity patents and technologies and we now believe that additional investment may be required to update FDA marketing authorizations prior to commercializing the Acueity assets. Because of these changed business plans related to the Acueity assets, we have re-evaluated the assets for potential impairment during the year ended December 31, 2017. We have concluded that these assets are impaired and have recorded an asset impairment charge of \$461,715 for the year ended December 31, 2017 to adjust the carrying value of these intangible assets to their estimated fair values to zero as of December 31, 2017. We concluded the patents were partially impaired and recorded impairment charges of \$718,970 for the year ended December 31, 2016 to adjust the carrying value of the these intangible assets to their estimated fair values at December 31, 2016.

We determined the fair values of the Acueity intangibles using an income approach (Level 3 of the fair value hierarchy). For purposes of the income approach, fair value was determined based on the present value of estimated future cash flows that a market participant could expect to generate from the development of products using the



patented technology acquired in the Acueity transaction, discounted at an appropriate risk-adjusted rate reflecting the weighted average cost of capital for a potential market participant. The discount rate used in valuation for these intangible assets was 48.50%. The estimated future cash flows, including an estimate of long-term future growth rates, reflect our own assumptions of what market participants would utilize to price the assets pursuant to ASC 820, *Fair Value Measurements*.

Amortization is computed using the straight-line method over the estimate useful lives of the assets as follows:

	Useful Life (in years)
Patents	10
Software	3

### ***Financial Instruments with Characteristics of Both Liabilities and Equity***

During the year ended December 31, 2017, the Company issued certain financial instruments, consisting of warrants to purchase common stock, which have characteristics of both liability and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured at fair value at subsequent reporting periods with the resulting change in fair value recorded in “change in fair value of common stock warrants” in the consolidated statement of operations. The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature. There were no outstanding warrants accounted for as liabilities as of December 31, 2017.

### ***Share-Based Payments***

The Company follows the provisions of ASC Topic 718, *Compensation - Stock Compensation* (“ASC 718”), 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 fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

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

We adopted ASU No. 2016-09 *Compensation - Stock Compensation*, effective January 1, 2017. As a result of the adoption of this guidance, we made an accounting policy election to recognize the effect of forfeitures in compensation cost when they occur. There was an immaterial impact on results of operations and financial position and no impact on cash flows at adoption.

**NOTE 4: RESTRICTED CASH**

Our restricted cash balance of \$55,000 as of December 31, 2017 and 2016, 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:

	December 31, 2017	December 31, 2016
Prepaid insurance	\$ 125,056	\$ 121,333
Tradeshows		20,000
Professional services	97,788	
Retainer and security deposits	14,218	14,218
Other	13,882	16,050
Total prepaid expenses	\$ 250,944	\$ 171,601

**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 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 period May 23, 2017 to December 31, 2017, the Company incurred qualified R&D expenses of approximately \$824,000. For the year ended December 31, 2017, we have recorded an R&D rebate receivable of \$358,277 and a corresponding offset to R&D expenses in the same amount.

**NOTE 7: FURNITURE AND EQUIPMENT**

Furniture and equipment consisted of the following:

	December 31, 2017	December 31, 2016
Furniture and equipment	170,917	210,528
Less: accumulated depreciation	(159,450 )	(155,409 )
Total furniture and equipment, net	\$ 11,467	\$ 55,119

Depreciation expense for the years ended December 31, 2017 and 2016 was \$25,956 and \$125,661, respectively.

**NOTE 8: INTANGIBLE ASSETS**

Intangible assets consisted of the following:

	December 31, 2017	December 31, 2016
Patents	\$ 120,000	\$ 639,000
Software	113,540	113,540
Intangible assets	233,540	752,540
Less: accumulated amortization	(157,854 )	(112,100 )
Total intangible assets, net	\$ 75,686	\$ 640,440

Intangible assets amounted to \$75,686 and \$640,440 as of December 31, 2017, and December 31, 2016, respectively, and consisted of patents and software acquired. The amortization period for the purchased software is three years. Amortization expense related to software for the years ended December 31, 2017 and 2016 was \$32,754 and \$28,806, respectively.

Patent assets are amortized based on their determined useful life. We continuously evaluate and reprioritize our research and development pipeline based on the most recent business strategies, and as a result have delayed plans to develop and invest further in Acueity patents and technologies. In 2017 and 2016, we evaluated the Acueity assets and determined that the assets were impaired for the years ended December 31, 2017 and 2016 and we reduced the net carrying value of the patents by \$461,715 and \$718,970.

The amortization period of the remaining patents is 10 years. Amortization expense related to patents was \$70,284 and \$149,015 for the years ended December 31, 2017 and 2016, respectively.

Future estimated amortization expenses as of December 31, 2017, for the five succeeding years and thereafter is as follows:

Years Ending December 31,	Amounts
2018	\$25,353
2019	13,000
2020	13,000
2021	13,000
2022	11,333
	\$75,686

#### **NOTE 9: PAYROLL LIABILITIES**

Payroll liabilities consisted of the following:

	December 31, 2017	December 31, 2016
Accrued bonus payable	\$ 566,000	\$ 609,337
Accrued vacation	147,861	94,514
Accrued payroll liabilities	71,006	66,048
Total payroll liabilities	\$ 784,867	\$ 769,899

#### **NOTE 10: FAIR VALUE OF FINANCIAL INSTRUMENTS**

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

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

*Level 1* —Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by us at the reporting date.

*Level 2* —Valuations based on inputs other than the quoted prices in active markets that are observable either directly or indirectly in active markets.

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

There were no financial assets outstanding that were required to be measured at fair value on a recurring basis at December 31, 2017 or December 31, 2016.

Warrants issued in the April 3, 2017 offering, which are discussed further in Note 11, contained provisions that could have required the Company to settle the warrants in cash in an event outside the Company's control or had price protection rights and were therefore accounted for as liabilities while they were outstanding, with changes in the fair values included in net loss for the respective periods. Because some of the inputs to the valuation model were either not observable or were not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability was classified as Level 3 in the fair value hierarchy.

The following table summarizes the changes in the Company's Level 3 warrant liability for the year ended December 31, 2017:

Warrant liability	
Beginning balance	\$
Issuances of warrants	1,612,413
Warrant exercises	(1,893,160)
Change in fair value	280,747
Ending balance	\$

The Company's intangible assets are classified within Level 3 of the fair value hierarchy, measured at fair value on a nonrecurring basis. Refer to Note 3 for further discussion.

There were no transfers between Level 1, Level 2 or Level 3 for the years ended December 31, 2017 or December 31, 2016.

**NOTE 11: STOCKHOLDERS' EQUITY**



The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of common stock, par value \$0.015 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, and 4,000 shares of Series A convertible preferred stock, through the filing of a certificate of designation with the Delaware Secretary of State, none of which are issued and outstanding as of December 31, 2017.

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

### 2016 Issuances of Additional Shares to Aspire Capital

On November 11, 2015, we terminated our prior agreement with Aspire Capital Fund, LLC (“Aspire Capital”) and entered into a new common stock purchase agreement. Concurrently with entering into the new purchase agreement, we also entered into a registration rights agreement with Aspire Capital in which we agreed to register 405,747 shares of our common stock.

During the first quarter of 2016, we sold a total of 405,747 shares of common stock to Aspire Capital under the stock purchase agreement dated November 11, 2015 with aggregate gross proceeds to the Company of \$2.2 million, or net proceeds of \$2.1 million after deducting costs of the offering.

On May 25, 2016, the Company terminated the November 11, 2015 stock purchase agreement with Aspire Capital and entered into a new common stock purchase agreement with Aspire Capital which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$10.0 million of shares of our common stock over the 30-month term of the purchase agreement, subject to the terms and conditions set forth therein. Concurrently with entering into the purchase agreement, the Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the purchase agreement. As part of the stock purchase agreement we issued 49,736 common shares as a commitment fee. The value of the common shares issued as a commitment fee of \$198,523 has been reflected as an addition to common stock and additional paid in capital of \$746 and \$197,777, respectively, which is amortized over the life of the stock purchase agreement. As of the date of filing this Annual Report with the SEC no shares of stock have been sold to Aspire Capital under the May 25, 2016 purchase agreement. As of December 31, 2017, 467,650 shares are available for sale to Aspire Capital under the May 25, 2016 purchase agreement.

### 2016 Public Offering of Common Stock

In August 2016, the Company completed an underwritten public offering of 1,150,000 shares of common stock at a price per share of \$2.50, with gross proceeds of \$2.9 million to the Company, or net proceeds of \$2.6 million after deducting underwriter discounts, commissions, non-accountable expense allowance and expense reimbursement.

### 2017 Public Offering of Class A and Class B Units Consisting of Common Stock, Series A Convertible Preferred Stock and Warrants

On March 28, 2017, the Company entered into an underwriting agreement with Aegis Capital Corp. relating to a public offering which closed on April 3, 2017. The offering generated gross proceeds to the Company of approximately \$4.4 million and net proceeds of approximately \$3.9 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

The offering included 664,000 Class A Units at a public offering price of \$0.75 per Class A Unit, which consisted of 664,000 shares of common stock and warrants to purchase 664,000 shares of common stock. The offering also included 3,502 Class B Units at a public offering price of \$1,000 per Class B Unit, which consisted of 3,502 shares of Series A convertible preferred stock convertible into a total of 4,669,329 shares of common stock and warrants to purchase 4,669,329 shares of common stock. In addition, the underwriter exercised the over-allotment to purchase an additional 530,000 shares of common stock and warrants to purchase 530,000 shares of common stock, which are included in the gross proceeds of \$4.4 million. The warrants had a per share exercise price of \$0.9375, were exercisable immediately and were scheduled to expire five years from the date of issuance.

As of December 31, 2017, all of the warrants issued in the April 3, 2017 offering have been exercised and are no longer outstanding and all of the shares of Series A convertible preferred stock have been converted into shares of common stock.

### *Accounting Treatment*

The Company allocated the proceeds from the sale of the Class A and Class B units to the separate securities issued. The Company determined that, on the date of issuance, the warrants were not considered indexed to its own stock because the underlying instruments were not “fixed-for-fixed” due to the price protection and fundamental transaction provisions and, therefore, the warrants should be accounted for as liabilities. At the end of each reporting period, the changes in fair value of the warrants during the period were recorded in non-operating income (expense) in the consolidated statement of operations.

The Company allocated the amount representing the fair value of the warrants at the date of issuance separately to the warrant liability and recorded the remaining proceeds as common stock, in the case of the Class A units, or as Series A convertible preferred stock, in the case of the Class B units. Due to the allocation of a portion of the proceeds to the warrants, the Series A convertible preferred stock contained a beneficial conversion feature upon issuance, which was recorded in the amount of \$1,284,066 based on the intrinsic value of the beneficial conversion feature. The discount on the Series A convertible preferred stock of \$1,284,066 caused by allocation of the proceeds to the warrant was recorded as a deemed dividend upon issuance of the Series A convertible preferred stock. As a result, total deemed dividends of \$2,568,132 were recorded upon issuance of the Series A convertible preferred stock, which is reflected as an addition to net loss in the consolidated statement of operations to arrive at net loss applicable to common shareholders.

*Exercise of 2017 Warrants*

On June 29, 2017, the Company offered to modify the rights of the holders of the warrants issued in the public offering the Company completed on April 3, 2017. The temporary modification included (a) lowering the exercise price of the warrants to \$0.26 per share, (b) setting the applicable volume-weighted average price (VWAP) at \$0.52 per share, and (c) allowing for temporary cashless exercise of the warrants for all holders that accepted the temporary modification before 8:00 a.m. Eastern daylight time on June 30, 2017. Holders of warrants to purchase a total of approximately 3.0 million shares of common stock accepted the offer resulting in the cancellation of those warrants and the issuance by the Company of a total of approximately 1.5 million shares of common stock (including shares held in abeyance). The shares of common stock are registered under the Securities Act of 1933, as amended. If delivery of the shares of common stock pursuant to the foregoing would result in the holder exceeding the 4.99% “Beneficial Ownership Limitation” (as defined in the warrant) then the shares in excess of such 4.99% will be held in abeyance by the Company pending further instruction from the holder. In connection with the temporary modification, the Company agreed to extend the “Lock-up Period” of the underwriting agreement between the Company and Aegis Capital Corp., dated March 28, 2017, by 45 days and the Company agreed not to enter into any further amendments to the warrants during such extended Lock-up Period without the prior written consent of each holder. During the third quarter of 2017, all remaining warrants were exercised for cash so that no warrants issued in the April 3, 2017 financing remained outstanding. Upon exercise of these warrants, the amount of the warrant liability at the date of exercise was reclassified from warrant liability to additional paid-in capital.

The following table summarizes the 2017 liability warrant activity:

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding as of December 31, 2016		
Warrants granted	5,863,332	\$ 0.9375
Warrants exercised	(5,863,332)	0.26
Outstanding as of December 31, 2017		\$

The Company estimated the fair value of the warrants using the Monte Carlo simulation (MCS) model, which is a type of income approach, where the current value of an asset is expressed as the sum of probable future cash flows across various scenarios and time frames discounted for risk and time. The significant assumptions include timing of future rounds of financing, timing and success rates of oncology clinical trials, and the probability of a merger and acquisition adjusted for a lack of marketability discount. The MCS model also includes a full term and an early conversion scenario that are each weighted at 50% in the final concluded fair value.

Inputs used in the valuation of the warrants at the issuance date of April 3, 2017 and June 30, 2017 are set forth below. All remaining warrants were exercised and no warrants issued in the April 2017 financing remained outstanding at December 31, 2017.

**Initial valuation**

Common stock price	\$0.75	
Exercise price	\$0.9375	
Expected volatility	50	%
Dividend yield	0	%
Risk-free interest rate	0.79% - 1.88	%
Expected term (years)	0.24 - 5	

**June 30, 2017 valuation**

Common stock price	\$0.50	
Exercise price	\$0.26	
Expected volatility	50	%
Dividend yield	0	%
Risk-free interest rate	0.79-1.88	%
Expected term (years)	0.08-4.76	

### *Conversion of Series A Convertible Preferred Stock*

During the year ended December 31, 2017, certain holders of the Series A convertible preferred stock exercised their conversion option and converted an aggregate of 3,502 shares of Series A convertible preferred stock into 4,669,329 shares of the Company's common stock based on the conversion ratio of 1,333.33 shares of common stock for each share of Series A convertible preferred stock. As of December 31, 2017, no shares of Series A convertible preferred stock were outstanding.

### October 2017 Public Offering

On October 26, 2017, the Company entered into an underwriting agreement with Maxim Group LLC relating to a public offering of common stock which closed on October 30, 2017. The offering generated gross proceeds to the Company of approximately \$5.5 million and net proceeds of \$4.9 million after deducting underwriting discounts, commission and other offering expenses paid by the Company.

The offering included 11,500,000 shares of common stock at a public offering price of \$0.44 per share. In addition, the underwriter exercised the over-allotment to purchase an additional 1,000,000 shares of common stock at the offering price of \$0.44 per share, which are included in the gross proceeds of \$5.5 million.

### December 2017 Public Offering and Private Placement

On December 20, 2017, the Company entered into a placement agent agreement with Maxim Group LLC relating to the sale of the Company's securities. Pursuant to the placement agent agreement, on December 20, 2017, the Company entered into a securities purchase agreement with certain purchasers named therein relating to the offering and sale of 5,300,000 shares of Company common stock at a public offering price of \$0.27 per share. The offering generated gross proceeds to the Company of approximately \$1.4 million and net proceeds of \$1.2 million after deduction underwriting discounts, commissions, and other offering expenses paid by the Company.

Concurrently with the public offering the Company also commenced a private placement whereby it issued and sold Class A and Class B Warrants, exercisable for an aggregate of 10,600,000 shares of common stock, at an exercise price of \$0.315 per share. The public offering and the private placement involve the same purchasers. The Class A and Class B Warrants exercise price is fixed at \$0.315 per warrant, and will become exercisable commencing six months from issuance. The Class A Warrants will expire eight months from issuance, while the Class B Warrants will expire

on the first anniversary of the date of issuance. Other than the different expiration dates, the Class A Warrants and Class B Warrants have identical terms. None of the Class A Warrants, the Class B Warrants nor the shares issuable upon exercise of such Warrants have been registered with the Securities and Exchange Commission. The Warrants cannot be exercised on a cashless basis. There are no redemption features embodied in the Warrants and they have met the conditions for equity classification.

### Outstanding Warrants

As of December 31, 2017, warrants to purchase 10,980,561 shares of common stock were outstanding including:

	<b>Outstanding Warrants to Purchase Shares</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
2011 private placement	283,470	\$18.75 - 24.00	May 8, 2018
2014 public offering	77,790	45.00	January 29, 2019
Placement agent fees for Company's offerings	16,135	31.80 - 186.45	March - November, 2018
Outside consulting	3,166	63.75	January 14, 2018
2017 Warrant A private placement	5,300,000	0.32	August 22, 2018
2017 Warrant B private placement	5,300,000	0.32	December 22, 2018
	10,980,561		



**NOTE 12: NET LOSS PER SHARE**

The Company accounts for and discloses net income (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 shares issuable upon the conversion of Series A convertible preferred stock, and 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:

	Year Ended December 31,	
	2017	2016
Numerator		
Net loss	\$(8,122,581 )	\$(6,368,885)
Deemed dividend attributable to preferred stock	(2,568,132 )	
Net loss attributable to common shareholders	\$(10,690,713)	\$(6,368,885)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	11,697,273	2,947,282
Net loss per share of common stock, basic and diluted:	\$(0.91 )	(2.16 )

There are no potential common shares excluded from the calculation of net loss per diluted share for the years ended December 31, 2017 and 2016 because the effect of them would be anti-dilutive. For the year ended December 31, 2017 and 2016, the average price of our common stock was less than the exercise price of the vested stock options and exercisable warrants.

**NOTE 13: INCOME TAXES**

The Company accounts for income taxes using the asset and liability method, under which 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.

On December 22, 2017, the President signed into law the Tax Cut and Jobs Act of 2017 (the “2017 Tax Act”). The 2017 Tax Act provisions applicable to the Company include a permanent reduction to the U.S. federal corporate income tax rate from 35% to 21%, the capitalization and amortization of research and development related expenses, and placing additional limits on the use of net operating losses. Under ASC Topic 740, *Accounting for Income Taxes*, companies are required to recognize the changes in the period of enactment.

Amounts recorded by the Company during the year ended December 31, 2017 where the accounting is considered to be complete relate to a reduction, in the amount of \$1.9 million, in the carrying value of the Company's U.S. deferred tax assets resulting from the 2017 Tax Act's reduction in the U.S. federal corporate income tax rate from 35% to 21%, which is fully offset by the valuation allowance.

The Company did not record an income tax benefit for its losses incurred for the years ending December 31, 2017 or 2016 due to uncertainty regarding utilization of its net operating loss carryforwards and due to its history of losses. The benefit for income taxes differs from the benefit computed by applying the federal statutory rate to loss before income taxes as follows:

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Expected federal income tax benefit at statutory federal rate	\$(2,761,678 )	\$(2,165,421 )
Share-based compensation	197,336	214,430
Other permanent items	2,668	1,034
Loss of tax attributes of former subsidiary		437,763
Effect of change in valuation allowance	(15,344,015)	843,386
Prior year true-up	(126,031 )	656,812
Tax rate change	1,912,427	
Effect of NOL limitation	16,119,293	
Other		11,996
Actual federal income tax benefit	\$	\$

The components of net deferred tax assets and liabilities are as follows:

	<b>As of December 31,</b>	
	<b>2017</b>	<b>2016</b>
Deferred tax assets		
Accrued bonuses	\$	\$ 207,175
Obsolete inventory	21,881	35,426
Accrued vacation	31,051	32,135
Net operating loss carryforwards	1,774,700	16,382,515
Intangible assets, net	634,521	949,088
Share-based compensation	620,789	934,995
Basis difference in fixed assets	33,241	53,819
Contribution, carryforward	677	315
Valuation allowance, long term	(3,089,306)	(18,557,979)
Deferred tax asset	27,554	37,489

Deferred tax liabilities

Other	(27,554 )	(37,489 )
Net deferred tax asset	\$	\$

Based on an assessment of all available evidence including, but not limited to the Company's limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, the Company has concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a full valuation allowance has been recorded against the Company's deferred income tax assets. Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code Section 382. In general, an "ownership change," as defined by the code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Any limitation may result in expiration of all or a portion of the net operating loss carryforwards before utilization. Since the Company's initial public offering, ownership changes have triggered a Section 382 limitation, which limits the ability to utilize net operating loss carryforwards.

The Company has incurred net operating losses from inception. At December 31, 2017, the Company had domestic federal net operating loss carryforwards of approximately \$49.4 million. In October 2017, the Company completed a public offering, which triggered an ownership change under section 382. We believe that as of December 31, 2017, the gross net operating loss carryforwards have been limited to approximately \$3.5 million, which are available to reduce future taxable income. These federal net operating loss carryforwards, expire at various dates beginning in 2030 through 2038. The Company recorded a valuation allowance against all of its net deferred tax assets of approximately \$3.1 million and \$18.6 million as of December 31, 2017 and 2016, respectively, for a net decrease of \$15.5 million from 2016 to 2017 and a net increase of \$800,000 from 2015 to 2016.

The Company files income tax returns in the U.S. The Company is subject to tax examinations for the 2012 tax year and beyond. The Company has no unrecognized tax positions and does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has not incurred any interest or penalties related to unrecognized tax positions. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expense.

#### **NOTE 14: 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. As of December 31, 2017 and 2016, the Company had \$6,967,469 and \$2,777,962 in excess of the FDIC insured limit, respectively.

#### **NOTE 15: COMMITMENTS AND CONTINGENCIES**

##### **Lease Commitments**

The Company has a commitment under an operating lease to pay future minimum lease payments of \$19,720, all of which is due in the year ending December 31, 2018.

The total rent expense for the years ended December 31, 2017 and 2016 was \$33,285 and \$325,960, respectively. Rent expense was included in general and administrative expenses for both years.

### **Besins Healthcare Luxembourg Settlement Agreement**

On January 28, 2016, the Company filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL*, Case No. 1:16-cv-00045-UNA. The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Defendant Besins Healthcare Luxembourg SARL (“Besins”). The complaint was served upon Besins on February 15, 2016. The Company’s claims arise from Besins’ breach of an Intellectual Property License Agreement dated May 14, 2015 (the “License Agreement”), under which Besins licensed to the Company the worldwide exclusive rights to develop and commercialize Afimoxifene Topical Gel, or AFTG, for the potential treatment and prevention of hyperplasia of the breast. The complaint sought compensatory damages, a declaration of the parties’ rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016, Besins filed its response to the Company’s complaint, generally denying liability for the Company’s claims and asserting counterclaims for breach of contract, fraud, negligent misrepresentation, and declaratory judgment. Besins sought unspecified money damages and preliminary and permanent injunctive relief, among other forms of relief, for its counterclaims. The Company filed its answer to Besins’ counterclaims on March 31, 2016, in which the Company disputed Besins’ allegations and denied that Besins is entitled to relief on its counterclaims. On August 4, 2016, the parties entered into a settlement agreement pursuant to which the parties dismissed this legal action and have settled all claims and counterclaims. Pursuant to the settlement agreement, Besins assumed, and Atossa shall have no further rights to, 4-hydroxy tamoxifen and AFTG in return for a termination payment to Atossa in the total amount of \$1,762,931. The termination payment was received in August 2016 and was included in other income in the consolidated statement of operations for year ended December 31, 2016.

### **Litigation and Contingencies**

On October 10, 2013, a putative securities class action complaint, captioned *Cook v. Atossa Genetics, Inc., et al.*, No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleged that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering’s registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. The complaint sought, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecified amount.



On February 14, 2014, the district court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the “Levi Group”) as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. On October 6, 2014 the Court granted defendants’ motion dismissing all claims against Atossa and all other defendants. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and appealed the Court’s dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On August 18, 2017, the Ninth Circuit affirmed in part and reversed in part the district court’s judgment.

On September 11, 2017, the Ninth Circuit entered an order and mandate remanding the case to the United States District Court for the Western District of Washington. On October 19, 2017, plaintiffs filed an amended complaint that conforms to the ruling by the Ninth Circuit. Since the claims under Sections 11, 12(a)(2) and 15 were dismissed by the district court and not appealed, the amended complaint only alleges violations of Section 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder against the company and one officer. All other claims and defendants have been dismissed. The alleged class period in the amended complaint is December, 2012 through October 4, 2013. On December 8, 2017, defendants filed an answer to the amended complaint. On February 7, 2018, following a mediation, the parties notified the district court that they had reached an agreement in principle to settle the action. The parties expect to file a stipulation of settlement with the court no later than March 15, 2018. The settlement will be funded by the company’s insurance carriers, and is subject to both preliminary and final approval by the district court. We do not believe the ultimate resolution of this matter will have a material effect on our financial position, results of operations or cash flows.

We are subject to other 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 16: STOCK BASED COMPENSATION***Stock Options and Incentive Plan*

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or 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 66,667 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan and on May 18, 2016, an additional 133,333 shares were reserved for issuance under the 2010 Plan. On May 9, 2017, the stockholders approved an additional 1,500,000 shares for issuance under the 2010 Plan.

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	30,018
2013	34,452
2014	49,532
2015	65,557
2016	220,419
2017	151,477
Total additional shares	551,455

The Company granted options to purchase 1,716,323 shares of common stock to employees and directors during the year ended December 31, 2017. The weighted average grant date fair value of options granted during 2017 was \$0.40. There are 100,456 options available for grant under the 2010 Plan as of December 31, 2017, and as a result of the evergreen provision contained in the 2010 Plan, an additional 1,272,910 shares were added to the 2010 Plan on January 1, 2018.

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 \$786,550 and \$876,189 for the years ended December 31, 2017 and 2016, respectively,

which was included in the following captions in the consolidated statements of operations.

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
General and administrative	\$ 621,668	\$ 850,378
Research and development	164,882	25,811
Total stock compensation expense	\$ 786,550	\$ 876,189

The fair value of stock options granted for the years ended December 31, 2017 and 2016 was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	<b>Year ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Risk free interest rate	1.86% - 2.04%	1.48% - 1.55%
Expected term	5.32- 6.36 years	5.58- 6.06 years
Dividend yield	-%	-%
Expected volatility	112.86% - 114.19%	115.52% - 115.58

Options issued and outstanding as of December 31, 2017 and their activities during the year 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, 2017	378,924	\$ 26.25		\$
Granted	1,716,323	0.47		
Forfeited	(3,167 )	15.00		
Expired	(19,081 )	25.05		
Outstanding as of December 31, 2017	2,072,999	4.10	9.041	\$
Exercisable as of December 31, 2017	608,040	11.77	8.348	\$
Vested and expected to vest	2,072,999	\$ 4.10	9.041	\$

At December 31, 2017, there were 1,461,648 unvested options outstanding and the related unrecognized total compensation cost associated with these options was \$976,606. This expense is expected to be recognized over a weighted-average period of 1.94 years.

**NOTE 17: RELATED PARTY TRANSACTIONS**

Shu-Chih Chen, Ph.D., a member of the Board of Directors and spouse of Steven C. Quay, Ph.D., M.D., the Company's CEO, has provided consultancy services to the Company. Those services primarily include providing scientific and technical expertise in Atossa's negotiations and ongoing arrangements with the manufacturer of endoxifen which is located in Taiwan. The cost of the services provided by Dr. Chen were approximately \$27,000 through December 31, 2016 and have been approved by the Company's audit committee.

Ensisheim Partners LLC, which is under sole ownership and control by Drs. Quay and Chen, purchased the following shares of common stock directly from the Company in at-the-market transactions which were approved by the Company's audit committee:

Purchase Date	Number of Shares	Price per Share
January 19, 2016	3,333	\$ 3.30
February 16, 2016	1,000	\$ 7.95
March 9, 2016	1,000	\$ 5.55

There were no related party transactions during the year ended December 31, 2017.

SIGNATURES

Pursuant to the requirements Section 13 or 15(d) of the Securities Exchange Act of 1934, the issuer, a corporation organized and existing under the laws of the State of Delaware, has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the City of Seattle, State of Washington, on the 8th day of March, 2018.

Atossa Genetics Inc.

By: /s/ Steven C. Quay

**Steven C. Quay, M.D., Ph.D.**

**Chairman, Chief Executive Officer and President**

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Steven C. Quay and Kyle Guse and each of them acting individually, as his true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

**Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated**

Signature	Office(s)	Date
/s/ Steven C. Quay <b>Steven C. Quay, M.D., Ph.D.</b>	Chairman, Chief Executive Officer and President (Principal Executive Officer)	March 8, 2018
/s/ Kyle Guse <b>Kyle Guse</b>	Chief Financial Officer, General Counsel and Secretary (Principal Financial and	March 8, 2018

Accounting Officer)

/s/ Richard I. Steinhart                      Director                      March 8, 2018  
**Richard I. Steinhart**

Shu-Chi Chen                      Director                      March 8, 2018  
**Shu-Chih Chen, Ph.D.**

/s/ Gregory Weaver                      Director                      March 8, 2018  
**Gregory Weaver**

/s/ Stephen J. Galli                      Director                      March 8, 2018  
**Stephen J. Galli, M.D.**

/s/ H. Lawrence Rimmel                      Director                      March 8, 2018  
**H. Lawrence Rimmel**

## EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein	
		Form	Date
<u>1.1</u>	<u>Underwriting Agreement between the Company and Aegis Capital Corp., dated August 30, 2016</u>	<u>Current Report on Form 8-K, as Exhibit 1.1</u>	<u>September 2, 2016</u>
<u>1.2</u>	<u>Underwriting Agreement between Atossa Genetics Inc. and Aegis Capital Corp. as representative of the several underwriters, dated March 28, 2017</u>	<u>Current Report on Form 8-K, as Exhibit 1.1</u>	<u>April 4, 2017</u>
<u>1.3</u>	<u>Underwriting Agreement between Atossa Genetics Inc. and Maxim Corp. as representative of the several underwriters, dated October 26, 2017</u>	<u>Current Report on Form 8-K, as Exhibit 1.1</u>	<u>October 30, 2017</u>
<u>3.1</u>	<u>Amended and Restated Certificate of Incorporation of Atossa Genetics Inc.</u>	<u>Registration Statement on Form S-1, as Exhibit 3.2</u>	<u>June 11, 2012</u>
<u>3.2</u>	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Atossa Genetics Inc.</u>	<u>Current Report on Form 8-K, as Exhibit 4.1</u>	<u>August 26, 2016</u>
<u>3.3</u>	<u>Bylaws of Atossa Genetics Inc.</u>	<u>Registration Statement on Form S-1, as Exhibit 3.4</u>	<u>June 11, 2012</u>
<u>3.4</u>	<u>Amendment to Bylaws of Atossa Genetics Inc.</u>	<u>Current Report on Form 8-K, as Exhibit 3.1</u>	<u>December 20, 2012</u>
<u>3.5</u>	<u>Certificate of Designation, Preferences, and Rights of Series A Junior Participating Preferred Stock of Atossa Genetics, Inc.</u>	<u>Current Report on Form 8-K, as Exhibit 3.1</u>	<u>May 22, 2014</u>
<u>3.6</u>	<u>Certificate of Designation of Preference, Rights and Limitations of Series A Convertible Preferred Stock</u>	<u>Current Report on Form 10Q, as Exhibit 3.1</u>	<u>May 11, 2017</u>
<u>4.1</u>	<u>Specimen common stock certificate</u>	<u>Registration Statement on Form S-1, as Exhibit 4.1</u>	<u>May 21, 2012</u>

<u>4.2</u>	<u>Form of Warrant from 2011 private placement</u>	<u>Registration Statement on Form S-1, as Exhibit 4.2</u>	<u>October 4, 2012</u>
<u>4.3</u>	<u>Form of Placement Agent Warrant from 2011 private placement</u>	<u>Registration Statement on Form S-1, as Exhibit 4.3</u>	<u>October 4, 2012</u>
<u>4.4</u>	<u>Form of Warrant dated September 30, 2012</u>	<u>Registration Statement on Form S-1, as Exhibit 4.4</u>	<u>October 4, 2012</u>
<u>4.5</u>	<u>Registration Rights Agreement, dated as of May 25, 2016, by and between the Company and Aspire Capital Fund, LLC.</u>	<u>Current Report on Form 8-K, as Exhibit 4.1</u>	<u>May 27, 2016</u>
<u>4.6</u>	<u>Form of Warrant Agreement from January 2014 Public Offering</u>	<u>Current Report on Form 8-K, as Exhibit 4.1</u>	<u>January 24, 2014</u>
<u>4.7</u>	<u>Form of Warrant issued to Dawson James Securities Inc. in January 2014</u>	<u>Current Report on Form 8-K, as Exhibit 4.2</u>	<u>January 24, 2014</u>
<u>4.8</u>	<u>Rights Agreement dated as of May 19, 2014, by and between the Company and VStock Transfer LLC, as rights agent, which includes as Exhibit B the Form of Rights Certificate</u>	<u>Current Report on Form 8-K, as Exhibit 4.1</u>	<u>May 22, 2014</u>
<u>4.10</u>	<u>Form of Common Stock Purchase Warrant A</u>	<u>Current Report on Form 8-K, as Exhibit 4.1</u>	<u>December 22, 2017</u>
<u>4.11</u>	<u>Form of Commons Stock Purchase Warrant B</u>	<u>Current Report on Form 8-K, as Exhibit 4.2</u>	<u>December 22, 2017</u>
<u>10.1#</u>	<u>Restated and Amended Employment Agreement with Steven Quay</u>	<u>Registration Statement on Form S-1, as Exhibit 10.3</u>	<u>February 14, 2012</u>
<u>10.3</u>	<u>Form of Indemnification Agreement</u>	<u>Registration Statement on Form S-1, as Exhibit 10.5</u>	<u>May 21, 2012</u>



<u>10.5#</u>	<u>Form of Incentive Stock Option Agreement</u>	<u>Registration Statement on Form S-1, as Exhibit 10.7</u>	<u>June 11, 2012</u>
<u>10.6#</u>	<u>Form of Non-Qualified Stock Option Agreement for Employees</u>	<u>Registration Statement on Form S-1, as Exhibit 10.8</u>	<u>June 11, 2012</u>
<u>10.7#</u>	<u>Form of Non-Qualified Stock Option Agreement for Non-Employee Directors</u>	<u>Registration Statement on Form S-1, as Exhibit 10.9</u>	<u>June 11, 2012</u>
<u>10.8</u>	<u>Form of Subscription Agreement</u>	<u>Registration Statement on Form S-1, as Exhibit 10.10</u>	<u>February 14, 2012</u>
<u>10.9</u>	<u>Patent Assignment Agreement by and between the Company and Ensisheim Partners, LLC</u>	<u>Registration Statement on Form S-1, as Exhibit 10.12</u>	<u>April 6, 2012</u>
<u>10.10#</u>	<u>Form of Restricted Stock Award Agreement</u>	<u>Registration Statement on Form S-1, as Exhibit 10.13</u>	<u>June 11, 2012</u>
<u>10.11</u>	<u>Office Lease with Sander Properties, LLC, dated March 4, 2011</u>	<u>Registration Statement on Form S-1, as Exhibit 10.20</u>	<u>April 6, 2012</u>
<u>10.12</u>	<u>Office Lease with Sander Properties, LLC, dated July 8, 2011</u>	<u>Registration Statement on Form S-1, as Exhibit 10.21</u>	<u>April 6, 2012</u>
<u>10.13</u>	<u>Office Lease with Sander Properties, LLC, dated September 20, 2011</u>	<u>Registration Statement on Form S-1, as Exhibit 10.22</u>	<u>April 6, 2012</u>
<u>10.14</u>	<u>Sublease with Fred Hutchinson Cancer Research Center, dated December 9, 2011</u>	<u>Registration Statement on Form S-1, as Exhibit 10.23</u>	<u>April 6, 2012</u>

<u>10.15#</u>	<u>Amended and Restated Employment Agreement between the Company and Kyle Guse dated May 18, 2016</u>	<u>Current Report on Form 8-K, as Exhibit 10.1</u>	<u>May 20, 2016</u>
<u>10.17</u>	<u>Office space Lease dated July 18, 2013 between Alexandria (ARE) and the Company.</u>	<u>Annual Report on Form 10-K, as Exhibit 10.33</u>	<u>March 27, 2014</u>
<u>10.20</u>	<u>Common Stock Purchase Agreement, between the Company and Aspire Capital Fund, LLC, dated as of November 11, 2015.</u>	<u>Quarterly Report on Form 10-Q, as Exhibit 10.1</u>	<u>November 12, 2015</u>
<u>10.21</u>	<u>Common Stock Purchase Agreement, between the Company and Aspire Capital Fund, LLC, dated as of May 25, 2016.</u>	<u>Current Report on Form 8-K, as Exhibit 10.1</u>	<u>May 27, 2016</u>
<u>10.22</u>	<u>Lab and Office space Lease Agreement dated March 24, 2014 between Alexandria (ARE) and the Company.</u>	<u>Annual Report on Form 10-K, as Exhibit 10.33</u>	<u>March 27, 2014</u>
<u>10.26</u>	<u>Office Space Assignment and Assumption of Lease and Consent to Assignment dated August 8, 2014 between Legacy Group, Inc. and the Company.</u>	<u>Quarterly Report on Form 10-Q, as Exhibit 10.1</u>	<u>August 12, 2014</u>

<u>10.30</u>	<u>Intellectual Property License Agreement between Atossa Genetics Inc. and Besins Healthcare Luxembourg SARL, dated May 14, 2015.</u>	<u>Current Report on Form 8-K, as Exhibit 10.1</u>	<u>May 18, 2015</u>
<u>10.31</u>	<u>Settlement and Termination of License Agreement between Besins Healthcare Luxembourg SARL and its Affiliates and Atossa Genetics, Inc. dated August 4, 2016.</u>	<u>Current Report on Form 8-K, as Exhibit 10.1</u>	<u>August 5, 2016</u>
<u>10.32</u>	<u>Stock Purchase Agreement by and among the Company, the National Reference Laboratory for Breast Health, Inc. and NRL Investment Group, LLC, dated December 16, 2015.</u>	<u>Current Report on Form 8-K, as Exhibit 10.1</u>	<u>December 16, 2015</u>
<u>10.33</u>	<u>Office space Lease Agreement dated October 1, 2015 between Hughes-Northwest and the Company.</u>	<u>Annual Report on Form 10-K, as Exhibit 10.35</u>	<u>March 30, 2016</u>
<u>10.34</u>	<u>2010 Stock Option and Incentive Plan, as amended</u>	<u>Current Report on Form 8-K, as Exhibit 1.1</u>	<u>October 30, 2017</u>
<u>10.35</u>	<u>Placement agreement between Atossa Genetics Inc. and Maxim Corp. as representative of the Purchasers, dated December 20, 2017</u>	<u>Current Report on Form 8-K, as Exhibit 10.1</u>	<u>December 22, 2017</u>
<u>10.36</u>	<u>Securities Purchase agreement between Atossa Genetics Inc. and each purchaser</u>	<u>Current Report on Form 8-K, as Exhibit 10.1</u>	<u>December 22, 2017</u>
<u>22.1</u>	<u>List of Subsidiaries</u>	<u>Filed herewith</u>	
<u>23.1</u>	<u>Consent of BDO USA LLP</u>	<u>Filed herewith</u>	
<u>24.1</u>	<u>Powers of Attorney</u>	<u>Filed Herewith on the signature page</u>	
<u>31.1</u>	<u>Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay</u>	<u>Filed herewith</u>	
<u>31.2</u>	<u>Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of Kyle Guse</u>	<u>Filed herewith</u>	
<u>32.1</u>	<u>Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay</u>	<u>Filed herewith</u>	
<u>32.2</u>	<u>Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse</u>	<u>Filed herewith</u>	
101.INS	XBRL Instance Document		

101.SCH XBRL Taxonomy Extension Schema Document

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Labels Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

# Indicates management contract or compensatory plan, contract or agreement.  
†† Schedules and exhibits omitted pursuant to Item 601 of Regulation S-K.