ATOSSA GENETICS INC
Form S-1/A
June 18, 2012

As filed with the Securities and Exchange Commission on June 18, 2012

Registration No. 333-179500

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 4 to
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 Number)

4105 E. Madison Street, Suite 320
Seattle, Washington 98112
(206) 325-6086

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

Steven C. Quay, M.D., Ph.D.
Chairman, Chief Executive Officer and President
4105 E. Madison Street, Suite 320
Seattle, Washington 98112
(206) 325-6086

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

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Approximate Date of Commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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. o

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. o

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 registration statement for the same offering. o

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 number of the earlier effective registration statement for the same offering. o

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 definitions large accelerated filer, accelerated file, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company x (Do not check if a smaller reporting company)

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.

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 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

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The information contained in this prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and these securities may not be sold until that registration statement becomes effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION DATED JUNE 18, 2012**

Up to 1,000,000 Shares

This is the initial public offering of up to 1,000,000 shares of our common stock. We expect the initial public offering price will be between $5.00 and $7.00 per share. Currently, no public market exists for our securities. We have applied for listing of the shares on the NASDAQ Capital Market under the symbol ATOS .

	Per Share	Total
Public offering price	$	$
Placement agent fees*	$	$
Proceeds, before expenses, to Company	$	$

* Does not include a non-accountable expense reimbursement fee of 3% of the gross proceeds of this offering.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in these securities involves a high degree of risk.

See Risk Factors contained in this prospectus beginning on page 10.

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

Dawson James Securities, Inc. is the placement agent for this offering. Dawson James is not purchasing or selling any shares of common stock, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of common stock, other than to use their best efforts (with no minumum) to arrange for the sale of common stock by us. We intend to close the offering within four trading days from the date of pricing of the offering. We have not arranged to place the funds from investors in an escrow, trust or similar account.

Delivery of the shares of common stock will be made on or about , 2012.

The date of this prospectus is , 2012.

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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Unless the context requires otherwise, in this prospectus the terms we, us and our as well as the Company refer t Atossa Genetics Inc. and our wholly-owned subsidiary, National Reference Laboratory for Breast Health Inc.

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PROSPECTUS SUMMARY

This summary highlights some information from this prospectus. It may not contain all the information important to making an investment decision. You should 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 Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes, included elsewhere in this prospectus.

The Company

We are a healthcare company focused on the prevention of breast cancer through the commercialization of diagnostic tests that can detect precursors to breast cancer, and through the research, development, and ultimate commercialization of treatments for pre-cancerous lesions.

Our diagnostic tests consist of patented medical devices cleared by the Food and Drug Administration, or FDA, that can collect fluid samples from the breast milk ducts, where, according to the National Cancer Institute, over 95% of breast cancers arise. These samples are processed at our wholly-owned National Reference Laboratory for Breast Health, which has been certified pursuant to the Clinical Laboratory Improvement Amendments, or CLIA, has been licensed in the states of California, Florida, Maryland, Rhode Island, and Washington, and is in the process of obtaining a license to accept testing samples from New York (which requires out-of-state laboratories to hold a state license). CLIA certification is legally required to receive reimbursement from federal or state medical benefit programs, like Medicare and Medicaid, and is a practical requirement for most third-party insurance benefit programs. Our CLIA-certified laboratory, which is permitted to accept samples from all 50 states under its CLIA certification, its state licenses, or, in New York under recognized exemption provisions while its license application is pending, examines the specimens by microscopy for the presence of normal, pre-malignant, or malignant changes as determined by cytopathology and biomarkers that distinguish usual ductal hyperplasia, a benign condition, from atypical ductal hyperplasia, which may lead to cancer. These cytopathological results provide patients and physicians with information about the care path that should be followed, depending on the individual risk of future cancer as determined by the results.

Additionally, we are conducting research on the treatment of these pre-cancerous cells by using our patented and FDA-cleared microcatheters to deliver, directly into the milk ducts, pharmaceutical formulations that can be used to treat these pre-cancerous lesions. By using this localized delivery method, patients are expected to receive high local concentrations of these drugs at the site of the pre-cancerous lesions, potentially promoting efficacy of the treatment while limiting systemic exposure, which has the potential to lower the overall toxicity of these treatments.

We launched our commercial operations in late 2011 and, as of June 8, 2012, have enrolled and sold MASCT System kits or provided ArgusCYTE collection kits to 34 doctors and clinics as providers of the ForeCYTE and/or ArgusCYTE tests. We have received, processed, and reported the results to physicians from 276 ForeCYTE samples and 13 ArgusCYTE samples as of March 31, 2012 and 858 ForeCYTE samples and 39 ArgusCYTE samples as of June 18, 2012. When we launched operations in December 2011, we did so as part of our field experience trial to collect information about the ease or difficulty of adoption of the ForeCYTE and ArgusCYTE tests in both mammography clinics and physicians offices, the number of sales calls to receive the first orders, and the growth of sales of specimen collection kits on a monthly basis. We intend to use the data from this field experience trial to form our national marketing efforts as we scale up our commercial operations going forward. As of December 31, 2011 and March 31, 2012, we have generated $1,500 and $54,713 in revenue, respectively, from the sale of our products and

services. We incurred net operating losses of approximately $1.0 million, $1.1 million and $3.4 million for our three months ended March 31, 2012 and our fiscal years ended December 31, 2010 and 2011, respectively. As of March 31, 2012, we had an accumulated deficit of approximately $5.7 million. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities, selling the MASCT System and generating laboratory service revenue from our tests, and making short-term borrowings from stockholders or other related parties when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

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Our Diagnostic Tests

We currently offer two diagnostic tests and plan to offer two additional tests in late 2012 or early 2013. The tests that we currently offer and that are in development consist of the following:

ForeCYTE	The ForeCYTE Breast Health Test, launched in December 2011, provides personalized information about the 10-year and lifetime risk of breast cancer for women between ages 18 and 65. It involves collecting a specimen of nipple aspirate fluid, or NAF, using our patented, FDA-cleared *Mammary Aspirate Specimen Cytology Test*, or MASCT, System (our MASCT System received 510(k) clearance from the FDA in 2003). The NAF specimen is collected by a physician and returned to our CLIA-certified laboratory. We study the patient s NAF specimen and use a proprietary molecular and cellular biomarker test that detects basal or luminal cells to identify the presence of atypical ductal hyperplasia, or ADH, which is considered a precursor to breast cancer. We then input these cytopathological test results, together with the patient s personal medical and reproductive history and family history, into a clinically-validated risk assessment algorithm that calculates 10-year and lifetime risk of breast cancer and presents these results in one of three risk tiers developed by The National Comprehensive Cancer Network: Normal (<15% lifetime risk), Intermediate (15 20% lifetime risk), or High (>20% lifetime risk). The ForeCYTE Test results contain recommendations for care paths in each risk group and personalized information so that patients and healthcare providers can make more informed treatment decisions. The algorithm was developed from a Swedish registry of 158,041 individuals, in whom 3,257 cancers occurred, and was validated by E. Amir, D.G. Evans, A. Shenton, and others in an independent study of 3,150 women, 64 of whom developed breast cancer. The algorithm incorporates family history, personal reproductive history, and the presence or absence of usual ductal hyperplasia, or UDH (which is benign), ADH (which is pre-malignant) or malignant changes.
ArgusCYTE	The ArgusCYTE Breast Health Test, launched in December 2011, provides information to help inform breast cancer treatment options and to help monitor potential recurrence. It involves collecting a blood specimen from a patient using our patented, FDA 510(k)-Exempt blood collection tube and submitting it to our CLIA-certified laboratory (our ArgusCYTE Breast Health Test blood collection tube was registered with the FDA in 2011). It can monitor breast cancer distant recurrence by obtaining a liquid biopsy or blood sample, and analyzing it for the presence of circulating tumor cells, which can then be analyzed to determine the expression of Estrogen Receptor/Progesterone Receptor, or ER/PR, and Human Epidermal Growth Factor Receptor, or Her2, in those cells, a predictor of the cancer s sensitivity to existing treatment options. The presence of circulating tumor cells in the blood sample may serve as an early indicator of the recurrence of breast cancer and the data obtained from the ArgusCYTE sensitivity analysis may help physicians better select which treatment options to use with a particular patient. The ArgusCYTE test uses a proprietary blood collection tube to obtain a blood sample for shipment and analysis at our CLIA-certified laboratory. The

supplier of the blood collection tube owns patents with respect to the tube, while we own patents concerning laboratory features utilized in the testing process.

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FullCYTE	The FullCYTE Breast Health Test, which we intend to launch in late 2012 or early 2013 and is currently in development, is designed to assess the individual breast ducts for pre-cancerous changes in women previously identified to be at high risk for breast cancer. It involves collecting ductal lavage samples from each of the five to seven individual breast milk ducts using our patented and FDA-cleared Mammary Ductal Microcatheter System (our Microcatheter System received 510(k) clearances from the FDA in 1999 and 2000) and analyzing the samples by the same molecular and cellular biomarkers used in the ForeCYTE test described above. From these tests, we are able to ascertain which individual duct contains pre-malignant or malignant changes, which may allow the physician to better target treatment to the specific duct with the pre-malignant changes or malignant changes and therefore avoid side effects associated with systemic treatment. Traditional biopsies, involving invasive procedures in which tissue is removed surgically, typically cut across the natural anatomy of the breast ductal system, making subsequent intraductal treatment difficult or, in certain cases, impossible.
NextCYTE	The NextCYTE Breast Cancer Test, which is in the prevalidation phase and which we intend to launch in late 2012 or early 2013, is designed to profile breast cancer specimens for prediction of treatment outcomes and distant recurrence in women newly diagnosed with breast cancer. It involves using surgery specimens and advanced genome sequencing techniques to quantify and analyze the entire tumor genetic transcriptome, which represents all genes that are being actively expressed within the tumor. We expect that physicians will be able to use the information provided by the NextCYTE test to better customize treatment options for women, based on the genetic composition of the individual tumor. We are currently conducting non-clinical trial research to verify the superiority of the technology regarding NextCYTE by profiling gene expression from breast cancer biopsy specimens obtained from commercial archival tissue banks, in which the five-year survival or death for the patients from whom the specimens are taken is known, and seeing if the algorithm can accurately predict the known outcome. The experiments are being conducted in a blinded fashion, without knowledge of the survival data, and we will not have knowledge of the outcome until the blind is broken (currently planned for September 2012). We own a pending PCT patent application on the NextCYTE technology and have an option through February 2013 to license additional technology to augment our existing technology from the University of Oslo in Norway.

We may not, however, achieve commercial market acceptance of any of our products and services. We must first demonstrate to physicians and other healthcare professionals the benefits of our tests and the MASCT System for their practice and these physicians and healthcare professionals may be reluctant to introduce new services into their practice due to uncertainty regarding reliability of the results of a new product or the learning curve associated with adoption of new services and techniques. Moreover, if third-party payors continue to refuse to cover the cost of collection of the NAF sample, whether from our MASCT System or competitors NAF collection devices, physicians may be less likely to recommend or use our products and services if the cost of performing a particular test will not be reimbursed. Even if we are successful in convincing physicians and other healthcare professionals to utilize our tests and services, we must obtain adequate capital to fund our operations until we become profitable and we may not be able to do so. Additionally, we have no prior experience with commercializing any products or services and will need to create an infrastructure to scale operations for commercialization, including hiring experienced personnel (including anatomic pathologists, cytologists, histotechnologists, skilled laboratory and information technology staff, and sales

representatives) and building a network of regional, specialty distributors, each with a staff of independent sales representatives who have experience in women s health products to target physicians and mammography clinics in the United States.

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Intraductal Treatment Research

Our Intraductal Treatment Research Program comprises our patented microcatheter-delivery technology and our patented pharmaceutical formulations for the intraductal treatment of breast pre-cancerous changes, ductal carcinoma in situ, or DCIS, and breast cancers. The method uses our Mammary Ductal Microcatheter System, invented by Dr. Susan Love, President of the Dr. Susan Love Research Foundation, and her colleagues, to administer proprietary pharmaceutical formulations into milk ducts that display pre-cancerous changes, with high local concentrations of the drugs in order to promote greater efficacy and limited systemic exposure, potentially lowering the overall toxicity of the treatment.

An October 2011 peer-reviewed paper published in *Science Translational Medicine* documented a study conducted at the Johns Hopkins Medical School demonstrating the prevention of breast cancer in rats with intraductal non-systemic chemotherapy, and a proof-of-principle Phase 1 clinical trial involving 17 women with breast cancer who subsequently received surgery. An accompanying editorial commented that intraductal treatment could be especially useful for women with premalignant lesions or those at high risk of developing breast cancer, thus drastically improving upon their other, less attractive options of breast-removal surgery or surveillance (termed watch and wait). We intend to build on these academic studies with a research program targeted initially at neoadjuvant therapy in DCIS and to begin preclinical studies during 2012. We have not yet begun the process of applying for FDA approval of our Intraductal Treatment Research Program.

Intellectual Property and FDA Marketing Clearances

As of February 8, 2012, we own more than 120 issued patents (31 in the United States and at least 90 in foreign countries), and 6 pending patent applications (4 in the United States, 1 pending foreign application and 1 pending International Patent Cooperation Treaty (PCT) application) directed to our products, services, and technologies.

Our Founder

Our founder and chief executive officer, Steven C. Quay, M.D., Ph.D., FCAP, invented the MASCT System. Dr. Quay is a board-certified anatomic pathologist who completed both an internship and residency in anatomic pathology at the Massachusetts General Hospital, a Harvard Medical School teaching hospital, and is a former faculty member of the pathology department of Stanford University School of Medicine. He holds 76 U.S. patents and has invented and developed five FDA-approved pharmaceuticals.

Our Commercialization Strategy

The ForeCYTE Test provides us with two revenue sources:

(i) revenue from the sale of the MASCT System device and patient kits to physicians, breast health clinics, and mammography clinics; and
(ii) service revenue from the preparation and interpretation of the NAF samples sent to our laboratory for analysis.

The ArgusCYTE test provides only laboratory service revenue.

We offer each component of the MASCT System for sale separately. We currently price our NAF sample collection device at approximately $250 per device and our patient kits at approximately $30 per kit, and the cytology and molecular diagnostics testing and analysis services are billed to federal and/or state health plans at the 2012 Medicare

reimbursement rates of either $384 or $1,275 per patient, depending on the complexity of the analysis performed. We expect that the substantial majority of patients will be billed at the $384 rate and that we would perform the more complex tests, corresponding with a reimbursement rate of $1,275, for only those patients who have an initial test result that requires further analysis. We have billed the testing and analysis regarding the 276 ForeCYTE samples processed through March 31, 2012 (which is equivalent to 138 patients) at the 2012 Medicare reimbursement rate of $384 per patient. We bill third-party payors at higher rates, as is customary for our industry. Currently, Medicare and certain insurance carriers do not reimburse for the NAF collection procedure by our MASCT System or for other NAF collection device systems similar to our MASCT System, although Medicare and certain insurance carriers do reimburse for the laboratory

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analysis of the NAF sample. Although we have received reimbursement from insurance carriers and Medicare for both our ForeCYTE and ArgusCYTE tests, any lack of Medicare or insurance coverage for the NAF collection procedure will require patients to bear the full costs of the NAF sample acquisition process used with the MASCT System, which may result in physicians and other healthcare professionals not adopting the MASCT System or recommending its use in patients. If this were to occur, we may be forced to reduce the price of the MASCT System, provide discounted pricing arrangements to secure sales, or we may not be able to sell the product and services components of the MASCT System at acceptable margins, all of which could limit our ability to generate revenue.

While we are conducting our field experience trial we are not charging for our ArgusCYTE collection kits and we currently price the ArgusCYTE test at approximately $1,500. Because we do not currently have a sufficiently reliable prior history of reimbursement with respect to the ArgusCYTE test, we currently do not recognize revenue until we have received reimbursement. As of March 31, 2012, we have not received reimbursement for any ArgusCYTE tests.

In December 2011, we began limited marketing of the ForeCYTE Test to physicians, primarily obstetric-gynecologists, as well as breast health and mammography clinics, for use in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. We are establishing relationships with breast cancer centers to provide the ArgusCYTE Test to their patients. We plan to use regional specialty product distributors, with independent sale representatives specializing in women s health, to commercialize the ForeCYTE and ArgusCYTE Tests; however, we currently do not have distributor relationships and we cannot be certain that we will be able to build these relationships to adequately address the regional or national market. As of March 1, 2012 we had one person involved in sales.

Risk Factors

Our business is subject to numerous risks as discussed more fully in the section entitled Risk Factors beginning on page 10. Principal risks of our business include, but are not limited to, the following:

we will need significant additional capital to execute our business strategy as currently contemplated and have not identified significant alternative sources of funding, should this offering be unsuccessful;
we have a history of operating losses and expect to incur losses for the foreseeable future and may never achieve profitability;
The MASCT System and other risk assessment tools, diagnostic tests and other predictive and personalized medicine products that we may develop may never achieve significant commercial market acceptance;
we are dependent on the commercial success of the MASCT System and the ForeCYTE and ArgusCYTE Tests;
we may not be successful in commercializing the MASCT System because physicians and clinicians may be slow to adopt our product and, even if commercialized, the fees we receive for our products and services may be significantly lower than currently expected;
our ability to commercialize the MASCT System may be limited because Medicare and certain insurance carriers are not expected to provide reimbursement for the NAF sample collections which are necessary for our tests (even though Medicare and certain insurance carriers do provide reimbursement for the laboratory analysis of the collected NAF samples through our ForeCYTE and ArgusCYTE tests);
we may not be able to hire, train or maintain the independent sales representatives and build the distributorship arrangements necessary to market and sell the MASCT System and our services as planned; and
because the offering is on a best efforts, no-minimum basis, we may raise substantially less than the total offering amount contemplated by this prospectus, and, even if the offering is fully subscribed, we will need additional capital in the future.

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Implications of being an Emerging Growth Company

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

Only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure.

Reduced disclosure about our executive compensation arrangements.

Not having to obtain non-binding advisory votes on executive compensation or golden parachute arrangements.

Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates, or we issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. We have taken advantage of these reduced reporting burdens in this prospectus, and the information that we provide may be different than what you might get from other public companies in which you hold stock.

Company Information

We were incorporated in Delaware in April 2009. Our principal executive offices are located at 4105 East Madison Street, Suite 320, Seattle, Washington 98112, and our telephone number is (206) 325-6086. Our corporate website is located at *www.atossagenetics.com* and our laboratory website is located at *www.nrlbh.com*. Information contained on, or that can be accessed through, our websites is not a part of this prospectus.

MASCT is our registered trademark and Oxy-MASCT and our name and logo are our trademarks. ForeCYTE, FullCYTE, NextCYTE, 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.

Our company name comes from Queen Atossa, daughter of Cyrus the Great and wife of Darius I, the King of the Achaemenid Empire. In about 470 BC, she became the first woman in recorded history to be diagnosed with breast cancer, of which she died.

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THE OFFERING

Securities offered by us:

Up to 1,000,000 shares of common stock.

Capitalization after the offering:

Up to 12,256,867 shares of common stock outstanding after the offering.

Use of proceeds:

We intend to use the net proceeds from this offering to expand our cytology and molecular diagnostics laboratory, fund the manufacture of MASCT System units, hire and train sales and marketing personnel, continue the research and development of the FullCYTE and NextCYTE Tests, support the internal research and development of the Intraductal Treatment Research Program, and for general corporate purposes. See Use of Proceeds.

Proposed NASDAQ trading symbol:

ATOS

The number of shares of our common stock outstanding is based on 11,256,867 shares of common stock outstanding as of March 31, 2012, and excludes 608,000 shares issuable upon the exercise of options outstanding as of March 31, 2012 under our 2010 Stock Option and Incentive Plan, or 2010 Plan, as well as 842,274 shares of common stock reserved for future issuance under our 2010 Plan, in addition to 6,833,840 shares of common stock underlying outstanding warrants with a weighted-average exercise price of $1.56 per share.

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SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. The summary financial data in this section is not intended to replace our financial statements and the related notes. Our historical results are not necessarily indicative of the results to be expected for any future period.

We were incorporated on April 30, 2009. The following statement of operations data, including share data, for the fiscal years ended December 31, 2010 and 2011 have been derived from our audited financial statements and related notes included elsewhere in this prospectus. The balance sheet data as of December 31, 2011 and December 31, 2010 has been derived from our audited financial statements included elsewhere in this prospectus. The statement of operations data, including share data, for the three months ended March 31, 2011 and 2012, and the balance sheet data as of March 31, 2012, have been derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect all adjustments necessary to fairly state our financial position as of March 31, 2012 and results of operations for the three months ended March 31, 2011 and 2012. The operating results for any period are not necessarily indicative of financial results that may be expected for any future period.

	For The Years Ended December 31,		For The Three Months Ended March 31,		From April 30, 2009 (Inception) Through March 31,
	2011	2010	2012 (Unaudited)	2011 (Unaudited)	2012 (Unaudited)
Statement of Operations Data:					
Revenue					
Diagnostic Testing Service	$	$	$52,713	$	$52,713
Product Sales	1,500		2,000		3,500
Total Revenue	1,500		54,713		56,213
Cost of Revenue					
Diagnostic Testing Service			(3,197)		(3,197)
Product Sales	(5,164)				(5,164)
Total Cost of Revenue	(5,164)		(3,197)		(8,361)
Loss on Reduction of Inventory to LCM	(92,026)		(23,807)		(115,833)
Gross Profit (Loss)	(95,690)		27,709		(67,981)
Selling expenses	(160,851)	(12,204)	(70,435)		(243,490)
General and Administrative expenses	(3,172,649)	(1,065,792)	(1,019,442)	(225,423)	(5,380,741)
Total Operating Expenses	(3,333,500)	(1,077,996)	(1,089,877)	(225,423)	(5,624,231)
Operating Loss	(3,429,190)	(1,077,996)	(1,062,167)	(225,423)	(5,692,210)
Interest Income	4,914	455	863		6,232
Interest Expense	(17,992)	(9,139)	(1,613)	(4,968)	(28,744)
Net Loss before Income Taxes	(3,442,269)	(1,086,680)	(1,062,917)	(230,391)	(5,714,722)
Income Taxes		250			250

Net Loss		$(3,442,269)	$(1,086,930)	$(1,062,917)	$(230,391)	$(5,714,972)
Loss per common share	basic	$(0.38)	$(0.18)	$(0.09)	$(0.04)	$(0.81)
Weighted average shares outstanding, diluted		$(0.38)	$(0.18)	$(0.09)	$(0.04)	$(0.81)
Weighted average shares outstanding, basic		9,117,746	5,935,897	11,256,867	6,000,067	7,039,480
Weighted average shares outstanding, diluted		9,117,746	6,004,721	11,256,867	6,000,067	7,039,480

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	As of March 31, 2012 (Unaudited)
Balance Sheet Data:	
Total assets	$1,365,979
Total liabilities	$779,292
Stockholders equity:	
Common Stock, $0.001 par value, 75,000,000 shares authorized, 11,256,867 shares outstanding, actual, as of March 31, 2012	11,257
Additional paid-in capital	6,290,402
Accumulated deficit	(5,714,972)
Total stockholders equity	586,687
Total liabilities & stockholders equity	$1,365,979

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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 following information about these risks, together with the other information contained in this prospectus, before purchasing our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the common stock could decline, and you may lose part or all of your investment in our company.

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 are a development stage company, with operations beginning in December 2008 around acquiring the MASCT System patent rights and assignments and the FDA clearance for marketing, which was completed in January 2009. We were incorporated in Delaware in April 2009 and our operations to date have consisted primarily of securing manufacturing for the MASCT and the Duct Microcatheter Systems, establishing our CLIA-certified laboratory, validating the Laboratory Developed Tests we use in the ForeCYTE and ArgusCYTE tests, conducting research and development on the FullCYTE and NextCYTE tests, and beginning the commercialization of our products. We will require significant additional capital to achieve our business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

Our revenue and income potential 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:

execute our business plan and commercialization strategy;
work with contract manufacturers to produce the MASCT and Microcatheter Systems in commercial quantities;
create brand recognition;
respond effectively to competition;
manage growth in operations;
respond to changes in applicable government regulations and legislation;
access additional capital when required;
sell our products and service at the prices currently expected; and
attract and retain key personnel.

Our independent auditors have issued a report questioning our ability to continue as a going concern.

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

We will depend on the proceeds from this offering to continue the commercial launch of the ForeCYTE and ArgusCYTE Tests, and we do not have specific plans to obtain funding from alternative sources; if the proceeds from this offering are insufficient, the further commercial launch of our tests may be delayed.

We expect to spend substantial amounts of capital to:

launch and commercialize the ForeCYTE and ArgusCYTE Tests, including the manufacture of the device in commercial quantities and building an independent distributor sales force to address certain markets;

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maintain laboratory facilities for our testing and analytical services, including necessary testing equipment; and
continue our research and development activities to advance our product pipeline.

We expect that we will require additional capital beyond the proceeds from this offering to complete our commercialization plans and may need to raise additional funds if we encounter delays or problems in the production of the MASCT System device in commercial quantities, or the establishment of a larger sales force. We have not identified sources for such additional funding 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.

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

We will need considerable amounts of capital to develop our business. We may raise funds through public or private equity offerings or debt financings. If we cannot raise funds on acceptable terms when needed, we may be unable to grow or maintain the business. 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 expressed doubt as to our ability to continue as a going concern, as reported in their report on our financial statements, 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, we currently sell the MASCT System for significantly less than it costs to manufacture, and we expect to continue to incur losses in the future.

We have a limited operating history and have incurred total net operating losses of approximately $5.7 million from our incorporation in April 2009 through March 31, 2012. We have received $56,213 in revenue as of March 31, 2012 and we do not expect that we will be in a position to generate significant revenue until we are able to launch our tests more broadly. Additionally, we will continue to incur further losses in connection with inventory costs for our medical test products, marketing and sales expenses in launching our products and services, research and development costs for additional tests, and the maintenance of our CLIA-certified laboratory. For example, the sales price of our MASCT System is currently substantially lower than its cost because the MASCT System is currently manufactured only in sufficient quantities to be utilized in our field experience trial and because the Company s current marketing strategy is to attempt to quickly penetrate the market of the products and services offered by the Company by offering the MASCT System at a price substantially lower than its cost to attract market awareness. This practice of selling our MASCT System substantially below its cost negatively impacts our profitability. Although we expect that the cost to manufacture our MASCT System will be substantially lower when we increase the volume of production for post-trial commercial launch and once we have been more successful in penetrating the market, if our expectation is not realized we may not be able to generate significant revenue nor achieve profitability. Accordingly, we may never achieve profitability.

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 were to raise additional capital by issuing equity securities, the value of the then outstanding common stock would be reduced, unless the additional equity securities were issued at a price equal to or greater than the market value of the common stock at the time of issuance of the new securities. If the additional equity securities were 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 and services that we have developed or may develop may never achieve significant commercial market acceptance.

We may not succeed in achieving commercial market acceptance of any of our products and services. In order to market the MASCT System and to gain market acceptance for the MASCT System and our

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ForeCYTE and ArgusCYTE Tests, we will need to demonstrate to physicians and other healthcare professionals the benefits of the MASCT System and its practical and economic application for their particular practice. Despite FDA clearance for the MASCT System, many physicians and healthcare professionals may be hesitant to introduce new services, or techniques, into their practice for many reasons, including 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 and services.

We will likely be increasingly required to offer discounted pricing arrangements to managed care payors and physicians and other referral services in response to competitive pressures.

There are other companies within the medical device product industry that have products used in NAF collection and there are laboratories other than ours that can process NAF samples. Because of this existing competition, as well as potential future competition from additional companies and laboratories, we will likely be increasingly required to offer discounted pricing arrangements to managed care payors, physicians and other referral services so that our products and services are selected over the products and services of others. If we offer such discounted pricing arrangements, our revenue will decrease and we may not generate sufficient revenue to cover our operating costs, which could materially adversely affect our business.

Additionally, such discounts could raise issues under the federal Anti-Kickback Statute and Medicare s discriminatory billing prohibition. If we were found to be in violation of such statute or prohibition, we could be subject to significant fines, and these fines would likely materially adversely affect our business and results of operations.

We may encounter difficulties in operating or maintaining our laboratory facility, which could cause delays and unexpected problems.

We have established the CLIA-certified National Reference Laboratory for Breast Health as a wholly-owned subsidiary and we rely on this physical facility in Seattle, Washington for the testing of patient samples. Our facility has received California, Florida, Maryland, Rhode Island, and Washington state laboratory licenses, and federal CLIA laboratory certification. However, our management team does not have significant prior experience with establishing and managing this type of laboratory facility. In addition, certain pieces of laboratory equipment required for the performance of our testing and analytical services may be difficult and costly to replace, and may require significant replacement lead-time. In the event that we are unable to maintain the laboratory facility in good working order, or if such laboratory or equipment is adversely affected by periodic malfunctions or man-made or natural disasters, then we may be unable to conduct business and meet potential customer demands for a significant period of time, which could negatively affect revenue and our long-term prospects.

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 the MASCT System, maintain our clinical and diagnostic laboratory, and attract and retain highly skilled professional, sales and marketing 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 do not currently maintain key man insurance with respect to Dr. Quay. The loss of his services for any reason could impede our ability to achieve our objectives, such as the commercialization of the MASCT System and the development of a core of healthcare professionals who use the MASCT System, particularly initially, as we seek to build a reputation among physicians and clinicians.

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 anatomic pathologists, cytologists, histotechnologists, skilled laboratory and information technology staff, experienced sales representatives, and other personnel, particularly in the Greater Seattle area as we expand our commercialization activities. These

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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, revenue and earnings may be adversely affected.

We have no prior experience with commercializing any products or services, and will need to establish a sophisticated sales and marketing effort in order to be successful.

We intend to build a network of regional, specialty distributors, each with a staff of independent sales representatives with experience in women s health products to target physicians and mammography clinics in the United States. Marketing our products to physicians and healthcare professionals will require us to educate such professionals on the comparative advantages of our products over other methods currently used for the detection and diagnosis of breast cancer. Experienced independent sales representatives may be difficult to locate and all sales representatives will need to undergo extensive training. We will need to incur significant costs to build, train, supervise and effectively deploy this independent sales force. We cannot be certain that we will be able to recruit sufficiently skilled sales representatives or that any new sales representatives will ultimately become productive. Independent sales representatives may carry competing products or products that provide a better financial return to them and therefore may not emphasize our products. If we are unable to recruit, train and retain qualified and productive independent sales personnel, our ability to successfully commercialize our products and services will be impaired.

We use third-party suppliers for the production of the MASCT and Microcatheter Systems, which are currently manufactured in small quantities. If such suppliers are not capable of producing quantities of these systems sufficient 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 MASCT and Microcatheter Systems, including the NAF collection device and patient collection kits and for the laboratory instruments, equipment, consumable supplies, and other materials necessary to perform the specialized diagnostic tests. If our third-party suppliers cannot produce the MASCT or Microcatheter Systems in quantities sufficient for our commercial needs on acceptable terms when needed, we may be unable to commercialize the MASCT System and Microcatheter System 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.

Currently Medicare and certain insurance carriers will not reimburse for the NAF collection procedure, which could slow or limit adoption of the MASCT System or prevent us from pricing the MASCT System at desired levels.

We may experience difficulty in locating, attracting, andretaining experienced and qualified personnel, whi[illegible]n coulda

The Halo® Breast Pap Test, an NAF collection device similar to the MASCT System, is being marketed by Halo Healthcare, Inc. (formerly Neomatrix, LLC) of Irvine, California (Halo Healthcare, Inc. owns the registered trademark Halo®). Certain insurance carriers do not currently reimburse for the HALO System procedures. For example, in September 2010, United Healthcare published a policy statement indicating that it would not cover the costs of these procedures because it believes there is insufficient clinical evidence to support medical efficacy, based on its conclusion that there is inadequate clinical evidence that automated nipple aspiration either allows for better clinical decision-making or reduces breast cancer mortality. United Healthcare also recommended further studies to determine the efficacy of cytological examination of ductal fluid in detecting atypical cells to identify women at increased risk of breast cancer, as well as comparisons of the results to established methods of detecting and diagnosing breast cancer. Similarly, Medicare does not currently reimburse for the NAF collection procedure. Lack of Medicare or insurance coverage will require patients to bear the full costs of the NAF sample acquisition process used with the MASCT System. As a result, and particularly in light of healthcare reform and cost-containment initiatives being undertaken widely across the United States, physicians and other healthcare professionals may be slow to adopt the MASCT System and may not recommend its use in patients. We may be forced to reduce the price of the MASCT System components in response to low demand or to provide discounted pricing arrangements in order to secure sales, or may not be able to sell the product and services components of the MASCT System at acceptable margins, which would severely limit our ability to generate revenue.

Currently Medicare and certain insurance carriers will notreimburse for the NAF collection procedure, which could s

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Our intended business to sell predictive medical products may expose us to possible litigation and product liability claims.

Our business may expose us to potential product liability risks from the MASCT System, ForeCYTE Test, and/or ArgusCYTE Test inherent in the testing, marketing and processing of predictive, or personalized medical products. Product liability risks may arise from, but are not limited to:

the inability of the MASCT System to extract a sufficient NAF sample from the breast, which may lead to an NAF sample size that is inadequate for proper processing at our laboratory and insufficient for screening, which could lead to an inaccurate assessment of the health of the patient;

failure by healthcare professionals to properly safeguard NAF samples collected using the MASCT System;

the potential loss, mislabeling or misplacement of NAF sample shipments and test kits;

the MASCT System is a manually operated device, and, as a result, human error may result in improper collection of NAF or application of the MASCT System;

inadequate cleaning of the collection pump between patients resulting in mixing of NAF samples from two patients or NAF samples attributed to the wrong patient;

improper fitting of the MASCT System device to the breast; and

inadequate cleaning of the breast prior to applying the MASCT System.

The ArgusCYTE Test must be run on fresh blood and improper storage conditions following drawing from the patient could lead to a missed diagnosis.

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.

Our laboratory activities, including the analysis and reading of the NAF tests could expose us to possible litigation based on malpractice, data aggregation errors, or misdiagnoses.

Through a wholly-owned subsidiary, we operate a CLIA-certified laboratory to analyze patient samples and to report the results to referring healthcare professionals, researchers and potential collaborators worldwide. We or our subsidiary may be subject to claims by an affected patient, healthcare provider, researcher or collaborator if laboratory personnel make any of the following mistakes, by way of example:

errors in the analysis of the tests;

incorrect aggregation, categorization or labeling of data;

improper, incorrect or inaccurate development of a computer database which categorizes, analyzes, or compares test data; or

misinterpretation of the results of the test or collected data.

We maintain insurance to protect against such suits, but we cannot be certain that the insurance will be sufficient to cover potential damages, or that it will be cost-effective for us to maintain such a policy. Any adverse outcome against us could involve significant monetary judgments and could severely impact our financial resources and would be expected to impair our ability in the future to obtain malpractice, or other insurance, for our laboratory services.

If our patents do not adequately protect our products, others could compete with us more directly, which would adversely affect our business.

Our commercial success will depend in part on our ability to obtain new patents and enforce existing patents, as well as our ability to maintain adequate protection of other intellectual property for our technologies and products in the United States and abroad. If we do not adequately protect our intellectual

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property, competitors may be able to use our technologies and erode or negate any competitive advantage we may otherwise have, which could adversely affect our business, negatively affect our position in the marketplace and limit our ability to commercialize our products. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

The patent positions of diagnostic, medical device, and pharmaceutical companies, including ours, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty, nor can we be certain that we are not infringing the patents of others. Our patents may be challenged, deemed unenforceable, invalidated or circumvented. In particular, on March 20, 2012, the U.S. Supreme Court issued a decision in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc*., No. 10-1150, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter. Although the Court s decision seems to impact diagnostics patents that merely apply a law of nature via a series of routine steps, the full impact of the *Prometheus* decision is not yet known. We will thus be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, existing products and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets, and we are willing and have the necessary resources to take enforcement action against such unauthorized use by third parties.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

we were the first to make the inventions covered by each of our patents and pending patent applications;
we were the first to file patent applications for these inventions;
others will not independently develop similar, or alternative technologies, or duplicate any of our technologies;
any of our pending patent applications will result in issued patents;
any of our issued patents will be valid or enforceable;
any patents issued to us will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
we will develop additional proprietary technologies or products that are patentable; or
the patents of others will not have an adverse effect on our business.

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

We rely on trade secrets to protect our proprietary know-how and technological advances, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain, or maintain, trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

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.

Although our patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell our products or services. Furthermore, we may

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not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may need to obtain licenses to these patents or to develop or obtain alternative technology.

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 as described in this prospectus and such licenses, if available at all, may not be available on commercially reasonable terms. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our proposed products and services, which would harm our business. 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.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, we could be delayed in bringing product or service candidates to market and our ability to operate could be harmed.

Our commercial success will depend in part on our ability to manufacture, use and sell products and services without infringing patents or other proprietary rights of third parties. Third parties may challenge or infringe upon our, or our licensors , existing or future patents. Although we are not currently aware of any pending or actual litigation, or other proceedings, or third-party claims of intellectual property infringement related to the MASCT System, the Mammary Ductal Microcatheter System or other product candidates, the medical device and diagnostic industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that it is employing their proprietary technology without authorization.

Legal proceedings involving our patents or patent applications, or those of others, could result in adverse decisions regarding the patentability of our inventions relating to our products or the enforceability, validity or scope of protection offered by our patents.

Even if we are successful in proceedings involving our intellectual property rights or those of others, we may incur substantial costs and divert management time and attention in pursuing these proceedings. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action, or challenge the validity of the patents in court. Patent litigation is costly and time-consuming and we may not have sufficient resources to bring enforcement actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market, or be precluded from participating in the manufacture, use or sale of our products or

product candidates or methods of treatment requiring licenses.

Risks Related to our Industry

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

Legal proceedings involving our patents or patent applications,or those of others, could result in adverse decisions

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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.

Changes in regulations, policies, or payor mix may adversely affect reimbursement for laboratory services and could have a material adverse impact on our revenue and profitability.

Most of our services will be billed to a party other than the physician who ordered the test. Reimbursement levels for healthcare services are subject to continuous and often unexpected changes in policies. Changes in governmental and third-party reimbursement rates and policies may result from statutory and regulatory changes, retroactive rate adjustments, administrative rulings, competitive bidding initiatives, and other policy changes. Uncertainty also exists as to the coverage and reimbursement status of new services. Government payors and insurance companies have increased their efforts to control the cost, utilization, and delivery of healthcare services. For example, at least yearly, Congress has considered and enacted changes in the Medicare fee schedule in conjunction with budgetary legislation. Further reductions of reimbursement for Medicare services or changes in policy regarding coverage of tests may be implemented from time to time. The payment amounts under the Medicare fee schedules are often used as a reference for the payment amounts set by other third-party payors. As a result, a reduction in Medicare reimbursement rates could result in a corresponding reduction in the reimbursements we may receive from such third-party payors. Changes in test coverage policies of other third-party payors may also occur. Such reimbursement and coverage changes in the past have resulted in reduced prices, added costs and reduced accession volume, and have imposed more complex regulatory and administrative burdens. Further changes in federal, state, and local third-party payor laws, regulations, or policies may have a material adverse impact on our business.

Failure to participate as a provider with payors, or operating as a non-contracting provider, could have a material adverse effect on revenue.

The healthcare industry has experienced a trend of consolidation among healthcare insurers, resulting in fewer but larger insurers with significant bargaining power in negotiating fee arrangements with healthcare providers, including laboratories. Managed care providers often restrict their contracts to a small number of laboratories that may be used for tests ordered by physicians in the managed care provider s network. We currently do not have any managed care provider contracts and there can be no assurance any contracts will be established. If we do not have a contract with a managed care provider, we may be unable to gain those physicians as clients. In cases in which we will contract with a specified insurance company as a participating provider, we will be considered in-network, and the reimbursement of third-party payments is governed by contractual relationships. Our in-network services will be primarily negotiated on a fee-for-service basis at a discount from our patient fee schedule, which could result in price erosion that would adversely affect revenue. Our failure to obtain managed care contracts, or participate in new managed care networks,

could adversely affect revenue and profitability. In cases in which we do not have a contractual relationship with an insurance company, or are not an approved provider for a government program, we will have no contractual right to collect for services and such payors may refuse to reimburse us for services, which could lead to a decrease in accession volume and a corresponding decrease in revenue. As an out-of-network provider, reductions in reimbursement rates for non-participating providers could also adversely affect us. Third-party payors, with whom we do not participate as a contracted provider, may also require that we enter into contracts, which may have pricing and other terms that are materially less favorable than the terms under which we intend to operate. While accession volume may increase as a result of these contracts, revenue per accession may decrease.

Use of our laboratory services as a non-participating provider is also expected to result in greater co-payments for the patient, unless we elect to treat patients as if we were a participating provider in accordance with applicable law. Treating such patients as if we were a participating provider may adversely

Failure to participate as a provider with payors, or operating asa non-contracting provider, could have a material ad

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impact results of operations because we may be unable to collect patient co-payments and deductibles. In some states, applicable law prohibits us from treating these patients as if we were a participating provider. As a result, referring physicians may avoid use of our services, which could result in a decrease in accession volume and adversely affect revenue.

Changes in FDA policies regarding the home brew exception from FDA review for laboratory-developed tests and reagents could adversely affect our business and results of operations.

Laboratory diagnostic tests developed and validated by a laboratory for its own use, also known as laboratory developed tests, which are referred to as LDTs or home brew tests, are subject to regulation under the federal Food, Drug and Cosmetic Act, or FDCA. To date, the FDA has decided, as a matter of enforcement discretion, not to exercise its authority with respect to most home brew tests performed by high complexity laboratories certified under CLIA, which is the type of laboratory that we have established. In addition, manufacturers and suppliers of analyte specific reagents, or ASRs, which we may utilize in our LDTs, are required to register with the FDA, conform manufacturing operations to the FDA s Quality System Regulation, or QSR, and comply with certain reporting and other record keeping requirements. The FDA regularly considers the application of additional regulatory controls over the development and use of LDTs by laboratories. It is possible that the FDA will require premarket notification or approval for LDT diagnostic tests that we may develop and perform in the future. The FDA held public hearings in the third quarter of 2010 to discuss how it will oversee LDTs. No definitive recommendations or findings have yet come from these hearings, but it is likely that the FDA will impose additional or new regulations affecting LDTs, including requiring premarket notification or approval for these tests. Any premarket notification or approval requirements could restrict or delay our ability to provide specialized diagnostic services and may adversely affect our business. FDA regulation of LDTs, or increased regulation of the various medical devices used in laboratory-developed testing, could increase the regulatory burden and generate additional costs and delays in introducing new tests.

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 PECOS, 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.

Our business is subject to rapid technological innovation, and the development by third parties of new or improved diagnostic testing technologies or information technology systems could have a material adverse effect on our business.

The anatomic pathology industry is characterized by rapid changes in technology, frequent introductions of new diagnostic tests, and evolving industry standards and client demands for new diagnostic technologies. Advances in technology may result in the development of more point-of-care testing equipment that can be

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operated by physicians or other healthcare providers in their offices, or by patients themselves, without the services of freestanding laboratories and pathologists, thereby reducing demand for our services. In addition, advances in technology may result in the creation of enhanced diagnostic tools that enable other laboratories, hospitals, physicians, patients, or third parties to provide specialized laboratory services superior to ours, or that are more patient-friendly, efficient, or cost-effective. Our success depends in part upon our ability to acquire or license on favorable terms or develop new and improved technologies for early diagnosis before its competitors and to obtain appropriate reimbursement for diagnostic tests using these technologies. Introduction of prophylactic treatments or cures for breast cancer could substantially reduce or eliminate demand for our services.

Risks Related to This Offering, the Securities Markets and Investment in our Securities

There has been no prior public market for our common stock and the lack of such a market may make resale of our stock difficult.

No prior public market has existed for our common stock and we cannot assure any investor that an active trading market will develop following this offering. We intend to apply for listing of our common stock on the NASDAQ Capital Market. However, we do not know whether an active trading market for our common stock will ever develop or continue, particularly in light of the relatively small size of this offering. If a public trading market does not develop, you may have difficulty selling your common stock.

Because the offering is on a best efforts basis with no minimum we may sell substantially less than the full 1,000,000 shares being offered, and, even if the offering is fully subscribed, we will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.

The placement agent in this offering will offer our common stock on a best efforts basis with no minimum. This means that we may raise substantially less than the total offering amount contemplated by this prospectus, and, as a result, we may not have the resources to achieve our business objectives. No refunds will be made available to investors if less than all of the shares of common stock are sold. We will likely need significant additional capital to continue to develop our business, which we may seek to raise through, among other things, public and private equity offerings and debt financing. Any equity financings will be dilutive to existing stockholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms or at all.

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. Following the completion of this offering, our directors, officers and entities affiliated with them will beneficially own over 35% of our outstanding voting securities. Accordingly, these stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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 the 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 amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the completion of this offering, 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

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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. For more information about these anti-takeover provisions as well as anti-takeover provisions under the Delaware General Corporation Law, please see Description of Securities Anti-Takeover Devices. These and other provisions in our corporate documents 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 Jumpstart our Business Startups Act of 2012, or 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.

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FORWARD-LOOKING STATEMENTS

This prospectus contains, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements. 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 version of comparable words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;
our ability to successfully develop and commercialize new tests and technologies currently in development and in the time frames currently expected;
our ability to engage third-party suppliers to manufacture the MASCT or Microcatheter System and its components at quantities and costs acceptable to us;
our ability to satisfy ongoing FDA requirements for the MASCT and Microcatheter System and to obtain regulatory approvals for our other products and services in development;
the benefits and clinical accuracy of the ForeCYTE and ArgusCYTE Tests and whether any product or service that we commercialize is safer or more effective than competing products and services;
our ability to establish and maintain intellectual property rights covering our products and services;
the willingness of health insurance companies and other third-party payors to approve our products and services for coverage and reimbursement;
our ability to establish and maintain an independent sales representative force to market our products and services that we may develop, both regionally and nationally;
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 liquidity sources; and
our ability to attract and retain key personnel.

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 entitled 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.

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USE OF PROCEEDS

We estimate that the net proceeds of the sale of the shares that we are offering will be approximately $4.9 million, assuming we sell all of the 1,000,000 shares we are offering, assuming an initial public offering price of $6.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, and after deducting estimated placement agent fees, the placement agent non-accountable expense reimbursement fee, other placement agent expense reimbursement obligations and estimated offering expenses that we must pay.

A $1.00 increase (decrease) in the assumed initial public offering price of $6.00 per share would increase (decrease) the net proceeds to us from this offering by approximately $900,000, 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 placement agent fees and estimated offering expenses payable by us.

Because we are conducting a best efforts offering with no minimum offering amount, there is no assurance that we will sell any shares or raise any proceeds.

The principal purposes of this offering are to obtain additional working capital to fund anticipated operating expenses, establish a public market for our common stock and facilitate future access to the public capital markets. We estimate that we will use the net proceeds from this offering for the following purposes:

up to approximately $500,000 of these net proceeds to expand our cytology and molecular diagnostics laboratory;
up to approximately $500,000 of these net proceeds to fund manufacture of a number of MASCT System units needed to launch the MASCT System across the United States as our initial national roll-out of the product;
up to approximately $1,500,000 of these net proceeds to hire and train sales and marketing personnel for initial regional marketing and subsequent national distribution;
up to approximately $1,000,000 of these net proceeds to develop and commence manufacturing and commercialization of the FullCYTE Test;
up to approximately $1,000,000 of these net proceeds to develop and commercialize the NextCYTE Test; and
the remaining net proceeds for the research and development of Intraductal Treatment Programs and for general working capital purposes.

If we raise less than $4.9 million in proceeds, we will utilize the proceeds raised in the manner set forth above until all proceeds are exhausted. For example, if we raise $850,000 in net proceeds (which is the approximate amount we would receive if we sold 25% of the shares we are offering), we would use $500,000 to expand our cytology and molecular diagnostics laboratory and $350,000 to fund the manufacture of a number of MASCT units needed to launch the MASCT System across the United States. If we raise $2,200,000 in net proceeds (which is the approximate amount we would receive if we sold 50% of the shares we are offering), we would use $500,000 to expand our cytology and molecular diagnostics laboratory, $500,000 to fund the manufacture of a number of MASCT units needed to launch the MASCT System across the United States and we would use $1,200,000 to hire and train sales and marketing personnel. Finally, if we raise $3,550,000 in net proceeds (which is the approximate amount we would receive if we sold 75% of the shares we are offering), we would use $500,000 to expand our cytology and molecular diagnostics laboratory, $500,000 to fund the manufacture of a number of MASCT units needed to launch the MASCT System across the United States, we would use $1,500,000 to hire and train sales and marketing personnel, we would use $1,000,000 to develop and commence manufacturing and commercialization of the FullCYTE test and we would use $50,000 to develop and commercialize the NextCYTE test.

A portion of the net proceeds may be used to acquire or invest in complementary businesses, technologies, services or products in the event that we identify opportunities for such acquisitions, or investments that we believe are in the best

interests of our stockholders. We have no current plans, agreements

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or commitments with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

Although we currently anticipate that we will use the net proceeds as described above, there may be circumstances where a reallocation of funds may be necessary. The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our development and commercialization efforts, the development of our business opportunities and our operating costs and expenditures. Accordingly, our management will have significant flexibility in applying these net proceeds. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

The costs and timing of commercialization of our products and development of business opportunities are highly uncertain, are subject to substantial risks and can often change. Accordingly, we may change the allocation of use of these proceeds as a result of contingencies such as the uptake of our products in the marketplace, competitive responses, and operating costs and expenditures.

Pending use of the proceeds from this offering as described above or otherwise, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

DIVIDEND POLICY

The Company does not anticipate that it will declare dividends in the foreseeable future, but rather intends to retain any future earnings for the development of the business. Payment of future cash dividends, if any, will be at the discretion of the Board of Directors of the Company after taking into account various factors, including the Company s financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any.

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DILUTION

Our net tangible book value as of March 31, 2012 was $550,052, or $0.05 per share of common stock. Net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the number of shares of common stock outstanding as of March 31, 2012. After giving effect to the sale by us of 1,000,000 shares of common stock being sold in this offering at an assumed initial public offering price of $6.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, and after deducting the 7% estimated placement agent fees, the 3% non-accountable expense reimbursement fee, placement agent expense reimbursement obligations and estimated offering expenses payable by us, our pro forma net tangible book value as of March 31, 2012 would have been approximately $5.4 million, or approximately $0.44 per share. This amount represents an immediate increase in net tangible book value of $0.40 per share to our existing stockholders and an immediate dilution in net tangible book value of approximately $5.56 per share to new investors.

The following table illustrates this hypothetical per-share dilution assuming we sell 100% of the shares that we are offering:

Assumed initial public offering price		$ 6.00
Net tangible book value per share as of March 31, 2012	$ 0.05	
Increase in net tangible book value per share attributed to new investors purchasing shares in this offering	0.40	
As-adjusted net tangible book value per share after this offering		0.44
Dilution per share to new investors		$ 5.56

A $1.00 increase (decrease) in the assumed initial public offering price of $6.00 per share would increase (decrease) our adjusted net tangible book value per share after this offering by approximately $0.07 and would increase (decrease) dilution per share to new investors by approximately $0.93, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated placement agent fees and estimated offering expenses payable by us. In addition, to the extent any outstanding options or warrants are exercised, you will experience further dilution.

The following table illustrates the dilution to purchasers in this offering assuming we sell 25% of the shares that we are offering at $6.00 per share:

Assumed initial public offering price		$ 6.00
Net tangible book value per share as of March 31, 2012	$ 0.05	
Increase in net tangible book value per share attributed to new investors purchasing shares in this offering	0.07	
As-adjusted net tangible book value per share after this offering		0.12
Dilution per share to new investors		$ 5.88

The following table illustrates the dilution to purchasers in this offering assuming we sell 50% of the shares that we are offering at $6.00 per share:

Assumed initial public offering price		$ 6.00
Net tangible book value per share as of March 31, 2012	$ 0.05	
	0.19	

Increase in net tangible book value per share attributed to new investors purchasing shares in this offering	
As-adjusted net tangible book value per share after this offering	0.23
Dilution per share to new investors	$ 5.77

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The following table illustrates the dilution to purchasers in this offering assuming we sell 75% of the shares that we are offering at $6.00 per share:

Assumed initial public offering price		$ 6.00
Net tangible book value per share as of March 31, 2012	$ 0.05	
Increase in net tangible book value per share attributed to new investors purchasing shares in this offering	0.29	
As-adjusted net tangible book value per share after this offering		0.34
Dilution per share to new investors		$ 5.66

The following table summarizes, as of March 31, 2012, the number of shares purchased from us, the total consideration paid or to be paid to us, and the average price per share paid or to be paid to us by existing stockholders and new investors purchasing a total of 1,000,000 shares of our common stock at an assumed offering price of $6.00 per share, which is the midpoint of the price range listed on the cover page of this prospectus.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	11,256,867	91.8 %	$ 6,898,540	53.5 %	$ 0.61
New investors	1,000,000	8.2 %	6,000,000	46.5	