ATOSSA GENETICS INC
Form S-1
February 13, 2017

As filed with the Securities and Exchange Commission on February 13, 2017

Registration Statement No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**26-4753208**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

107 Spring Street

Seattle, Washington 98104

Telephone: (800) 351-3902

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Steven C. Quay

Chairman, Chief Executive Officer and President

107 Spring Street

Seattle, Washington 98104

Telephone: (800) 351-3902

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Kyle Guse	Ryan A. Murr
Chief Financial Officer and General Counsel	Gibson, Dunn & Crutcher LLP
107 Spring Street	555 Mission Street, Suite 3000
Seattle, Washington 98104	San Francisco, California 94105
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Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

The registrant is an emerging growth company, as defined in Section 2(a) of the Securities Act. This Registration Statement complies with the requirements that apply to an issuer that is an emerging growth company.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, par value $0.015 per share	$ 1.575	$4,000,000	$ 463.60

(1) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this Registration Statement also covers any additional shares of Common Stock which may become issuable to prevent dilution from stock splits, stock dividends and similar events.

(2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices per share of the registrant's Common Stock reported on The NASDAQ Capital Market on February 10, 2017.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the Registration Statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION DATED _____, 2017

$4,000,000

of Shares of Common Stock

This is a firm commitment public offering of $4,000,000 of shares of our Common Stock by Atossa Genetics Inc. Our Common Stock is listed on The NASDAQ Capital Market under the symbol "ATOS." On February 10, 2017, the last reported sale price of our Common Stock was $1.52 per share.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 (the "***JOBS Act***") and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Our business and an investment in our securities involve a high degree of risk. See "Risk Factors" beginning on page 5 of this prospectus for a discussion of information that you should consider before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[1]	$	$
Proceeds, before expenses, to us	$	$

(1) We have also agreed to pay the underwriter a nonaccountable expense allowance of 1% of gross offering proceeds (excluding the over-allotment option) and reimbursement for certain of its accountable expenses up to a maximum of $79,500. See “Underwriting” beginning on page 21 of this prospectus for a description of compensation payable to the underwriters.

We have granted a 45-day option to the underwriters to purchase up to additional shares of Common Stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment therefor on or about , 2017.

Aegis Capital Corp.

, 2017

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our Common Stock. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where such offer is not permitted.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

You should read this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus before making an investment in the securities of Atossa Genetics Inc. See “Where You Can Find Additional Information” on page _ for more information. You should rely only on the information contained in or incorporated by reference in this prospectus or a prospectus supplement. The Company has not authorized anyone to provide you with different information. This document may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that information contained in this prospectus, or in any document incorporated by reference, is accurate only as of any date on the front cover of the applicable document. Our business, financial condition, results of operations and prospects may have changed since that date.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- whether we can obtain approval from the U.S. Food and Drug Administration (the "***FDA***") and foreign regulatory bodies, to sell, market and distribute our therapeutics and devices under development;
- our ability to successfully complete clinical trials of our pharmaceutical candidates under development, including endoxifen and our intraductal microcatheters to administer therapeutics, including the study we recently opened using fulvestrant;
- the success, cost and timing of our product and drug development activities and clinical trials, including whether the ongoing clinical study using our intraductal microcatheters to administer fulvestrant will enroll or be completed in a timely fashion or at all;
- our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;
- our ability to successfully develop and commercialize new therapeutics currently in development or that we might identify in the future and in the time frames currently expected;
- our ability to successfully defend ongoing litigation, including the securities class action appeal from dismissal filed against us on November 3, 2014, and other similar proceedings that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;
- our ability to establish and maintain intellectual property rights covering our products;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;

the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;

- our expectations as to future financial performance, expense levels and capital sources;

- our ability to attract and retain key personnel; and

- our ability to raise capital, including our ability to sell up to 467,650 shares of Common Stock to Aspire Capital Fund, LLC ("***Aspire Capital***") under the terms of the May 25, 2016 Common Stock purchase agreement with Aspire Capital (the "***Aspire Purchase Agreement***").

This prospectus also contains estimates and other statistical data provided by independent parties and by us relating to market size and growth and other industry data. These and other forward-looking statements made in this prospectus are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this prospectus, particularly in the section titled "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this prospectus. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

PROSPECTUS SUMMARY

The following summary of our business highlights certain of the information contained elsewhere in or incorporated by reference into this prospectus. Because this is only a summary, however, it may not contain all of the information that may be important to you. You should carefully read the following summary together with the more detailed information regarding our Company and the securities being sold in this offering, including "Risk Factors" and other information incorporated by reference herein.

Our Company

We are a clinical-stage pharmaceutical company focused on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our leading program uses our patented intraductal microcatheters which deliver pharmaceuticals through the breast ducts. We initiated a Phase 2 clinical study in March 2016 using our microcatheters to deliver fulvestrant as a potential treatment of ductal carcinoma in-situ, or DCIS, and breast cancer. This study was initiated at Columbia University Medical Center Breast Cancer Programs and is in the process of being transferred to Montefiore Medical Center. Our second pharmaceutical program under development is oral endoxifen for breast cancer patients who are refractory to tamoxifen. Endoxifen is an active metabolite of tamoxifen, which is an FDA approved drug for breast cancer patients to prevent recurrence as well as new breast cancer. We are also evaluating endoxifen as a potential preventive therapy for breast cancer, a potential therapy to reduce mammographic density, and other breast health conditions. We believe that the potential market for intraductal administration of fulvestrant or similar drugs in DCIS patients is up to $800 million annually and that the potential market for endoxifen in the treatment and prevention settings is up to $1 billion annually.

We plan to complete, in the first quarter of 2017, the manufacturing of a supply of proprietary endoxifen in sufficient quantities for a Phase 1 clinical study. We expect to initiate this Phase 1 clinical study in the second quarter of 2017. We plan to commence a Phase 2 clinical study of endoxifen in the second half of 2017. We anticipate completing enrollment in the fulvestrant microcatheter study by August 2017.

Our Common Stock is currently quoted on The NASDAQ Capital Market under the symbol "ATOS."

Summary of Our Clinical-Stage Programs Under Development

Delivery of Therapeutics via our Microcatheters

We believe our patented intraductal microcatheters may be useful in delivering a number of therapeutics to the ducts in the breast. Doing so is intended to provide a therapeutic directly to the breast tissue while at the same time reducing the delivery of the drug to healthy tissue. We must obtain FDA approval of any drug delivered via our intraductal microcatheters devices, which will require expensive and time-consuming studies. For example, we must complete clinical studies to demonstrate the safety and tolerability of fulvestrant using our delivery method. We may not be successful in completing these studies and obtaining FDA approval.

The initial drug we are studying using our microcatheters for intraductal delivery is fulvestrant. Fulvestrant is FDA-approved for metastatic breast cancer. It is administered as a monthly injection of two shots, typically into the buttocks. In 2012, a published study documented that the single dose cost of intramuscular fulvestrant was approximately $12,000.

We own one issued patent and several pending applications directed to the treatment of breast conditions, including cancer, by the intraductal administration of therapeutics including fulvestrant.

We do not yet have FDA's input, but our preliminary analysis, subject to FDA feedback, is that the intraductal fulvestrant program could qualify for designation under the 505(b)(2) status. This would allow us to file with only clinical data and without having to perform additional, significant clinical or pre-clinical studies. As a result, the path to market could be both faster and less expensive than a standard new drug application program.

To support this development program, we have successfully produced microcatheters for the fulvestrant Phase 2 clinical trial. The FDA has also issued a "Safe to Proceed" letter for our first Investigational New Drug application (an "***IND***") for the Phase 2 study and the institutional review board approval has also been received.

In March 2016, we opened enrollment in the fulvestrant microcatheter study, which was initially being conducted by The Columbia University Medical Center Breast Cancer Program. The principal investigator for this study transferred from Columbia to Montefiore Medical Center in January 2017, and as a result we transferred the study to Montefiore in February 2017. We expect to complete enrollment in the study by August 2017. The study includes women with DCIS or invasive breast cancer slated for mastectomy or lumpectomy. This study will assess the safety, tolerability and distribution of fulvestrant when delivered directly into breast milk ducts of these patients compared to those who receive the same product intramuscularly. Six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution, and 24 participants will receive fulvestrant by intraductal instillation utilizing our microcatheter device. The total dose administered via our microcatheters will not exceed 500 mg.

The study was presented at the CTRC-AARC San Antonio Breast Cancer Symposium, which was held December 6-10, 2016. The study was presented in the "Ongoing Clinical Trials" category, which features studies that have not been completed and which does not permit the presentation of study results.

The primary endpoint of the clinical trial is to assess the safety, tolerability and distribution of intraductally administered fulvestrant in women with DCIS or Stage 1 or 2 invasive ductal carcinoma prior to mastectomy or lumpectomy. The secondary objective of the study is to determine if there are changes in the expression of Ki67 as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimen. Digital breast imaging before and after drug administration in both groups will also be performed to determine the effect of fulvestrant on any lesions as well as breast density of the participant. Additional information about the study can be found at: *https://clinicaltrials.gov/ct2/show/NCT02540330?term=atossa&rank=2*.

We estimate that the total potential market for intraductal treatment of DCIS with fulvestrant or a similar drug is up to $800 million in annual sales. This estimate includes treatment of DCIS patients prior to surgery as well as patients who would use intraductal treatment as an alternative to surgery. Our estimated potential market size is based in part on a report obtained in January 2017 from Defined Health, a leading market research firm.

Endoxifen

Our second pharmaceutical program under development is oral endoxifen for breast cancer patients who are refractory to tamoxifen. Endoxifen is an active metabolite of tamoxifen, which is an FDA approved drug for breast cancer patients to prevent recurrence as well as new breast cancer. We believe that up to 50% of the one million women eligible to take tamoxifen in the United States each year are refractory, meaning that they have inadequate endoxifen levels (for any number of reasons including low levels of a liver enzyme) and they have an increased risk for breast cancer recurrence. We are also evaluating endoxifen as a potential preventive therapy for breast cancer, a potential therapy to reduce mammographic density, and other breast health conditions.

We have filed patent applications covering endoxifen and we are in the process of manufacturing an initial supply of our proprietary endoxifen drug for initial Phase 1 studies. We expect to initiate the Phase 1 study in the second quarter of 2017. We plan to conduct the Phase 1 study through a clinical research organization in Australia, pending approval from the associated ethics committee. The anticipated primary endpoint of this placebo-controlled, repeat dose study of 48 healthy female volunteers is to assess the pharmacokinetics of both an oral and topical formulation of endoxifen over 28 days. The secondary endpoint is to assess safety and tolerability.

Subject to successful completion of the Phase 1 study and other regulatory requirements, we plan to initiate a Phase 2 study of endoxifen in the second half of 2017.

We believe that the potential market for endoxifen in the treatment and prevention settings is up to $1 billion in annual sales. This estimate is based in part on a report obtained from Defined Health in January 2017.

Our Pre-Clinical Programs Under Development

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating other therapeutic candidates to treat breast conditions, including breast cancer. Factors we are considering in evaluating potential drug candidates include, for example, the ability to obtain expedited regulatory approval, significance of unmet medical need, size of the patient population, intellectual property opportunities and the anticipated pre-clinical and clinical pathway.

Our Medical Devices

Our medical devices include the ForeCYTE Breast Aspirator and the FullCYTE Breast Aspirator, which collect specimens of nipple aspirate fluid ("***NAF***") for cytological testing at a laboratory, and a universal transport kit to assist with the packaging and transport of NAF samples to a laboratory. We also own the exclusive rights to manufacture and sell various medical devices (although we do not currently maintain an inventory of our devices) consisting primarily of tools to assist breast surgeons, which we acquired from Acueity Healthcare, Inc. in 2012. We are not currently commercializing our breast aspirator devices, transportation kits, tools for breast surgeons nor any NAF cytology tests.

Our patented intraductal microcatheter devices are being developed for the targeted delivery of potential pharmaceuticals and are currently being used in a Phase 2 clinical trial, as described above.

Intellectual Property

As of January 31, 2017, and based on a recent periodic review of our patent estate, we own 78 issued patents (33 in the United States and approximately 45 in foreign countries), and 11 pending patent applications (5 in the United States, and 6 international applications) directed to ForeCyte, FullCyte, and Acueity devices, various tests, intraductal treatments, and therapeutics. Excluding certain patents and applications that are no longer being maintained or prosecuted, our patent estate consists primarily of the following:

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Description	U.S. Patents Issued [1]	Expiration	U.S. Pending[1]	Foreign Patents Granted[1]	Expiration	Foreign Pending[1]
Intraductal Treatment Program	0	N/A	3	2	2017 - 2031	1
Therapeutics	0	N/A	3	0	N/A	2
ForeCyte Breast Aspirator Program	2	2017 - 2031	0	12	2017 - 2031	0
Fullcyte Microcatheters, Fullcyte Breast aspirator and Diagnostics/tests Programs	29	2017 - 2031	1	31	2017 - 2031	3
Acueity Tools	12	2017 - 2024	0	0	2017 - 2024	0

(1) The total number of patents issued or pending, as applicable, in the respective descriptive columns exceed the totals because some patents and applications contain more than one type of claim directed to methods, kits, compositions, devices and/or technology. The patent counts disclosed herein and in our patent estate are subject to change.

Atossa and Atossa Genetics (stylized) are our registered trademarks.

Implications of being an Emerging Growth Company

We are an "emerging growth company," as defined in the JOBS Act, and, for as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the "***Sarbanes-Oxley Act***"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three-year period. We are choosing to "opt out" of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards, and intend to take advantage of the other exemptions.

Corporate Information

Our corporate website is located at *www.atossagenetics.com*. Information contained on, or that can be accessed through, our website is not a part of this prospectus. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Unless otherwise noted, the term “Atossa Genetics” refers to Atossa Genetics Inc., a Delaware corporation, the terms “Atossa,” the “Company,” “we,” “us,” and “our,” refer to the ongoing business operations of Atossa and the historic business o the NRLBH, whether conducted through Atossa Genetics or the NRLBH; however unless the context otherwise indicates, references to “we,” “our” or the “Company” as they relate to laboratory tests generally refers to activities conducted by the NRLBH. We were incorporated in Delaware in April 2009. Our principal executive offices are located at 107 Spring Street, Seattle WA 98104, and our telephone number is (800) 351-3902.

Mammary Aspiration Specimen Cytology Test (MASCT), is our registered trademark and Oxy-MASCT and our name and logo are our trademarks. ForeCYTE, FullCYTE, NextCYTE, ForeCYTE Breast Aspirator and ArgusCYTE are our service marks. This prospectus also includes additional trademarks, trade names and service marks of third parties, which are the property of their respective owners.

THE OFFERING

Common stock covered by this Prospectus:	Up to $4 million of shares of Common Stock.
Common stock outstanding as of January 31, 2017:	3,786,913 shares.
Use of proceeds:	The net proceeds from this offering after deducting estimated underwriting discounts and commissions and offering expenses payable by us will be approximately $ million (or $ million if the underwriters exercise in full their option to purchase additional shares of Common Stock from us), assuming an offering price per share of $, the last reported sale price of our Common Stock on The NASDAQ Capital Market on February , 2017. We intend to use the net proceeds from this offering for working capital and general corporate purposes. See "Use of Proceeds" for a more detailed description of the intended use of proceeds from this offering.
Risk factors:	The shares offered hereby involve a high degree of risk. See "Risk Factors" beginning on page 5.
Dividend policy:	We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying cash dividends on our Common Stock.
Trading Symbol:	Our Common Stock currently trades on The NASDAQ Capital Market under the symbol "ATOS."

RISK FACTORS

A purchase of our shares of Common Stock is an investment in our securities and involves a high degree of risk. You should carefully consider the risks and uncertainties and all other information contained in or incorporated by reference in this prospectus. If any of these risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the Common Stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to Our Business

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

We were incorporated in Delaware in April 2009. Initially, our operations were focused on establishing our CLIA-certified laboratory, commercializing our ForeCYTE and FullCYTE Breast Aspirators and manufacturing our intraductal microcatheters. In December 2015, we sold our laboratory, ceased generating revenue and refocused our business on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Because of our limited operating history, particularly in the area of pharmaceutical development, our revenue and income potential cannot be based on prior results and is uncertain. Any evaluation of our business and prospects must be considered in light of these factors and the risks and uncertainties often encountered by companies in the development stage. Some of these risks and uncertainties include our ability to:

- Obtain successful results from our clinical studies;
- obtain regulatory approvals in the United States and elsewhere for our pharmaceuticals and intraductal microcatheters we are developing;
- work with contract manufacturers to produce our pharmaceuticals under development and our intraductal microcatheter in clinical and commercial quantities on acceptable terms and in accordance with required standards;
- respond effectively to competition;

- manage growth in operations;
- respond to changes in applicable government regulations and legislation;
- access additional capital when required; and
- attract and retain key personnel.

We may not continue as a going concern.

We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. The report issued by our independent auditors also emphasized our ability to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital, we may be unable to develop and commercialize our product offerings or geographic reach and we could be forced to cease operations.

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

For the nine months ended September 30, 2016, we incurred a net loss of $3,845,235 and we had an accumulated deficit of $54,780,098. As of the date of filing this prospectus, we expect that our existing resources will be sufficient to fund our planned operations for at least the next three to six months. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. The revenue we have generated to date consisted of mainly laboratory services; however, we sold our laboratory business on December 16, 2015 and we currently have no other products and services approved for commercialization. We may not receive or maintain regulatory clearance for our products and other sources of capital may not be available when we need them or on acceptable terms. If we are unable to raise in a timely fashion the amount of capital we anticipate needing; we would be forced to curtail or cease operations.

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

When we elect to raise additional funds or when additional funds are required, we may raise such funds from time to time through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. These financing arrangements may not be available on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from developing our device and pharmaceutical candidates, pursuing acquisition, licensing, development and

commercialization efforts and our ability to continue operations, generate revenues and achieve or sustain profitability will be substantially harmed.

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

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

We expect to spend substantial amounts of capital to:

- develop our pharmaceutical and microcatheter programs under development;
- perform clinical studies for the pharmaceuticals and microcatheters we are developing;
- continue our research and development activities to advance our product pipeline; and
- obtain clinical supplies of the pharmaceuticals and microcatheters we are developing.

We have not identified other sources for additional funding, other than our equity line of credit with Aspire Capital, and cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products and services or our research and development activities. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations. Because our independent auditors have emphasized in their report on our financial statements doubt as to our ability to continue as a “going concern,” our ability to raise capital may be severely hampered. Similarly, our ability to borrow any such capital may be more expensive and difficult to obtain until this “going concern” issue is eliminated.

We have a history of operating losses and we expect to continue to incur losses in the future.

We have a limited operating history and have incurred net losses each year. Our net losses for the nine months ended September 30, 2016 were $3,845,235. We will continue to incur further losses in connection with research and development costs for development of our programs, including ongoing and additional clinical studies.

Our business may be affected by legal proceedings.

We have been in the past, and may become in the future, involved in legal proceedings. For example, on October 10, 2013, a securities class action complaint was filed against us, certain of our directors and officers and the underwriters from our initial public offering. This action was purportedly brought on behalf of a class of persons and entities who purchased our Common Stock between November 8, 2012 and October 4, 2013, inclusive. The complaint alleges that the defendants made false or misleading statements. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against us and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. 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 have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants filed their answering brief on April 13, 2015, and plaintiffs filed their reply brief on May 18, 2015. Oral argument for the appeal has been set to begin on May 9, 2017. Although we believe this complaint is without merit and plan to defend it vigorously, the costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted.

On January 28, 2016, we 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 Besins. Our 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 seeks compensatory damages, a declaration of the parties' rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016 Besins responded to our complaint by denying our claims and asserting counterclaims including breach of contract, fraud and negligent misrepresentation, and seeking relief in the forms of compensatory damages, injunctive relief, and declaratory relief. In August 2016, we resolved and settled this dispute by transferring the Afimoxifene program to Besins for a payment to us of $1.8 million.

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

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

If we raise additional capital by issuing equity securities, including sales of shares of Common Stock to Aspire Capital pursuant to the Aspire Purchase Agreement, the value of the then outstanding Common Stock may be reduced. If the additional equity securities are issued at a per share price less than the per share value of the outstanding shares, then all of the outstanding shares would suffer a dilution in value with the issuance of such additional shares. Further, the issuance of debt securities in order to obtain additional funds may impose restrictions on our operations and may impair our working capital as we service any such debt obligations.

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

We may not succeed in achieving commercial market acceptance of any of our products. In order to gain market acceptance for the drugs and microcatheters under development, we will need to demonstrate to physicians and other healthcare professionals the benefits of these therapies including the clinical and economic application for their particular practice. Many physicians and healthcare professionals may be hesitant to introduce new services or techniques into their practice for many reasons, including lack of time and resources, the learning curve associated with the adoption of such new services or techniques into already established procedures, and the uncertainty of the applicability or reliability of the results of a new product. In addition, the availability of full or even partial payment for our products and tests, whether by third party payors (e.g., insurance companies), or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products.

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

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

We may experience difficulty in locating, attracting, and retaining experienced and qualified personnel, which could adversely affect our business.

We will need to attract, retain, and motivate experienced clinical development and other personnel, particularly in the greater Seattle area as we expand our pharmaceutical development activities. These employees may not be available in this geographic region. In addition, competition for these employees is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage organization such as ours. If we are unable to attract and retain qualified personnel, our development activities may be adversely affected.

Compounds that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and top-line or preliminary clinical trial data reports may ultimately differ from actual results once data are more fully evaluated.

Successful development of anti-cancer and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer and other breast conditions is expensive, difficult, and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products, and completing manufacturing to support clinical studies;
- pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;

- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products;

- equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;

- inefficient cost structure of a compound, finished drug or device compared to alternative treatments;

- obstacles resulting from proprietary rights held by others, such as patent rights for a particular compound;

- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, perceived cost/benefit of participating in the study, eligibility criteria for tests, and competition with other clinical testing programs;

- preclinical or clinical testing requiring significantly more time than expected, resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;

- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;

- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;

- delays in reaching or failing to reach agreement on acceptable terms with manufacturers or prospective clinical research organizations, or CROs, and trial sites; and

- failure of third parties, such as CROs, academic institutions, collaborators, cooperative groups and/or investigator sponsors, to conduct, oversee and monitor clinical trials and results.

In addition, from time to time we expect to report top-line data for clinical trials. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, top-line results may differ from future results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In

addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular compound and our business in general.

If the development of our products is delayed or fails, or if top-line or preliminary clinical trial data reported differ from actual results, our development costs may increase and the ability to commercialize our products may be harmed, which could harm our business, financial condition, operating results or prospects.

We may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our products.

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the European Medicines Agency (the "***EMA***") in the E.U.

Our product candidates are currently in research or development and we have not received marketing approval for our products. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Our products may be considered "combination" products in that they use both medical devices and drugs. For example, our intraductal microcatheters utilize both a medical device and the drug they are intended to deliver. As a result, the regulatory pathway for these products may be more complex and obtaining regulatory approvals may be more difficult.

Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. The number, size, design and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the compound, the disease or condition that the products is designed to address and the regulations applicable to any particular products. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a product for many reasons, including, but not limited to:

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

If our products are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

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

We may in the future decide to seek accelerated approval pathway for our products. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint under an accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. There can be no assurance that the FDA will agree that any endpoint we suggest with respect to any of our drug candidates is an appropriate surrogate endpoint. Furthermore, there can be no assurance that any application will be accepted or that approval will be granted. Even if a product candidate is granted accelerated approval, such accelerated approval is contingent on the sponsor’s agreement to conduct one or more post-approval confirmatory

trials. Such confirmatory trial(s) must be completed with due diligence and, in some cases, the FDA may require that the trial(s) be designed and/or initiated prior to approval. Moreover, the FDA may withdraw approval of a product candidate or indication approved under the accelerated approval pathway for a variety of reasons, including if the trial(s) required to verify the predicted clinical benefit of a product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug, or if the sponsor fails to conduct any required post-approval trial(s) with due diligence.

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

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

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

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

- they may be found ineffective or cause harmful side effects;
- they may be difficult to manufacture on a scale necessary for commercialization;
- they may experience excessive product loss due to contamination, equipment failure, inadequate transportation or storage, improper installation or operation of equipment, vendor or operator error, inconsistency in yields or variability in product characteristics;
- they may be uneconomical to produce;

- we may fail to obtain reimbursement approvals or pricing that is cost effective for patients as compared to other available forms of treatment or that covers the cost of production and other expenses;

- they may not compete effectively with existing or future alternatives;

- 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.

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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 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 status of elements of the Affordable Care Act are uncertain at this time. In almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe 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 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 into the desired location, which could lead to ineffective treatment;
- adverse events related to drugs we are developing; and
- inaccurate test results from the nipple aspirate fluid collected with our medical devices.

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*, 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank Int'l*, 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 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 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 and services.

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 a pharmaceutical from a third party. We may not be able to secure such a license on acceptable terms. Litigation or patent interference 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 for the production of the 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. For example, in 2011, the FDA initiated a review of the premarket clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the “Refuse to Accept” guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete,

or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review. 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.

If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to occur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition.

In the EU, we must comply with the EU Medical Device Vigilance System (MEDDEV 2.12/1 rev.8) which is intended to protect the health and safety of patients, users and others by establishing reporting procedures and reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents (which are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, may lead to or may have led to the death of a patient, or user or other persons or to a serious deterioration in such person's state of health) must be reported by manufacturers through a Manufacturer's Incident Reports to competent authorities within periods of time specified in the MEDDEV 2.12/1 rev. 8. Such incidents are evaluated and, where appropriate, information is disseminated between the competent authorities of the EU Member States. The MEDDEV 2.12/1 rev. 8 is also intended to facilitate a direct, early and harmonized establishment of Field Safety Corrective Actions, or FSCAs, across the EU Member States in which the device is being marketed. A FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include device recall, modification, exchange, or destruction. FSCAs must be reported by the manufacturer or the manufacturer's European Authorized Representative, to its customers and/or the end users of the device through a Field Safety Notice. FSCAs must also be reported to the competent authorities of the EU Member States. Failure to comply with any of these requirements could significantly and adversely affect our business.

The statements and actions of the Trump administration could negatively affect our business.

President Trump has stated that he will repeal the Patient Protection and Affordable Care Act, as amended, reduce government regulation, and lower the prices of pharmaceuticals. He has also placed a temporary ban on immigration from certain countries. These statements and potential actions on these topics could negatively impact our stock price and could make it more difficult to develop our programs. For example, lower pharmaceutical prices could reduce the potential market for our drugs under development and reduced government regulation could encourage competition. The recent temporary ban on immigration from certain countries could make it more difficult for us and our partners to hire qualified personnel.

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.

The 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 EU 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 EU 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 EU to the U.S. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties 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 was 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.

Healthcare policy changes, including recently enacted legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations

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***"), enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries

Other significant measures contained in the PPACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our future diagnostics customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic products.

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, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management's attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

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 September 28, 2015, we received a letter from NASDAQ stating that the Company was not in compliance with NASDAQ Listing Rule 5550(a)(2), because the Company's Common Stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. We regained compliance with the $1.00 minimum bid price requirement in September 2016 after effectuating a reverse stock split.

If our stock price does not satisfy the $1.00 minimum bid price requirement and if we don't otherwise satisfy the other continued listing requirements, 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, Aspire 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, Aspire 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 January 31 2017, our stock price has ranged from $1.30 to $10.65. 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 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 is concentrated among a small number of stockholders, including our founders, directors, officers, and entities related to these persons. Our directors, officers and entities affiliated with them beneficially own approximately 16.7% of our outstanding voting securities (including all outstanding vested and unvested options held by such persons). 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. Although we have hired additional employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

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 are an "emerging growth company" and we cannot be certain if we will be able to maintain such status or if the reduced disclosure requirements applicable to emerging growth companies will make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to adopt certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies"

including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may remain as an “emerging growth company” for up to five full fiscal years following our initial public offering. We would cease to be an “emerging growth company,” and therefore not be able to rely upon the above exemptions, if we have more than $1 billion in annual revenue in a fiscal year, we issue more than $1 billion of non-convertible debt over a three-year period, or we have more than $700 million in market value of our Common Stock held by non-affiliates as of any June 30 before the end of the five full fiscal years. Additionally, we cannot predict if investors will find our Common Stock less attractive because we will rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

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 $10.0 million available under the Aspire Purchase Agreement, we will still need additional capital to fully implement our business, operating, and development plans.

When we elect to raise additional funds or additional funds are required, we may raise such funds from time to time through public or private equity offerings, debt financings, corporate collaboration, and licensing arrangements or other financing alternatives, 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 and other preferences, which 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.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of $4,000,000 of shares of Common Stock in this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares from us in full), assuming a public offering price of $ per share, which was the last reported sale price of our Common Stock on The NASDAQ Capital Market on February , 2017, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase or decrease in the assumed public offering price of $ per share would increase or decrease the net proceeds from this offering by approximately $ million and $ million, respectively, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) by shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the public offering price or the number of shares by these amounts would have a material effect on our anticipated uses of the net proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We anticipate that we will use the net proceeds from this offering for working capital and general corporate purposes. We may also use a portion of the net proceeds from this offering for the acquisition of, or investment in, complementary business, products, or technologies, although we have no present commitments or agreements for any specific acquisitions or investments. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities

These expected uses of the net proceeds from this offering represent our intentions based upon our current financial condition, results of operations, business plans, and conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

DIVIDEND POLICY

We have not declared any dividends and do not anticipate that we will declare dividends in the foreseeable future; rather, we intend to retain any future earnings for the development of the business. Payment of future cash dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any.

DILUTION

If you invest in our Common Stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of Common Stock and the adjusted net tangible book value per share of our Common Stock after this offering.

The net tangible book value of our Common Stock as of September 30, 2016, was approximately $, or approximately $ per share. Net tangible book value per share represents the amount of our total tangible assets, excluding goodwill and intangible assets, less total liabilities, divided by the total number of shares of our Common Stock outstanding.

Dilution per share to new investors represents the difference between the amount per share paid by purchasers for each share of Common Stock in this offering and the net tangible book value per share of our Common Stock immediately following the completion of this offering.

After giving effect to the sale of shares of Common Stock offered by this prospectus supplement at an offering price of $ per share in connection with this offering and after deducting the estimated underwriting discounts and offering expenses, our pro forma net tangible book value as of September 30, 2016 would have been approximately $ or approximately $ per share. This represents an immediate increase in net tangible book value of approximately $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to purchasers of shares of Common Stock in this offering, as illustrated by the following table:

Offering price per share	$
Net tangible book value per share as of September 30, 2016	$
Increase per share attributable to the offering	$
As adjusted net tangible book value per share after this offering	$
Dilution per share to new investors	$

20

The discussion of dilution, and the table quantifying it, assumes no exercise of any outstanding options or warrants or the issuance of other potentially dilutive securities. The exercise of potentially dilutive securities having an exercise price less than the offering price would increase the dilutive effect to new investors.

The number of shares of Common Stock shown above to be outstanding after this offering is based on 3,786,913 shares outstanding as of September 30, 2016, and excludes the following as of September 30, 2016:

- 394,090 shares of our Common Stock subject to options outstanding having a weighted average exercise price of $21.75 per share;
- 292,405 shares of our Common Stock that have been reserved for issuance in connection with future grants under our 2010 Stock Option and Incentive Plan, as amended; and
- 402,228 shares of our Common Stock that have been reserved for issuance upon exercise of outstanding warrants having exercise prices ranging from $24.00 to $186.00 per share.

UNDERWRITING

Aegis Capital Corp. is acting as the representative of the underwriters and the sole book-running manager in this offering. We have entered into an underwriting agreement dated with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of Common Stock listed next to its name in the following table:

Underwriters	Number of Shares
Aegis Capital Corp.	
Total	

The underwriters are committed to purchase all the shares of Common Stock offered by us other than those covered by the option to purchase additional shares described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement.

Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-allotment Option. We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of additional shares (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price per share, less the underwriting discounts and commissions. If this option is exercised in full, the total offering price to the public will be $ and the total net proceeds, before expenses, to us will be $.

Discounts, Commissions and Non-Accountable Expense Allowance. The following table shows the public offering price, underwriting discount, non-accountable expense allowance and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total Without Over-Allotment Option	Total With Over-Allotment Option
Public offering price	$	$	$
Underwriting discount (%)	$	$	$
Nonaccountable expense allowance (%)	$	$	$
Proceeds, before expense, to us	$	$	$

The underwriters propose to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of up to $ per share. If all of the shares offered by us are not sold at the public offering price per share, the underwriters may change the offering price per share and other selling terms by means of a supplement to this prospectus.

We have also agreed to pay the representative a nonaccountable expense allowance of % of the aggregate offering proceeds (excluding the over-allotment option), and to reimburse certain of the representative's out of pocket expenses, including the fees of underwriters' counsel, up to a total of $79,500.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discounts, commissions and non-accountable expense allowance will be approximately $.

Lock-Up Agreements. We have agreed with the representative that we will not offer or sell any securities for a period of 90 days from the closing date of this offering, subject to certain exceptions. In addition, all of our directors and executive officers have entered into lock up agreements with the representative prior to the commencement of this offering pursuant to which each of these persons, for a period of 90 days from the closing date of this offering, without the prior written consent of the representative, agree not to (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our securities or any securities convertible into or exercisable or exchangeable for common shares owned or acquired on or prior to the closing date of this offering (including any common shares acquired after the closing date of this offering upon the conversion, exercise or exchange of such securities); (2) file or caused to be filed any registration statement relating to the offering of any shares of our capital shares; or (3) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of common shares, whether any such transaction described in clause (1), (2), or (3) above is to be settled by delivery of common shares or such other securities, in cash or otherwise, except for certain exceptions and limitations.

The lock-up period described in the preceding paragraph will be automatically extended if: (1) during the last 17 days of the lock-up period, we issue an earnings release or announce material news or a material event; or (2) prior to the

expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the date of the earnings release.

Electronic Offer, Sale and Distribution of Securities. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares and warrants to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

NASDAQ Capital Market Listing. Our Common Stock is listed on The NASDAQ Capital Market under the symbol "ATOS."

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales. Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position that may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

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Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares or Common Stock or preventing or retarding a decline in the market price of our shares or Common Stock. As a result, the price of our Common Stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our Common Stock. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive market making. In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our Common Stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, then that bid must then be lowered when specified purchase limits are exceeded.

Certain Relationships

The underwriters and their affiliates have provided, or may in the future provide, various investment banking, commercial banking, financial advisory, brokerage, and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees and expense reimbursement.

The underwriters and their affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of our company. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

DESCRIPTION OF SECURITIES TO BE REGISTERED

Our authorized capital stock consists of 75,000,000 shares of Common Stock, $0.015 par value per share, and 10,000,000 shares of preferred stock, $0.015 par value per share.

Common Stock

Holders of Common Stock are entitled to receive ratably dividends out of funds legally available, if and when declared from time to time by our Board of Directors. We have never paid any cash dividends on our Common Stock and our Board of Directors does not anticipate that we will pay cash dividends in the foreseeable future. The future payment of dividends, if any, on our Common Stock is within the discretion of the Board of Directors and will depend upon earnings, capital requirements, financial condition and other relevant factors. Holders of Common Stock are entitled to one vote for each share held on each matter to be voted on by stockholders. There is no cumulative voting in the election of directors. In the event of liquidation, dissolution or winding up of the affairs of us, holders of Common Stock are to share in all assets remaining after the payment of liabilities and any preferential distributions payable to preferred stockholders, if any. The holders of Common Stock have no preemptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the Common Stock. The rights of the holders of the Common Stock are subject to any rights that may be fixed for holders of preferred stock, if any. All of the outstanding shares of Common Stock are fully paid and non-assessable.

Certificate of Incorporation

Under our certificate of incorporation, as amended, our Board of Directors, without further action by our stockholders, currently has the authority to issue up to 10,000,000 shares of preferred stock and to fix the rights (including voting rights), preferences and privileges of these “blank check” preferred shares. Such preferred stock may have rights, including economic rights, senior to our Common Stock. As a result, the issuance of the preferred stock could have a material adverse effect on the price of our Common Stock and could make it more difficult for a third party to acquire a majority of our outstanding Common Stock.

Anti-Takeover Devices

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited

tender offers or other unilateral takeover proposals to negotiate with our Board of Directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies. In accordance with our certificate of incorporation, our Board of Directors is divided into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may only be removed from office for cause and only by the affirmative vote of holders of 75% or more of the outstanding shares of capital stock then entitled to vote at an election of directors. Furthermore, any vacancy on our Board of Directors, however occurring, including any vacancy resulting from an increase in the size of the board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our Board of Directors.

Undesignated Preferred Stock. Our certificate of incorporation authorizes "blank-check" preferred stock, which means that our Board of Directors has the authority to designate one or more series of preferred stock without stockholder approval. These series of preferred stock may have superior rights, preferences and privileges over our Common Stock, including dividend rights, voting rights, and liquidation preferences. The ability of our Board of Directors to issue shares of our preferred stock without stockholder approval could deter takeover offers and make it more difficult or costly for a third party to acquire us without the consent of our Board of Directors.

Section 203 of the Delaware General Corporation Law. In addition, our certificate of incorporation does not opt out of Section 203 of the Delaware General Corporation Law, which protects a corporation against an unapproved takeover by prohibiting a company from engaging in any business combination with any interested stockholder (defined as a stockholder owning more than 15% of the outstanding shares) for a period of three years from the time such stockholder became a 15% holder unless approved by our Board of Directors.

Stockholder Rights Agreement. 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 our 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 our Common Stock (or, in the case of a person who beneficially owned 15% or more of our Common Stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of our 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 our 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 our 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.

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Transfer Agent and Registrar

We have appointed VStock Transfer, LLC, 18 Lafayette Place, Woodmere, New York 11598 (Telephone: (212) 828-8436; Facsimile (646) 536-3179) as our transfer agent and registrar.

Listing

Our Common Stock is listed on The NASDAQ Capital Market under the symbol “ATOS.”

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

LEGAL MATTERS

Certain legal matters relating to the validity of the Common Stock offered by this prospectus will be passed upon for us by Gibson, Dunn & Crutcher LLP, San Francisco, California. Certain legal matters will passed upon for the underwriters by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements as of December 31, 2015 and 2014 and for each of the two years in the period ended December 31, 2015 incorporated by reference in this Prospectus have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company’s ability to continue as a going concern) which is

incorporated by reference in the Prospectus, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are required to file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document filed by us at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our filings with the SEC are also available to the public at the SEC's Internet web site at *http://www.sec.gov*.

We have filed a registration statement, of which this prospectus is a part, covering the securities offered hereby. As allowed by SEC rules, this prospectus does not include all of the information contained in the registration statement and the included exhibits, financial statements and schedules. You are referred to the registration statement, the included exhibits, financial statements and schedules for further information. This prospectus is qualified in its entirety by such other information.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-35610):

- our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 30, 2016;
- portions of our definitive Proxy Statement on Schedule 14A, filed with the SEC on April 13, 2016;
- our current reports on Form 8-K filed with the SEC on January 29, 2016, February 8, 2016, May 16, 2016, May 20, 2016, May 27, 2016, June 7, 2016, July 27, 2016, August 5, 2016, August 23, 2016, August 26, 2016, September 2, 2016 and December 12, 2016; and

- our Quarterly Reports on Forms 10-Q for the quarters ended March 31, 2016, filed with the SEC on May 5, 2016, June 30, 2016, filed with the SEC on August 12, 2016 and September 30, 2016 filed with the SEC on November 14, 2016.

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We also elect to incorporate by reference information filed after the effective date of this prospectus. All documents subsequently filed by us pursuant to Section 13(a), 13(c) and 14 or 15(d) of the Exchange Act, prior to the termination date of the offering set forth herein shall be deemed incorporated by reference to this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Kyle Guse, Chief Financial Officer, Atossa Genetics Inc., 107 Spring Street, Seattle, Washington, 98104, telephone: (800) 351-3902. Copies of the above reports may also be accessed from our web site at *http://www.atossagenetics.com*.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

$4,000,000 of shares

of Common Stock

PROSPECTUS

Aegis Capital Corp.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, payable by the Company in connection with the registration and sale of the Common Stock being registered. All amounts are estimates except the SEC registration fee.

SEC registration fee	$464
Printing expense	$5,000
Legal fees and expenses	$40,000
Accounting fees and expenses	$30,000
Transfer Agent Fees	$1,000
Miscellaneous Fees	$3,536
Total	$80,000

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of

fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions, or other distributions; or
- any transaction from which the director derived an improper personal benefit.
- These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our Board of Directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our Board of Directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements provide that we will indemnify each of these directors and executive officers to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees, judgments, fines, and settlement amounts, to each indemnified director, executive officer, or affiliate in connection with any proceeding in which indemnification is available, and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as an officer or director brought on behalf of the Company or in furtherance of our rights.

We maintain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The Company has sold the following securities within the past three years which were not registered under the Securities Act:

On April 1, 2014, the Company issued options to purchase 300,000 shares of its Common Stock, exercisable at $1.69 per share which was the fair market value on the date of grant, to Ben Chen as an inducement grant for the employment of Mr. Chen as the Company's Sr. Vice President of Global Regulatory Affairs and Quality Assurance. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On June 2, 2014, the Company issued options to purchase 200,000 shares of its Common Stock, exercisable at $1.41 per share which was the fair market value on the date of grant, to John Sawyer as an inducement grant for the employment of Mr. Sawyer as the Company's Sr. Vice President of Global Regulatory Affairs and Quality Assurance. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On September 2, 2014, the Company issued options to purchase 200,000 shares of its Common Stock, exercisable at $1.86 per share which was the fair market value on the date of grant, to Scott Youmans as an inducement grant for the employment of Mr. Youmans as the Company's Sr. Vice President of Operations. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On December 15, 2014, the Company issued options to purchase 200,000 shares of its Common Stock, exercisable at $0.96 per share which was the fair market value on the date of grant, to Pieter Van der Poel as an inducement grant for the employment of Mr. Van der Poel as the Company's Vice President of European Commercial Operations. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

From March 4, 2015 to March 31, 2015 we sold 2,653,199 shares of Common Stock to Aspire Capital under the November 8, 2013 agreement with them, with total gross proceeds to the Company of $4,292,349.

On May 4, 2015, the Company issued options to purchase 200,000 shares of its Common Stock, exercisable at $1.44 per share which was the fair market value on the date of grant, to Cindy Atha as an inducement grant for the employment of Ms. Atha as the Company's Vice President of Sales and Marketing. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On May 26, 2015 Company entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $25 million of shares of our Common Stock over the 30-month term of the agreement. Under the agreement, on May 26, 2015, Aspire Capital was issued 375,000 shares of Common Stock as a commitment fee. These transactions were exempt from registration under Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving any public offering.

On May 26, 2015, the Company issued options to purchase 100,000 shares of its Common Stock, exercisable at $1.49 per share which was the fair market value on the date of grant, to Dr. Gerald Engley as an inducement grant for the employment of Mr. Engley as the Company's Sr. Director of Medical Affairs. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On October 12, 2015, the Company issued options to purchase 200,000 shares of its Common Stock, exercisable at $0.79 per share which was the fair market value on the date of grant, to Janet Rea as an inducement grant for the employment of Ms. Rea as the Company's Vice President of Regulatory Affairs and Quality. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On November 11, 2015, Company entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $25 million of shares of our Common Stock over the 30-month term of the agreement. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On January 19, 2016, Ensisheim Partners, LLC, an entity wholly-owned by Drs. Steven C. Quay and Shu-Chih Chen, purchased 50,000 shares from the Company in an at-market transaction. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On February 16, 2016, Ensisheim Partners, LLC purchased 15,000 shares from the Company in an at-market transaction. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On March 9, 2016, Ensisheim Partners, LLC purchased 15,000 shares from the Company in an at-market transaction. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

On May 25, 2016 the Company entered into a stock purchase agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $10.0 million of shares of our Common Stock over the 30-month term of the agreement. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

Item 16. Exhibits and Financial Statement Schedules.

See Exhibit Index set forth on page II-6 to this Registration Statement.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

The undersigned registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on February 13, 2017.

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 constitutes and appoints Steven C. Quay, M.D., Ph.D. and Kyle Guse as attorneys-in-fact, with power of substitution, in any and all capacities, to sign any and all amendments and post-effective amendments to this Registration Statement, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	**Office(s)**	**Date**
/s/ Steven C. Quay **Steven C. Quay, M.D., Ph.D.**	Chairman, Chief Executive Officer and President (Principal Executive Officer)	February 13, 2017
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	February 13, 2017
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	February 13, 2017
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	February 13, 2017
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	February 13, 2017
/s/ Gregory L. Weaver **Gregory L. Weaver**	Director	February 13, 2017
/s/ Richard I. Steinhart **Richard I. Steinhart**	Director	February 13, 2017

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein Form	Date
1.1	Underwriting Agreement between the Company and Aegis Capital Corp., dated August 30, 2016	Current Report on Form 8-K, as Exhibit 1.1	September 2, 2016
2.1††	Agreement and Plan of Reorganization, dated September 30, 2012, by and among the Company, Acueity Healthcare, Inc., and Ted Lachowicz, as Stockholder Representative	Registration Statement on Form S-1, as Exhibit 2.1	October 4, 2012
3.1	Amended and Restated Certificate of Incorporation of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.2	June 11, 2012
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Atossa Genetics Inc.	Current Report on Form 8-K, as Exhibit 4.1	August 26, 2016
3.2	Bylaws of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.4	June 11, 2012
3.3	Amendment to Bylaws of Atossa Genetics Inc.	Current Report on Form 8-K, as Exhibit 3.1	December 20, 2012
3.4	Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock	Current Report on Form 8-K, as Exhibit 3.1	May 22, 2014
4.1	Specimen Common Stock Certificate	Registration Statement on Form S-1, as Exhibit 4.1	May 21, 2012
4.2	Form of Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.2	October 4, 2012
4.3	Form of Placement Agent Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.3	October 4, 2012
4.4	Form of Warrant dated September 30, 2012	Registration Statement on Form S-1, as Exhibit	October 4, 2012

		4.4	
4.5	Form of Warrant Agreement from January 2014 Public Offering	Current Report on Form 8-K, as Exhibit 4.1	January 20, 2014
4.6	Form of Warrant issued to Dawson James Securities Inc. in January 2014	Current Report on Form 8-K, as Exhibit 4.2	January 20, 2014
4.7	Rights Agreement between the Company and VStock Transfer, LLC, dated May 19, 2014	Current Report on Form 8-K, as Exhibit 3.1	May 22, 2014
4.8	Form of Pre-Funded Warrant from June 5, 2015 offering	Current Report on Form 8-K, as Exhibit 4.1	June 10, 2015
4.9	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated May 25, 2016	Current Report on Form 8-K, as Exhibit 4.1	May 27, 2016
5.1	Opinion of Gibson, Dunn & Crutcher, LLP	Filed herewith	
10.1#	Restated and Amended Employment Agreement with Steven Quay	Registration Statement on Form S-1, as Exhibit 10.3	February 14, 2012
10.2#	Restated and Amended Employment Agreement with Shu-Chih Chen	Registration Statement on Form S-1, as Exhibit 10.4	February 14, 2012

10.3	Form of Indemnification Agreement	Registration Statement on Form S-1, as Exhibit 10.5	May 21, 2012
10.4#	Atossa Genetics Inc. 2010 Stock Option and Incentive Plan, as amended	Quarterly Report on Form 10-Q, as Exhibit 10.3	November 14, 2016
10.5#	Form of Incentive Stock Option Agreement	Registration Statement on Form S-1, as Exhibit 10.7	June 11, 2012
10.6#	Form of Non-Qualified Stock Option Agreement for Employees	Registration Statement on Form S-1, as Exhibit 10.8	June 11, 2012
10.7#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	Registration Statement on Form S-1, as Exhibit 10.9	June 11, 2012
10.8	Form of Subscription Agreement	Registration Statement on Form S-1, as Exhibit 10.10	February 14, 2012
10.9	Patent Assignment Agreement by and between the Company and Ensisheim Partners, LLC	Registration Statement on Form S-1, as Exhibit 10.12	April 6, 2012
10.10#	Form of Restricted Stock Award Agreement	Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.11	Office Lease with Sander Properties, LLC, dated March 4, 2011	Registration Statement on Form S-1, as Exhibit 10.20	April 6, 2012
10.12	Office Lease with Sander Properties, LLC, dated July 8, 2011	Registration Statement on Form S-1, as Exhibit 10.21	April 6, 2012
10.13	Office Lease with Sander Properties, LLC, dated September 20, 2011	Registration Statement on Form S-1, as Exhibit 10.22	April 6, 2012
10.14	Sublease with Fred Hutchinson Cancer Research Center, dated December 9, 2011	Registration Statement on Form S-1, as Exhibit 10.23	April 6, 2012
10.15†	Purchase Agreement between the Company and Hologic Inc., dated May 11, 2011	Registration Statement on Form S-1, as Exhibit 10.28	June 25, 2012
10.16†	Supply and Distribution Agreement, dated as of September 21, 2012, between the Company and Diagnostics Test Group LLC	Registration Statement on Form S-1, as Exhibit 10.31	October 4, 2012
10.17	Amended and Restated Employment Agreement between the Company and Kyle Guse dated May 18, 2016#	Current Report on Form 8-K, as Exhibit 10.1	May 20, 2016
10.18	Purchase Agreement, dated as of March 27, 2013, by and between the Company and Aspire Capital Fund, LLC	Annual Report on Form 10-K, as Exhibit 10.30	March 28, 2013

10.19	Purchase Agreement, dated as of November 8, 2013, by and between the Company and Aspire Capital Fund, LLC	Quarterly Report on Form 10-Q, as Exhibit 10.2	November 12, 2013
10.20	OwnerChip Program Agreement dated September 1, 2013, by and between The National Reference Laboratory for Breast Health, Inc. and Affymetrix, Inc.	Quarterly Report on Form 10-Q, as Exhibit 10.1	November 12, 2013
10.21	License and Services Agreement dated June 10, 2013, between Atossa Genetics and A5 Genetics KFT	Annual Report on Form 10-K, as Exhibit 10.32	March 27, 2014

10.22	Office Space Lease dated July 18, 2013 between Alexandria (ARE) and the Company	Annual Report on Form 10-K, as Exhibit 10.33	March 27, 2014
10.23	Lab and Office Space Lease Agreement dated March 24, 2014 between Alexandria (ARE) and the Company	Annual Report on Form 10-K, as Exhibit 10.35	March 27, 2014
10.24	Offer Letter Agreement dated March 20, 2014 between the Company and Ben Chen#	Post-Effective Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 10.34	April 28, 2014
10.25#	Offer Letter Agreement dated May 23, 2013 between the Company and with Peter Carbonaro	Quarterly Report on Form 10-Q, as Exhibit 10.1	May 14, 2014
10.26#	Offer Letter Agreement dated November 12, 2012 between the Company and Chris Destro	Quarterly Report on Form 10-Q, as Exhibit 10.2	May 14, 2014
10.27	Office Space Assignment and Assumption of Lease and Consent to Assignment dated August 8, 2014 between Legacy Group, Inc. and the Company	Quarterly Report on Form 10-Q, as Exhibit 10.1	August 12, 2014
10.28#	Offer Letter Agreement dated May 23, 2014 between the Company and with John Sawyer	Annual Report on Form 10-K, as Exhibit 10.30	March 30, 2015
10.29	Intellectual Property License Agreement dated May 14, 2015 between the Company and Besins Healthcare Luxembourg SARL	Current Report on Form 8-K, as Exhibit 10.1	May 18, 2015
10.30	Placement Agent Agreement dated June 5, 2015 among the Company, Roth Capital Partners, LLC and Dawson James Securities, Inc.	Current Report on Form 8-K, as Exhibit 10.1	June 10, 2015
10.31	Form of Subscription Agreement from June 5, 2015 offering.	Current Report on Form 8-K, as Exhibit 10.2	June 10, 2015
10.32	Stock Purchase Agreement, between the Company, National Reference Laboratory For Breast Health and the NRL Investment Group, LLC, dated as of December 16, 2015	Current Report on Form 8-K, as Exhibit 10.1	December 16, 2016
10.33	Office Lease Agreement dated October 1, 2015 between Hughes-Northwest, Inc. and the Company.	Annual Report on Form 10-K, as Exhibit 22.1	March 30, 2016
10.34	Employment Separation Agreement and Release dated February 3, 2016 between Scott Youmans and the Company.	Current Report on Form 8-K, as Exhibit 10.1	February 8, 2016
10.35	Common Stock Purchase Agreement, between the Company and Aspire Capital Fund, LLC, dated as of May 25, 2016	Current Report on Form 8-K, as Exhibit 10.1	May 27, 2016

10.36	Settlement and Termination of License Agreement between Besins Healthcare Luxembourg SARL and its Affiliates and Atossa Genetics, Inc. dated August 4, 2016	Current Report on Form 8-K, as Exhibit 10.1	August 5, 2016
21.1	List of Subsidiaries	Annual Report on Form 10-K, as Exhibit 22.1	March 30, 2016
23.1	Consent of BDO USA, LLP.	Filed herewith	
23.2	Consent of Gibson, Dunn & Crutcher, LLP	Filed as part of Exhibit 5.1 to this Registration Statement on Form S-1	
24.1	Powers of Attorney	Included on the signature page in Part II of this Registration Statement on Form S-1	

#Indicates management contract or compensatory plan, contract or agreement.

†Confidential treatment has been granted for portions of this exhibit. These portions have been omitted from this Registration Statement and submitted separately to the Securities and Exchange Commission.

‡Schedules and exhibits omitted pursuant to Item 601 of Regulation S-K.