Registration No. 333-169703

# 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**

(State or other jurisdiction of incorporation or organization)

3841

(Primary Standard Industrial Classification Code Number)

26-4753208

(I.R.S. Employer Identification Number)

Seattle Life Sciences Building 1124 Columbia Street, Suite 621 Seattle, Washington 98104 (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 and Chief Executive Officer Seattle Life Sciences Building 1124 Columbia Street, Suite 621 Seattle, Washington 98104 (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.  $\Box$ 

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

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

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.

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 $\square$ Accelerated filer $\square$ Non-accelerated filer $\square$ Smaller reporting company x (Do not check if a smaller reporting 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.					

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 FEBRUARY 4, 2011



# 3,000,000 Units Comprised of Common Stock, Class A Warrants, Class B Warrants and Class C Warrants

This is the initial public offering of our Units. We are offering 3,000,000 Units, with each Unit consisting of: (i) one share of common stock, (ii) one Class A Warrant, (iii) one Class B Warrant and (iv) one Class C Warrant.

Each Class A Warrant will be exercisable, for a period of ten trading days beginning on the sixth trading day following our announcement of registration of our laboratory facilities, to acquire one share of common stock on a cashless, net exercise basis at a price of \$0.05 per share. We will have the obligation for 90 days following the expiration of the exercise period to redeem any unexercised, expired Class A Warrants that are surrendered to the Company at \$0.25 per unexercised Class A Warrant. Each Class B Warrant will be exercisable, for a period of ten trading days beginning on the sixth trading day following our announcement of our commercial launch of the MASCT System, to acquire one share of common stock on a cashless, net exercise basis at a price of \$0.05 per share. We will have the obligation for 90 days following the expiration of the exercise period to redeem any unexercised, expired Class B Warrants that are surrendered to the Company at \$0.25 per unexercised Class B Warrant. Each Class C Warrant will be exercisable for a period of five years beginning on the date one year after the Class C Warrants are separated from the Units, to acquire one share of common stock at a price equal to 55% of the Unit offering price. We will have the right to redeem the Class C Warrants at \$0.25 per share of common stock underlying the Class C Warrants in the event (i) the average of the closing price of our common stock exceeds 200% of the exercise price for 10 consecutive trading days while the warrants are exercisable and (ii) there is then an effective registration statement with a current prospectus on file with the Securities and Exchange Commission, or the SEC.

We expect the initial public offering price will be between \$5.00 and \$7.00 per Unit. Currently, no public market exists for our securities. We intend to apply for listing of the Units on the NYSE Amex under the symbol "ATOSU." The securities underlying the Units will separate from the Units on the 90 th day after the date of this prospectus, unless Dawson James Securities, Inc., the representative of the underwriters, determines that an earlier separation date is acceptable based on its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular. We intend to issue a press release announcing when such separation will occur. Once the securities comprising the Units separate, the Units will automatically cease trading and be cancelled, and the common stock and Class C Warrants underlying the Units are expected to be listed on the NYSE Amex under the symbols "ATOS" and "ATOSW," respectively. The Class A Warrants and the Class B Warrants will not be listed for trading.

	Per Unit	Total
Public offering price	\$	\$
Underwriting discount (1)	\$	\$
Proceeds, before expenses, to Company	\$	\$

(1) Does not include a non-accountable expense reimbursement fee in the amount of up to 2% of the gross proceeds of this offering. Additionally, we will issue Dawson James a warrant representing the right to purchase a number of Units equal to 8% of the Units sold in this offering.

Investing in these securities involves a high degree of risk. See "Risk Factors" contained in this prospectus beginning on page 7.

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.					
We have granted the underwriter an option for a period of 45 days to purchase from us, on the same terms and conditions set forth above, up to an additional 450,000 Units to cover overallotments.					
The date of this prospectus is, 2011.  DAWSON JAMES SECURITIES, INC.					

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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 Units and underlying securities 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 to Atossa Genetics Inc.

#### 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 development-stage healthcare company focused on the commercialization of a cellular and molecular diagnostic risk assessment product and related service for the detection of pre-cancerous conditions in nipple aspirate fluid, or NAF, that could lead to breast cancer, and on the development of second-generation products and services. Our primary focus is the commercialization of the Mammary Aspirate Specimen Cytology Test, which we call the MASCT System, our patented and U.S. Food and Drug Administration, or FDA, cleared product and related testing and analysis services for breast conditions, including cancer. Although current mammography procedures can detect cancer already present in the breast, academic studies indicate that pre-cancerous cellular changes in NAF, specifically atypical ductal hyperplasia, can be detected up to eight years before cancer is diagnosed by mammography. This information may allow for the implementation of preventive measures such as lifestyle changes and pharmaceutical interventions that may prevent breast cancer from developing or treat breast cancer earlier, if it develops. At this time, however, Medicare and certain insurance carriers will not reimburse the costs of the NAF collection procedure, citing insufficient clinical evidence to support medical efficacy, better clinical decision-making, or a reduction in breast cancer mortality. To date, we have not generated revenues from the sale of any product, and we do not expect to generate any significant revenues unless and until we begin our commercial launch of the MASCT System. Our ability to launch the MASCT System is substantially dependent on the successful completion of this offering. We have incurred net operating losses of \$93,105 and \$744,356 for our fiscal year ended December 31, 2009 and for the nine months ended September 30, 2010, respectively. Our current operations are funded by a \$500,000 line of credit from our founder and chief executive officer, Dr. Steven C. Quay, M.D., Ph.D., under which \$420,000 curre

The MASCT System is a device and method for the collection, shipment and clinical laboratory analysis of nipple aspirate fluid, or NAF. A number of medical devices have been designed by others for the collection of NAF, which contains cells and molecular diagnostic biomarkers. The clinical analysis by qualified pathologists, whether or not affiliated with us, of the biomarkers contained in NAF, whether collected using the MASCT System or by other means, is useful in detecting breast cancer and cellular changes that may be precursors to breast cancer. The use of the MASCT System by non-affiliated pathologists would be expected to yield comparable results. We intend to offer each component of the MASCT System for sale separately. The product components of the MASCT System consist of a reusable hand-held pump for the collection of NAF, single-use patient kits that include two NAF sample vials per kit, and shipment kits for the transportation of NAF samples to our specialized cytology and molecular diagnostics laboratory to be established in Seattle, Washington. Through our laboratory, if successfully established, we intend to provide the MASCT System services, which would consist of receiving and accessioning the two NAF samples from each patient, preparing routine and immunohistochemistry, or IHC, staining of slides from the NAF samples, and generating a report of the findings. We expect that by selling the MASCT System under limited "collection only" licenses, purchasers will be required under our patent rights to submit the NAF samples gathered with our system to our laboratory for screening. Our patents do not, however, prevent physicians from collecting NAF using a different technology or system and independently performing comparable diagnostic analysis on the fluid sample.

We have entered into a lease for laboratory space in Seattle, Washington and expect our laboratory to be operational in the first quarter of 2011. We have also engaged a contract manufacturer to produce, upon successful completion of this offering, 20 MASCT System pumps and 10,000 testing kits, which we intend to field test for purposes of confirming the proper operation of the device and its ability to collect adequate NAF samples in the first quarter of 2011. We intend to commence commercial manufacturing of the MASCT System components following the completion of this offering and to begin our commercial launch of the MASCT System in the second quarter of 2011. We cannot be certain, however, that our initial field testing of the MASCT System will be successful or that we will be able to engage one or more large-volume medical device manufacturers to produce the MASCT System on terms acceptable to us within our anticipated timelines, or at all. In addition, because our commercial launch of the MASCT System is dependent on the timing and amount of proceeds received from this offering, our product launch may be delayed if we are unable to complete this offering in the planned timeframe.

We anticipate that the MASCT System will be used initially in conjunction with standard mammography or cervical Pap smear exams and has the potential to become a critical assessment tool for identifying women at high risk for breast cancer. Our MASCT System NAF collection procedure takes about five minutes, was painless in clinical testing, and does not use any radiation. In a study published in November 2010, the lifetime risk for women 40 to 74 years of age of developing cancer from the radiation in normal mammograms was found to be 86 per 100,000 women. We currently intend to price our NAF sample collection device at approximately \$200 per device, our patient kits at approximately \$50 per kit, and the cytology and molecular diagnostics testing and analysis at the 2011 national Medicare reimbursement rates of between \$110 and \$1.233 per patient, depending on the complexity of the analysis performed and without taking into account any patient reimbursement from third-party insurers. Market conditions at or after launch, however, including general economic conditions and changes in third-party reimbursement policies, may prevent us from pricing the MASCT System and our services as currently planned.

Our founder and chief executive officer, Steven C. Quay, M.D., Ph.D., 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. We acquired from Ensisheim Partners LLC, or Ensisheim, all of the ownership rights to five U.S. and eight foreign patents (in the European Union, Canada, Australia, Hong Kong, Switzerland, Germany, France and the United Kingdom) covering the manufacture, use and sale of the MASCT System, pending patent applications for improvements, as well as the FDA marketing authorization for the MASCT System. Ensisheim is a limited liability company solely owned by Dr. Quay and his wife, Dr. Shu-Chih Chen, who is our chief scientific officer and a member of our board of directors.

Our operations began 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. Our operations to date have consisted primarily of securing laboratory and office space, hiring laboratory personnel, ordering equipment and supplies, engaging a third-party vendor for the manufacture of the MASCT System in limited quantities for field testing, securing patent rights and assignments, filing new patent applications, acquiring FDA market clearances and securing development bids to complete preparation for manufacturing the MASCT System. We currently have no other operations.

We have experienced operating losses since inception. We have not yet received any revenues and will not be in a position to expect revenues until we are able to produce and sell the MASCT System. We anticipate that we will incur additional losses while establishing the manufacturing of the MASCT Systems and while we build our laboratory and hire and train personnel for our laboratory and our sales force. In addition, Medicare and certain private insurance carriers currently do not reimburse for the NAF collection procedure that will be used with the MASCT System, which could delay or prevent commercial adoption of the MASCT System and our services as the absence of Medicare or insurance coverage will require patients to fully bear the costs of the sample acquisition. We intend to seek reimbursement for the MASCT System from third-party payors and plan to apply for a Current Procedural Terminology, or CPT, code from the American Medical Association, or AMA, for the procedure of collecting NAF with our device, to enable reimbursement of the collection procedure, but we cannot be certain that we will be successful in these efforts.

## The MASCT System

The MASCT System is intended to supplement, and not replace, mammography and is primarily a risk assessment tool for identifying women at risk for developing breast cancer. Using the MASCT System's NAF collection device, a nurse or physician's assistant can collect a sample of NAF, which may contain cells and molecular diagnostic biomarkers that are useful in detecting cancers and pre-cancerous cellular changes. These changes include atypical ductal hyperplasia, or ADH, a condition in which the cells lining the milk ducts of the breast experience abnormal, premalignant growth, which confers a higher risk of developing breast cancer. Analysis of the collected fluid can enable physicians to determine and/or differentiate among normal versus premalignant versus malignant cells. Pre-cancerous cytology changes in NAF have been shown to occur up to eight years before cancerous changes can be detected by mammography. Although the MASCT is intended to be an adjunctive procedure to mammography, some physicians may view both the MASCT System and mammography as screening tools for existing breast cancer, which could cause the MASCT System to be deemed directly competitive with mammography, an established procedure.

In a study of women with normal mammograms who were undergoing breast reduction surgery, which was conducted at the Virginia Mason Medical Center in Seattle, Washington and published in *Plastic and Reconstructive Surgery* in October 2009, the incidence of ADH was found to be 4.4%. A separate study conducted in 2007 of 4,970 women found an incidence of ADH of 4.0% by biopsy. ADH can be definitively diagnosed only by NAF analysis or a breast tissue biopsy. In a study of approximately 2.5 million screening mammograms done between 1996 and 2005 and collected from mammography registries participating in the Breast Cancer Surveillance Consortium, the incidence of biopsy-proven ADH was 0.4%, suggesting that mammography fails to detect ADH in over 90% of patients.

A number of medical devices have been designed over the years that apply negative pressure to the nipple to induce the expression of NAF, which is then collected by carefully touching a capillary tube to any apparent drops of NAF. Published literature suggests that in general, these devices are successful in obtaining NAF from about 39% to 66% of all patients, and that this sample collection variability has prevented the routine adoption of NAF cytology for breast cancer screening. The MASCT System was designed to overcome this shortcoming by placing a hydrophilic, or water seeking, membrane in contact with the nipple during the cycles of negative pressure to "wick" fluid from the orifice of the ducts by capillary action, thereby increasing the frequency of obtaining NAF in women. The results of a clinical trial sponsored by Nastech Pharmaceutical Company, Inc. of 31 women conducted in 2003 demonstrated that the MASCT System was able to collect measurable NAF in 97% (30) of the women tested. The NAF samples collected in this study ranged from less than one to 37 microliters, with an average of seven microliters, and all samples collected were deemed to be clinically useful. No adverse events were reported in the study.

The MASCT System also requires no use of radiation. A study that analyzed the results of six peer-reviewed medical research publications reported in December 2009 that low dose radiation from mammograms can increase cancer incidence by 1.5 to 2.5 fold in high-risk women, increasing the complexity of managing high-risk patients. Unlike a biopsy, the MASCT System is a non-invasive and painless procedure.

#### **Commercialization Strategy**

We believe that commercialization of the MASCT System will provide us with two main revenue sources: (i) sales-based revenue from the sale of the MASCT System device and patient kits to physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from the preparation and interpretation of the NAF samples sent to our laboratory for analysis.

We intend to market the MASCT System to physicians, 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 plan to hire a direct sales force of approximately eight people initially to commercialize the MASCT System and our services in the Northwestern United States, where there are approximately 290 mammography clinics. According to the FDA, each mammography clinic registered in the United States performs an average of 4,500 mammograms per year. Based on the use of the MASCT System as an adjunct to the approximately 1.3 million mammograms done in Northwestern United States, we believe the total addressable market for products and services for the collection and analysis of NAF in conjunction with mammography in this region could exceed \$100 million, of which we will seek to capture a portion. This estimate, however, is not intended, and should not be considered, to be a projection of our revenues, which will be impacted by various factors described under "Risk Factors" and elsewhere in this prospectus. Assuming a successful regional launch, we plan to expand nationally during the first half of 2012 and intend to grow our sales force to approximately 100 people in the United States. We currently have no sales personnel, however, and we cannot be certain that we will be able to build a sales force adequate either to complete our regional launch of the MASCT System or to address the national market.

Our ability to commercially launch the MASCT System is substantially dependent on the success of this offering. With the exception of a \$500,000 line of credit from our chief executive officer, under which \$420,000 currently remains available, we have not identified alternative sources of funding should this offering be unsuccessful.

We believe that by maintaining our own clinical laboratory, we will be able to generate additional service revenues through cytology and molecular diagnostic testing, in addition to the sale of our MASCT Systems. We have leased a facility for our clinical laboratory in Seattle, Washington and intend to establish and qualify the operations and procedures of our laboratory in the first quarter of 2011. We will submit applications for accreditation by the College of American Pathologists and for licensure by state and federal agencies in order to allow the preparation, screening and interpretation of cytology and for the molecular diagnostics testing of NAF patient samples at our facility. If we experience delays or encounter difficulties in the application and accreditation process, we may not be able to establish or qualify our laboratory as currently planned, which would impair our ability to generate revenues from testing services.

#### **Trading Market**

Currently, there is no trading market for our securities. We intend to apply for listing of the Units, our common stock and the Class C Warrants on the NYSE Amex under the symbols "ATOSU," "ATOS" and "ATOSW," respectively. The Class A Warrants and Class B Warrants will not be listed for trading.

# **Risk Factors**

Our business is subject to numerous risks as discussed more fully in the section entitled "Risk Factors" beginning on page 7. 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, expect to incur losses for the foreseeable future and may never achieve profitability;
- The MASCT System and second-generation risk assessment tools, diagnostic tests and other predictive and personalized medicine products that the Company may develop may never achieve significant commercial market acceptance;
- · we are dependent on the commercial success of the MASCT System;
- we have not yet engaged any manufacturers for the production of the MASCT System in commercial quantities, and any inability to engage manufacturers for such production at acceptable quantities, costs or timelines could delay or prevent our commercial launch of the MASCT System;
- · we may not be successful in commercializing the MASCT System because physicians and clinicians may be slow to adopt our product;
- · our ability to commercialize the MASCT System may be limited because Medicare and certain insurance carriers are not expected to provide reimbursement for use of our product;
- · we may encounter difficulties in registering or becoming certified under state and/or federal laboratory regulations for our cytology and molecular diagnostics laboratory for the testing and analysis of NAF samples; and
- · we may not be able to hire, train or maintain the sales force necessary to market and sell the MASCT System and our services as planned.

#### **Company Information**

Our operations began 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. Our principal executive offices are located at Seattle Life Sciences Building, 1124 Columbia Street, Suite 621, Seattle, Washington 98104, and our telephone number is (206) 325-6086. Our website is located at <a href="https://www.atossagenetics.com">www.atossagenetics.com</a>. Information contained on, or that can be accessed through, our website is not a part of this prospectus.

MASCT, Oxy-MASCT and our name and logo are our trademarks. This prospectus also includes additional trademarks, trade names and services marks, 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.

#### THE OFFERING

Securities offered by us:

3,000,000 units, or the Units. Each Unit consists of:

- · one share of our common stock;
- one Class A Warrant exercisable for one share of our common stock on a cashless, net
  exercise basis for a period of ten trading days beginning on the sixth trading day after our
  announcement of the registration of our laboratory facilities at an exercise price of \$0.05 per
  share. We will have the obligation for 90-days following the exercise period to redeem any
  unexercised, expired Class A Warrants that are surrendered to the Company at \$0.25 per
  unexercised Class A Warrant.;
- one Class B Warrant exercisable, for a period of ten trading days beginning on the sixth trading day after our announcement of our commercial launch of the MASCT System, to acquire one share of common stock on a cashless, net exercise basis at a price of \$0.05 per share. We will have the obligation for 90-days following the exercise period to redeem any unexercised, expired Class B Warrants that are surrendered to the Company at \$0.25 per unexercised Class B Warrant; and
- one Class C Warrant exercisable for one share of common stock commencing on the first anniversary of the date of this prospectus, and remaining exercisable until the fifth anniversary of the separation of the Class C Warrants from the Units at an exercise price equal to 55% of the Unit offering price. We will have the right to redeem the Class C Warrants at \$0.25 per share of common stock underlying the Class C Warrants in the event (i) the average of the closing price of our common stock exceeds 200% of the exercise price for 10 consecutive trading days while the warrants are exercisable and (ii) there is then an effective registration statement with a current prospectus on file with the SEC.

Use of proceeds:

We intend to use the net proceeds from this offering to engage one or more contract manufacturers to produce the MASCT System in commercial quantities, to establish a cytology and molecular diagnostics laboratory focused on breast cancer and to launch the MASCT System in the Northwestern United States, including hiring and training sales personnel. We also intend to use a portion of the proceeds from this offering to develop a second generation of the MASCT System, to develop additional laboratory biomarker tests and to launch a national roll-out of the MASCT System.

**NYSE Amex Market trading Symbols:** 

We intend to apply for listing of our common stock, the Units and the Class C Warrants on the NYSE Amex under the symbols, "ATOS," "ATOSU" and "ATOSW," respectively. The Class A Warrants and the Class B Warrants will not be listed for trading.

**Capitalization:** 

6,000,067 shares of common stock outstanding before the offering (1).

9,000,067 shares of common stock outstanding after the offering but without assuming the exercise of any the warrants sold in the offering (1).

The number of shares of our common stock to be outstanding before the offering is based on 6,000,067 shares of common stock outstanding as of December 31, 2010, and excludes 1,000,000 shares of common stock reserved for future issuance under our 2010 Stock Option and Incentive Plan, as well as the shares underlying the Class A, Class B and Class C Warrants. Although the Class A and Class B Warrants have a nominal exercise price of \$0.05 per share and are exercisable under a cashless, or net exercise feature that provides for the rounding up of fractional shares issued upon such net exercise, the exercisability of these warrants will be subject to the achievement of certain performance milestones, the achievement of which and the timing of achievement are uncertain.

Unless otherwise indicated, all information in this prospectus assumes that the underwriters do not exercise their right to purchase up to 450,000 additional Units to cover overallotments, if any.

#### 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 year ended December 31, 2009 have been derived from our audited financial statements and related notes included elsewhere in this prospectus. The statement of operations data, including share data, for the nine months ended September 30, 2010 and the period from April 30, 2009 (inception) through September 30, 2009, and the balance sheet data as of September 30, 2010 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 September 30, 2010 and results of operations for the nine months ended September 30, 2010 and the period from April 30, 2009 (inception) through September 30, 2009. The operating results for any period are not necessarily indicative of financial results that may be expected for any future period.

	April 30, 2009 (Inception) through December 31, 2009		Nine Months Ended September 30, 2010 (Unau		(Inception		30, 2009 on) through oer 30, 2009
Statement of Operations Data:							
O							
Operating expenses:	ď	21.250	ď	1 200	ď		17.500
Research and development General and administrative	\$		\$	1,306	\$		17,500
General and administrative		101,607		738,251			75,605
Other operating income:				-			-
Interest income		_		455			-
Interest expense		_		(5,129)			-
Income taxes		_		125			125
Net loss	\$	(122,857)	\$	(744,231)	\$		(93,105)
Net loss per share—basic and diluted	\$	(0.03)	\$	(0.13)	\$		(0.02)
		4 005 045		E 04 4 00 4			2 002 002
Weighted-average number of shares used in share calculation—basic and diluted		4,037,847		5,914,204			3,993,093
		Dece 31,	As of December 31, 2009 Actual			otember 30, 2010 As-adjusted	
						(Unaudited)	
Balance Sheet Data:		ф	05.464	Ф 22	0.50	ф	46 000 050
Total assets		\$	85,464		253	\$	16,232,253
Total liabilities			53,781	558,	882		558,882
Stockholders' (deficit) equity:	0.007 -1						
Common Stock, \$0.001 par value, 75,000,000 shares authorized, 4,899,882 and 6,00							
outstanding, actual, as of December 31, 2009 and September 30, 2010, respectively shares outstanding, as-adjusted, as of September 30, 2010	and 9,000,0	707	4.900	c	000		9,000
			,	-,			
Additional paid-in capital  Accumulated deficit			149,640	334,			16,531,585
Total stockholders' (deficit) equity			(122,857) 31,683	(867,			(867,214)
Total stockholders' (deficit) equity  Total liabilities & stockholders' equity		\$	85,464	(526, \$ 32,	629) 253	\$	15,673,371 16,232,253
Total Habilities & stockholders equity		Φ	05,404	Ψ 32,	200	Φ	10,232,233

The September 30, 2010 as-adjusted balance sheet data reflects the sale of 3,000,000 Units in this offering at an assumed initial public offering price of \$6.00 per Unit, which is the mid-point of the price range listed on the cover page of this prospectus, after deducting 10% estimated underwriting discounts and commissions and estimated offering expenses payable by us.

#### RISK FACTORS

A purchase of the Units is an investment in the Company's securities and involves a high degree of risk. You should consider carefully 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, the business, financial condition or results of operations of the Company would likely suffer. In that case, the value of our securities, including the market price of the common stock, Units, Class A Warrants, Class B Warrants or Class C Warrants could decline, and you may lose part or all of your investment in our company.

### Risks Relating to the Company

### The Company has limited operating history and as such an investor cannot assess its profitability or performance based on past results.

The Company is 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 April 2009 and as such have limited operating history. The Company's operations to date have consisted primarily of securing laboratory and office space, hiring laboratory personnel, ordering equipment and supplies, engaging a third-party vendor for the manufacture of the MASCT System in quantities sufficient for initial field testing, securing patent rights and assignments, filing new patent applications, acquiring FDA market clearances, and securing development bids to complete preparation for manufacturing the MASCT System. The Company requires significant additional capital to achieve its business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

The Company's revenue and income potential is uncertain. Any evaluation of the Company's 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 the Company's ability to:

- · execute its business plan and commercialization strategy;
- engage one or more contract manufacturers to produce the MASCT System in commercial quantities;
- · create brand recognition;
- · respond effectively to competition;
- · manage growth in its operations;
- · respond to changes in applicable government regulations and legislation;
- · access additional capital when required; and
- · attract and retain key personnel.

# The Company's independent auditors have issued a report questioning the Company's ability to continue as a going concern.

The report of the Company's independent auditors contained in the Company's financial statements explains that the Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations.

We will depend on the proceeds from this offering to commence the commercial launch of the MASCT System, and we do not have specific plans to obtain funding from alternative sources; if the proceeds from this offering are insufficient to effect the commercial launch of the MASCT System, the Company may be required to cease operations.

The Company expects to spend substantial amounts of capital to:

- · launch and commercialize the MASCT System, including contracting for the manufacture of the device in commercial quantities and building an internal sales force to address certain markets;
- · establish, qualify and maintain laboratory facilities for the Company's testing and analytical services;
- · continue its research and development activities to advance its product pipeline.

The Company expects that it will require additional capital beyond the proceeds from this offering to complete the commercialization of the MASCT System in the United States and may need to raise additional funds if it encounters delays or problems in the production of the MASCT System device in commercial quantities, or the establishment of its sales force or laboratory facilities. The Company has not identified sources for such additional funding and cannot be certain that additional funding will be available on acceptable terms, or at all. The Company has secured a \$500,000 line of credit from its chief executive officer, pursuant to which \$420,000 currently remains available and under which the Company continues to fund its current operations, but the Company currently has no specific plans in place to obtain funding from alternative sources. In addition, the Company will be required to reserve \$1,500,000 of the proceeds of this offering to meet the redemption obligations of the Class A and B Warrants until following their respective exercise periods and will thus not be able to use this portion of the proceeds for operations of the Company. If the Company is unable to raise additional capital in sufficient amounts or on acceptable terms, it may have to significantly delay, scale back or discontinue the commercialization of the MASCT System or its research and development activities, which could force the Company to cease its operations.

## Failure to raise additional capital as needed could adversely affect the Company and its ability to grow.

The Company will need considerable amounts of capital to develop its business. It may raise funds through public or private equity offerings or debt financings. If the Company cannot raise funds on acceptable terms when needed, it may not be able to grow or maintain the business. Furthermore, such lack of funds may inhibit the Company's ability to respond to competitive pressures or unanticipated capital needs, or may force the Company to reduce operating expenses, which could significantly harm the business and development of operations. Because the Company's independent auditors have expressed doubt as to the Company's ability to continue as a "going concern," as reported in the financial statements of the Company, its ability to raise capital may be severely hampered. Similarly, the Company's ability to borrow any such capital may be more expensive and difficult to obtain until this "going concern" issue is eliminated.

# The Company has a history of operating losses and expects to continue to incur losses in the future.

The Company has a limited operating history and has incurred net operating losses of \$867,214 since its inception from April 30, 2009 through September 30, 2010. The Company has not yet received any revenues and will not be in a position to generate revenues until it is able to produce and sell the MASCT System. The Company will incur additional losses in connection with engaging one or more contract manufacturers to produce the MASCT System for commercial sale, building a sales force for the product and establishing its laboratory facilities for the testing and analysis of NAF samples, and may never achieve profitability.

# Raising funds by issuing equity, or debt securities, could dilute the value of the common stock and impose restrictions on the Company's working capital.

If the Company were to raise additional capital by issuing equity securities, the book 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 raise additional funds may impose restrictions on the Company's operations and may impair the Company's working capital as it services any such debt obligations.

The MASCT System and second-generation risk assessment tools, diagnostic tests and other predictive and personalized medicine products that the Company may develop may never achieve significant commercial market acceptance.

The Company may not succeed in achieving commercial market acceptance of any of its products and services. In order to market the MASCT System and to gain market acceptance for the MASCT System and the Company's services, the Company 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 are 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 the Company's 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 the Company's products.

The Company may not be able to establish its cytology and molecular diagnostics laboratory for the performance of its planned testing and analytical services or may encounter difficulties in operating or maintaining this laboratory facility, which could cause delays and unexpected problems.

The Company has only begun to establish its laboratory and will rely on a single physical facility in Seattle, Washington for the testing of NAF samples. The Company plans to submit applications to obtain certification for its laboratory under CLIA and Washington state regulations and apply to become accredited by the College of American Pathologists, and must meet various standards imposed by both federal and state regulatory authorities. There is no guarantee that the Company's facility will be adequate or that the Company will obtain Washington state or federal CLIA certification for this facility as planned. The Company's management team does not have significant prior experience with establishing this type of laboratory facility. In addition, if established, this facility and certain pieces of laboratory equipment required for the performance of the Company's testing and analytical services would be expected to be difficult and costly to replace and may require significant replacement lead-time. In the event that the Company is unable to establish its intended laboratory facility or, if after completion, such laboratory or equipment is adversely affected by periodic malfunctions or man-made, or natural disasters, the Company may be unable to conduct its business and meet potential customer demands for a significant period of time.

# The loss of the services of the Company's chief executive officer could adversely affect its business.

The Company's success is dependent in large part upon its ability to execute its business plan, manufacture the MASCT System, establish its clinical and diagnostic laboratory, and to attract and retain highly skilled professional, sales and marketing personnel. In particular, due to the relatively early stage of the Company's business, its future success is highly dependent on the services of Dr. Quay, its chief executive officer and founder, to provide the necessary experience to execute the Company's business plan. The Company does not currently maintain "key man" insurance with respect to Dr. Quay. The loss of his services for any reason could impede the Company's ability to achieve its 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 the Company seeks to build a reputation among physicians and clinicians.

The Company may experience difficulty in locating, attracting, and retaining experienced and qualified personnel, which could adversely affect its business.

The Company 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 it commences its initial launch of the MASCT System. These employees may not be available in this geographic region. In addition, competition for these employees is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage organization such as the Company. If the Company is not able to attract and retain qualified personnel, revenues and earnings may be adversely affected.

The Company has no prior experience with commercializing any products or services, and it will need to establish a sophisticated sales and marketing organization in order to successfully commercialize the MASCT System.

The Company intends to build a direct sales force to be comprised initially of eight sales professionals to target physicians and mammography clinics in the Northwestern United States and plans eventually to expand its sales team to include sales professionals nationwide. Marketing the MASCT System to physicians and healthcare professionals will require the Company to educate them on the comparative advantages of the MASCT System over other methods currently used for the detection and diagnosis of breast cancer. Experienced sales representatives may be difficult to locate and all sales representatives will need to undergo training. The Company will need to incur significant costs to build its internal sales force. Based on its current operating plan, the Company expects to incur costs of approximately \$3.5 million in connection with initial hiring and building its national sales force. The Company cannot be certain that it will be able to recruit sufficiently skilled sales representatives, or that any new sales representatives will ultimately become productive. If the Company is unable to recruit, train and retain qualified and productive sales personnel, its ability to commercialize the MASCT System and any second generation products and to generate revenues will be impaired.

The Company will need to engage third-party suppliers for the production of the MASCT System in commercial quantities, and the inability to find such suppliers, or to maintain relationships with them, could adversely affect the Company's business.

The Company does not currently have any long-term contracts or arrangements with any laboratory equipment and disposable reagent suppliers, or any device or kit manufacturers for the production of the MASCT System and its components in commercial quantities. While the Company has entered into a short-term contract with a third party medical device manufacturer to produce limited quantities of the MASCT System to permit the Company to perform field testing prior to commercial launch, there can be no assurance that commercial quantities of the MASCT System can be manufactured by this supplier. The Company anticipates that it will need to rely on third-party suppliers for the continued manufacture and supply of the MASCT System, 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 the Company is unable to identify third-party suppliers to produce the MASCT System in quantities sufficient for the Company's planned product launch on acceptable terms, or at all, the Company will not be able to commercialize the MASCT System and generate revenues from its sales as planned. In addition, if at any time after commercialization of the MASCT System, the Company is unable to secure essential equipment or supplies in a timely, reliable and cost-effective manner, it could experience disruptions in its 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 the Company from pricing the MASCT System at desired levels.

The HALO System, an NAF collection device similar to the MASCT System, is being sold by Neomatrix, Inc., or Neomatrix, of Irvine, California. Previously, Cytyc, Inc., or Cytyc, of Marlboro, Massachusetts, marketed FirstCyte, a device to collect NAF by ductal lavage. Certain insurance carriers do not currently reimburse for the HALO System or FirstCyte 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 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. The Company 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 contracts, or may not be able to sell the product and services components of the MASCT System at acceptable margins, which would severely limit the Company's ability to generate revenues.

Competitive bidding practices under Medicare and healthcare reform generally may prevent us from furnishing services to certain patients or medical providers and bidding pressures may negatively affect our future revenues and potential profitability.

The Company expects to bill the Medicare program directly for services we perform for Medicare patients. In 2003, Congress required the Centers for Medicare & Medicaid Services, or CMS, to conduct a demonstration program on using competitive bidding for clinical lab tests that are furnished without a face-to-face encounter between the individual and the entity performing the test, to determine whether competitive bidding could be used to provide lab services at reduced cost to Medicare, while continuing to maintain quality and access to care. Although this requirement was repealed by Congress in 2008, the reintroduction and widespread use of competitive bidding, if implemented for clinical lab services, could have a significant effect on the clinical laboratory industry in general and on the Company's business in particular. The Company could be precluded from furnishing certain clinical laboratory services to Medicare beneficiaries if the Company is not the successful bidder or, as part of the competitive bidding process, the Company could be required to bill at significantly lower rates than currently projected in order to participate in the Medicare program. In addition, states could initiate efforts to establish competitive bidding processes for the provision of clinical laboratory services under the state Medicaid program.

Additionally, the Company could face pricing pressures under the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA. The PPACA is expected to substantially change the way healthcare is financed by both governmental and private payors. The PPACA provides for changes to extend medical benefits to those who currently lack insurance coverage, encourages improvements in the quality of health care items and services, and significantly impacts the U.S. medical industry in a number of ways. By extending coverage to a larger population, the PPACA may substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare, Medicaid and State Children's Health Insurance Program, as well as the creation of a government-sponsored healthcare insurance source, or some combination of both. Such restructuring of the coverage of medical care in the United States could impact the extent of reimbursement for medical devices and services, including the Company's planned laboratory services.

In addition, both the federal and state governmental authorities in the United States continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of healthcare. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the products and services and may further limit our commercial opportunity. There may be future changes that result in reductions in current coverage and reimbursement levels for current and future products and services, and the Company cannot predict the scope of any future changes or the impact that those changes would have on its operations or potential profitability. All of these changes could negatively affect the Company's future revenues and potential profitability.

The Company's intended business to sell predictive medical products exposes the Company to possible litigation and product liability claims.

The Company's business exposes it to potential product liability risks from the MASCT System 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 the Company's 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 due to fatigue or distraction by the healthcare professional 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.

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 the Company's business. Any successful product liability claim may prevent the Company 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 the Company's products.

The Company's intention to provide a laboratory to analyze and read the NAF tests expose it to possible litigation based on malpractice, data aggregation errors, or misdiagnoses.

The Company will need to establish and operate a CLIA-certified laboratory to analyze and read NAF samples collected using the MASCT System, and intends to report the results to referring healthcare professionals, researchers and potential collaborators worldwide. The Company 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 NAF tests;
- · incorrect aggregation, categorization or labeling of NAF data;
- · improper, incorrect or inaccurate development of a computer database which categorizes, analyzes, or compares NAF test data; or
- · misinterpretation of the results of the test or collected data.

We intend to maintain insurance to protect the Company 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 outcome against the Company could involve significant monetary judgments and could severely impact the Company's financial resources and would be expected to impair the ability of the Company in the future to obtain malpractice, or other insurance, for its laboratory services.

If the Company's patent positions do not adequately protect its products, others could compete with the Company more directly, which would adversely affect its business.

The Company's commercial success will depend in part on its ability to obtain new patents and enforce its existing patents, as well as its ability to maintain adequate protection of other intellectual property for its technologies and products in the United States and abroad. If the Company does not adequately protect its intellectual property, competitors may be able to use its technologies and erode or negate any competitive advantage it may have, which could adversely affect its business, negatively affect its position in the marketplace and limit its ability to commercialize its products. The laws of some foreign countries do not protect the Company's proprietary rights to the same extent as the laws of the United States, and the Company may encounter significant problems in protecting its proprietary rights in these countries.

The patent positions of diagnostic and medical device 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. The Company will be able to protect its proprietary rights from unauthorized use by third parties only to the extent that its proprietary technologies, existing products and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets, and the Company is willing and has the resources to take enforcement action against such unauthorized use by third parties.

The degree of future protection for the Company's proprietary rights is uncertain, and the Company cannot ensure that:

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

# The Company may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

The Company relies on trade secrets to protect its proprietary know-how and technological advances, particularly where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. The Company relies in part on confidentiality agreements with its employees, consultants, outside scientific collaborators and other advisors to protect its 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 the Company's trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of the Company's proprietary rights. Failure to obtain, or maintain, trade secret protection could enable competitors to use the Company's proprietary information to develop products that compete with the Company's products or cause additional, material adverse effects upon the Company's competitive business position.

The Company's current patent portfolio may not include all patent rights needed for the full development and commercialization of the Company's products. The Company cannot be sure that patent rights it may need in the future will be available for license on commercially reasonable terms, or at all.

Although the Company's patents may prevent others from making, using or selling similar products, they do not ensure that the Company will not infringe the patent rights of third parties. The Company may not be aware of all patents or patent applications that may impact its ability to make, use or sell the MASCT System or its other proposed product or service offerings. Furthermore, the Company may 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 its patents and limit its ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, the Company may need to obtain licenses to these patents or to develop or obtain alternative technology.

The Company may not be able to obtain any licenses or other rights to patents, technology or know-how from third parties necessary to conduct its 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 the Company from developing or commercializing its proposed products and services, which would harm its business. Litigation or patent interference proceedings need to be brought against third parties, as discussed below, to enforce any of the Company's 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 the Company is involved in such litigation, it could cause delays in bringing product or service candidates to market and harm its ability to operate.

The Company's commercial success will depend in part on its 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 the Company is 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 or its 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 the Company's technologies infringes these patent claims or that it is employing their proprietary technology without authorization.

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

Even if the Company is successful in proceedings involving its intellectual property rights or those of others, it may incur substantial costs and divert management time and attention in pursuing these proceedings. If the Company is unable to avoid infringing the patent rights of others, it 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 the Company may not have sufficient resources to bring enforcement actions to a successful conclusion. In addition, if the Company does not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, the Company may incur substantial monetary damages; encounter significant delays in bringing its product candidates to market; or be precluded from participating in the manufacture, use or sale of its product candidates or methods of treatment requiring licenses.

Our Chief Executive Officer has lent the Company approximately \$105,000 under promissory notes that have matured. Accordingly, he can demand repayment at any time.

Steven C. Quay, M.D., Ph.D., the Company's co-founder and Chief Executive Officer has lent the Company a total of \$105,000 through the date of this prospectus under promissory notes that have matured and are currently payable on demand. Although Dr. Quay has not demanded repayment, if he was to do so prior to the completion of this offering, we expect we would be unable to repay these notes with existing cash on hand. Accordingly, we would need to draw down an equivalent amount under the \$500,000 credit line that Dr. Quay has provided the Company, of which \$420,000 remains available as of the date of this prospectus. If an insufficient amount remained available under this credit line and Dr. Quay demanded repayment of the \$105,000 of matured indebtedness prior to the completion of this offering, we would need to raise capital from other sources or risk defaulting on this debt.

#### Risks Related to the Company's Industry

The inadvertent or unintentional failure to comply with the complex government regulations concerning privacy of medical records could impact the Company with fines and adversely affect its reputation.

The federal privacy regulations, among other things, restrict the Company's 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, the Company could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

The Company intends to implement policies and practices that it believes will make it compliant with the privacy regulations. However, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject the Company 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, the Company is required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject it 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 the Company.

Changes in regulations, policies, or payor mix may adversely affect reimbursement for laboratory services and could have a material adverse impact on the Company's revenues and profitability.

Most of the Company's 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 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 the Company will 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 the Company's business.

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

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. If the Company does not have a contract with a managed care provider, it may be unable to gain those physicians as clients. In cases in which it will contract with a specified insurance company as a participating provider, it will be considered "in-network," and the reimbursement of third-party payments is governed by contractual relationships. The Company's in-network services will be primarily negotiated on a fee-for-service basis at a discount from the Company's patient fee schedule, which could result in price erosion that would adversely affect revenues. The Company's failure to obtain managed care contracts, or participate in new managed care networks, could adversely affect revenues and profitability. In cases in which the Company does not have a contractual relationship with an insurance company, or is not an approved provider for a government program, it will have no contractual right to collect for services and such payors may refuse to reimburse it for services, which could lead to a decrease in accession volume and a corresponding decrease in revenues. As an out-of-network provider, reductions in reimbursement rates for non-participating providers could also adversely affect the Company. Third-party payors, with whom the Company does not participate as a contracted provider, may also require that it enter into contracts, which may have pricing and other terms that are materially less favorable to the Company than the terms under which it intends to operate. While accession volume may increase as a result of these contracts, revenues per accession may decrease.

Use of the Company's laboratory services as a non-participating provider is also expected to result in greater copayments for the patient unless the Company elects to treat them as if it were a participating provider in accordance with applicable law. Treating such patients as if the Company were a participating provider may adversely impact results of operations because it may be unable to collect patient copayments and deductibles. In some states, applicable law prohibits the Company from treating these patients as if it were a participating provider. As a result, referring physicians may avoid use of the Company's services which could result in a decrease in accession volume and adversely affect revenues.

Changes in FDA policies regarding the "home brew" exception from FDA review for laboratory-developed tests and reagents could adversely affect the Company's 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 the Company intends to establish. The Company does not believe that the cytology or IHC testing of NAF samples in the MASCT System are LDTs; however, the Company's second generation biomarker tests will be LDTs for which it does not currently intend to apply for FDA premarket notification or approval. In addition, manufacturers and suppliers of analyte specific reagents, or ASRs, which the Company may utilize for use in its 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 the Company 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 the Company's ability to provide specialized diagnostic services and may adversely affect its business. FDA regulation of LDTs, or increased regulation of the various medical devices used in laboratory-developed testing, c

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.

If the Company is successful in obtaining reimbursement from government healthcare program, the Company will be 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 the Company's inability to receive payment for its services or attempts by third-party payors, such as Medicare and Medicaid, to recover payments from the Company that have already been made. 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, the Company could be adversely affected if it was determined that the services it provided were not medically necessary and not reimbursable, particularly if it were asserted that the Company contributed to the physician's referrals to it of unnecessary services. It is also possible that the government could attempt to hold the Company liable under fraud and abuse laws for improper claims submitted by an entity for services

The Company's 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 the Company's 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 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 the Company's 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 the Company's or that are more patient-friendly, efficient, or cost-effective. The Company's success depends upon its 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 its services.

Risks Related to This Offering, the Securities Markets and Investment in the Company's Securities

There has been no prior public market for the Company's securities and the lack of such a market may make resale of the securities difficult.

No prior public market has existed for the Company's securities and the Company cannot assure any investor that a market will develop subsequent to this offering. The Company intends to apply for listing of its common stock, the Units and the Class C Warrants on the NYSE Amex. However, it does not know whether a market for the Company's securities will ever develop or continue. If the Company's securities are not listed on the NYSE Amex, or a public trading market does not otherwise develop, you may have difficulty selling your Units, common stock or Class C Warrants. If the Company is not successful in listing on the NYSE Amex, it may then apply for listing of its securities on the NASDAQ Capital Market, or have its securities quoted on the OTC Bulletin Board, or the Pink OTC Market, Inc., an Internet-based quotation service for over-the-counter securities. The OTC Bulletin Board and Pink OTC Markets generally have lower trading volume and liquidity, which could result in lower trading prices and a decreased ability to sell securities.

The Class A and Class B Warrants to be issued in this offering will not be listed on a securities exchange, are exercisable for a period of only 10 days beginning on the sixth trading day after achievement of a performance milestone and may lose all value if the performance milestones are not met or if the trading price of the Company's common stock drops below \$0.05 per share.

Although the Company intends to apply for the listing of its common stock, Units and Class C Warrants on the NYSE Amex, it does not plan to list the Class A Warrants or the Class B Warrants. Even if there is a secondary market, it may not provide enough liquidity to allow you to trade or sell the warrants easily. Accordingly, you will need to exercise the Class A Warrants and the Class B Warrants for common stock in order to convert them into securities listed for trading on an exchange. However, the Class A Warrants and the Class B Warrants may not be exercised unless and until performance milestones are first satisfied. More specifically, the Class A Warrants will become exercisable only after our announcement of the registration of our laboratory facilities and the Class B Warrants will become exercisable only after our announcement of the MASCT System. If the milestones are not met within two years from the date of issuance, the warrants would expire, with the warrant holders only being entitled, at that point for a 90-day period, to surrender the expired warrants to the Company for redemption at a price of \$0.25 per warrant. There can be no assurance that we will achieve either or both of these milestones, in which case one or both of the warrants could expire with little or no value.

In addition, the Class A Warrants and Class B Warrants must be exercised within 10 days beginning on the sixth trading day after the date on which we announce the achievement of the relevant milestone and will expire if not exercised during that ten-day period. The Company intends to issue a press release announcing the achievement of the milestones and the date by which the Class A Warrants or Class B Warrants, as applicable, must be exercised. If you do not exercise your Class A Warrants or Class B Warrants on or before the expiration date, you will receive only \$0.25 per unexercised warrant if you surrender the unexercised, expired warrant within 90-days of the exercise period and you will receive no consideration for the warrant beyond the 90-day period. Additionally, because the Class A Warrants and Class B Warrants have an exercise price of \$0.05 per share, if our stock price was to drop to or below \$0.05 per share prior to exercising the warrants, these warrants could not be exercised to acquire a share and the Class A Warrants and Class B Warrants would expire without value.

#### Purchasers of Units will be entitled to exercise the warrants offered as part of the Units only if they hold the Units through the date of separation.

The Company intends to apply for the listing of the Units on the NYSE Amex so that the Units will be tradable upon the completion of this offering. The securities underlying the Units will separate from the Units on the 90th day after the date of this prospectus, unless Dawson James Securities, Inc. determines that an earlier separation date is acceptable based on its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, the Company's securities in particular. Each Class A Warrant will be exercisable for a period of ten trading days beginning on the sixth trading day after our announcement of the registration of our laboratory facilities (which will in no event be prior to the separation of the Units), each Class B Warrant will be exercisable for a period of ten trading days beginning on the sixth trading day after our announcement of the commercial launch of the MASCT System (which will in no event be prior to the separation of the Units) and each Class C Warrant will be exercisable for a period of five years after the separation of the securities underlying the Units. Because the warrants will not be exercisable until the separation of the Units as described above, purchasers of Units will be required to hold the Units through the respective dates on which the warrants become exercisable in order to have the ability to exercise these warrants.

# Holders of the Company's common stock will incur substantial dilution as a result of the exercise of the Class A Warrants and Class B Warrants and other issuances of securities by the Company.

The Company anticipates that upon the completion of this offering, it will issue 3,000,000 shares of common stock underlying the Units. An additional 6,000,000 shares of common stock may be issued within ten trading days after the sixth trading day following our announcement of the milestones triggering the exercisability of the Class A Warrants and the Class B Warrants, which are exercisable on a cashless, net exercise basis at a price of \$0.05 per share. The issuance of additional securities by the Company upon the exercise of these warrants, as well as stock options that the Company has issued or may issue to employees, officers, directors and consultants, would result in substantial dilution to the Company's stockholders and could adversely affect the trading price for the Company's common stock.

# The Company does not expect to receive any proceeds from the exercise of the Class A Warrants or Class B Warrants and may not receive any proceeds from the exercise of the Class C Warrants to be issued in this offering.

Because the exercise price of the Class A Warrants and Class B Warrants is \$0.05 per share and because these warrants are exercisable on a cashless, net exercise basis, the Company expects to receive no proceeds from any exercises of these warrants. Furthermore, the Company must reserve \$0.25 per Class A Warrant and \$0.25 per Class B Warrant (\$1,500,000 if a total of 3,000,000 Units are sold in this offering) until the earlier of 90-days following the 10-day exercise period for each warrant or 90-days following two years from this offering and cannot use this reserved cash for operations. The Class C Warrants have an exercise price equal to 55% of the Unit price in this offering, and will be exercisable commencing on the first anniversary of the date of this prospectus and remaining exercisable until the fifth anniversary of the separation of the Class B Warrants from the Units. The Company's stock price may trade below the Class C Warrant exercise price, in which case the holders would not exercise the warrants. Even if the Company's stock price trades above the warrant exercise price, the warrant holders may choose not to exercise these warrants for a period of several years, or at all, or they may elect the exercise the Class C Warrants pursuant to the cashless, or net exercise provisions in the warrants, in which case the Company would not receive any cash proceeds from the exercise. In addition, the Company has the right to redeem the Class C Warrants at \$0.25 per share of common stock underlying the Class C Warrants in the event (i) the average of the closing price of the Company's common stock exceeds 200% of the exercise price for 10 consecutive trading days while the warrants are exercisable and (ii) there is then an effective registration statement with a current prospectus on file with the SEC. As a result, the Company may not receive any proceeds from the exercise of the Class C Warrants for several years, if at all.

The ownership of the Company's common stock is concentrated among a small number of stockholders, and if its principal stockholders, directors and officers choose to act together, they may be able to control the Company's management and operations, which may prevent the Company from taking actions that may be favorable to you.

The Company's ownership is concentrated among a small number of stockholders, including our founders, directors, officers and entities related to these persons. Upon the completion of this offering, and after giving effect to the expected full exercise of the Class A Warrants, the Company's directors, officers and entities affiliated with them will beneficially own approximately 29.4% of the outstanding voting securities of the Company. Accordingly, these stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by the Company's stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of its assets. In addition, they could dictate the management of our business and affairs. 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 the Company's charter documents and Delaware law could delay or prevent a change in control which could limit the market price of the Company's common stock and could prevent or frustrate attempts by the Company's stockholders to replace or remove current management and the current board of directors.

The Company's amended and restated certificate of incorporation and amended and restated bylaws, which are to become effective upon the completion of this offering, contain provisions that could delay or prevent a change in control of the Company or changes in the board of directors of the Company that our stockholders might consider favorable. 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 the Company's 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 and cause the Company to take other corporate actions. Furthermore, the existence of these provisions, together with Delaware law, might hinder or delay an attempted takeover other than through negotiations with the board of directors.

The Company does 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 sale.

The Company has never and does not anticipate that it will declare or pay a cash dividend. The Company expects to retain earnings, if any, for its business and does not anticipate paying dividends on common stock at any time in the foreseeable future. Because it does not anticipate paying dividends in the future, the only opportunity to realize the value of the common stock will likely be through a sale of those shares.

#### FORWARD-LOOKING STATEMENTS

This prospectus contains, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements. Such statements are subject to certain risks and uncertainties which could cause actual results to differ materially than those projected, or anticipated. Actual results could differ materially from those projected in the forward-looking statements. Although we believe our assumptions underlying the forward-looking statements are reasonable, 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 those words or other comparable words. Forward looking statements contained in this prospectus include, but are not limited to, statements about:

- · our ability to engage third-party suppliers to manufacture the MASCT System and its components at quantities and costs acceptable to us;
- · our ability to satisfy ongoing FDA requirements for the MASCT System and to obtain regulatory approvals for our other products and services in development;
- the benefits and clinical accuracy of the MASCT System and our services, 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 the MASCT System and our services;
- · the willingness of insurance companies and other third-party payors to approve our products and services for coverage and reimbursement;
- · our ability to establish and maintain a sales force to market the MASCT System and other products and services that we may develop;
- · our ability to sell the MASCT System and our services at prices acceptable to us;
- 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 the MASCT System and our 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 made 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. 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.

#### USE OF PROCEEDS

We estimate that the net proceeds of the sale of the Units that we are offering will be approximately \$16.0 million, or approximately \$18.3 million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of \$6.00 per Unit, which is the midpoint of the range listed on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions, underwriter 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 Unit would increase (decrease) the net proceeds to us from this offering by approximately \$2.7 million, assuming the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 markets. We estimate that we will use the net proceeds from this offering primarily for the following purposes:

- up to approximately \$750,000 of these net proceeds to establish a cytology and molecular diagnostics laboratory focused exclusively on breast cancer;
- up to approximately \$1.5 million of these net proceeds to manufacture MASCT System units needed to launch the MASCT System in Northwestern United States as the initial market for the distribution of the product;
- up to approximately \$3.5 million of these net proceeds to hire and train sales and marketing personnel for initial regional marketing and subsequent national distribution;
- · up to approximately \$3.2 million of these net proceeds to develop and commence manufacturing and commercialization of the Oxy-MASCT System, a second-generation version of the MASCT System; and
- · up to approximately \$3.0 million to develop second generation biomarker tests for tumor-related indications and complementary molecular diagnostic assays.

We will set aside a total of \$1.5 million of the offering proceeds for the potential redemption of the Class A Warrants and Class B Warrants. Following the achievement of the warrant exercise milestones, or upon the second anniversary of this offering (whichever is earlier), we will be able to better estimate the potential redemption amount. We anticipate using the remaining up to approximately \$4.0 million in net proceeds (which amount may be up to \$1.5 million less, depending on the potential for Warrant redemptions), assuming an initial public offering price of \$6.00 per Unit and no exercise of the underwriters' over-allotment option, for general corporate purposes, such as general and administrative expenses, capital expenditures, working capital, prosecution and maintenance of our intellectual property, repayment of outstanding indebtedness to Dr. Quay (the terms of which are described below), as well as the potential investment in technologies or products that complement our business. We expect these expenses to include the repayment of current liabilities of \$558,882 through September 30, 2010, including accrued payroll of \$166,071, accrued expenses of \$285,811 and repayment of loans to related parties of \$107,000, although the allocation of the remainder of the up to \$4.0 million in net proceeds among the purposes described in the preceding sentence cannot be determined at this time.

We have borrowed an aggregate of \$105,000 from Dr. Quay pursuant to two promissory notes that were callable by Dr. Quay starting on December 31, 2010. As of the date of this prospectus, Dr. Quay has not called the notes. The notes bear an annual interest rate of 10% accruing from June 30, 2010 and carry a pass-through loan origination fee of \$4,000. Additionally, we issued a third promissory note to Dr. Quay in November 2010 in connection with a \$500,000 line of credit extended us by Dr. Quay. Pursuant to the terms of the note, all principal amounts borrowed under the line of credit bear interest at an annual rate of 10%, and all principal and accrued interest will be due and payable in full on December 31, 2011. As of the date of this prospectus, we have borrowed \$80,000 under the line of credit. All amounts that have been borrowed from Dr. Quay have been used to provide general working capital and to fund our operations to date.

Although we currently anticipate that we will use the net proceeds as described above, there may be circumstances in which a reallocation of funds may be necessary, or the proceeds may not be sufficient to achieve our business goals as currently planned. The amount, timing and allocation of our actual expenditures will depend on numerous factors, including the relative costs of commercial production of the MASCT System, hiring and training our sales and marketing personnel, establishing our planned laboratory and developing and testing additional applications of the MASCT System, as well as the timing of our planned commercial launch and the level of market demand for the MASCT System in the Northwestern United States at the time of launch. If the costs to establish our laboratory, to engage manufacturers for the commercial production of the MASCT System or to hire and train our sales and marketing personnel exceed our current estimates, we may, for example, allocate more of the proceeds to these uses and defer development of the Oxy-MASCT System.

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 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.

Management will retain broad discretion in the allocation of the net proceeds of this offering. 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.

## 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.

## **CAPITALIZATION**

The following table sets forth the Company's capitalization as of September 30, 2010 on:

- · an actual basis; and
- an as-adjusted basis to reflect the receipt of the net proceeds from the sale of Units in this offering at an assumed initial public offering price of \$6.00 per Unit, which is the midpoint of the range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

A potential investor should read this capitalization table together with the financial statements and the related notes appearing elsewhere in this prospectus, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information included in this prospectus.

	As of September 30, 2010	
	Actual As Adjusted	
	(unaud	ited)
Common Stock, \$0.001 par value, 75,000,000 shares authorized and 6,000,067 and 9,000,067 shares outstanding, actual		
and as-adjusted, respectively (1)	6,000	9,000
Additional paid-in capital	334,585	16,531,585
Deficit accumulated during development stage	(867,214)	(867,214)
Total stockholders' (deficit) equity	(526,629)	15,673,371

(1) The number of shares of the Company's common stock to be outstanding before the offering is based on 6,000,067 shares of common stock outstanding as of September 30, 2010, and excludes 1,000,000 shares of common stock reserved for future issuance under our 2010 Stock Option and Incentive Plan, but without assuming that any of the warrants issued in this offering have been exercised..

#### DILUTION

Our net tangible book value as of September 30, 2010 was \$(526,629), or \$(0.09) 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 September 30, 2010. After giving effect to the sale by us of 3,000,000 shares of common stock underlying the Units 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 10% estimated underwriting discounts and commissions, underwriter expense reimbursement obligations and estimated offering expenses payable by us, our pro forma net tangible book value as of September 30, 2010 would have been approximately \$1.7 million, or approximately \$1.74 per share. This amount represents an immediate increase in net tangible book value of \$1.83 per share to our existing stockholders and an immediate dilution in net tangible book value of approximately \$4.26 per share to new investors.

The following table illustrates this hypothetical per-share dilution:

Assumed initial public offering price		\$ 6.00
Net tangible book value per share as of September 30, 2010	\$ (0.09)	
Increase in net tangible book value per share attributed to new investors purchasing shares in this offering	 1.83	
As-adjusted net tangible book value per share after this offering		 1.74
Dilution per share to new investors		\$ (4.26)

A \$1.00 increase (decrease) in the assumed initial public offering price of \$6.00 per Unit would increase (decrease) our adjusted net tangible book value per share after this offering by approximately \$0.30 and would increase (decrease) dilution per share to new investors by approximately \$0.30, 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 underwriting discounts and commissions 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 summarizes, as of September 30, 2010, 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 3,000,000 shares of our common stock, which represents 3,000,000 shares underlying the Units 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, and which excludes the up to 6,000,000 shares issuable upon exercise of the Class A Warrants and Class B Warrants on a cashless, or net exercise basis, at an exercise price of \$0.05 per share, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We have excluded the exercise of the Class A Warrants and the Class B Warrants because the ability to exercise these warrants is subject to the achievement of performance milestones which, although we expect to achieve, the ultimate achievement and timing of achievement is uncertain.

	Shares Purchased			Total Cons	sideration	Average
	Number	Percent		Amount	Percent	 Price Per Share
Existing stockholders (after giving effect to reverse stock split)	6,000,067	67%	\$	327,540	2%	\$ 0.05
New investors	3,000,000	33%		16,200,000	98%	5.40
Total	9,000,067	100%	\$	16,527,540	100%	\$ 1.84

A \$1.00 increase (decrease) in the assumed initial public offering price of \$6.00 per Unit would increase (decrease) the total consideration paid by new investors by \$3.0 million and increase (decrease) the percent of total consideration paid by new investors by 0.33% assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions, underwriter expense reimbursement obligations and estimated offering expenses payable by us.

Assuming the underwriters' over-allotment option is exercised in full, sales by us in this offering will reduce the percentage of shares held by existing stockholders to approximately 39% and will increase the number of shares held by our new investors to approximately 9,450,000, or 61%.

The number of shares of our common stock to be outstanding after this offering is based on 6,000,067 shares of our common stock outstanding as of September 30, 2010 and excludes:

- 9,000,000 shares of common stock issuable upon exercise of the Class A Warrants and Class B Warrants (having an exercise price of \$0.05 per share and exercisable on a cashless basis), and the Class C Warrants, having an exercise price equal to 55% of the Unit offering price; and
- · 1,000,000 shares of common stock reserved for future issuance under our 2010 Stock Option and Incentive Plan.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations should be read in conjunction with the "Summary Financial Information" and the financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements, which are based on assumptions about the future of the Company's business. The actual results will likely differ materially from those contained in the forward-looking statements. Please read "Forward-Looking Statements" included elsewhere in this prospectus for additional information regarding forward-looking statements used in this prospectus.

#### Overview

We are a development-stage healthcare company focused on the commercialization of cellular and molecular diagnostic risk assessment products and related services for the detection of pre-cancerous conditions that could lead to breast cancer, and on the development of second-generation products and services. Although current mammography procedures can detect cancer already present in the breast, academic studies indicate that pre-cancerous cytological changes in NAF can be detected up to eight years before cancer is detected by mammography. This information allows for the implementation of preventive measures such as lifestyle changes and pharmaceutical interventions that may prevent breast cancer from developing or treat breast cancer earlier, if it develops. Our primary focus is the commercialization of our patented and FDA-cleared product and related testing and analysis services for breast cancer, the MASCT System.

## **Current Operations**

Our operations began 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 have experienced operating losses since inception. Our operations to date have consisted primarily of securing laboratory and office space, hiring laboratory personnel, ordering equipment and supplies, engaging a third-party vendor for the manufacture of the MASCT System in limited quantities for field testing, securing patent rights, filing new patent applications, acquiring FDA market clearances and securing development bids to complete preparation for manufacturing the MASCT System in commercial quantities. We have no other operations and have not received any revenues, nor will we be in a position to expect revenues until we are able to produce and sell the MASCT System. We expect to select a large volume contract medical device manufacturer to begin manufacturing the MASCT System for commercialization in the first quarter of 2011 at an estimated cost of approximately \$1.5 million.

In September 2010, we entered into a month-to-month lease for approximately 1,300 square feet of laboratory space at a monthly rent of \$3,657. We intend to use this space for the initial development of a laboratory for the testing and analysis of NAF samples collected using the MASCT System and believe that this facility will be sufficient for our planned operations over the next 12 months. We expect that we will need to establish additional office and laboratory space in the Greater Seattle area in the second half of 2011.

We believe that commercialization of the MASCT System will provide us with two main revenue sources: (i) sales-based revenue from the sale of the product component of the MASCT System to physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from the preparation and interpretation of the NAF samples sent to our laboratory for analysis.

We plan to develop a specialty trained sales force to market the MASCT System on a localized territorial basis, thereby developing personal relationships with the healthcare professionals to whom our sales personnel can provide service and support. We intend to develop a specialized laboratory for the processing and analysis of the MASCT System tests submitted by client healthcare professionals. We anticipate that we will need to develop a staff of anatomic pathologists to read the test results. In addition to Dr. Quay, we intend to hire other board-certified pathologists to assist in the interpretation of the NAF samples.

In order to execute on our long-range plans, we will use a portion of the proceeds raised in this offering to produce and market the MASCT System. We are developing a laboratory that will initially have only a minimal staff until such time, if ever, that the sales of the MASCT System and demand for laboratory interpretations can justify additional laboratory staff and sales personnel. If funds from this offering are not sufficient to produce the MASCT System or to develop the laboratory, we anticipate that we will have to cease operations if we cannot obtain funds from other sources. While we may seek to raise additional funds through the issuance of additional equity or debt securities, short-term or long-term borrowings or strategic partnerships, we currently do not have any specific plans to obtain funding from alternative sources.

#### **Critical Accounting Policies and Estimates**

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

While our significant accounting policies are more fully described in Note 3 to our financial statements included at the end of this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

#### Revenue Recognition

Although we have yet to generate any revenues, we expect that we will recognize product and service revenue when the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or the service has been performed, (iii) our price to the customer is fixed or determinable and (iv) collection of the resulting accounts receivable is reasonably assured. We will recognize revenue for product sales upon transfer of title to the customer. We will recognize revenue for services upon performance of the service. Customer purchase orders and/or contracts will generally be used to determine the existence of an arrangement. Shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery or that services have been rendered. We will assess whether a price is fixed or determinable based upon the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We will record reductions to revenue for estimated product returns and pricing adjustments in the same period that the related revenue is recorded. These estimates will based on industry-based historical data, historical sales returns, if any, analysis of credit memo data, and other factors known at the time.

#### Cash and Cash Equivalents

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

## Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

# Research and Development Expenses

Research and development costs are generally expensed as incurred. Our research and development expenses consist of costs incurred for internal and external research and development.

#### Share Based Payments

In December 2004, the Financial Accounting Standards Board, or the FASB, issued the Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share-Based Payment", which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in the FASB's ASC Topic 718, "Compensation — Stock Compensation." Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees or independent contractors are required to provide services. Share-based compensation arrangements include stock options and warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or SAB 107, which expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for SFAS No. 123(R). Companies may elect to apply this statement either prospectively, or on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123.

We have fully adopted the provisions of FASB ASC 718 and related interpretations as provided by SAB 107. As such, compensation cost is measured on the date of grant as the fair value of the share-based payments. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

### **Results of Operations**

Discussion of Fiscal Year Ended December 31, 2009

For the year ended December 31, 2009, we had no revenues and total expenses of \$122,857, consisting of \$21,250 in expenses for research and development, or R&D, and \$101,607 in expenses for general and administrative, or G&A, costs. The R&D expenses included \$16,250 paid to Ensisheim in royalties pursuant to an exclusive license agreement for the patents and patent applications covering the MASCT System, as well as \$5,000 paid to an unrelated party for prototype development for the MASCT System. The G&A expenses included \$1,348 paid to Ensisheim for rent for our office space and \$88,522 for legal and professional fees related to company incorporation, initial set-up, patent prosecution and maintenance fees and financial accounting and auditing fees. Our license agreement with Ensisheim was terminated in June 2010.

We have yet to generate any revenues since our inception on April 30, 2009.

Comparison of the Nine Months Ended September 30, 2010 and the Period from April 30, 2009 (inception) through September 30, 2009

For the nine months ended September 30, 2010, we had no revenues and total expenses of \$739,557, consisting of G&A costs of \$738,251 and R&D expenses of \$1,306. This compares to G&A expenses of \$75,605 and R&D expenses of \$17,500 over the period from April 30, 2009 (inception) through September 30, 2009.

As discussed below, we expect that our R&D and G&A expenses will continue to increase in the foreseeable future, and that if we successfully complete this offering and launch the MASCT System and our related laboratory service offerings, we would also begin to incur sales and marketing expenses as we build a regional and ultimately national sales force. We may limit our fixed sales and marketing costs initially by employing temporary workers or those who are compensated on a commission basis. However, we expect our expenditures to increase significantly in future periods.

Research and Development Expenses. We had R&D expenses of \$1,306 for the nine months ended September 30, 2010, and \$17,500 for the period from April 30, 2009 through September 30, 2009. We expect that R&D expenses will increase as we finalize the product design for the first-generation MASCT System and develop a second-generation system and related technologies.

General and Administrative Expenses. G&A expenses for the nine months ended September 30, 2010 were \$738,251, primarily consisting of \$331,863 in legal and professional services in connection with our preparation for this offering, \$194,116 in salary expense, \$90,614 in outside consulting in connection with our preparation for this offering, \$52,500 for website development and internet services, and \$12,204 in advertising and promotion. G&A expenses for the period from April 30, 2009 through September 30, 2009 were \$90,105, related principally to legal and professional expenses related to this offering. The increase in expenses was attributed to the longer period in 2010 and an increase in business activity in preparation for this offering. We expect that our G&A expenses will continue to increase if we successfully complete this offering as we add full-time accounting and finance personnel and incur additional costs as a publicly traded company. Additionally, G&A costs will rise as we increase headcount to coordinate the production and manufacture of the MASCT System and to build a sales force.

## **Liquidity and Capital Resources**

To date, we have funded our operations primarily through private placements of common stock and loans from Dr. Quay, our Chairman and Chief Executive Officer. As of September 30, 2010, we had received net proceeds of approximately \$256,540 from the sale of equity securities and, as of that date, we had approximately \$29,531 of cash and cash equivalents. We issued a promissory note for \$100,000 in principal to Dr. Quay on June 30, 2010, under which the principal amount of the loan was funded to us on July 12, 2010. This note matured and became callable on December 31, 2010. To date, Dr. Quay has not demanded repayment of this note. On November 3, 2010, the Company issued a promissory note to Dr. Quay in connection with a \$500,000 line of credit extended to the Company by Dr. Quay. Pursuant to the terms of the note, all principal amounts borrowed under the line of credit bear interest at a rate of 10% per annum, and all principal and accrued interest will be due and payable in full on December 31, 2011. As of the date of this prospectus, the Company has borrowed \$80,000 under the line of credit.

We have a history of operating losses because we have yet to establish an ongoing source of revenues sufficient to cover our operating costs. The report of our independent auditors contained in our financial statements as of and for the year ended December 31, 2009 expresses substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital, we could be forced to cease operations.

#### Cash Flows

For the nine months ended September 30, 2010, we incurred a net loss of \$744,356. Net cash used in operating activities was approximately \$256,833. Net cash provided by financing activities was approximately \$202,000 and consisted of private placements of our common stock, through which we received net proceeds of \$102,000, and a promissory note for \$100,000 in principal to Dr. Quay. For the year ended December 31, 2009, we incurred a net loss of \$122,857, and net cash used in operating activities was approximately \$75,176. During the year ended December 31, 2009, net cash provided by financing activities was approximately \$159,540, of which \$154,540 was raised through private placements of our common stock.

#### **Funding Requirements**

We expect to incur substantial expenses and generate ongoing operating losses for the foreseeable future as we prepare for the manufacturing and launch of the MASCT System and build and operate our planned diagnostics laboratory. To fund our operations for at least the next 12 months under our current business plan, we estimate that we would need between \$10 million and \$12 million of additional capital. If we are unable to raise this amount of capital, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following, among others:

- the amount of capital raised in this offering and whether investors exercise the Class B Warrants for cash, thereby providing additional capital;
- the time and expense needed to complete the design and manufacturing of the MASCT System and the design and build-out of our planned laboratory;
- the expense associated with engaging one or more third-party contractors to manufacture the MASCT System in commercial quantities;
- the expense associated with building a sales force to market the MASCT System; and

• the degree of patient and physician acceptance of the MASCT System and the degree to which third-party payors approve the MASCT System and laboratory analysis for reimbursement.

To date, we have not generated any revenues. We do not expect to generate revenue unless or until we are able to manufacture and launch the MASCT System and build and operate our planned laboratory. We expect our continuing operating losses to result in increases in cash used in operations over at least the next year. We expect the proceeds of this offering, together with our existing resources as of the date of this prospectus, to be sufficient to fund our planned operations for at least the next 12 months. However, we may require additional funds earlier than we currently expect to successfully manufacture and commercialize the MASCT System or build and operate our laboratory. Because of the numerous risks and uncertainties associated with the development and commercialization of the MASCT System and our services, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated research and development activities.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders may result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable.

#### **Off-Balance Sheet Arrangements**

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

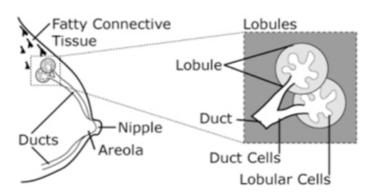
### **Recent Accounting Pronouncements**

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company. The adoption of these accounting pronouncements, including those not yet effective, is not anticipated to have a material effect on the financial position or results of operations of the Company.

#### SCIENTIFIC AND INDUSTRY BACKGROUND

## **Breast Anatomy and Nipple Aspirate Fluid Collection**

The female breast has two main components: milk-producing, or glandular, tissue (lobes and ducts) and connective/fatty tissue. The breast is divided into 15 to 20 lobes that extend outward from the nipple and contain clusters of milk-producing glands. The lobes are further divided into smaller compartments called lobules. Each cluster drains into a duct, which connects the lobules and the nipple. In the ducts, cells closest to the outer portions of the lobules are called luminal cells and those deeper in the duct wall are called basal cells. The molecular-based determination of whether cells are luminal or basal in origin aids in the sub-typing of pre-cancerous changes and cancers. The breast is held together by fatty connective tissue, which provides support and contains nerves as well as blood and lymphatic vessels.



Since the early studies conducted in the 1950s by Dr. George Papanicolaou, the inventor of the "Pap smear" for cervical cancer, it has been understood that adult non-pregnant, non-lactating women continuously secrete fluid into the milk ducts of the breast. This fluid does not normally escape because the nipple orifices are occluded by smooth muscle contraction, and dried secretions. This fluid contains several cell types, including breast duct cells that are shed, which may be normal, hyperplastic, atypical, or even malignant. The fluid also contains molecular diagnostic biomarkers, including associated proteins, complex lipids, RNA and DNA.

A number of medical devices have been designed over the years that apply negative pressure to the nipple to induce the expression of NAF, which is then collected by carefully touching a capillary tube to any apparent drops of NAF. The medical literature reports that in general, these devices are successful in obtaining NAF from 39% to 66% of all patients, and that this sample collection variability has prevented the routine adoption of NAF cytology for breast cancer screening.

The MASCT System was designed to overcome this shortcoming by placing a hydrophilic, or water seeking, membrane in contact with the nipple during the cycles of negative pressure to "wick" fluid from the orifice of the ducts by capillary action, thereby increasing the frequency of obtaining NAF in women.

## **Breast Cancer and Atypical Ductal Hyperplasia**

Atypical ductal hyperplasia, or ADH, is a condition in which the cells lining the breast duct grow excessively and abnormally. Without other risk factors, it produces up to a five-fold increased risk of breast cancer. With a family history of breast cancer, a diagnosis of ADH increases the risk of breast cancer 11 to 22-fold, and in one study, one-third of the women with a biopsy of ADH had an occult cancer growing nearby. Another study examined changes in chromosome markers in ADH that are typical for invasive ductal cancer to determine if ADH was monoclonal for these changes, as expected of cancer, or polyclonal, as expected of hyperplasia, or excessive cell proliferation. The results of this study showed that 40% of ADH was monoclonal and had the hallmarks of a cancerous growth.

The analysis of NAF for these chromosomal changes and the changes in expression of related proteins may help determine the malignant or non-malignant properties of ADH in a particular patient and thus provide information allowing a personalized medicine therapeutic approach.

#### The Role of Immunohistochemistry (IHC) in the Molecular Classification of Breast Cancer and Pre-Cancerous Lesions

Standard pathology and cytology criteria to classify breast cancer and pre-cancerous changes have limitations in predicting tumor behavior, sensitivity to molecular targeted treatments, such as Herceptin (trastuzumab), or the development of drug resistance. A method of predicting tumor behavior and treatment response that involves identifying molecular biomarkers in breast tissue is immunohistochemistry, or IHC. IHC is the process of localizing antigens (e.g. proteins) in cells of a tissue section exploiting the principle of antibodies binding specifically to antigens in cells. Specific molecular markers are characteristic of particular cellular events such as proliferation or cell death. Visualizing an antibody-antigen interaction can be accomplished in a number of ways. In the most common instance, an antibody is conjugated to an enzyme, such as peroxidase, that can catalyze a color-producing reaction. The use of IHC has become standard of care in many clinical settings, for example, the measurement of estrogen or progesterone receptors or HER2 antigens in breast cancer.

In May 2010, an international study from 21 academic institutions involving 42 investigators was published, describing the IHC-based molecular sub-typing of breast cancers from 10,159 women and the correlation with survival over 15 years. Five IHC biomarkers were used to identify six molecular subtypes. The five IHC markers were: the estrogen receptor and the progesterone receptors (two hormone receptors expressed by luminal cells), the human epidermal growth factors receptor-2 (HER2, a protein marker used to select specific adjuvant therapies), and cytokeratin 5/6 (CK5/6) and EGFR (proteins expressed by basal cells). The incidence of each sub-type, and the treatment options available, are shown in the following table:

Molecular Subtype	Incidence	Treatment Options
Luminal 1, Basal Negative	60%	Tamoxifen, Raloxifene
Luminal 1, Basal Positive	6%	Tamoxifen, Raloxifene, EGFR inhibitors
Luminal 2, Basal Negative	6%	Tamoxifen, Raloxifene, Trastuzumab
Non-Luminal HER2+	6%	Trastuzumab
Core Basal Subgroup	9%	EGFR inhibitors
Five Negative Phenotype	7%	Non-receptor targeted chemotherapy
	30	

The six IHC molecular subtypes had very different five and 15 year survival rates.

These and other findings indicate that the six subtypes of breast cancer defined by the expression of five immunohistochemical markers have distinct biological characteristics that are associated with important differences in short-term and long-term outcomes. The application of these markers in the clinical setting could improve the targeting of adjuvant therapies to those women most likely to benefit.

These same markers have been studied in pre-cancerous changes and have been found useful in distinguishing future biological behavior of otherwise cytologically indistinct samples. For example, CK5/6 expression in usual ductal hyperplasia is associated with an increased risk of later development of cancer. Similarly, estrogen or progesterone receptor, HER2, and EGFR expression in a setting of hyperplasia are found in lesions that more frequently progress to breast cancer. In fact, ADH and usual ductal hyperplasia can be distinguished by IHC staining in cases where the cytology is indistinguishable. Thus, IHC testing on NAF samples with pre-cancerous changes can provide information about the possibility of future progression to breast cancer.

## The Role of NAF Cytology in the Diagnosis and Treatment of Atypical Ductal Hyperplasia

In a study of women with normal mammograms who were undergoing breast reduction surgery, which was conducted at the Virginia Mason Medical Center in Seattle, Washington and published in *Plastic and Reconstructive Sugery* in October 2009, the incidence of ADH was found to be 4.4%. A separate study conducted in 2007 of 4,970 women found an incidence of ADH of 4.0% by biopsy. ADH can be definitively diagnosed only by NAF analysis or a breast tissue biopsy. In a study of approximately 2.5 million screening mammograms done between 1996 and 2005 and collected from mammography registries participating in the Breast Cancer Suveillance Consortium, the incidence of biopsy-proven ADH was 0.4%, suggesting that the use of biopsies in conjunction with screening mammography fails to detect ADH in over 90% of patients.

A comprehensive study of the predictive value of NAF cytology for identifying women at risk for breast cancer was conducted at the University of California at San Francisco over a 19 year period. This study, conducted by Margaret Wrensch and others at the University of California San Francisco, showed in two studies, the first with a sample size of 4,046 women and the second with a sample size of 3,627, that women with abnormal cytology in breast fluid obtained by nipple aspiration had an increased relative risk of breast cancer compared with women from whom fluid was not obtained and with women whose fluid had normal cytology. The nipple aspirate fluids were collected from women in the San Francisco Bay Area during the period from 1972 through 1991, classified the women according to the most severe epithelial cytology observed in fluid specimens, and determined breast cancer incidence through March 1999. The groups were stratified into women with acellular, normal, hyperplasia, or atypical NAF cytology and the incidence of breast cancer determined in the two groups over an average of 21 and nine years follow-up, respectively. The incidence of hyperplasia by NAF cytology was 13.6% and the incidence of ADH was 1.6%. Breast cancer occurred in 3.7% of the women with acellular cytology and in 8.2% and 11.0% of the women with hyperplasia and atypia, respectively.

Drug therapy clinical trials for preventing breast cancer in high risk women are called chemoprevention trials. In a five year chemoprevention study of over 19,700 women with ADH or other factors that placed them at a high risk for invasive breast cancer, the use of either tamoxifen or raloxifene, drugs that block or interfere with the actions of estrogen receptors, reduced the incidence of breast cancer by approximately 50%. Side effects were higher with tamoxifen compared to raloxifene. A separate study of raloxifene vs. placebo showed a 72% reduction in cancer incidence at four years and a 66% reduction at eight years.

In a study of NAF specimens in 33 women at the start and six months after taking either tamoxifen or raloxifene, NAF cytology was unchanged in 85%, worsened in 4%, and improved in 11% while the biomarker PSA, which has been shown to be controlled by sex hormones and inversely associated with breast cancer, increased from abnormally low (37 ng/L) to within the normal range (112 ng/L) during treatment. United States patent 7,128,877, owned by the Company, covers the testing of NAF for the biomarker PSA. Other classes of drugs, including inhibitors of aromatase, an enzyme involved in making estrogen, are being tested or considered for testing in breast cancer chemoprevention trials. The Company believes that increased use of pharmaceutical treatments with chemopreventive agents in high risk women will lead to more NAF cytology studies to both diagnose ADH and follow the effects of treatment.

Finally, changes in diet and/or the use of dietary supplements are considered to have a possible impact on breast cancer occurrence and can potentially change the cytology or the presence of biomarkers in NAF. A study of the effect of dietary intervention in 71 women over a one year period was conducted. The probability of obtaining a cellular NAF cytology increased with dietary fat intake, reaching over seven-fold increase for the highest to lowest quartile of fat intake. Furthermore, cellular NAF decreased with increasing plasma levels of dietary supplement antioxidants, lutein and alpha-carotene. The National Cancer Institute, or NCI, is currently sponsoring seven studies of the use of NAF sample collection and analysis of cytology and molecular biomarkers as study endpoints to monitor the efficacy of chemoprevention clinical trials using pharmaceuticals or dietary supplements. The Company believes the successful outcome of one or more of these studies could increase the use of NAF analysis.

#### The Role of NAF Cytology and Molecular Diagnostic Biomarkers in Screening for Breast Cancer

The sensitivity of a test for detecting an abnormality is an important measure in screening populations for the presence of occult disease. With mammography as the well accepted standard for the detection of breast cancer, a comparison of the sensitivity of NAF cytology and molecular diagnostic biomarkers for detecting cancer against the sensitivity of mammography suggests that the MASCT System could also serve as a screening tool for breast cancer, in addition to ADH and other pre-cancerous conditions.

The following table shows the relative sensitivity of mammography and NAF cytology and biomarkers for detecting cancers, confirmed by needle biopsy.

Sensitivity
77-78%
82%
68%
75-84%
54%
36%

- (1) Reflects sensitivity of mammography for the detection of breast cancer in a review of 183,134 screening mammograms in Albuquerque, New Mexico.
- (2) Reflects sensitivity of DNA methylation-specific PCR for the detection of breast cancer in NAF, in a study of specimens of tumor, normal tissue and NAF collected from 22 breast cancer patients with ductal carcinoma *in situ* or stage I cancer.
- (3) Reflects sensitivity of proteomic analysis for the detection of breast cancer in NAF, in a study of 20 subjects with breast cancer.
- (4) Reflects sensitivity of NAF cytology alone for the detection of residual breast cancer, as reflected in the results of a study of 70 subjects with ductal carcinoma *in situ* or stage I cancer published in the British Journal of Cancer in 2001.

While NAF cytology seems well suited to identifying ADH, the sensitivity of NAF cytology alone for detecting cancer is not ideal. However, when its use is combined with other scientific collection and biomarker methods, which include DNA methylation and SELDI-TOF proteomics, sensitivity levels are comparable to those found in mammography. This suggests that NAF cytology, in combination with other biomarker tests, could serve as an alternative testing and screening methodology which may be less painful and less invasive to women than mammography and biopsy and require no exposure to radiation. Assuming the successful completion of this offering, the Company intends to explore the development of such biomarker tests beginning in 2011 (See "Business—Research and Development").

#### BUSINESS

#### Overview

The Company is a development-stage healthcare company focused on the commercialization of cellular and molecular diagnostic risk assessment products and related services for the detection of pre-cancerous conditions that could lead to breast cancer, and on the development of second-generation products and services. The Company's primary focus is the commercialization of the MASCT System, a patented, FDA-cleared cellular and molecular diagnostic risk assessment product and related testing and analysis services for the detection of breast cancer. The Company owns all proprietary rights for the development, manufacture, use and commercialization of the MASCT System and holds the FDA marketing authorization. To date, the Company has not commenced the sale or marketing of the MASCT System, nor has it begun providing laboratory services.

The MASCT System is a device and method for the collection, shipment and clinical analysis of NAF. A number of medical devices have been designed by others for the collection of NAF, which contains cells and molecular diagnostic biomarkers. The clinical analysis by qualified pathologists, whether or not affiliated with the Company, of the biomarkers contained in NAF, whether collected using the MASCT System or by other means, is useful in detecting breast cancer and cellular changes that may be precursors to breast cancer. The use of the MASCT System by non-affiliated pathologists would be expected to yield comparable results. The Company intends to offer each component of the MASCT System for sale separately. The product components of the MASCT System consist of a reusable hand-held pump for the collection of NAF, a patient kit that includes two NAF sample vials, and a shipment kit for the transportation of NAF samples to a specialized cytology and molecular diagnostics laboratory that the Company intends to establish. Through this laboratory, if successfully established, the Company intends to provide the MASCT System services, which would consist of receiving and accessioning the two NAF samples from each patient, preparing routine and specially-stained slides from the NAF samples, and generating a report of the findings. The Company plans to establish its laboratory in the first quarter of 2011 and , subject to the successful completion of this offering, to commence its commercial launch of the MASCT System in the second quarter of 2011. The Company has not commenced any operations at its laboratory facility other than the occupancy of office space and minor tenant improvements at this time. Because the Company's product launch may be delayed if it is unable to complete this offering in the planned timeframe.

Although current mammography procedures can detect cancer already present in the breast, academic studies indicate that pre-cancerous cellular changes in NAF can be detected up to eight years before cancer is detected by mammography. This information allows for the implementation of preventive measures such as lifestyle changes and pharmaceutical interventions that may prevent breast cancer from developing or treat breast cancer earlier, if it develops. At this time, however, Medicare and certain insurance carriers will not reimburse the costs of the NAF collection procedures, citing insufficient clinical evidence to support medical efficacy, better clinical decision-making, or a reduction in breast cancer mortality. The Company anticipates that the MASCT System will initially be used in conjunction with standard mammography exams and has the potential to become a significant assessment tool for identifying women at risk for breast cancer. Although the MASCT System is intended to be an adjunctive procedure to mammography, some physicians may view both the MASCT System and mammography as screening tools for existing breast cancer, which could cause the MASCT System to be deemed directly competitive with mammography, an established procedure. This could limit market adoption of the MASCT System.

The MASCT System NAF collection procedure takes about five minutes, was painless in clinical testing, and does not use radiation. The Company expects to price its NAF sample collection device at approximately \$200 per device, its patient kits at approximately \$50 per kit, and the cytology and molecular diagnostics testing and analysis at between \$110 and \$1,236 per patient, depending on the complexity of the analysis performed and without taking into account any patient reimbursement from third-party payors. Market conditions at or after launch, however, including general economic conditions and changes in third-party reimbursement policies, may prevent the Company from pricing the MASCT System and its services as currently planned.

Effective testing and analysis of the NAF samples collected using the MASCT System requires both highly skilled pathologists and other medical personnel with specialized expertise and laboratory facilities with the necessary testing procedures and equipment. The Company intends to register under the CLIA regulations for the performance of so-called "complex" tests. Because NAF samples are among the smallest medical samples handled by clinical laboratories, specialized procedures, protocols and equipment will be required to maximize the diagnostic value of each sample. The Company anticipates that it will use both conventional cytology and advanced molecular diagnostic technologies in its laboratory and engage a staff of professional medical personnel to deliver accurate and comprehensive diagnostic reports.

The MASCT System requires no use of radiation. In a study published in November 2010, the lifetime risk for women 40 to 74 years of age of developing cancer from the radiation in normal mammograms was found to be 86 per 100,000 women. Unlike a biopsy, the MASCT System is a non-invasive and painless procedure.

The Company estimates that there are over 8,600 mammography clinics, as well as dedicated breast health clinics, and obstetrics/gynecology medical practices in the United States that can utilize the MASCT System. The Company intends to build an internal sales force to market the MASCT System to physicians and clinics specializing in women's health. The Company plans to hire a direct sales force of approximately eight people initially to commercialize the MASCT System in the Northwestern United States, where there are approximately 290 mammography clinics registered with the FDA. If this regional launch is successful, the Company anticipates expanding nationally during the first half of 2012 and grow its sales force to approximately 100 people in the United States. The Company currently has no sales personnel, and there is no assurance that the Company will be able to recruit and retain the sales force necessary to meet anticipated demand.

## **MASCT System Development and Ownership History**

Atossa Healthcare, Inc. was incorporated in 1998 by Dr. Quay to conduct research on breast cancer diagnostic tests, from which the MASCT System was invented. Nastech Pharmaceutical Company, Inc., or Nastech, a company developing nasal drug delivery products, acquired Atossa Healthcare, Inc. in August 2000, and Dr. Quay became chairman, chief executive officer and president of Nastech. In 2003, Nastech conducted clinical trials of the MASCT System for the collection of NAF for cytological testing, and the product received FDA clearance in May 2003.

After receiving FDA clearance, Nastech, which changed its name to MDRNA, Inc., and recently to Marina Biotech, Inc., did not engage in any further development of the MASCT System. In January 2009, Ensisheim acquired from Nastech five issued U.S. patents covering the MASCT System, as well as the FDA marketing authorization, for cash and the assumption of debt related to unpaid patent expenses, in an amount of approximately \$50,000.

The operations of the Company began in December 2008 around acquiring the MASCT System patent rights and assignments and the FDA market clearance for marketing, which was completed in January 2009. The Company was incorporated in April 2009 as a Delaware corporation and subsequently acquired from Ensisheim all ownership and commercialization rights relating to the MASCT System, including the five issued U.S. patents, and eight foreign patents (in the European Union, Canada, Australia, Hong Kong, Switzerland, Germany, France and the United Kingdom) covering the manufacture, use and sale of the MASCT System, pending patent applications for improvements, and the FDA marketing authorization for the MASCT System. In connection with the contribution of these assets by Ensisheim, the Company issued shares of its common stock to Ensisheim. The Company has no royalty or other ongoing obligations to Ensisheim relating to the acquired assets.

### **Design of the MASCT System**

The MASCT System is a specially engineered, hand-held, manual breast pump with unique features that include the ability to wick fluids out of the breast in a very short period of time (approximately five minutes), as well as a proprietary collection system that sanitarily captures NAF produced from the breast ducts. The MASCT System is constructed from injection molded plastic components with standard material gaskets and parts. The membrane filter material that makes contact with the nipple is available from multiple domestic suppliers. In July 2010, the Company entered into an agreement with a leading medical device design company to produce 20 MASCT System pumps and 10,000 patient kits for field testing by the Company. The Company intends to commence field testing in the first quarter of 2011.

## **Clinical Development of the MASCT System**

Under the direction of Dr. Quay, a clinical trial of the MASCT System was conducted at the State University of New York, Stony Brook, New York in 2003 to test the efficiency of NAF collection in normal women. Thirty-one healthy, non-pregnant, pre-menopausal female volunteer subjects were tested with the MASCT System device for the ability to collect NAF samples and to observe the morphology of breast gland cells in the NAF (cytological examination), using the NAF cytology classification system of the College of American Pathologists, or CAP, as described in the table below.

Category	Interpretation	Cytology Characteristics
Category 0	Scant ductal epithelial cells and negative for atypical or malignant cells	No or <10 ductal cells.
Category I	Normal ductal cytology	Normal ductual epithelial cells.
Category II	Usual ductal hyperplasia	Cell groups with >10-50 cells.
Category III	Atypical ductal hyperplasia	Distinct large nuclei with irregular nuclear borders.
Category IV	Suspicious for malignancy	Single cells and groups of cells suspicious for cancer.

Of the 31 subjects, 30, or 97%, had measurable NAF; 24 from both breasts and six from only one breast. NAF samples ranged from less than one to 37 microliters, with an average of seven microliters, and all samples collected were deemed to be clinically useful. 58 of 60 NAF samples were reported as cytology Category I, and two of 60 were reported as cytology Category II under the CAP's classification system for NAF cytology. No adverse events were reported in the study. Based on the results of the study, a premarket notification for the intended use of the MASCT System for the collection of NAF for cytological testing was submitted to the FDA and subsequently cleared by the FDA, indicating that the NAF collected using the MASCT System can be used in the determination and/or differentiation of normal versus premalignant versus malignant cells.

#### The Market

#### **United States Laboratory Testing Market**

Anatomic Pathology. Anatomic pathology involves the diagnosis of cancer and other medical conditions through the examination of tissues (biopsies) and the analysis of cells (cytology) taken from patients. Generally, the anatomic pathology process involves the preparation of slides by trained histo-technologists or cytologists and the review of those slides by anatomic pathologists. Although anatomic pathologists do not treat patients, they establish a definitive diagnosis and may also consult with the referring physician. As a result of the greater degree of complexity and sophistication in anatomic pathology services, 2011 Medicare reimbursement rates for the anatomic pathology services of the type that the Company expects to perform are between \$110 and \$1,236 per patient. The patient fee schedule for self-pay or private payors for these tests can range from two to more than three times the Medicare reimbursement rate.

Molecular Diagnostics. Molecular diagnostics typically involve unique and complex genetic and molecular tests performed by skilled personnel using sophisticated instruments. As a result, molecular diagnostics are typically offered by a limited number of commercial laboratories. According to PriceWaterhouseCoopers, molecular diagnostics represents one of the fastest growing segments of the \$37 billion market for *in vitro* diagnostics, which includes test tube diagnostics such as glucose monitoring for diabetes care but excludes diagnostics for research use. The Medicare reimbursement rate in 2010 for microarray-based molecular diagnostics tests is \$1,250 while the reimbursement rate for fluorescent cellular probe-based tests is \$479 per probe. This market segment is expected to grow 14% annually between 2007 and 2012, from \$2.6 billion to \$5.0 billion.

Clinical Pathology. The clinical pathology market generally involves chemical testing and analysis of body fluids using standardized laboratory tests. These tests typically do not require the interpretive expertise of a pathologist and are frequently routine, automated, and performed by large national or regional clinical laboratory companies and hospital laboratories. The Company currently does not intend to offer routine, automated, standardized laboratory tests.

## United States Market for MASCT System Procedures and Laboratory Tests

Testing in Women at High Risk for Breast Cancer

The Company expects that the MASCT System will initially be adopted by physicians and other healthcare professionals for use in women at high risk for breast cancer. The Company believes, based on the assumptions described below, that up to approximately 52.6 million MASCT System studies could be conducted annually in women at high risk for breast cancer in conjunction with mammography under current American Cancer Society, or ACS, recommendations for screening mammography.

Women Undergoing Diagnostic Mammograms. Breast cancer screening by mammography involves performing a screening mammogram and typically reviewing the mammogram while the patient is still present in the clinic. If the screening mammogram shows suspicious changes, a more extensive diagnostic mammogram is performed, usually on the same day. In an audit of 46,857 consecutive mammograms performed in the radiology department at the University of California, San Francisco between 1997 and 2000, 10,007, or 21%, were diagnostic mammograms. The audit also documented an increased incidence of future cancer in those women who underwent a diagnostic mammogram, regardless of the diagnosis at the time. Applying this frequency to the estimated 39.0 million total mammograms performed each year in the United States yields approximately 8.1 million diagnostic mammograms. The Company believes all women undergoing a diagnostic mammogram, who may be at higher risk of developing breast cancer in the future, would be candidates for MASCT System testing.

*Breast Cancer Survivors.* Women who have had breast cancer are at a higher risk for the recurrence of cancer or for a new malignancy. The ACS has estimated that in 2010, there were more than 2.5 million breast cancer survivors in the United States. The Company believes these women would be candidates for regular MASCT System screening.

Post Menopausal Breast Cancer. There is substantial evidence that post menopausal breast cancer is linked to high levels of estrogen, which induces cancer related biomarkers such as Cathepsin D. In December 2002, the National Institute of Environmental Health Sciences added estrogen to its list of known cancer-causing agents. The Cathepsin D gene, coding for a ubiquitous lysosomal aspartyl protease, is overexpressed in aggressive human breast cancers, and its transcription is induced by estrogens in hormone-responsive breast cancer cells. Since the serum levels of estrogen drop significantly when the ovaries stop producing it at menopause, the source of the hormone in breast cancer was not understood. In 2006, investigators at Northwestern University demonstrated that NAF contains estrogen and related sex hormones, that there is no correlation between serum and the concentrations of these hormones in NAF, preventing serum tests from identifying these high risk patients, and that the likely source is synthesis within the breast itself. The authors concluded that measuring female sex hormone biomarkers like Cathepsin D in NAF may be useful in identifying post menopausal women at high risk for breast cancer and in monitoring chemoprevention trials, since the mechanism of action in these current therapies is interference with female sex hormone activity. The Company has an issued U.S. patent covering the testing of NAF for the biomarker Cathepsin D. There are approximately 52 million women age 50 and over, and therefore peri- or post-menopausal, in the United States, and the Company believes NAF sex hormone screening could help identify women who have high levels of these hormones in the breast and are thus at high risk.

High Risk Women. The Breast Cancer Risk Assessment Tool (based on the Gail model) has been established by the NCI and the National Surgical Adjuvant Breast and Bowel Project, or NSABP, to identify women with an increased risk of breast cancer. The risk factors included in the test are: personal history of breast abnormalities, age, age at first menarche, age at first live birth, breast cancer among first-degree relatives (sisters, mother, or daughters), breast biopsies, obesity and race. Approximately 12 million women in the United States are in the high risk group. A study of 6,904 women for an average follow up of 14.6 years demonstrated that NAF cytology may be most useful for women at highest absolute risk by the Risk Assessment Tool because modest differences in relative risk are amplified. In this group, the incidence of breast cancer by NAF cytology ranged from 5.3 to 10.3 per 1,000 women (non-yielder to hyperplasia/atypia).

## Testing in Normal Risk Women

The Company believes that if it is able to develop, produce and successfully market the MASCT System for use as an additional test in conjunction with all mammography and all cervical cancer screenings (Pap smear), the potential annual U.S. market size would be between 39.0 million and 55 million women. This conclusion is based on the following data:

*MASCT System in conjunction with mammography, all ages.* According to the Mammography Quality Standards Act (MQSA) National Statistics as of January 1, 2011, 39.0 million mammograms are performed annually in the United States.

*MASCT System in conjunction with cervical cancer screening (Pap smear), all ages.* According to the National Cancer Institute as of December 2010, approximately 55 million Pap smear examinations are performed annually in the U.S., of which about 3.5 million, or 6%, were abnormal.

#### **Commercialization Strategy**

The Company's commercialization strategy is based on creating two main revenue sources: (i) product sales-based revenue from the sale of the MASCT System to physicians, breast health clinics, and mammography clinics and (ii) service-based revenue for the preparation and interpretation of the NAF samples sent to the Company's laboratory. This is intended to result in revenues from both the sale and the use of the MASCT System.

In order to achieve its two-pronged revenue base, the Company will need to manufacture, through medical device suppliers, the MASCT System components, i.e., the collection device and patient NAF specimen kits and will need to establish a direct sales force to call on physicians and breast health and mammography clinics to market and sell the MASCT System. The collection device is reusable when sanitized between patients. The kit contains the patient contact materials, preservative fluid for the collected samples, and bar-coded patient identification labeling. The kit components are designed to work properly with the collection device and the Company is not aware of any commercially available parts or components which could be substituted for the Company's kits.

The Company intends to use funds raised from this offering to select and engage an established medical device contract manufacturer to produce commercial quantities of the MASCT System during the first quarter of 2011 and to commence such commercial manufacture and production of the MASCT System during the second quarter of 2011. The Company also plans to begin certification of its laboratory facility for the analysis of NAF samples during the first quarter of 2011 and to begin developing an internal sales and marketing force by the second quarter of 2011.

The Company's product- and service-based income plan is intended to provide revenues from multiple, different sources with different timing in the procedure cycle. The Company expects to generate product revenues from the sale of kits in bulk to clinics and physicians for the testing of their patients, and laboratory services revenues after its laboratory analyzes the results of these tests and renders a diagnosis.

## Manufacture of MASCT System

In July 2010, the Company entered into an agreement with a contract manufacturer to produce 20 MASCT System pumps and 10,000 patient kits for field testing by the Company to confirm the proper operation of the MASCT System device and its ability to collect adequate NAF samples during the first quarter of 2011. The Company has also received a proposal for completion of the Computer Aided Design, or CAD, files that will permit high volume, low cost manufacturing of the MASCT System. The Company plans to select one or more established medical device contract manufacturers and commence manufacturing of its MASCT System devices in commercial quantities during the first quarter of 2011 following the completion of field testing. There can be no assurance that the Company will be able to enter into agreements for the production of commercial quantities of the MASCT System on acceptable terms, or at all.

## **Specialty Sales Team**

To market the MASCT System and its related laboratory diagnostic services, the Company will need to hire sales representatives with technical knowledge in, for example, molecular diagnostics, mammography, obstetrics/gynecology office practices, and women's health clinics. As a result, the Company will expect its sales representatives to develop long-lasting, consultative relationships with the referring physicians they serve. Similarly, the Company anticipates that each of its client service associates will provide dedicated support services to its physician clients. The Company intends to hire representatives who will provide physician clients and their office staff with a knowledgeable and consistent point of contact, thereby strengthening the Company's client relationships.

The Company will focus its marketing and sales efforts on encouraging physicians and breast health and mammography clinics to use the MASCT System in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. The sales representatives will concentrate on a geographic area based on the number of physician clients and prospects, which will be identified using several national physician databases that provide address information, patient demographic information, and other data. The Company will also use the FDA website containing contact information on the approximately 8,600 Mammography Quality Standards Act (MQSA)-certified clinics to identify potential clients.

### **Company Laboratory**

The Company has entered into a lease for a laboratory facility and intends to establish a clinical laboratory at this facility in the first quarter of 2011 for the cytology and molecular diagnostics testing and reading of results of collected NAF samples. The Company believes that by maintaining its own clinical laboratory, it will be positioned to generate substantial additional service revenues through cytology and molecular diagnostic testing, in addition to the sale of the MASCT System pumps and patient kits. The Company is in the process of acquiring the laboratory equipment necessary to begin operations and has begun limited operations of the laboratory facility consisting of the occupancy of office space and conducting minor tenant improvements. The Company intends to register under the Washington state Medical Tests Site (MTS) and federal CLIA certification programs in the first quarter of 2011. Registration is mandatory before seeking Medicare reimbursement for services. Before registration, the Company must also apply for out-of-state licenses, and laboratory standard operating procedures will need to be established. Following registration, inspections by state and federal agencies to CLIA-standards must be completed successfully for certification, which could take up to 12 months. However, once the Company's laboratory is registered with the MTS and CLIA, the Company may begin to process patient samples and bill for services (prior to the receipt of certification). Although the Company can process patient samples and bill for its services prior to receipt of certification, there can be no assurance that the Company will be able to successfully qualify its laboratory within the Company's intended timeframes, or at all.

The Company intends to establish a comprehensive quality assurance program for its laboratory, designed to drive accurate and timely test results and to ensure the consistent high quality of its testing services. In addition to the compulsory proficiency programs and external inspections required by CMS and other regulatory agencies, the Company intends to develop a variety of internal systems and procedures to emphasize, monitor, and continuously improve the quality of its operations.

The Company intends to participate in externally administered quality surveillance programs, and seek accreditation of its laboratory by the College of Anatomic Pathology, or CAP. The CAP accreditation program involves both unannounced on-site inspections of laboratories and participation in CAP's ongoing proficiency testing program. CAP is an independent, non-governmental organization of board-certified pathologists that accredits laboratories nationwide on a voluntary basis and that has been accredited by CMS to inspect laboratories to determine adherence to the CLIA standards. A laboratory's receipt of accreditation by CAP satisfies the Medicare requirement for participation in proficiency testing programs administered by an external source, one of Medicare's requirements for reimbursement eligibility.

# MASCT System NAF Sample Collection and Testing Process

By focusing on NAF samples and the cytology and molecular diagnostic technologies utilizing NAF, the entire process from specimen collection to delivery of the comprehensive patient diagnoses using the MASCT System will be tailored to the specific needs of the Company's referring physicians. When a nurse or physician's assistant uses the MASCT System to take a NAF specimen from a patient for diagnostic testing, he or she will complete a requisition form (either by hand or electronically, via electronic medical records, or EMR, technology or via an EMR web interface), attach a bar-coded label to each NAF specimen from the requisition, and package the specimen for shipment to the Company.

The Company will supply physicians with pre-addressed packaging for added convenience. The Company intends to schedule daily specimen collections from its referring physicians, which creates reliability and convenience and relieves referring physicians of the administrative burden and cost of handling logistical details. Once the specimen arrives in the Company's laboratory, the Company will scan the bar coded label on the requisition and enter all pertinent information about the specimen, including patient billing information, into a work-flow software system. A cytotechnologist will then prepare the specimen for interpretation. It is preferable to prepare NAF slides with liquid-based cytology technique, using cellular concentration and monolayer slide method. This approach aids interpretation, because it optimizes cellularity. The prepared specimen will be delivered to one of the Company's pathologists for analysis. After diagnosis, the pathologist will use an off-the-shelf software system to prepare a comprehensive report, which might include any relevant images from the NAF. The diagnostic report will then be delivered to the physician via secure Internet software, remote printer, fax or mail. Should the physician have questions, the Company's pathologists will be available for consultations.

The Company has not purchased or developed the technology necessary to support these products and services, including electronic requisition forms and work-flow software, but intends to do so following completion of this offering.

The practice of anatomic pathology requires a pathologist to make a specific diagnosis, which referring physicians rely on to determine appropriate treatment plans and monitor the effectiveness of treatment. In addition to Dr. Quay, the Company intends to hire other board-certified pathologists and cytotechnologists to assist in the interpretation of the NAF samples.

#### **Growth Strategy**

The Company intends to launch the MASCT System in the second quarter of 2011 near its headquarters in Seattle and initially to focus its sales and marketing efforts in Washington, Oregon, and Idaho. The Company will market to both mammography clinics and physicians' offices initially in the region. The Company will collect information about the ease or difficulty of adoption of the MASCT System in each location, the number of sales calls needed to receive the first orders and the growth of sales of kits on a monthly basis. The outcome of the Company's initial marketing efforts in this region could impact the Company's national marketing strategies, for example, by changing its emphasis from mammography clinics to physicians' offices. These three states have approximately 290 mammography clinics registered with the FDA that perform approximately 1.2 million mammograms per year. The Company believes that this would represent a total addressable market for products and services for the collection and analysis of NAF in conjunction with mammography of over \$100 million annually. While this estimate is not intended, and should not be considered, to be a projection of the Company's revenues, the Company will seek to capture a portion of this market.

The Company plans to market the MASCT System nationally after its regional marketing and selling effort, if successful, and after it has established the operation of its clinical and diagnostic laboratory. This will provide it with experience and knowledge of the issues and problems that may arise as it markets the MASCT System and the facilities to provide the testing and reading of the samples. Assuming a successful regional launch, the Company intends to commence its national launch of the MASCT System during the first quarter of 2012.

### **Research and Development**

We intend to use a portion of the proceeds from this offering to develop the next generation of the MASCT System as well as new biomarker tests for the analysis of NAF samples. We refer to these as our "second-generation" products and services, which are described more fully below. Because of limited resources, we have spent only \$1,306 on research and development for the nine months ended September 30, 2010 and will not be able to conduct any further research and development activities until this offering is completed. The further research activities necessary for the Company to fully develop and seek marketing approval for these products depend substantially on the successful completion of this offering. If the Company is unable to raise sufficient funds from the proceeds of this offering, it will not be able to further develop, obtain marketing approval for, or commercialize any of its second-generation products.

#### Second Generation Oxy-MASCT Product Development

In 2001, Dr. Quay discovered that administration of a synthetic version of a natural hormone, oxytocin, increases the production of NAF and was named as the inventor on U.S. patent number 6,689,073 for this finding. The Company anticipates that it will develop a second generation product, Oxy-MASCT  $\hat{O}$ , based on this research. The Oxy-MASCT System will include a single dose formulation of oxytocin to increase the amount of NAF collected, to be given to the patient before NAF collection, and the pump and collection kit of the first generation MASCT System. The increase in NAF could permit the Company to perform both cellular examination and biomarker studies on the same sample. The Oxy-MASCT technology is covered by three U.S. and eight foreign patents owned by the Company. The Company plans to initiate clinical trials of the Oxy-MASCT System for the collection of NAF during the fourth quarter of 2011, and, if the results of these trials are favorable, to file with the FDA for market clearance of the Oxy-MASCT System as a Class III medical device in 2013. If the Company is successful in developing and obtaining marketing approval for a product based on the Oxy-MASCT technology, it may market the Oxy-MASCT product to the core of healthcare professionals who use the MASCT System.

#### Second Generation Biomarker Test Development

The Company intends to engage in research activities relating to the study and analysis of NAF samples to develop molecular diagnostic biomarkers for breast health and disease. The Company believes that some of these tests may be developed to serve the growing worldwide "personalized medicine" market, which is estimated to reach \$50 billion in 2012. As defined by the United States President's Council on Advisors on Science and Technology report "Priorities for Personalized Medicine" dated September 2008, "Personalized Medicine" refers to the tailoring of medical treatment to the individual characteristics of each patient, and to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventative or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not. Personalized medicine emphasizes the systematic use of genetic and other molecular diagnostic information about an individual patient to select or optimize that patient's preventative or therapeutic care.

The Company's patents and patent applications provide the basis for its research efforts. These patents and patent applications are directed to over 60 specific individual biomarkers that have been identified in NAF from patients with breast cancer. The Company conducted only limited research and development activities in 2010. To date, the Company has not conducted any research or development activities with respect to second generation biomarker tests, other than obtaining patents and filing patent applications.

The Company believes that each of the stages of breast cancer, from normal growth, to hyperplasia, to ADH, to early-stage cancer, and finally to invasive cancer is associated with specific biomarker patterns. As a result, the Company intends to develop second generation biomarker tests involving DNA methylation patterns, mass spectrometry proteomics, and other microarray-based biomarker panels using a multi-phased clinical development platform, which it intends to fund through additional equity and/or debt financings, as well as revenue-based earnings from sales of the MASCT System. This clinical development platform, if established, would consist of:

- a clinical research phase, in which the Company would establish a research plan, conduct literature reviews to form the basis of clinical research, secure access to archival tumor or pre-cancerous biopsy samples and conduct feasibility studies on these samples with the goal of identifying patterns and changes that occur in pre-cancerous hyperplasia compared to normal tissue and that correlate with the later development of cancer;
- a development phase, in which the Company would conduct additional clinical studies to refine the biomarker set in a specific patient population of interest, with the goal of developing a final biomarker panel and testing and verifying assay chemistry, automation and analysis specifications;
- a validation phase, in which the Company would conduct one or more validation studies with prospectively designed endpoints to test its candidate biomarker panel and the corresponding quantitative expression score; and
- a commercialization and product expansion phase, in which the Company would perform additional studies designed to support a commercialized test's clinical utility and potentially to broaden its use in additional patient populations or for additional indications.

#### **Billing and Reimbursement**

## Billing for the MASCT System Medical Device and Patient Kits and the NAF Collection Procedure

Currently Medicare and certain insurance carriers do not cover the cost of collecting the NAF sample. The Company intends to work with physicians and other interest groups to obtain coverage for the procedures but this process can be lengthy, costly, and might not be successful. Failure to receive reimbursement could limit the adoption and utilization of the MASCT System. Because the process can be done by a nurse or physician's assistant, takes less than five minutes, and the MASCT System supplies will contain everything to obtain, label, and ship the NAF samples, the charge for collecting NAF samples should be below the average cost of a mammogram.

### **Billing for Diagnostic Services**

Billing for diagnostic services is generally complex. As a result, the Company intends to rely on a third-party billing company to perform most of its billing and collection services. Laboratories must bill various payors, such as private insurance companies, managed care companies, governmental payors such as Medicare and Medicaid, physicians, hospitals, and employer groups, each of whom may have different billing requirements. The Company expects to be obligated to bill in the specific manner prescribed by the various payors. Additionally, the audit requirements that must be met to ensure compliance with applicable laws and regulations, as well as internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

- · additional billing procedures required by government payor programs;
- · variability in coverage and information requirements among various payors;
- · missing, incomplete or inaccurate billing information provided by referring physicians;
- · billings to payors with whom the Company does not have contracts;
- · disputes with payors as to who is responsible for payment;
- · disputes with payors as to the appropriate level of reimbursement;
- · training and education of employees and clients;
- · compliance and legal costs; and
- · cost related to, among other factors, medical necessity denials and the absence of advance beneficiaries' notices.

In general, the Company expects to perform the requested tests and report test results even if the billing information is incorrect or missing. The Company will subsequently attempt to obtain any missing information and correct incomplete or erroneous billing information received from the healthcare provider. Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable. When all issues relating to the missing or incorrect information are not resolved in a timely manner, the related receivables will be written off to the allowance for doubtful accounts.

### Reimbursement

Depending on the billing arrangement and applicable law, the party that reimburses the Company for its services will be (i) a third party who provides coverage to the patient, such as an insurance company, managed care organization, or a governmental payor program; (ii) the physician or other authorized party (such as another laboratory) who ordered the test or otherwise referred the test to us; or (iii) the patient. A large percentage of revenues are likely to be derived from Medicare, so Medicare coverage and reimbursement rules will be significant to the Company's operations.

Reimbursement for services under the Medicare program is based principally on two sets of fee schedules. Generally, anatomic pathology services, including most of the services the Company provides, are paid based on the Medicare physician fee schedule. The physician fee schedule is designed to set compensation rates for those medical services provided to Medicare beneficiaries that require a degree of physician supervision. Clinical laboratory tests that are not physician pathology services, such as most blood and urine tests, are paid by Medicare based on the clinical laboratory fee schedule. Outpatient diagnostic laboratory tests are typically paid according to the laboratory fee schedule.

For the anatomic pathology services that the Company will provide, it will be reimbursed under the Medicare physician fee schedule, and beneficiaries are responsible for applicable coinsurance and deductible amounts. The physician fee schedule is based on assigned relative value units for each procedure or service, and an annually determined conversion factor is applied to the relative value units to calculate the reimbursement. The formula used to calculate the fee schedule conversion factor has resulted in significant decreases in payment levels in recent years, and for the 2011 final rule, mandates a reduction of approximately 23%.

Future decreases in the Medicare physician fee schedule are expected unless Congress acts to change the fee schedule methodology or mandates freezes or increases each year. Because the vast majority of the Company's laboratory services will be reimbursed based on the physician fee schedule, changes to the physician fee schedule could result in a greater impact on the Company's revenues than changes to the Medicare laboratory fee schedule.

The Company expects to bill the Medicare program directly. Generally, it will be permitted to directly bill the Medicare beneficiary for clinical laboratory tests only when the service is considered not medically necessary and the patient has signed an Advanced Beneficiary Notice, or ABN, reflecting acknowledgment that Medicare is likely to deny payment for the service. In most situations, the Company is required to rely on physicians to obtain an ABN from the patient. When the Company is not provided an ABN, it is generally unable to recover payment for a service for which Medicare has denied payment for lack of medical necessity.

In billing Medicare, the Company is required to accept the lowest of: its actual charge, the fee schedule amount for the state or local geographical area, or a national limitation amount, as payment in full for covered tests performed on behalf of Medicare beneficiaries. Payment under the laboratory fee schedule has been limited by Congressional action such as freezes on the otherwise applicable annual Consumer Price Index, or CPI, update to the fee schedule amount. The CPI update of the laboratory fee schedule for 2010 was minus 1.9%.

The Medicare statute permits CMS to adjust statutorily prescribed fees for some medical services, including clinical laboratory services, if the fees are "grossly excessive." Medicare regulations provide that if CMS or a carrier determines that an overall payment adjustment of less than 15% is needed to produce a realistic and equitable payment amount, then the payment amount is not considered "grossly excessive or deficient." However, if a determination is made that a payment adjustment of 15% or more is justified, CMS could provide an adjustment of 15% or less, but not more than 15%, in any given year. The Company cannot provide any assurance that fees payable by Medicare for clinical laboratory services could not be reduced as a result of the application of this rule or that the government might not assert claims for recoupment of previously paid amounts by retroactively applying these principles.

The payment amounts under the Medicare fee schedules are important not only for reimbursement under Medicare, but also because the schedule is often used as a reference for the payment amounts set by other third-party payors. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for laboratory services furnished to Medicaid recipients, and insurance companies and managed care organizations typically reimburse at a percentage of the Medicare fee schedule.

The Company's reimbursement rates will also vary depending on whether it is considered an "in-network," or participating, provider. If it enters into a contract with an insurance company, the Company's reimbursement will be governed by its contractual relationship, and it will typically be reimbursed on a fee-for-service basis at a discount from the patient fee schedule. If the Company does not have a contract with an insurance company, it will be classified as "out-of-network," or as a non-participating provider. In such instances, it would have no contractual right to reimbursement for services.

## **Reimbursement Strategy**

## Significance of CPT Codes

Reimbursement for medical procedures and laboratory services is based on obtaining a Current Procedural Terminology, or CPT, code from the AMA. CPT is a listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of CPT is to provide a uniform and accurate description of medical, surgical and diagnostic services, thereby serving as a means for reliable nationwide communication among physicians and other healthcare providers, patients and third parties.

CPT descriptive terms and identifying codes currently serve a wide variety of important functions. This system of terminology is the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. CPT is also used for administrative management purposes such as claims processing and developing guidelines for medical care review.

## Category I CPT Codes

Category I CPT codes describe a procedure or service identified with a five-digit CPT code and descriptor nomenclature. The inclusion of a descriptor and its associated specific five-digit identifying code number in this category of CPT codes is generally based upon the procedure being consistent with contemporary medical practice and being performed by many physicians in clinical practice in multiple locations.

 $In \ developing \ new \ and \ revised \ regular \ CPT \ codes \ the \ Advisory \ Committees \ and \ the \ Editorial \ Panel \ require:$ 

- · that the service/procedure has received approval from the FDA for the specific use of devices or drugs;
- that the suggested procedure/service is a distinct service performed by many physicians/practitioners across the United States;
- · that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature;
- · that the suggested service/procedure is neither a fragmentation of an existing procedure/service nor currently reportable by one or more existing codes: and
- that the suggested service/procedure is not requested as a means to report extraordinary circumstances related to the performance of a procedure/service already having a specific CPT code.

## Category III CPT Codes - Emerging Technology

Category III CPT codes are a temporary set of tracking codes for new and emerging technologies. These codes are intended to facilitate data collection on and assessment of new services and procedures. The Category III codes are intended for data collection purposes in the FDA approval process or to substantiate widespread usage. As such, the Category III codes may not conform to the usual CPT code requirements for Category I. The Panel has established the following criteria for evaluating Category III code requests, any one of which is sufficient for consideration by the Editorial Panel:

- · a protocol for a study of procedures being performed;
- · support from the specialties who would use the procedure;
- · availability of U.S. peer-reviewed literature; and
- · descriptions of current United States trials outlining the efficacy of the procedure.

In general, these codes will be assigned a numeric-alpha identifier (eg, 1234T). These codes will be located in a separate section of CPT, following the "Category II" section. Introductory language in this code section explains the purpose of the Category III codes.

Since Category III CPT codes are intended to be used for data collection purposes to substantiate widespread usage or in the FDA approval process, they are not intended for services/procedures that are not accepted by the Editorial Panel because the proposal was incomplete, more information is needed, or the Advisory Committee did not support the proposal.

Category III CPT codes are not referred to the AMA / Specialty RVS Update Committee, or RUC, for valuation because no relative value units, or RVUs, will be assigned. Payment for these services/procedures is based on the policies of payors and local Medicare carriers, although most payers deny coverage for services reported under Category III codes.

### CPT Code for MASCT System NAF Collection Procedure

The NAF collection procedure of the MASCT System does not currently have a procedure-specific Category I CPT code, which is important for reimbursement by Medicare for eligible patients, and which is part of the basis by which insurance companies make reimbursement decisions. A non-specific Category I CPT code, 19499 (unlisted procedure, breast), can be used initially by physicians and insurance carriers will often pay for such procedures with proper documentation. Medicare does not typically reimburse for CPT 19499 procedures.

Beginning in the first quarter of 2011, the Company expects to begin the process of obtaining a Category III CPT code with which to collect clinical data to support a Category I CPT code application for the use of NAF collection as an adjunct to mammography. It is expected it may take 12 months to obtain the Category III CPT code and up to two years to collect data to make an application to the AMA for a Category I CPT code. The Company expects physicians will be able to use either the non-specific Category I CPT code 19499 with documentation or the MASCT System specific Category III code to obtain reimbursement.

## CPT Code for Cytology and IHC Biomarker Testing

Category I laboratory procedure codes for cytology, IHC biomarker tests, microarray-based analysis of molecular probes, and in situ hybridization of DNA and RNA probes currently exist and it is expected that reimbursement for these codes by Medicare will be at the established rates shown in the following table:

2010 CPT Code	Description	R	011 Medicare National eimbursement te (Per Patient) (1)
88161	Cytopathology, smears; preparation, screening and interpretation	\$	109.72
88162	Cytopathology, smears; extended study involving over 5 slides and/or multiple stains	\$	156.30
88360	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, each antibody; manual	\$	246.66
88360 (5)	Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, five antibody panel; manual	\$	1,233.33
88342	Immunohistochemistry (including tissue immunoperoxidase), each antibody	\$	207.94
88342 (5)	Immunohistochemistry (including tissue immunoperoxidase), five antibody panel	\$	1,003.70
88385	Array-based evaluation of multiple molecular probes; 51 through 250 probes	\$	1,148.40
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer-assisted technology	\$	512.36

(1) Assumes two samples from each patient.

Laboratories typically set patient fee schedules at two to four times the Medicare reimbursement rate for the same procedure.

### **Intellectual Property**

The Company owns five issued U.S. patents and eight corresponding issued patents in Australia, Canada, the European Union, Hong Kong and Japan as well as pending patent applications in the U.S., Europe and Japan. The patents cover both the MASCT System and the Company's proposed Oxy-MASCT System. The patented technology of the MASCT System encompasses the invention of a proprietary, patented process for obtaining fluid and cells from within the breast, in a reproducible and non-invasive method, through a device that allows pressure to be applied to the nipple, thereby increasing the amount of fluid that is extracted from the ducts and lobules of the breast. The Oxy-MASCT System, a second generation product in development, is derived from additional patented technologies (under patents filed in 2001) in which samples of breast fluid, containing cancer markers, abnormal cells and malignant cells, are obtained from the breast nipple following administration of oxytocin, a brain pituitary hormone. Third-party studies conducted in Europe in 2007 have shown that oxytocin administration increases NAF by as much as 10-fold. The Company has also patented its test kit collection system, which will allow the company to have the fluids processed exclusively by its own laboratory.

As of December 31, 2010, the Company owned 13 issued patents (five U.S. and eight foreign) and six pending applications (one U.S. and five foreign), including one expired patent issued in the EU, now entering national phase. The Company owns patents and patent applications covering the development, manufacture, use and sale of the MASCT System and the Oxy-MASCT System, as well as breast cancer biomarkers.

		<b>United States</b>		Foreign						
Description	Issued	Expiration	Pending	Issued	Expiration	Pending				
MASCT System	5	2016-2020	4	8	2016-2020	5				
Oxy-MASCT System	3	2016-2020	3	8	2016-2020	5				
Breast cancer biomarkers	3	2016-2020	2	8	2016-2020	5				
Total (1)	5	2016-2020	4	8	2016-2020	5				

(1) Certain of the Company's patents and pending patent applications contain claims covering one or more of the MASCT System, the Oxy-MASCT System and breast cancer biomarkers. Some pending applications, if issued, would expire in 2029.

The Company has applied with the United States Patent and Trademark Office for registration of the use of the marks Atossa (and design), MASCT, and Oxy-MASCT.

The technologies and products covered by the Company's patents can be summarized as:

- MASCT System collection device for NAF;
- The method of making a diagnosis from NAF, using "whole cells, cell fragments, cell membranes, a protein, a peptide, a glycoprotein, a lipid, a glycolipid, a DNA polynucleotide, an RNA polynucleotide, or a combination thereof;" and
- · The use of the drug oxytocin or oxytocin analogues to increase the amount of NAF produced.

The Company believes that its patents also provide protection against third party laboratories providing diagnostic services with NAF samples collected with the MASCT System and technology. Specifically, the MASCT System collection kits to be provided by the Company are protected under an issued U.S. patent owned by the Company and will be sold under a limited "collection only" patent license (specifically, claims 1–15 of US Patent 6,689,073), which will permit physicians to collect NAF samples but will not allow for assessing, transferring, and processing samples within the vial. Certain claims under the same U.S. patent 6,689,073, owned by the Company, protect those processes of assessing, transferring and processing samples to detect or quantify breast disease markers and the detection of these biomarkers, which will not be licensed with the sale of the MASCT System. The foreign patent counterparts contain similar claims. The Company expects that it will be able to monitor compliance with the license terms by tracking the receipt of samples from purchasers of kits. To the extent that kits are being sold where there is not a corresponding number of samples being returned, that would serve as a "red flag" that the purchaser may be violating the terms of the patent license. The Company expects to monitor compliance with these license terms and enforce the Company's patent rights. At the present time, the Company does not expect to offer kits for sale under a more liberal license, although we may choose to do so at a later time. Parties violating the terms of our patent may be subject to damages and an injunction barring further violations. Our patents do not, however, prevent physicians from collecting NAF using a different technology or system and independently performing comparable diagnostic analysis on the fluid sample.

### Competition

The Company believes that the MASCT System for NAF collection will compete in the medical device product industry with Neomatrix and with academic scientists and physicians who use "homemade" NAF fluid collection systems for research purposes. The Neomatrix device is automated and provides warmth and nipple aspiration simultaneously and is the only non-"homemade" NAF collection system of which the Company is currently aware. The advantages of the MASCT System compared to the Neomatrix device include a lower acquisition cost and portability. The disadvantages of the MASCT System compared to the Neomatrix device include the requirement that a nurse or other healthcare provider manually operate the device, which may result in increased risks of human error and improper sample collection, and the reduced availability of experience with the device among the medical community.

The Company believes it will compete in the anatomic pathology laboratory industry based on the patent portfolio for the MASCT System, the technical expertise provided by the Company's focus on diagnoses utilizing NAF, service-focused relationships with referring physicians, and its advanced technology. The Company does not believe that its competitors can transport or process NAF samples collected with the MASCT System without infringing the Company's patent estate.

Laboratories that could process NAF samples not collected with the MASCT System include thousands of local and regional pathology groups, national laboratories, hospital pathologists, and academic laboratories. The largest such competitors include Laboratory Corporation of America and Quest Diagnostics Incorporated.

Characteristics of each source of competition include:

**Local and Regional Pathology Groups.** Local and regional pathology groups focus on servicing hospitals, often maintaining a staff of pathologists on site that can provide support in the interpretation of certain results. The business models of these laboratories tend to be focused on the efficient delivery of individual tests for a multitude of diseases rather than the comprehensive assessment of only NAF samples, and their target groups tend to be hospital pathologists as opposed to community physicians.

*National Laboratories*. National laboratories typically offer a full suite of tests for a variety of medical professionals, including general practitioners, hospitals, and pathologists. Their emphasis on providing a broad product portfolio of commoditized tests at the lowest possible price often limits such laboratories' ability to handle difficult or complex specimens requiring special attention, such as NAF samples. In addition, national laboratories typically do not provide ready access to a specialized pathologist for interpretation of test results.

**Hospital Pathologists**. Pathologists working in a hospital traditionally provide most of the diagnostic services required for hospital patients and sometimes also serve non-hospital patients. Hospital pathologists typically have close interaction with treating physicians, including face-to-face contact. However, hospital pathologists often do not have the depth of experience, specialization, and expertise necessary to perform the specialized services needed for NAF samples.

Academic Laboratories. Academic laboratories generally offer advanced technology and know-how. In fact, the vast majority of NAF sample processing over the last years has been in academic laboratories primarily for research purposes. These laboratories typically pursue multiple activities and goals, such as research and education, or are generally committed to their own hospitals. Turn-around time for specimen results reporting from academic laboratories is often slow. This limits the attractiveness of academic laboratories to outside physicians who tend to have focused specialized needs and require results to be reported in a timely manner.

Alternative Diagnostic Tools. The Company also anticipates that the MASCT System will face challenges in market adoption due to the reliance of physicians and other medical professionals on existing diagnostic tools for breast cancer, including mammograms, ultrasound examinations, magnetic resonance imaging (MRI), fine needle aspiration and core biopsies, among others. These methods are currently more widely used and accepted by physicians, and may continue to be more widely used than the Company's proposed products and services because they are currently reimbursed by third-party payors. In addition, physicians and other medical professionals may view the MASCT System as a screening tool for existing breast cancer, like mammography, rather than as an adjunctive procedure to mammography. As a result, the MASCT System could be deemed to compete directly with mammography, an established procedure, which could impair market adoption of the MASCT System. The advantages of the MASCT System compared to ultrasound, mammography, or magnetic resonance imaging include obtaining cytology and molecular information, the ease and simplicity of the procedure, and the cost, especially compared to MRI. The disadvantages of the MASCT System compared to ultrasound, mammography, and MRI include a lower sensitivity to detection of cancer. The advantage of the MASCT System compared to fine needle aspiration and core biopsies include the reduced sample size and the consequent limitation of the range of molecular studies that can be conducted.

#### **Information Systems**

The Company will need to acquire, develop and implement laboratory information management systems, or LIMS, that support the Company's operations and physician services. There are a number of commercial vendors of LIMS for anatomic pathology laboratories, and the Company intends initially to use such third-party supplied products for its laboratory operations. Its information systems, to the extent such systems hold or transmit patient medical information, must be capable of being operated in compliance with state and federal laws and regulations relating to the privacy and security of patient medical information, including a comprehensive federal law and regulations referred to as HIPAA. While the Company intends to establish its information systems to be compliant with such laws, including HIPAA, such laws are complex and subject to interpretation.

#### **Government Regulation**

### **United States Medical Device Regulation**

The Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, govern registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, and post-market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDCA, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We intend to manufacture and market a medical device that is regulated by the FDA, comparable state agencies and regulatory bodies in other countries. We also intend to operate a clinical and diagnostic laboratory which will use reagents and test kits some of which are regulated medical devices.

The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the extent of control deemed necessary to ensure the device's safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to the FDA's current good manufacturing practice requirements, as reflected in its QSR. Most pathology staining kits, reagents, and routine antibody-based Immunohistochemistry protocols which the Company intends to use initially are Class I devices. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or postmarket surveillance. The MASCT System is a Class II device. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, and include life-sustaining, life-supporting, or implantable devices, and devices not "substantially equivalent" to a device that is already legally marketed.

Most Class I devices, including the laboratory staining kits and reagents the Company intends to use, and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from FDA. Class I and Class III devices that have not been so exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval, or PMA, approval prior to commercial marketing. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. In the case of the MASCT System, a clinical trial was conducted. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more. After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or (if the device as modified is not substantially equivalent to a legally marketed predicate device) PMA approval. While the determination as to whether new authorization is needed is initially left to the manufacturer, the FDA may review this determination and evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall th

All clinical trials must be conducted in accordance with regulations and requirements collectively known as Good Clinical Practice, or GCP. GCPs include the FDA's Investigational Device Exemption, or IDE, regulations, which describe the conduct of clinical trials with medical devices, including the recordkeeping, reporting and monitoring responsibilities of sponsors and investigators, and labeling of investigation devices. They also prohibit promotion, test marketing, or commercialization of an investigational device, and any representation that such a device is safe or effective for the purposes being investigated. GCPs also include FDA's regulations for institutional review board approval and for protection of human subjects (informed consent), as well as disclosure of financial interests by clinical investigators.

Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of clinical trials, if any, that the Company may sponsor, may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a premarket notification for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial (or a change to a previously approved protocol or trial that requires approval), or place a clinical trial on hold;
- · patients do not enroll in clinical trials or follow up at the rate expected;
- · institutional review boards and third-party clinical investigators may delay or reject the Company's trial protocol or changes to its trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the Company's anticipated schedule or consistent with the clinical trial protocol, investigator agreements, good clinical practices or other FDA requirements;
- · third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- · regulatory inspections of clinical trials or manufacturing facilities, which may, among other things, require the Company to undertake corrective action or suspend or terminate its clinical trials;
- · changes in governmental regulations or administrative actions;
- · the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; and
- $\cdot$  the FDA concludes that the Company's trial design is inadequate to demonstrate safety and effectiveness.

After a device is approved and placed in commercial distribution, numerous regulatory requirements apply. These include:

- · establishment registration and device listing;
- $\cdot \quad \text{the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures;}\\$
- · labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;

- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur; and
- · corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health.

The FDA enforces regulatory requirements by conducting periodic, announced and unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors. Failure to comply with applicable regulatory requirements, including those applicable to the conduct of our clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- · warning letters or untitled letters;
- · fines and civil penalties;
- · unanticipated expenditures;
- · delays in clearing or approving or refusal to clear or approve products;
- · withdrawal or suspension of FDA clearance;
- · product recall or seizure;
- · orders for physician notification or device repair, replacement, or refund;
- · production interruptions;
- · operating restrictions;
- · injunctions; and
- · criminal prosecution.

The Company and its contract manufacturers, specification developers and suppliers are also required to manufacture the MASCT System in compliance with current Good Manufacturing Practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes the Company or any of its contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down the Company's manufacturing operations, require recall of the MASCT System, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against the Company or its officers or other employees. Any such action by the FDA would have a material adverse effect on the Company's business.

#### **CLIA** and State Regulation

As a future provider of cytology and molecular diagnostic services, the Company is required to hold certain federal, state and local licenses, certifications, and permits. Under CLIA, it is required to hold a certificate applicable to the type of work it performs and to comply with certain CLIA-imposed standards. CLIA regulates all laboratories by requiring they be certified by the federal government and comply with various operational, personnel, facilities administration, quality, and proficiency requirements intended to ensure that laboratory testing services are accurate, reliable, and timely. CLIA does not preempt state laws that are more stringent than federal law.

To obtain and renew its CLIA certificates, which it is required to renew every two years, the Company will be regularly subject to survey and inspection to assess compliance with program standards and may be subject to additional random inspections. Standards for testing under CLIA are based on the level of complexity of the tests performed by the laboratory. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests where a CLIA certificate is required. Both NAF cytology and molecular diagnostic testing are high complexity tests. CLIA certification is a prerequisite to be eligible for reimbursement under Medicare and Medicaid.

The Clinical Laboratory Improvement Amendments of 1988, or CLIA '88, was passed to improve quality control at cytology laboratories performing gynecological diagnoses (Pap smears for cervical cancer). Under CLIA '88, the number of slides a cytotechnologist may screen each day is regulated (no more than 100 slides in any 24 hour period, and must have at least 8 hours to complete the examination of 100 slides, which results in an average of 12.5 slides per hour) and quality control procedures require rescreening of a minimum of 10% randomly selected within-normal-limits, or WNL, slides per day. In addition, specialized proficiency testing requirements apply not just to the laboratory, but to the individuals performing the test, specialized personnel standards, and quality control procedures. The Company will not be seeking certification to perform cervical Pap smears and therefore does not believe these provisions of CLIA '88 apply to it.

In addition to CLIA requirements, the Company will be subject to various state laws. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states, including Washington, where the Company is located, have done so. The Washington state Medical Test Site, or MTS, Licensure law (Chapter 70.42 RCW) was passed in May 1989 to allow the state to regulate clinical laboratory testing. In October 1993, Washington became the first state to have its clinical laboratory licensure program judged by the Federal Health and Human Services Centers for Medicare and Medicaid Services, or CMS, as equivalent to CLIA and was granted an exemption. In addition, New York, Maryland, Pennsylvania, Rhode Island, and California, have implemented their own laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements.

#### Privacy and Security of Health Information and Personal Information; Standard Transactions

The Company will be subject to state and federal laws and implementing regulations relating to the privacy and security of the medical information of the patients it treats. The principal federal legislation is part of HIPAA. Pursuant to HIPAA, the Secretary of the Department of Health and Human Services, or HHS, has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions, while protecting the privacy and security of the patient information exchanged. These regulations also confer certain rights on patients regarding their access to and control of their medical records in the hands of healthcare providers such as the Company.

Four principal regulations have been issued in final form: privacy regulations, security regulations, standards for electronic transactions, and the National Provider Identifier regulations. The HIPAA privacy regulations, which fully came into effect in April, 2003, establish comprehensive federal standards with respect to the uses and disclosures of an individual's personal health information, referred to in the privacy regulations as "protected health information," by health plans, healthcare providers, and healthcare clearinghouses. The Company is a healthcare provider within the meaning of HIPAA. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payment for services, and healthcare operations activities;
- a patient's rights to access, amend, and receive an accounting of certain disclosures of protected health information;
- the content of notices of privacy practices for protected health information; and
- · administrative, technical and physical safeguards required of entities that use or receive protected health information.

The federal privacy regulations, among other things, restrict the Company's 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 by 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, the Company could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

The Company will implement policies and practices that it believes brings it into compliance with the privacy regulations. However, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject the Company 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, the Company is required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject it 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 the Company.

The final HIPAA security regulations, which establish detailed requirements for physical, administrative, and technical measures for safeguarding protected health information in electronic form, became effective on April 21, 2005. The Company intends to employ what it considers to be a reasonable and appropriate level of physical, administrative and technical safeguards for patient information. Failure to comply with the security regulations could subject the Company to sanctions or penalties and negative publicity.

The final HIPAA regulations for electronic transactions, referred to as the transaction standards, establish uniform standards for certain specific electronic transactions and code sets and mandatory requirements as to data form and data content to be used in connection with common electronic transactions, such as billing claims, remittance advices, enrollment, and eligibility. The Company intends to outsource to a third-party vendor the handling of its billing and collection transactions, to which the transaction standards apply. Failure of the vendor to properly conform to the requirements of the transaction standards could, in addition to possible sanctions and penalties, result in payors not processing transactions submitted on our behalf, including claims for payment.

The HIPAA regulations on adoption of national provider identifiers, or NPI, required healthcare providers to adopt new, unique identifiers for reporting on claims transactions submitted after May 23, 2007. The Company intends to obtain NPIs for its laboratory facilities and pathologists so that it can report NPIs to Medicare, Medicaid, and other health plans.

The healthcare information of the Company's future patients will includes social security numbers and other personal information that are not of an exclusively medical nature. The consumer protection laws of a majority of states now require organizations that maintain such personal information to notify each individual if their personal information is accessed by unauthorized persons or organizations, so that the individuals can, among other things, take steps to protect themselves from identity theft. The costs of notification and the adverse publicity can both be significant. Failure to comply with these state consumer protection laws can subject a company to penalties that vary from state to state, but may include significant civil monetary penalties, as well as to private litigation and adverse publicity. California recently enacted legislation that expanded its version of a notification law to cover improper access to medical information generally, and other states may follow suit.

#### Federal and State Fraud and Abuse Laws

The federal healthcare Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referrals or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under a governmental payor program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, opportunity to earn income, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions that, if met, will provide healthcare providers and other parties with an affirmative defense against prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

From time to time, the Office of Inspector General, or OIG, issues alerts and other guidance on certain practices in the healthcare industry. In October 1994, the OIG issued a Special Fraud Alert on arrangements for the provision of clinical laboratory services. The Fraud Alert set forth a number of practices allegedly engaged in by some clinical laboratories and healthcare providers that raise issues under the "fraud and abuse" laws, including the Anti-Kickback Statute. These practices include: (i) laboratories providing employees to furnish valuable services for physicians (other than collecting patient specimens for testing for the laboratory) that are typically the responsibility of the physicians' staff; (ii) providing free testing to a physician's managed care patients in situations where the referring physicians benefit from such reduced laboratory utilization; (iii) providing free pick-up and disposal of bio-hazardous waste for physicians for items unrelated to a laboratory's testing services; (iv) providing general-use facsimile machines or computers to physicians that are not exclusively used in connection with the laboratory services; and (v) providing free testing for healthcare providers, their families, and their employees (professional courtesy testing).

The OIG emphasized in the Special Fraud Alert that when one purpose of an arrangement is to induce referrals of program-reimbursed laboratory testing, both the clinical laboratory and the healthcare provider, or physician, may be liable under the Anti-Kickback Statute, and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Another issue about which the OIG has expressed concern involves the provision of discounts on laboratory services billed to customers in return for the referral of more lucrative federal healthcare program business. In a 1999 Advisory Opinion, the OIG concluded that a proposed arrangement whereby a laboratory would offer physicians significant discounts on non-federal healthcare program laboratory tests might violate the Anti-Kickback Statute. The OIG reasoned that the laboratory could be viewed as providing such discounts to the physician in exchange for referrals by the physician of business to be billed by the laboratory to Medicare at non-discounted rates. The OIG indicated that the arrangement would not qualify for protection under the discount safe harbor because Medicare and Medicaid would not get the benefit of the discount. Subsequently, in a year 2000 correspondence, the OIG stated that the Anti-Kickback Statute may be violated if there were linkage between the discount offered to the physician and the physician's referrals of tests covered under a federal healthcare program that would be billed by the laboratory directly. Where there was evidence of such linkage, the arrangement would be considered "suspect" if the charge to the physician was below the laboratory's "average fully loaded costs" of the test.

Generally, arrangements that would be considered suspect, and possible violations under the Anti-Kickback Statute, include arrangements between a clinical laboratory and a physician (or related organizations or individuals) in which the laboratory would (1) provide items or services to the physician or other referral source without charge, or for amounts that are less than their fair market value; (2) pay the physician or other referral source amounts that are in excess of the fair market value of items or services that were provided; or (3) enter into an arrangement with a physician or other entity because it is a current or potential referral source. HIPAA also applies to fraud and false statements. HIPAA created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services, as well as the retention of any overpayment. A violation of this statute is a felony and may result in fines or imprisonment or exclusion from governmental payor programs.

## **Physician Referral Prohibitions**

Under a federal law directed at "self-referral," commonly known as the Stark Law, prohibitions exist, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the laboratory performing the tests. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts.

Any arrangement between a laboratory and a physician or physicians' practice that involves remuneration will prohibit the laboratory from obtaining payment for services resulting from the physicians' referrals, unless the arrangement is protected by an exception to the self-referral prohibition or a provision stating that the particular arrangement would not result in remuneration. Among other things, a laboratory's provision of any item, device, or supply to a physician would result in a Stark Law violation unless it was used only to collect, transport, process, or store specimens for the laboratory, or was used only to order tests or procedures or communicate related results. This may preclude a laboratory's provision of fax machines and computers that may be used for unrelated purposes. Most arrangements involving physicians that would violate the Anti-Kickback Statute would also violate the Stark Law. Many states also have "self-referral" and other laws that are not limited to Medicare and Medicaid referrals. These laws may prohibit arrangements which are not prohibited by the Stark Law, such as a laboratory's placement of a phlebotomist in a physician's office to collect specimens for the laboratory. Finally, recent amendments to these laws require self-disclosure of violations by providers.

#### **Discriminatory Billing Prohibition**

In response to competitive pressures, the Company will be increasingly required to offer discounted pricing arrangements to managed care payers and physicians and other referral services. Discounts to referral sources raise issues under the Anti-Kickback Statute. Any discounted charge below the amount that Medicare or Medicaid would pay for a service also raises issues under Medicare's discriminatory billing prohibition. The Medicare statute permits the government to exclude a laboratory from participation in federal healthcare programs if it charges Medicare or Medicaid "substantially in excess" of its usual charges in the absence of "good cause." In 2000, the OIG stated in informal correspondence that the prohibition was violated only if the laboratory's charge to Medicare was substantially more than the "median non-Medicare/—Medicaid charge." On September 15, 2003, the OIG issued a notice of proposed rulemaking addressing the statutory prohibition. Under the proposed rule, a provider's charge to Medicare or Medicaid would be considered "substantially in excess of [its] usual charges" if it was more than 120% of the provider's mean or median charge for the service. The proposed rule was withdrawn in June 2007. At that time, the OIG stated that it would continue to evaluate billing patterns of individuals and entities on a case-by-case basis.

#### **Corporate Practice of Medicine**

The Company's contractual relationships with the licensed healthcare providers are subject to regulatory oversight, mainly by state licensing authorities. In certain states, for example, limitations may apply to the relationship with the pathologists that the Company intends to employ or engage, particularly in terms of the degree of control that the Company exercises or has the power to exercise over the practice of medicine by those pathologists. A number of states, including New York, Texas, and California, have enacted laws prohibiting business corporations, such as the Company, from practicing medicine and employing or engaging physicians to practice medicine. These requirements are generally imposed by state law in the states in which the Company operates, vary from state to state, and are not always consistent among states. In addition, these requirements are subject to broad powers of interpretation and enforcement by state regulators. Some of these requirements may apply to the Company even if it does not have a physical presence in the state, based solely on the employment of a healthcare provider licensed in the state or the provision of services to a resident of the state. The Company believes that it operates in material compliance with these requirements. However, failure to comply can lead to action against the Company and the licensed healthcare professionals that it employs, fines or penalties, receipt of cease and desist orders from state regulators, loss of healthcare professionals' licenses or permits, the need to make changes to the terms of engagement of those professionals that interfere with the Company's business, and other material adverse consequences.

## State Laboratory Licensure

The Company intends that its laboratory will be certified by CLIA and be licensed in the state of Washington. However, many state licensure laws require a laboratory that solicits or tests specimens from individuals within that state to hold a license from that state, even if the testing occurs in another state. The Company intends to accept testing from California, New York, Pennsylvania, Maryland, New Jersey, and Rhode Island, which require out-of-state laboratories to hold state licenses. The Company intends to apply for licenses in these states. Similarly, many of the states from which it will solicit specimens require that a physician interpreting specimens from that state be licensed by that particular state, irrespective of where the services are to be provided. In the absence of such a state license, the physician may be considered to be engaged in the unlicensed practice of medicine.

The Company may become aware from time to time of other states that require out of state laboratories or physicians to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. The Company intends to follow instructions from the state regulators as how to comply with such requirements.

## Referrals after Becoming a Public Company

Once the Company's stock is publicly traded, it will not be able to accept referrals from physicians who own, directly or indirectly, shares of its stock unless it complies with the Stark Law exception for publicly traded securities. This requires, among other things, \$75 million in stockholders' equity (total assets minus total liabilities). The parallel safe harbor requires, among other things, \$50 million in undepreciated net tangible assets, in order for any distributions to such stockholders to be protected under the Anti-Kickback Statute.

#### **Other Regulatory Requirements**

The Company's laboratory will be subject to federal, state, and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste, and biohazardous waste, including chemical, biological agents and compounds, and human tissue. The Company intends to use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors will be licensed or otherwise qualified to handle and dispose of such waste.

The Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating to workplace safety for healthcare employers, including requirements mandating work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations, and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. Pursuant to its authority under the FDCA, the FDA has regulatory responsibility over instruments, test kits, reagents, and other devices used to perform diagnostic testing by laboratories such as ours. Specifically, the manufacturers and suppliers of analyte specific reagents, or ASRs, which we will obtain for use in diagnostic tests, are subject to regulation by the FDA and are required to register their establishments with the FDA, to conform manufacturing operations to the FDA's Quality System Regulation and to comply with certain reporting and other record keeping requirements. The FDA also regulates the sale or distribution, in interstate commerce, of products classified as medical devices under the FDCA, including *in vitro* diagnostic test kits. Such devices must undergo premarket review by the FDA prior to commercialization unless the device is of a type exempted from such review by statute or pursuant to the FDA's exercise of enforcement discretion.

The FDA maintains that it has authority to regulate the development and use of LDTs or "home brews" as medical devices, but to date has not exercised its authority with respect to "home brew" tests as a matter of enforcement discretion. The FDA regularly considers the application of additional regulatory controls over the sale of ASRs and the development and use of "home brews" by laboratories such as the Company's.

The FDA has conducted public hearings to discuss oversight of LDTs. While the outcome of those hearings is unknown, it is probable that some form of premarket notification or approval process will become a requirement for certain LDTs. Pre-market notification or approval of the Company's future LDTs would be costly and delay the ability of the Company to commercialize such tests.

## **Compliance Program**

Compliance with government rules and regulations is a significant concern throughout the industry, in part due to evolving interpretations of these rules and regulations. The Company will seek to conduct its business in compliance with all statutes and regulations applicable to its operations. To this end, it has determined that it will establish an informal compliance program that reviews for regulatory compliance procedures, policies, and facilities throughout its business. To better focus compliance efforts, the Company intends to hire an experienced compliance officer when appropriate and develop a formal compliance program. The Company will endeavor to make all suitable adjustments or modifications as become known or necessary in order to comply with these complex set of laws and regulations.

## **Legal Proceedings**

The Company is not a party to any material legal proceedings.

## **Employees**

As of December 31, 2010, the Company had three executive officers, one of whom serves in such capacity as a consultant to the Company, and one other employee. The Company expects that it will hire more employees as it expands.

# **Property**

The Company leases approximately 1,300 square feet of office and laboratory space in the Seattle Life Sciences Center in Seattle, Washington, under a sixmonth lease which will convert into a month-to-month lease starting in March 2011. The Company believes that its current facilities will be adequate to meet its needs for the next 12 months. The Company intends to lease additional or alternative office and laboratory space in the Greater Seattle area in the second half of 2011, if needed.

## Insurance

The Company currently maintains commercial general and office premises liability insurance. At the time the Company establishes its laboratory and launches the MASCT System, it expects to obtain liability insurance for its products and services. As a general matter, providers of diagnostic services may be subject to lawsuits alleging medical malpractice or other similar legal claims. Some of these suits involve claims for substantial damages. The Company believes that it will be able to obtain adequate insurance coverage in the future at acceptable costs, but cannot assure that it will be able to do so.

#### MANAGEMENT

The following table sets forth information regarding the members of the board of directors of the Company and its executive officers as of December 31, 2010:

#### **Executive Officers, Directors and Prospective Directors**

Name	Age	Position(s)
Steven C. Quay, M.D., Ph.D.	60	Chairman of the Board of Directors, Chief Executive Officer and President
Christopher Benjamin	36	Chief Financial Officer
Shu-Chih Chen, Ph.D.	49	Director, Chief Scientific Officer
John Barnhart	53	Director
Stephen Galli, M.D.	60	Director Nominee
Alexander Cross, Ph.D.	78	Director Nominee

Stephen Galli, M.D. and Alexander Cross, Ph.D. have agreed to serve on the board of directors of the Company concurrent with the closing of this offering.

The Company's bylaws provide that the number of directors authorized to serve on the board of directors of the Company may be established, from time to time, by action of the board of directors of the Company. Vacancies in the existing board of directors of the Company are filled by a majority vote of the remaining directors on the board of directors of the Company. Directors serve for a one-year term until each subsequent annual meeting of stockholders and until their respective successors have been elected and qualified or until death, resignation or removal. The Company's executive officers are appointed by and serve at the discretion of the board of directors of the Company.

Dr. Quay is the Chief Executive Officer and Chairman of the board of directors of the Company. Dr. Shu-Chih Chen is the Chief Scientific Officer and a director. Drs. Quay and Chen are husband and wife. They currently beneficially own a majority of the outstanding voting securities of the Company. Following the completion of this offering and exercise of the Class A Warrants, they will remain substantial minority stockholders.

Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer and Chairman of the board of directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc. from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008. From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at the Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the MASCT System. He oversaw the clinical testing and regulatory filing of the MASCT device with the FDA that led to its ultimate marketing clearance. Including the patents for the MASCT System, Dr. Quay has a total of 70 U.S. patents, 98 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the FDA. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. Dr. Quay is a member of the American Society of Investigative Pathology, the Association of Molecular Pathology, the Society for Laboratory Automation and Screening and the Association of Pathology Informatics. He was selected to serve on the Company's board of directors because of his role as the founder of the Company and the inventor of the MASCT System, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the MASCT System.

Christopher Benjamin. Mr. Benjamin has served as Chief Financial Officer of the Company since July 2010. His experience includes both public and private company financial reporting expertise. Based in Seattle, Mr. Benjamin has served as President of Rogue CFO Consulting since November 2007, as well as serving as the Chief Financial Officer for NexTec and Redfin Corporations and acting as the Accounting Manager and Assistant Controller for the Bsquare Corporation. His responsibilities at these companies included monthly financial reporting and analysis, audit and cash management, forecasting, oversight of the General Ledger, as well as ensuring compliance with GAAP, FASB and SEC reporting standards. From February 2003 to November 2005, Mr. Benjamin worked at Cascade Natural Gas Corporation, where his responsibilities included serving as Manager of Financial Reporting and Fixed Assets, along with Sarbanes Oxley process documentation, process flow creation and SEC reporting support. He received his M.B.A. from the University of Washington in Seattle in 2007 and a B.A. in accounting from the University of Fraser Valley in Abbotsford, British Columbia, Canada in 1997.

Shu Chih Chen, Ph.D. Dr. Chen has served as Chief Scientific Officer and director of the Company since the Company was incorporated in April 2009. Prior to joining the Company, Dr. Chen served as President of Ensisheim beginning in 2008, was founder and President of SC2Q Consulting Company from 2006 to 2008, and served as Head, Cell Biology, Nastech Pharmaceuticals Company, Inc. from 2002 to 2006. During 1995 and 1996, she was an Associate Professor at National Yang Ming University, Taipei, Taiwan, and served as the principal investigator of an NIH RO1 grant studying tumor suppression by gap junction protein connexin 43 at the Department of Molecular Medicine at Northwest Hospital before working in the research department at Nastech Pharmaceutical Company. She is named as an inventor on four patent applications related to cancer therapeutics. Dr. Chen received her Ph.D. degree in microbiology and public health from Michigan State University in 1992 and has published extensively on Molecular Oncology. She received her B.S. degree in medical technology from National Yang Ming University, Taipei, Taiwan in 1984. Dr. Chen was selected to serve on the Company's board of directors because of her qualifications as a professor and researcher in the field of cancer therapeutics.

John Barnhart. Mr. Barnhart has served as a director of the Company since July 2009. He is the founder and has been the Managing Director of the Visconti Group, a management consulting group in Seattle, Washington, since November 2003. He held prior executive positions at The Walt Disney Company, Sony Pictures Entertainment, and Walt Disney Imagineering. He received a B.S. degree in engineering from California State University, Long Beach in 1974. Mr. Barnhart was selected to serve on the Company's board of directors because of his understanding and experience with development and marketing of consumer products and services.

Stephen Galli, M.D. Dr. Galli will become a member of the Company's board of directors upon the completion of this offering. Dr. Galli is Chair of the Department of Pathology, Professor of Pathology and of Microbiology & Immunology and the Mary Hewitt Loveless, M.D., Professor, Stanford University School of Medicine, Stanford, California, and has served in these capacities since February 1999. Before joining Stanford, he was on the faculty of Harvard Medical School. He holds 13 U.S. patents and has over 340 publications. He is past president of the American Society for Investigative Pathology and current president of the Collegium Internationale Allergologicum. In addition to receiving awards for his research, he was recently recognized with the 2010 Stanford University President's Award for Excellence Through Diversity for his recruitment and support of women and underrepresented minorities at Stanford University. He received his B.A. degree in biology, magna cum laude, from Harvard College in 1968 and his M.D. degree from Harvard Medical School in 1973 and completed a residency in anatomic pathology at the Massachusetts General Hospital in 1977. Dr. Galli has been selected as a director nominee because of his qualifications as a professor and physician, and his specialized expertise as a pathologist.

Alexander D. Cross, Ph.D. Dr. Cross will become a member of the Company's board of directors upon completion of this offering. Dr. Cross has served on the board and as a member of the Audit, Compensation, and Nominating and Governance Committees of a number of public companies, including MDRNA, Inc. and Ligand Pharmaceuticals Inc. Dr. Cross also served as Chairman of the Board and CEO of Cytopharm, Inc. until August 2006. Dr. Cross has been a consultant in the fields of pharmaceuticals and biotechnology since January 1986 and has served as a principal of NDA Partners, LLC since 2003. Previously, Dr. Cross served as President and CEO of Zoecon Corporation, a biotechnology company, from April 1983 to December 1985, and Executive Vice President and Chief Operating Officer from 1979 to 1983. Dr. Cross also previously held several corporate management positions at Syntex Corporation from 1961 through 1979. Dr. Cross holds 109 issued United States patents and is the author of 90 peer-reviewed publications. Dr. Cross received his B.Sc., Ph.D. and D.Sc. degrees from the University of Nottingham, England, and is a Fellow of the Royal Society of Chemistry. Dr. Cross has been selected as a director nominee because of his qualifications as a scientist, business executive and audit committee financial expert, and his prior experience as a director and committee member of public companies.

#### Scientific Advisory Board

The Company has established a Scientific Advisory Board to provide strategic resources to the Company's management and its board of directors. It is intended that the Company's scientific advisory board will have knowledge in breast cancer, NAF, and breast cancer biomarkers. The Company expects to expand the board members in the future. The initial Scientific Advisory Board currently consists of:

**Dr. Edward Sauter, M.D., Ph.D.** Dr. Sauter is the Associate Dean for Research and Professor of Surgery at the University of North Dakota School of Medicine & Health Sciences. He received his M.D. from the Louisiana State School of Medicine and his Ph.D. from the University of Pennsylvania. He completed his general surgery residency at the Ochsner Clinic, in New Orleans, Louisiana. Dr. Sauter also completed a Surgical Oncology Fellowship at Fox Chase Cancer Center in Philadelphia, Pennsylvania. Dr. Sauter was Vice-Chair for Research in the Department of Surgery and Professor at the University of Missouri-Columbia. He also completed his MHA while at the University of Missouri. Dr. Sauter is widely recognized for his research and clinical experience in breast cancer. Among his many accomplishments, Dr. Sauter and a team of researchers pioneered noninvasive and minimally invasive techniques to predict breast cancer risk using NAF. Dr. Sauter is the co-author of over 100 peer-reviewed publications on breast cancer, the majority of which pertain to cytology and molecular diagnostic biomarkers in NAF.

Dr. Sauter and the Company entered into a consulting agreement on February 18, 2010 which provides a \$5,000 signing fee and \$1,000 per month for up to four hours per month of Dr. Sauter's time. The agreement also provides reasonable travel expenses in connection with his work for the Company. The agreement currently extends through December 31, 2011.

## **Director Compensation**

Upon completion of this offering, Mr. Barnhart and Drs. Galli and Cross, as non-employee directors of the Company, will receive the following:

- an initial director compensation fee of \$50,000, paid in shares of the Company's common stock and that vests ratably over one year from the date of grant;
- · an annual director retainer of \$50,000, paid in shares of the Company's common stock and that vests ratably over one year from the date of grant;
- an in-person meeting fee of \$1,500 and a telephone meeting fee of \$1,000.

In addition to the above, annual compensation for service on the Audit Committee will be \$12,000 for the Chair and \$8,000 for each member, paid in fully vested shares of the Company's common stock or options, payable quarterly in arrears; and annual compensation for service on the Compensation Committee and Nominating/Governance Committee will be \$10,000 for the Chair and \$6,000 for each member, paid in fully vested shares of the Company's common stock or options, payable quarterly in arrears.

All committee members will also receive a cash payment of \$2,000 per in-person meeting for the Chair and \$1,500 per in-person meeting for each member and \$1,500 per telephonic meeting for the Chair and \$1,000 per telephonic meeting for each member.

The employee directors will receive no compensation for their board service. All directors will receive reimbursement for reasonable travel expenses.

### **Director Independence**

The board of directors of the Company has reviewed the materiality of any relationship that each of our directors and prospective directors has with the Company, either directly or indirectly. Based on this review, the board of directors of the Company has determined that John Barnhart, a current director, and the following director nominees will be "independent directors" as defined by Section 803(A)(2)(b) of the NYSE Amex LLC Company Guide at the time they become directors (upon the completion of this offering): Stephen Galli, M.D. and Alexander Cross, Ph.D.

## **Committees of the Board of Directors of the Company**

The board of directors of the Company has provided for the establishment of an audit committee, a compensation committee and a nominating/governance committee effective upon the completion of this offering. The composition and function of each of these committees is described below.

#### Audit Committee

Upon completion of this offering, the audit committee will be comprised of Dr. Cross (chair), Mr. Barnhart and Dr. Galli. The board of directors of the Company has determined that Dr. Cross is an audit committee financial expert, as defined by the rules of the SEC. The audit committee will be authorized to:

- · approve and retain the independent registered public accounting firm to conduct the annual audit of the Company's financial statements;
- · review the proposed scope and results of the audit;
- · review and pre-approve audit and non-audit fees and services;
- · review accounting and financial controls with the independent auditors and the Company's financial and accounting staff;
- · review and approve transactions between the Company and its directors, officers and affiliates;
- · recognize and prevent prohibited non-audit services; and
- · establish procedures for complaints received by the Company regarding accounting matters; oversee internal audit functions, if any

The Company believes that the composition of its audit committee will meet the independence requirements of the applicable rules of the SEC and NYSE Amex upon completion of this offering.

## Compensation Committee

Upon the completion of this offering, the compensation committee will be comprised of Mr. Barnhart (chair) and Dr. Cross. All members of the compensation committee will qualify as independent directors under the current definition promulgated by NYSE Amex. The compensation committee will be authorized to:

- · review and recommend the compensation arrangements for management;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- · administer stock incentive and purchase plans; and
- · oversee the evaluation of the board of directors of the Company and management.

## Nominating and Governance Committee

Upon the completion of this offering, the nominating and governance committee will be comprised of Dr. Galli (chair) and Mr. Barnhart. All members of the nominating and governance committee will qualify as independent directors under the current definition promulgated by NYSE Amex. The nominating and governance committee will be authorized to:

- · identify and nominate candidates for election to the board of directors of the Company; and
- · develop and recommend to the board of directors of the Company a set of corporate governance principles applicable to the Company.

### **Compensation Committee Interlocks and Insider Participation**

No prospective member of our compensation committee has at any time been an employee of ours. None of our executive officers serves as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

#### **Code of Business Conduct and Ethics**

The Company intends to adopt a code of business conduct and ethics that applies to all its employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics will be available on the Company's website. The Company expects that any amendments to the code, or any waivers of its requirements, will be disclosed on its website.

## Limitation of Directors' and Officers' Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to specified conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. The Company's certificate of incorporation and amended and restated bylaws limit the liability of its directors to the fullest extent permitted by Delaware law.

The Company has obtained director and officer liability insurance to cover liabilities the Company's directors and officers may incur in connection with their services to the Company. The Company's certificate of incorporation and amended and restated bylaws also provide that it will indemnify and advance expenses to any of its directors and officers who, by reason of the fact that he or she is an officer or director, is involved in a legal proceeding of any nature. The Company will repay certain expenses incurred by a director or officer in connection with any civil, criminal, administrative or investigative action or proceeding, including actions by the Company or in its name. Such indemnifiable expenses include, to the maximum extent permitted by law, attorney's fees, judgments, fines, settlement amounts and other expenses reasonably incurred in connection with legal proceedings. A director or officer will not receive indemnification if he or she is found not to have acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the Company's best interest.

Such limitation of liability and indemnification does not affect the availability of equitable remedies. In addition, the Company has been advised that in the opinion of the SEC, indemnification for liabilities arising under the Securities Act of 1933, as amended, is against public policy as expressed in the Securities Act and is therefore unenforceable.

There is no pending litigation or proceeding involving any of the Company's directors, officers, employees or agents in which indemnification will be required or permitted. The Company is not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

#### **EXECUTIVE COMPENSATION**

#### Remuneration of Officers

The Company did not accrue or pay any remuneration or compensation to any officer, director or employee in 2009. In 2010, the Company has accrued salary payments to Dr. Steven C. Quay and Dr. Shu-Chih Chen commencing as of September 30, 2010 in the amounts and on the terms as defined below. The monthly accruals are approximately \$20,833, and \$16,667, respectively.

Upon the completion of this offering, the Company's compensation committee will be responsible for reviewing and evaluating key executive employee base salaries, setting goals and objectives for executive bonuses and administering benefit plans. The compensation committee will provide advice and recommendations to the board of directors of the Company on such matters. See "Committees of the Board of Directors—Compensation Committee" for further details on the role of the compensation committee.

## Summary Compensation Table — 2010 and 2009

The following table sets forth the compensation earned by the Company's Chief Executive Officer, Chief Scientific Officer and Chief Financial Officer (collectively, the "Named Executive Officers") for fiscal 2010 and 2009:

Name and Position	Year	s	alary(1)	Bonus	A	Option wards(2)	All Other ompensation	Total
Steven C. Quay, M.D., Ph.D.	2010	\$	154,762	\$ 0	\$	169,000	\$ 0	\$ 323,762
President and Chief Executive Officer	2009	\$	0	\$ 0	\$	0	\$ 0	\$ 0
Christopher Benjamin	2010	\$	16,200	\$ 0	\$	0	\$ 0	\$ 16,200
Chief Financial Officer	2009	\$	0	\$ 0	\$	0	\$ 0	\$ 0
Shu Chi Chen, Ph.D.	2010	\$	123,810	\$ 0	\$	67,000	\$ 0	\$ 190,810
Chief Scientific Officer	2009	\$	0	\$ 0	\$	0	\$ 0	\$ 0

- (1) The Company did not accrue or pay any remuneration or compensation to any officer, director or employee in 2009. In 2010, the Company has accrued salary payments to Dr. Steven C. Quay and Dr. Shu-Chih Chen as of December 31, 2010 in the amounts and on the terms as defined below. The monthly accruals are approximately \$20,833, and \$16,667, respectively.
- (2) This column reflects the aggregate grant date fair value of equity awards granted in the applicable year and calculated in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the calculations for these amounts are set forth in the notes to our audited financial statements included elsewhere in this prospectus.

#### **Outstanding Equity Awards at Fiscal Year-End**

The following table shows information regarding our outstanding equity awards at December 31, 2010 for the Named Executive Officers.

	Number of Securities Underlying	Number of Securities Underlying Unexercised	Option Exercise	
	Unexercised Options	Unearned Options	Option Expiration	
Name	Exercisable	Unexercisable	Price (\$)	Date
Steven C. Quay, M.D., Ph.D.	62,500	187,500	\$ 5.00	7/22/2015
Christopher Benjamin	0	0	-	-
Shu Chi Chen, Ph.D.	25,000	75,000	\$ 5.00	7/22/2015

#### **Employment Agreements**

Employment Agreement with Steven Quay, M.D., Ph.D.

The Company has entered into an employment agreement with Dr. Quay to act as the Company's chief executive officer. The agreement provides for an initial base salary of \$250,000 per year and an annual target bonus of up to 40% of Dr. Quay's then-current base salary, payable upon the achievement of performance goals to be established annually by the compensation committee. Following completion of this offering, the compensation committee is expected to meet to determine the performance goals for Dr. Quay. It is anticipated that these goals will be based on achievement of shorter term corporate goals, including MASCT System manufacturing scale-up and launch, filling additional key senior management positions in marketing and sales, finance, and laboratory management, and establishing laboratory registration and certification, and longer term goals, including the development of second generation products such as the Oxy-MASCT System and second generation biomarkers.

Under the employment agreement, Dr. Quay received an option to purchase 250,000 shares of common stock at an exercise price of \$5.00 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. 25% of the shares of common stock underlying the option, or 62,500 shares, vested on December 31, 2010, and the remaining 75%, or 187,500 shares, will vest in equal quarterly installments over the next three years, so long as Dr. Quay remains employed with the Company.

During the employment term, the Company will make available to Dr. Quay employee benefits provided to other key employees and officers of the Company. To the extent these benefits are based on length of service with the Company, Dr. Quay will receive full credit for prior service with the Company. Participation in health, hospitalization, disability, dental and other insurance plans that the Company may have in effect for other executives, all of which shall be paid for by the Company with contribution by Dr. Quay as set for the other executives, as and if appropriate.

Dr. Quay will be entitled to six weeks of paid vacation per year for each full year of employment, pro rated for each partial year. Vacation time not taken during a calendar year will not be accrued to the next calendar year.

Dr. Quay has also agreed that, for the period commencing on the date of his employment agreement with the Company and during the term of his employment and for a period of 12 months following voluntary termination of his employment with the Company that he will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Dr. Quay to refrain from disclosing any proprietary information and to assign to the Company any inventions which directly concern the MASCT System, Oxy-MASCT System, or future products, research, or development, or which result from work they perform for the Company or using its facilities.

#### Consulting Agreement with Christopher Benjamin

The Company has entered into an agreement with Christopher Benjamin to act as the Company's interim chief financial officer. The agreement provides a monthly retainer fee of \$2,250 for up to 25 hours of work per month and \$100 per hour beyond that level. The agreement may be terminated by the Company upon 30 days written notice.

#### Employment Agreement with Shu-Chih Chen

The Company has entered into an employment agreement with Dr. Chen to act as the Company's chief scientific officer. The agreement provides for an initial base salary of \$200,000 per year and an annual target bonus of up to 30% of Dr. Chen's then-current base salary, payable upon the achievement of performance goals to be established annually by the compensation committee. Following completion of this offering, the compensation committee is expected to meet to determine the performance goals for Dr. Chen. It is anticipated that these goals will be based on achievement of shorter term corporate goals, including filling additional key positions in research and development as well as laboratory management, and establishing laboratory registration and certification, and longer term goals, including the management of the development of second generation products such as the Oxy-MASCT System and second generation biomarkers.

Under the employment agreement, Dr. Chen received an option to purchase 100,000 shares of common stock at an exercise price of \$5.00 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. 25% of the shares of common stock underlying the option, or 25,000 shares, vested on December 31, 2010, and the remaining 75%, or 75,000 shares, will vest in equal quarterly installments over the next three years, so long as Dr. Chen remains employed with the Company.

During the employment term, the Company will make available to Dr. Chen employee benefits provided to other key employees and officers of the Company. To the extent these benefits are based on length of service with the Company, Dr. Chen will receive full credit for prior service with the Company. Participation in health, hospitalization, disability, dental and other insurance plans that the Company may have in effect for other executives, all of which shall be paid for by the Company with contribution by Dr. Chen as set for the other executives, as and if appropriate.

Dr. Chen will be entitled to six weeks of paid vacation per year for each full year of employment, pro rated for each partial year. Vacation time not taken during a calendar year will not be accrued to the next calendar year.

Dr. Chen has also agreed that, for the period commencing on the date of her employment agreement with the Company and during the term of her employment and for a period of 12 months following voluntary termination of her employment with the Company that she will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Dr. Chen to refrain from disclosing any proprietary information and to assign to the Company any inventions which directly concern the MASCT System, Oxy-MASCT System, or future products, research, or development, or which result from work she performs for the Company or using its facilities.

## **Severance Benefits and Change in Control Arrangements**

The Company has agreed to provide the severance benefits and change in control arrangements described below to its named executive officers.

## Dr. Steven Quay

Pursuant to his employment agreement, if (i) the Company terminates the employment of Dr. Quay without cause, or (ii) Dr. Quay terminates his employment for good reason, then Dr. Quay will be entitled to receive all accrued but unpaid compensation, plus a severance payment equal to twelve months of base salary. In addition, upon such event, the vesting of all shares of common stock underlying options then held by Dr. Quay will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30 th day after the effective date of termination of Dr. Quay's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Dr. Quay materially violates certain provisions of his employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

In addition, under the terms of his employment agreement, in the event of a "change in control" of the Company (as defined in the employment agreement) during Dr. Quay's employment term, Dr. Quay will be entitled to receive a one-time payment equal to 2.9 times his base salary, and the vesting of all outstanding equity awards then held by Dr. Quay will accelerate such that they are fully vested as of the date of the change in control.

#### Dr. Shu-Chih Chen

Pursuant to her employment agreement, if (i) the Company terminates the employment of Dr. Chen without cause, or (ii) Dr. Chen terminates her employment for good reason, then Dr. Chen will be entitled to receive all accrued but unpaid compensation, plus a severance payment equal to twelve months of base salary. In addition, upon such event, the vesting of all shares of common stock underlying options then held by Dr. Chen will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30 th day after the effective date of termination of Dr. Chen's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Dr. Chen materially violates certain provisions of her employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

In addition, under the terms of her employment agreement, in the event of a "change in control" of the Company (as defined in the employment agreement) during Dr. Chen's employment term, Dr. Chen will be entitled to receive a one-time payment equal to 2.9 times her base salary, and the vesting of all outstanding equity awards then held by Dr. Chen will accelerate such that they are fully vested as of the date of the change in control.

## 2010 Stock Option and Incentive Plan

The Company's 2010 Stock Option and Incentive Plan, or the 2010 Plan, provides for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval.

Plan Administration. The 2010 Plan may be administered by the full board or the compensation committee. It is the current intention of the Company that the 2010 Plan be administered by the compensation committee. The compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2010 Plan. The compensation committee may delegate to our chief executive officer the authority to grant stock options to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

*Eligibility*. Persons eligible to participate in the 2010 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants and prospective officers) of the Company and its subsidiaries as selected from time to time by the compensation committee in its discretion.

Plan Limits. Initially, the total number of shares of common stock available for issuance under the 2010 Plan is 1,000,000 shares. On January 1, 2012 and each January 1 thereafter, the number of shares of common stock reserved and available for issuance under the 2010 Plan will be cumulatively increased by 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31. Subject to these overall limitations, the maximum aggregate number of shares of Stock that may be issued in the form of incentive stock options or stock appreciation rights to any one individual will not exceed 50% of the initial 2010 Plan limit of 1,000,000, cumulatively increased on January 1, 2012 and each January 1 thereafter by the lesser of (i) the 4% annual increase applicable to the 2010 Plan for such year or (ii) 500,000 shares.

Stock Options. The 2010 Plan permits the granting of (i) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (ii) options that do not so qualify. Options granted under the 2010 Plan will be non-qualified options if they fail to qualify as incentive options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and its subsidiaries. Non-qualified options may be granted to any persons eligible to receive incentive options and to non-employee directors and key persons. The option exercise price of each option will be determined by the compensation committee but may not be less than 100% of the fair market value of the common stock on the date of grant. Fair market value for this purpose will be the last reported sale price of the shares of common stock on the NYSE Amex on the date of grant; provided, that if the date of grant is the first day on which trading prices for our common stock are reported on the NYSE Amex, the fair market value will be the price to the public of shares of our common stock in this offering. The exercise price of an option may not be reduced after the date of the option grant, other than to appropriately reflect changes in our capital structure.

The term of each option will be fixed by the compensation committee and may not exceed 10 years from the date of grant. The compensation committee will determine at what time or times each option may be exercised. Options may be made exercisable in installments and the exercisability of options may be accelerated by the compensation committee. In general, unless otherwise permitted by the compensation committee, no option granted under the 2010 Plan is transferable by the optionee other than by will or by the laws of descent and distribution, and options may be exercised during the optionee's lifetime only by the optionee, or by the optionee's legal representative or guardian in the case of the optionee's incapacity.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the compensation committee or by delivery (or attestation to the ownership) of shares of common stock that are beneficially owned by the optionee for at least six months or were purchased in the open market. Subject to applicable law, the exercise price may also be delivered to the Company by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the compensation committee may permit non-qualified options to be exercised using a net exercise feature which reduces the number of shares issued to the optionee by the number of shares with a fair market value equal to the exercise price.

To qualify as incentive options, options must meet additional federal tax requirements, including a \$100,000 limit on the value of shares subject to incentive options that first become exercisable by a participant in any one calendar year.

Stock Appreciation Rights. The compensation committee may award stock appreciation rights subject to such conditions and restrictions as the compensation committee may determine. Stock appreciation rights entitle the recipient to shares of common stock equal to the value of the appreciation in the stock price over the exercise price. The exercise price is the fair market value of the common stock on the date of grant. The term of a stock appreciation right will be fixed by the compensation committee and may not exceed 10 years.

*Restricted Stock.* The compensation committee may award shares of common stock to participants subject to such conditions and restrictions as the compensation committee may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified restricted period.

Restricted Stock Units. The compensation committee may award restricted stock units to any participants. Restricted stock units are generally payable in the form of shares of common stock, although restricted stock units granted to the chief executive officer may be settled in cash. These units may be subject to such conditions and restrictions as the compensation committee may determine. These conditions and restrictions may include the achievement of certain performance goals (as summarized above) and/or continued employment with the Company through a specified vesting period. In the compensation committee's sole discretion, it may permit a participant to make an advance election to receive a portion of his or her future cash compensation otherwise due in the form of a restricted stock unit award, subject to the participant's compliance with the procedures established by the compensation committee and requirements of Section 409A of the Code. During the deferral period, the deferred stock awards may be credited with dividend equivalent rights.

Adjustments for Stock Dividends, Stock Splits, Etc. The 2010 Plan requires the compensation committee to make appropriate adjustments to the number of shares of common stock that are subject to the 2010 Plan, to certain limits in the 2010 Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

*Tax Withholding.* Participants in the 2010 Plan are responsible for the payment of any federal, state or local taxes that the Company is required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. Subject to approval by the compensation committee, participants may elect to have the minimum tax withholding obligations satisfied by authorizing the Company to withhold shares of common stock to be issued pursuant to the exercise or vesting.

Amendments and Termination. The board of directors of the Company may at any time amend or discontinue the 2010 Plan and the compensation committee may at any time amend or cancel any outstanding award for the purpose of satisfying changes in the law or for any other lawful purpose. However, no such action may adversely affect any rights under any outstanding award without the holder's consent. To the extent required under the NYSE Amex rules, any amendments that materially change the terms of the 2010 Plan will be subject to approval by our stockholders. Without approval by our stockholders, the compensation committee may not reduce the exercise price of options or stock appreciation rights or effect repricing through cancellation or re-grants, including any cancellation in exchange for cash. Amendments shall also be subject to approval by our stockholders if and to the extent determined by the compensation committee to be required by the Code to preserve the qualified status of incentive options or to ensure that compensation earned under the 2010 Plan qualifies as performance-based compensation under Section 162(m) of the Code.

## **Other Benefits**

The Company offers health, dental, disability, and life insurance to its full-time employees.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Dr. Quay is the president, chief executive officer and chairman of the board of directors of the Company. Dr. Chen is the chief scientific officer and a director of the Company. Drs. Quay and Chen are husband and wife. Prior to the completion of this offering, Drs. Quay and Chen were the Company's majority stockholders. After the completion of this offering and exercise of the Class A Warrants, Drs. Quay and Chen will no longer be majority stockholders but will remain substantial minority stockholders. Ensisheim Partners, LLC, which holds 66.3% of the outstanding common stock of the Company prior to this offering, is wholly owned by Drs. Quay and Chen, and they are the beneficial owners of the Shares of the Company's stock owned by that entity.

Ensisheim was the original owner of the patents covering the MASCT System, which were acquired by the Company in June 2010. Ensisheim has no further interest or right to the U.S. patents and foreign counterparts that cover the manufacture, use, and selling of the MASCT System, the pending patent applications for improvements, or the FDA marketing authorization for the MASCT System that was transferred to the Company. Ensisheim did not receive any monetary compensation in connection with the transfer and assignment to the Company of the patents, patent applications and FDA marketing authorization but received shares of common stock of the Company in consideration for its contribution of these assets. Ensisheim holds patents and patent applications for inventions created by the owners in fields unrelated to the Company's business and provides a corporate structure for consulting activities of the owners in fields unrelated to the Company's business. Drs. Quay and Chen currently devote substantially all of their professional efforts to the business of the Company.

On December 24, 2009, the Company entered into a commercial lease agreement with Ensisheim for office space located in Seattle, Washington, at an annual rent of \$13,200 plus applicable sales tax. The original term of the lease was to expire on December 31, 2010. From April 30, 2009 (inception) through September 30, 2010, the Company incurred \$6,848 of rent expense for the lease. As of September 30, 2010, security deposit for the lease amounted to \$1,100. On July 15, 2010, the Company and Ensisheim terminated the lease, effective July 1, 2010.

The Company has borrowed an aggregate of \$105,000 from Dr. Quay pursuant to promissory notes that are due and payable in full on or before December 31, 2010. The notes bear an annual interest rate of 10% accruing from June 30, 2010 and carry a pass-through loan origination fee of \$4,000. To date, Dr. Quay has not demanded repayment of these notes.

On November 3, 2010, the Company issued a promissory note to Dr. Quay in connection with a \$500,000 line of credit extended to the Company by Dr. Quay. Pursuant to the terms of the note, all principal amounts borrowed under the line of credit bear interest at a rate of 10% per annum, and all principal and accrued interest will be due and payable in full on December 31, 2011. As of the date of this prospectus, the Company has borrowed \$80,000 under the line of credit.

In July 2010, in connection with the departure of Robert L. Kelly, a former officer, the Company entered into a consulting agreement with a limited liability company controlled by Mr. Kelly. Under the agreement, the Company was to receive consulting services relating to capital raising and investor relations. The agreement was terminated by the Company in September 2010, through which time a total of \$30,000 had been paid.

# **Indemnification Agreements**

Prior to the completion of this offering, the Company intends to enter into indemnification agreements with each of its directors and certain of its executive officers. These agreements will require the Company to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Company, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

# **Related Party Transaction Policies**

Related party transactions to be entered into after the completion of this offering and that the Company is required to disclose publicly under the federal securities laws will require prior approval of the Company's independent directors without the participation of any director who may have a direct or indirect interest in the transaction in question. Related parties include directors, nominees for director, principal stockholders, executive officers and members of their immediate families. For these purposes, a "transaction" will include all financial transactions, arrangements or relationships, ranging from extending credit to the provision of goods and services for value and will include any transaction with a company in which a director, executive officer immediate family member of a director or executive officer, or principal stockholder (that is, any person who beneficially owns five percent or more of any class of the Company's voting securities) has an interest by virtue of a 10% or greater equity interest. The Company's policies and procedures regarding related party transactions are not expected to be a part of a formal written policy, but rather, will represent a course of practice determined to be appropriate by the board of directors of the Company.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information as of December 31, 2010 regarding the beneficial ownership of the Company's common stock by each of its executive officers and directors, individually and as a group and by each person who beneficially owns in excess of five percent of the common stock after giving effect to any exercise of warrants or options held by that person within 60 days after December 1, 2010. Unless indicated otherwise, the address for the beneficial holders is c/o Atossa Genetics Inc., Seattle Life Sciences Center, 1124 Columbia Street, Suite 621, Seattle, WA 98104.

	Shares	Percentage of Common Stock Beneficially Owned				
	Beneficially	Before	After			
Name of Beneficial Owner	Owned	Offering (1)	After Offering (2)	Offering (3)		
Directors and Officers						
Steven C. Quay, M.D., Ph.D. (4)	4,355,754	71.8%	48.1%	28.9%		
Shu-Chih Chen, Ph.D. (5)	4,001,461	66.4%	44.3%	26.6%		
John Barnhart	48,602	*	*	*		
Christopher Benjamin	0	_	_	_		
All Current Officers and Directors as a Group (4 persons)	4,429,356	72.8%	48.7%	29.4%		
Director Nominees						
Stephen Galli, M.D.	17,674	*	*	*		
Alexander D. Cross, Ph.D. (6)	88,366	1.5%	1.0%	*		

- Less than 1%
- (1) Based on 6,000,067 shares of common stock issued and outstanding as of December 1, 2010.
- (2) Assumes the sale of 3,000,000 shares of common stock, representing all of the shares underlying the Units and no exercise of the Class A Warrants underlying the Units.
- (3) Assumes the sale of 9,000,000 shares of common stock, representing 3,000,000 shares underlying the Units and an additional 6,000,000 shares issuable upon exercise of the Class A Warrants.
- (4) Consists of (i) 316,793 shares of common stock directly owned by Dr. Quay, (ii) 3,976,461 shares of common stock owned by Ensisheim and (iii) 62,500 shares of common stock issuable upon the exercise of stock options held by Dr. Quay and exercisable within 60 days after December 31, 2010. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.
- (5) Consists of (i) 3,976,461 shares of common stock owned by Ensisheim and (ii) 25,000 shares of common stock issuable upon the exercise of stock options held by Dr. Chen and exercisable within 60 days after December 31, 2010. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.
- (6) Represents 88,366 shares of common stock held by the Alexander D. Cross Family Trust. Mr. Alexander D. Cross has sole voting and investment power over the securities held by the trust and as such, is deemed to be the beneficial owner of the shares held by this entity.

## DESCRIPTION OF SECURITIES

# Capitalization

The Company is authorized to issue 75,000,000 shares of common stock, par value \$0.001 per share, of which 6,000,067 shares were outstanding as of the date of this prospectus, and 10,000,000 shares of undesignated preferred stock, par value \$0.001 per share, none of which have been designated or issued.

As of December 31, 2010, there were 56 record holders of the Company's common stock.

## Units

*Unit Composition.* The Company is offering for sale 3,000,000 Units, with each Unit consisting of (i) one share of common stock, (ii) one Class A Warrant, (iii) one Class B Warrant and (iv) one Class C Warrant. A description of the common stock, Class A Warrants and Class B Warrants is set forth below. The securities underlying the Units will automatically separate from the Units on the 90th day after the date of this prospectus, unless Dawson James Securities, Inc., the representative of the underwriters, determines that an earlier separation date is acceptable based on its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, the Company's securities in particular. The Company will issue a press release announcing when such separation will occur. Separation of the Units will occur no later than the announcement of the achievement of the first of the two milestones that make the Class A and Class B Warrants exercisable, as described more fully below.

*Rights as Stockholder.* Unit holders do not have any voting or other rights as a stockholder of the Company. Upon the separation of the Units, a Unit holder will be deemed to have become the holder of record of the underlying common stock as of the date of separation. If the date of separation is a date upon which the stock transfer books of the Company are closed, the Unit holder will be deemed to have become the record holder of the underlying common stock the next day on which the stock transfer books of the Company are open.

Listing of Units. The Units are expected to be listed for trading on the NYSE Amex under the symbol "ATOSU." Upon the separation of the Units, we intend to request that AMEX delist the Units as an AMEX-listed security, thereby providing that the Units will no longer trade on an exchange. We also expect to notify the Depositary Trust Corporation and our transfer agent the Units have been separated and are therefore no longer outstanding. With these actions, we expect that there will be no further trading in the Units after the separation date. The Company will announce the separation of the Units by way of a press release, to be issued no later than the day of separation. Additionally, the Company will announce the separation on a Current Report filed on Form 8-K with the U.S. Securities and Exchange Commission. See information under the caption "Additional Information." Investors will not receive individual notices of separation.

## **Common Stock**

*Voting Rights.* Holders of shares of common stock are entitled to one vote for each share on all matters to be voted on by the stockholders. Holders of common stock do not have cumulative voting rights.

*Dividend and Distribution Rights.* Dividends, if any, may be declared from time to time by the board of directors of the Company or any authorized committee of the board of directors in its discretion from funds legally available therefore. In the event of a liquidation, dissolution or winding up, the holders of common stock are entitled to share pro rata all assets remaining after payment in full of all liabilities and all amounts due to holders of preferred stock that may have a liquidation preference that is senior to the common stock.

No Preemptive Rights. Holders of common stock have no preemptive rights to purchase additional shares of the Company's common stock.

Other Rights. There are no conversion or redemption rights or sinking fund provisions with respect to the common stock.

*Listing of Common Stock.* The common stock is expected to be listed for trading on the NYSE Amex under the symbol "ATOS." Trading of the common stock will not commence until the Units are separated.

## **Class A Warrants and Class B Warrants**

Below is a summary of the material terms of the Class A Warrants and Class B Warrants, including relevant provisions of the Warrant Agent Agreement between the Company and VStock Transfer, LLC, the Warrant Agent for the Class A Warrants, Class B Warrants and Class C Warrants, or VStock Transfer. This summary is qualified with reference to the Warrant Agent Agreement and the Class A Warrant Certificate and Class B Warrant Certificate, copies of which have been filed as exhibits to the Company's registration statement, of which this prospectus is a part. Investors are urged to review the Warrant Agent Agreement and the form of Class A Warrant Certificate and Class B Warrant Certificate for additional information regarding the Class A Warrants and Class B Warrants, respectively.

*Purchase Rights.* Each Class A Warrant and Class B Warrant will entitle the holder to acquire one share of common stock during the exercise period and subject to the conditions set forth below.

Warrant Agent; Book Entry and Certificated Warrants. VStock Transfer will serve as the warrant agent for the Class A Warrants and Class B Warrants. VStock Transfer also serves as the transfer agent and registrar for the Units, common stock and Class C Warrants. Certificates representing Class A Warrants and Class B Warrants are expected to be issued in "book entry" form, deposited with the Depository Trust Company and registered in the name of Cede & Co., a nominee of Depository Trust Company. If warrant certificates cannot be issued in book entry form, or if a warrant holder requests in writing that a warrant certificate be issued in physical form, then the warrant agent will issue a Class A Warrant Certificate or Class B Warrant Certificate, as applicable.

Listing of Class A Warrants and Class B Warrants. The Class A Warrants and Class B Warrants will not be listed for trading on any securities exchange.

Class A Warrants Exercise Period. The Class A Warrants will be exercisable at the option of the holder for a period of ten trading days, beginning the sixth trading day after our announcement the registration of the Company's laboratory facilities with the Washington-state Medical Test Site (MTS) licensure program and the receipt of our MTS license and Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate (the "Laboratory Registration"). The Company intends to issue a press release announcing the Laboratory Registration and the commencement of the 10-day exercise period. If any Class A Warrants are not exercised prior to the expiration of this 10-day period, or if the Company does not issue an announcement of the Laboratory Registration on or before the second anniversary of the date of this prospectus, then those warrants will expire and will thereafter only represent the right to receive the consideration described below under the caption "Put Right."

Class B Warrants Exercise Period. The Class B Warrants will be exercisable at the option of the holder for a period of ten trading days, beginning the sixth trading day after our announcement of the Company's commercial launch of the MASCT System. The Company intends to issue a press release announcing the commercial launch of the MASCT System and the commencement of the 10-day exercise period. If any Class B Warrants are not exercised prior to the expiration of this 10-day period, or if the Company does not issue an announcement of the commercial launch of the MASCT System on or before the second anniversary of the date of this prospectus, then those warrants will expire and will thereafter only represent the right to receive the consideration described below under the caption "Put Right."

*Exercise Price*. Each Class A Warrant and Class B Warrant will have an exercise price of \$0.05 per share of common stock, which may only be paid on a cashless "net exercise" basis. When exercising a Class A Warrant and Class B Warrant on a net exercise basis, the holder will be entitled to receive a number of shares of common stock for each Class A Warrant and Class B Warrant, rounded up to the nearest whole number, calculated using the following formula:

$$X = (\underline{A - \$0.05})$$

Where:

- X = the number of shares of common stock to be issued to the holder per warrant
- A = the five trading-day average closing price of the Company's common stock immediately following separation of the Units

Because the number of shares of common stock to be issued upon exercise of the Class A Warrant and Class B Warrant will be rounded up to the nearest whole share, each Class A Warrant or Class B Warrant, as applicable, will represent the right to acquire one share of common stock irrespective of the common stock value, unless the five-day average price of the common stock is equal to or less than \$0.05 per share, in which case the Class A Warrant or Class B Warrant, as applicable, would have no value other than the right to receive the consideration described below under the caption "Put Right.". The exercise price and the number of shares of common stock purchasable upon the exercise of each warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, stock splits and recapitalizations, although the Company does not expect any such events to occur prior to the expiration of the Class A Warrants or Class B Warrants, as applicable.

Rights as Stockholder. Warrant holders do not have any voting or other rights as a stockholder of the Company. Upon the exercise of the Class A Warrants and Class B Warrants, a holder will be deemed to have become the holder of record of the underlying common stock as of the date upon which the applicable warrant certificate (if issued) was surrendered and the exercise notice was submitted. If the date of such surrender (if applicable) and submission is a date upon which the stock transfer books of the Company are closed, the holder will be deemed to have become the record holder of the common stock the next day on which the stock transfer books of the Company are open.

Limits on Exercise. The Class A Warrants and Class B Warrants provide that no exercise will be effected, and the holder of a warrant will not have the right to exercise a warrant, if after giving effect to the exercise the holder, together with any affiliates, would beneficially own in excess of 9.99% of the number of shares of common stock of the Company outstanding immediately after giving effect to the issuance of shares upon exercise. The holder may not waive the 9.99% limit. To the extent that a warrant holder cannot exercise a Class A Warrant or Class B Warrant due to this limitation, the unexercised portion of the warrant will expire at the end of the 10-day exercise period.

Amendment. With the consent of holders of Class A Warrants or Class B Warrants representing a majority of the shares issuable upon exercise of all outstanding Class A Warrants or Class B Warrants, respectively, the Company and VStock Transfer, as the Warrant Agent, may modify the Warrant Agent Agreement or modify the rights of the holders of the Class A Warrants or Class B Warrants, as applicable; provided, however, that no modifications made be made to the terms upon which the Class A Warrants or Class B Warrants are exercisable without the consent of the holder of each outstanding warrant that would be affected by the proposed amendment.

Fundamental Transaction .. The Class A Warrants and Class B Warrants may be exercisable for securities, property or rights other than Company common stock if any of the following transactions (each referred to below in this subsection as a Fundamental Transaction) occur while such warrants are issued and outstanding:

- · the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person;
- the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions;
- any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which
  holders of Company common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and such offer has
  been accepted by the holders of 50% or more of the outstanding Company common stock;
- the Company, directly or indirectly, in one or more related transactions, effects any reclassification, reorganization or recapitalization of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for securities other than the Company's securities, cash or property; or
- the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination).

Following the occurrence of a Fundamental Transaction, upon any exercise of a Class A Warrant or Class B Warrant, the holder will have the right to receive, for each share of common stock that would have been issuable prior to the occurrence of the Fundamental Transaction, securities of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (e.g., cash) payable in connection with the Fundamental Transaction on each share of common stock that was outstanding immediately prior to the Fundamental Transaction. For example, if the Company is acquired in a merger where each share of Company common stock will receive upon closing one share of the acquiring company, plus \$1.00 per share, then the holders of Class A Warrants or Class B Warrants would be entitled upon exercise to receive the same combination of cash and stock. If holders of common stock are given any choice as to the type of consideration they will receive in a Fundamental Transaction, then the warrant holders will, upon exercise of the warrants, be given the same choice.

Redemption Rights . The Company will have no rights to call the Class A Warrants or Class B Warrants for redemption.

*Put Right.* Holders of Class A Warrants or Class B Warrants that have expired unexercised shall be entitled, for a period of 90 days from the date of warrant expiration, to tender the expired warrants to the Warrant Agent for redemption at a price of \$0.25 per warrant. Warrants that are not tendered to the Warrant Agent within this 90-day period will no longer be eligible for redemption under this put right.

Ranking. The Class A Warrants and Class B Warrants are equal in seniority to the Class C warrants.

## **Class C Warrants**

Below is a summary of the material terms of the Class C Warrants, including relevant provisions of the Warrant Agent Agreement. This summary is qualified with reference to the Warrant Agent Agreement and the Class C Warrant Certificate, copies of which have been filed as exhibits to the Company's registration statement, of which this prospectus is a part. Investors are urged to review the Warrant Agent Agreement and the form of Class C Warrant Certificate for additional information regarding the Class C Warrants.

*Purchase Rights.* Each Class C Warrant will entitle the holder to acquire one share of common stock during the exercise period and subject to the conditions set forth below.

Warrant Agent; Book Entry and Certificated Warrants. VStock Transfer will serve as the warrant agent for the Class C Warrants. VStock Transfer also serves as the transfer agent and registrar for the Units, common stock, Class A Warrants and Class C Warrants. Certificates representing Class C Warrants are expected to be issued in "book entry" form, deposited with the Depository Trust Company and registered in the name of Cede & Co., a nominee of Depository Trust Company. If warrant certificates cannot be issued in book entry form, or if a warrant holder requests in writing that a warrant certificate be issued in physical form, then the warrant agent will issue a Class C Warrant Certificate.

Listing of Class C Warrants .. The Class C Warrants are expected to be listed for trading on the NYSE Amex under the symbol "ATOSW." Trading will not commence until the Class C Warrants are separated from the Units.

*Exercise Period* . Subject to the redemption right described below, the Class C Warrants will be exercisable at the option of the holder commencing on the first anniversary of the date of this prospectus and continuing until the fifth anniversary of the date of separation of the Units. The Company intends to issue a press release announcing the separation of the securities and the commencement of the exercise period. If any Class C Warrants are not exercised prior to the expiration of this five-year exercise period, those warrants will expire.

*Exercise Price*. Each Class C Warrant will have an exercise price equal to 55% of the Unit offering price. With an assumed Unit offering price of \$6.00 per Unit, which is the midpoint of the estimated price range on the cover of this prospectus, the Class C Warrant exercise price would initially be \$3.30 per share. The Class C Warrants may be exercised only for full shares of common stock.

The Class C Warrants must be exercised for cash, unless the Company does not then have an effective registration statement under the Securities Act of 1933 covering the issuance of the shares underlying the Class C Warrants, in which case they may only be exercised on a cashless, net exercise basis. When exercising a Class C Warrant on a net exercise basis, the holder will be entitled to receive a number of shares of common stock upon exercise calculated using the following formula:

$$X = \underbrace{Y (A - B)}_{A}$$

Where:

X = the number of shares of common stock to be issued to the holder under Class C Warrants being exercised

Y = the number of Class C Warrants being exercised

A = the ten trading-day average closing price of the Company's common stock prior to exercise

B = the exercise price of the Class C Warrants (initially \$3.30, based on an assumed offering price of \$6.00 per Unit), subject to any applicable adjustments

The exercise price and the number of shares of common stock purchasable upon the exercise of each warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, stock splits and recapitalizations. No fractional shares (or cash payments in respect of fractional share interests) will be issued upon any exercise of the Class C Warrants. If the cashless exercise of a Class C Warrant would result in the issuance of a fractional share under the above formula, the number of shares of common stock issued upon such exercise of the Class C Warrant will be rounded up to the nearest whole share.

Rights as Stockholder. Warrant holders do not have any voting or other rights as a stockholder of the Company. Upon the exercise of the Class C Warrants, a holder will be deemed to have become the holder of record of the underlying common stock as of the date upon which the Class C Warrant Certificate (if issued) was surrendered and the exercise notice was submitted. If the date of such surrender (if applicable) and submission is a date upon which the stock transfer books of the Company are closed, the holder will be deemed to have become the record holder of the common stock the next day on which the stock transfer books of the Company are open.

Limits on Exercise. The Class C Warrants provide that no exercise will be effected, and the holder of a warrant will not have the right to exercise a warrant, if after giving effect to the exercise the holder, together with any affiliates, would beneficially own in excess of 4.99% of the number of shares of common stock of the Company outstanding immediately after giving effect to the issuance of shares upon exercise. The holder may, upon 61 days prior written notice, waive this 4.99% limit and thereby elect to increase the exercise limit to 9.99% of the total shares outstanding. The holder may not waive the 9.99% limit. To the extent that a warrant holder cannot exercise a Class C Warrant due to this limitation, the unexercised portion of the Class C Warrant will expire at the end of the exercise period.

Amendment. With the consent of holders of Class C Warrants representing a majority of the shares issuable upon exercise of all outstanding Class C Warrants, the Company and VStock Transfer, as the Warrant Agent, may modify the Warrant Agent Agreement or modify the rights of the holders of the Class C Warrants; provided, however, that no modifications made be made to the terms upon which the Class C Warrants are exercisable without the consent of the holder of each outstanding Class C Warrant that would be affected by the proposed amendment.

Fundamental Transaction .. The Class C Warrants may be exercisable for securities, property or rights other than Company common stock if any of the following transactions (each referred to below in this subsection as a Fundamental Transaction) occur while Class C Warrants are issued and outstanding:

- the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person:
- the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions
- · any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of Company common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and such offer has been accepted by the holders of 50% or more of the outstanding Company common stock;
- the Company, directly or indirectly, in one or more related transactions, effects any reclassification, reorganization or recapitalization of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for securities other than the Company's securities, cash or property; or

• the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination).

Following the occurrence of a Fundamental Transaction, upon any exercise of a Class C Warrant, the holder will have the right to receive, for each share of common stock that would have been issuable prior to the occurrence of the Fundamental Transaction, securities of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (e.g., cash) payable in connection with the Fundamental Transaction on each share of common stock that was outstanding immediately prior to the Fundamental Transaction. For example, if the Company is acquired in a merger where each share of Company common stock will receive one share of the acquiring company's common stock, plus \$1.00 per share, then the holders of Class C Warrants would be entitled upon exercise to receive the same combination of stock and cash. If holders of Company common stock are given any choice as to the type of consideration they will receive in a Fundamental Transaction, then the warrant holders will, upon exercise of the warrants, be given the same choice.

Redemption Rights . The Company will have the right to redeem the Class C Warrants at \$0.25 per share of common stock underlying the Class C Warrants in the event (i) the average of the closing price of the common stock exceeds 200% of the exercise price for 10 consecutive trading days while the warrants are exercisable and (ii) there is then an effective registration statement with a current prospectus on file with the SEC covering the exercise of the Class C Warrants for cash. In the event that the Company wishes to call the Class C Warrants for redemption, it will provide warrant holders with 30 days prior notice of the redemption, during which time the holders of Class C Warrants may continue to exercise the warrant. At the end of the 30-day period, and assuming the Company has complied with applicable redemption requirements, the warrant holders will thereafter be entitled only to receive the redemption value, subject to the surrender of warrant certificates, if applicable.

Put Right. The Class C Warrants will have no put rights by the holder.

Ranking. The Class C Warrants are equal in seniority to the Class A Warrants and Class B Warrants.

## **Preferred Stock**

The board of directors of the Company is authorized to provide for the issuance of any or all of the shares of preferred stock in series and, by filing a certificate pursuant to the applicable law of the State of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof.

The authority of the board of directors of the Company with respect to each series of preferred stock includes determination of the following characteristics:

- · The number of shares constituting that series and the distinctive designation of that series;
- · The dividend rate on the shares of that series, whether dividends shall be cumulative, and, if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of that series;
- · Whether that series shall have voting rights, in addition to the voting rights provided by law, and, if so, the terms of such voting rights;
- · Whether that series shall have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors of the Company shall determine;
- · Whether or not the shares of that series shall be redeemable, and, if so, the terms and conditions of such redemption, including the date or dates upon or after which they shall be redeemable, and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates;

- · Whether that series shall have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund:
- · The rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the Company, and the relative rights of priority, if any, of payment of shares of that series; and
- · Any other relative rights, preferences and limitations of that series.

## **Anti-Takeover Devices**

Upon completion of this offering, the Company's certificate of incorporation and bylaws will include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

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

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

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

# **No Trading Market**

There is currently no established public trading market for the Company's securities. A trading market in the securities may never develop. The Company intends to apply for listing of the Units, its common stock and the Class B Warrants on the NYSE Amex under the trading symbols "ATOSU," "ATOS" and "ATOSW," respectively. If for any reason the Units, the Company's common stock or the Class B Warrants are not so listed or a public trading market does not develop, purchasers of the Units may have difficulty selling their securities. The Class A Warrants will not be listed for trading on any exchange.

# **NYSE Amex Listing Requirements**

The NYSE Amex has established quantitative standards for initial listing of companies as well as continuation of listing standards. The NYSE Amex has four differing listing standards applicable for initial listing. The initial listing standard that most effectively applies to the Company consists of a market value of the public float of \$15 million, a minimum per share price of \$2.00, stockholders equity of at least \$4 million, and at least 400 public stockholders with at least 1.0 million shares. In addition, the NYSE Amex has qualitative standards concerning corporate governance, director independence, and conflicts of interest that must be met. The Company believes that following this offering it will meet the requirements for initial listing.

## **Dividends**

The Company does not anticipate declaring dividends but anticipates that it will use any funds for further development and growth of the Company.

# **Transfer Agent**

VStock Transfer, LLC, 150 West 46<sup>th</sup> Street, New York, New York (Telephone: (212) 828-8136; Facsimile (646) 536-3179) will serve as transfer agent for the Units, Class A Warrants, Class B Warrants, Class C Warrants and common stock of the Company.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options and warrants or in the public market after this offering, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of equity securities in the future.

Upon the completion of this offering, we will have outstanding an aggregate of 9,000,067 shares of common stock, assuming no exercise of the warrants issued in this offering, no exercise by the underwriters of their over-allotment option and no exercise of options or warrants outstanding as of September 30, 2010. None of our shares of common stock outstanding as of the date of this prospectus are being registered for sale under this prospectus.

## **Rule 144**

Of the shares to be outstanding immediately after the closing of this offering, we expect that approximately 6,000,000 shares will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares of our common stock outstanding after this offering will be "restricted securities" under Rule 144 of the Securities Act. "Restricted securities" as defined under Rule 144 were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. These shares may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act. All of our restricted securities outstanding as of the date of this prospectus that would otherwise be eligible for sale under Rule 144 after the completion of this offering will be subject to a 12-month lock-up period under the lock-up agreements described below. In addition, resale of certain of the restricted shares that will become available for sale in the public market after the expiration of the lock-up period will be limited by volume and other resale restrictions under Rule 144 because those shares are held by our affiliates. As of the date of this prospectus, approximately 4,340,000 shares of our outstanding common stock are owned directly and beneficially by affiliates.

## **Lock-Up Agreements**

As of the effective date of this prospectus, the holders of all the Company's outstanding shares of common stock have entered into lock-up agreements with the underwriters restricting the sale of such shares, including all the shares owned directly and beneficially by affiliates of the Company.

The lock-up agreements restrict the sale of such shares from the effective date of the registration statement of which this prospectus is a part for a period of 12 months, after which time the provisions of the lock-up agreement expire. However, such shares cannot be sold publicly even after the expiration of the lock-up period unless registered under the Securities Act or sold pursuant to provisions of Rule 144.

The lock-up agreements are more fully described under the caption "Underwriting" in this prospectus.

## U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following discussion sets forth the material U.S. federal income tax considerations in connection with the purchase of the Units and of the ownership and disposition of the common stock, Class A Warrants, Class B Warrants and Class C Warrants underlying the Units and the exercise or expiration of the warrants, in each case to U.S. Holders and Non-U.S. Holders (each as defined below); provided, that this discussion applies only to holders that hold common stock and warrants as capital assets; provided, further, that this discussion does not include tax considerations that arise from rules of general application to all taxpayers and that would be applicable independently from the purchase, ownership or disposition of the Units, the common stock, the Class A Warrants, the Class B Warrants or the Class C Warrants, and does not address all aspects of U.S. federal income taxation that may be important to particular holders in light of their individual circumstances or to holders who may be subject to special tax rules, including, without limitation, partnerships (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes), dealers in securities or foreign currency, traders in securities that use a mark-to-market method of accounting for securities holdings, U.S. expatriates, U.S. persons whose functional currency is not the U.S. dollar, "controlled foreign corporations", "passive foreign investment companies", insurance companies, tax-exempt organizations, banks, financial institutions, broker-dealers, holders who hold common stock as part of a hedge, straddle, conversion, constructive sale or other integrated security transaction, or who acquired common stock pursuant to the exercise of compensatory stock options or otherwise as compensation, all of whom may be subject to tax rules that differ significantly from those summarized below.

This discussion is based upon the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and the U.S. Internal Revenue Service's, or IRS's, current administrative rules, practices and interpretations of law, all as in effect on the date of this prospectus, and all of which are subject to change, possibly with retroactive effect, and to differing interpretations, which could result in U.S. federal income tax consequences different from those described below. We have not sought, and will not seek, a ruling from the IRS regarding the U.S. federal income tax consequences of this offering. The following discussion does not address the tax consequences of this offering under federal estate, foreign, state, or local tax laws, or the alternative minimum tax provisions of the Code. Accordingly, you are urged to consult your tax advisor with respect to the particular tax consequences of this offering.

For purposes of this description, a "U.S. Holder" is a beneficial owner of common stock or a warrant that is:

- · An individual citizen or resident of the United States:
- · a corporation or other entity taxable as a corporation that is created or organized in or under the laws of the U.S., any state thereof or the District of Columbia:
- · an estate, the income of which is subject to U.S. federal income taxation, regardless of its source; or
- a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust (or the trust was in existence on August 20, 1996, and validly elected to continue to be treated as a U.S. person).

For purposes of this discussion, a Non-U.S. Holder is a beneficial owner of common stock or a warrant that is not a U.S. Holder and is not a partnership for U.S. federal income tax purposes. If an entity classified as a partnership for U.S. federal income tax purposes holds common stock or a warrant, the tax treatment of a partner will depend on the status of the partner and the activities of the partnership. Any holder of common stock or a warrant that is a partnership, or any partner in such a partnership, should consult its tax advisors.

THIS SUMMARY IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSTRUED TO BE, LEGAL, OR TAX ADVICE. THE U.S. FEDERAL INCOME TAX TREATMENT OF THE UNITS IS COMPLEX .. EACH HOLDER WHO ACQUIRES UNITS IS STRONGLY URGED TO CONSULT HIS, HER OR ITS OWN TAX ADVISER WITH RESPECT TO THE U.S. FEDERAL, STATE, LOCAL AND FOREIGN INCOME, ESTATE AND OTHER TAX CONSEQUENCES OF THE ACQUISITION OF THE UNITS, WITH SPECIFIC REFERENCE TO SUCH PERSON'S PARTICULAR FACTS AND CIRCUMSTANCES.

## U.S. Holders

#### Common Stock

*Distributions*. Distributions with respect to common stock, if any, will be includible in the gross income of a U.S. Holder as ordinary dividend income to the extent paid out of current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. Any portion of a distribution in excess of current or accumulated earnings and profits would be treated as a return of the holder's tax basis in its common stock and then as gain from the sale or exchange of the common stock. Newly enacted legislation requires U.S. Holders that are individuals, estates or trusts with incomes in excess of \$200,000 (\$250,000 for a married couple filing a joint return) to pay up to an additional 3.8% tax on dividends and capital gains for taxable years beginning after December 31, 2012.

Distributions to U.S. Holders that are corporate shareholders, constituting dividends for U.S. federal income tax purposes, may qualify for the 70% dividends received deduction, or DRD, which is generally available to corporate shareholders that own less than 20% of the voting power or value of the outstanding stock of the distributing corporation. A U.S. holder that is a corporate shareholder holding 20% or more of the distributing corporation may be eligible for an 80% DRD. No assurance can be given that we will have sufficient earnings and profits (as determined for U.S. federal income tax purposes) to cause any distributions to be eligible for a DRD. In addition, a DRD is available only if if the stock is held for at least 46 days during the 91-day period beginning on the date that is 45 days before the date on which the stock becomes ex-dividend with respect to such dividend and to the extent that taxable income requirements of the corporate shareholder are satisfied. The length of time that a U.S. Holder has held stock is reduced by any period during which the U.S. Holder's risk of loss with respect to the stock maybe be diminished by reason of the existence of options, contracts to sell, short sales, or other similar transactions. Also, to the extent that a corporation incurs indebtedness that is directly attributable to an investment in the stock on which the dividend is paid, all or a portion of the DRD may be disallowed. Corporate shareholders should consult their tax advisors regarding the availability of a DRD in light of their particular circumstances. In addition, any dividend received by a corporation may also be subject to the extraordinary distribution provisions of the Tax Code.

Dispositions . If you sell or otherwise dispose of any shares of common stock, you will recognize capital gain or loss equal to the difference between your amount realized and your adjusted tax basis of such shares of common stock. The respective tax bases of the common stock, the Class A Warrants and the Class B Warrants underlying the Units acquired in this offering will be determined by first allocating the purchase price for each Unit among the common stock, the Class A Warrants and the Class B Warrants in proportion to their respective fair market values on the date the Unit is purchased. (See "Warrants – Cashless Exercise" and "Warrants – Exercise for Cash" below for a discussion of tax basis with respect to common stock received upon exercise of a Class A Warrant or a Class B Warrant). Such capital gain or loss will be long-term capital gain or loss if your holding period for such shares of common stock is more than one year. Your holding period for the common stock underlying a Unit will begin on the date the Unit is purchased. (See "Warrants – Cashless Exercise" and "Warrants - Exercise for Cash" below for a discussion of holding period with respect to common stock received upon exercise of a Class A Warrant or a Class B Warrant). The deductibility of capital losses is subject to limitations.

## Warrants

Dispositions. If you sell or otherwise dispose of a warrant, you will recognize capital gain or loss equal to the difference between the amount realized and your adjusted tax basis of such warrant. The respective tax bases of the common stock, the Class A Warrants, Class B Warrants and Class C Warrants underlying the Units acquired in this offering will be determined by first allocating the purchase price for each Unit among the common stock, the Class A Warrants, the Class B Warrants and the Class C Warrants in proportion to their respective fair market values on the date of the Unit is purchased. Such capital gain or loss will be long-term capital gain or loss if your holding period for a warrant is more than one year. Your holding period for the warrants underlying a Unit will begin on the date the Unit is purchased. In the event a warrant lapses unexercised, you will recognize a capital loss in an amount equal to the adjusted tax basis of the warrant. Such capital loss will be long-term if your holding period of such warrant was more than one year at the time of lapse. The deductibility of capital losses is subject to limitations.

Cashless Exercise. The Class A Warrants and Class B Warrants will be exercised only by way of cashless exercise, while the Class C Warrants can be exercised in a cashless manner only if the Company does not have an effective registration statement under the Securities Act of 1933 covering the issuance of the shares underlying the Class C Warrants. The tax consequences of a cashless exercise of a warrant are not clear under current tax law. It is possible that a cashless exercise may be treated as a recapitalization for U.S. federal income tax purposes, in which case no gain or loss would be recognized in connection with such exercise, other than with respect to cash received in lieu of a fractional share. In this case, a U.S. Holder's tax basis in the common stock received would equal the holder's basis in the warrant (plus any gain recognized from the receipt of cash in lieu of a fractional share minus the amount of cash received). If a cashless exercise is treated as a recapitalization, the holding period of the common stock will include the holding period of the warrant. The Company intends to treat the Class A Warrants and Class B Warrants as equity for U.S. federal income tax purposes and the cashless exercise of the Class A Warrants and Class B Warrants and the cashless exercise of the Class C Warrants, if applicable, as a recapitalization.

However, it is also possible that a cashless exercise could be treated as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. Holder could be deemed to have surrendered warrants equal to the number of common shares having a value equal to the exercise price for the total number of warrants to be exercised. The U.S. Holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the warrants deemed surrendered to pay the exercise price and the holder's tax basis in such warrants deemed surrendered. In this case, a U.S. Holder's tax basis in the common stock received would equal the sum of the fair market value of the warrants deemed surrendered to pay the exercise price and the holder's tax basis in the warrants exercised. A U.S. Holder's holding period for the common stock would commence on the date following the date of exercise of the warrant.

In addition, upon a cashless exercise of a warrant, cash received in lieu of a fractional share of common stock will be treated as a payment in a taxable exchange for such fractional share of common stock, and gain or loss will be recognized on the receipt of cash in an amount equal to the difference between the amount of cash received and the amount of adjusted tax basis allocable to the fractional share of common stock.

DUE TO THE ABSENCE OF AUTHORITY ON THE U.S. FEDERAL INCOME TAX TREATMENT OF A CASHLESS EXERCISE, THERE CAN BE NO ASSURANCE WHICH, IF ANY, OF THE ALTERNATIVE TAX CONSEQUENCES AND HOLDING PERIODS DESCRIBED ABOVE WOULD BE ADOPTED BY THE IRS OR A COURT OF LAW. ACCORDINGLY, HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES OF A CASHLESS EXERCISE.

*Exercise for Cash* . Your tax basis in shares of common stock received upon exercise of a Class CB Warrant for cash will equal the tax basis of the Class C Warrant, increased by the amount paid upon exercise of the warrant. Your holding period of shares of common stock received upon exercise of a warrant will begin on the day following the date on which the warrant is exercised.

Constructive Distributions .. A shareholder may be deemed to receive a constructive distribution pursuant to Section 305 of the Code. Such a constructive distribution could occur if at any time during the period you hold warrants, we pay a taxable dividend to our stockholders and, in accordance with the anti-dilution provisions of the warrants, we adjust the exercise price of the warrant. That adjustment will be taxable as a dividend, return of capital, or capital gain in accordance with the earnings and profits rules under the Code, notwithstanding that you will not receive a cash payment. In addition, the occurrence of, or failure to make, adjustments to either the number of shares of common stock to be issued upon exercise of a warrant or to the warrant's exercise price in connection with a stock split, combination, recapitalization or other similar transaction affecting the common stock, could result in a constructive distribution. Furthermore, we may be obligated to adjust the conversion rate of the warrants or, in lieu of such adjustment, to provide for the conversion of warrants into warrants or shares of an acquirer. See "Description of Securities." Depending on the circumstances, such modification could result in a deemed exchange of your warrant for a new warrant, potentially resulting in the recognition of taxable gain or loss. You should consult your tax advisor regarding the proper treatment of any adjustments to the warrants.

## Information Reporting and Backup Withholding

Information reporting requirements will apply to payments of dividends on shares of common stock or deemed dividends on a warrant and to the proceeds of a sale of a warrant or shares of common stock paid to you unless you are an exempt recipient such as a corporation or, in some circumstance, a tax-exempt organization.

Backup withholding will apply to those payments if you fail to provide your correct taxpayer identification number, certify your exempt status, or report in full interest and dividend income. Selected U.S. Holders, including, among others, corporations, financial institutions and some tax exempt organizations, generally are not subject to backup withholding. Backup withholding tax is not an additional tax, and you may use amounts withheld as credit against your U.S. federal income tax liability or may claim a refund as long as you timely provide the required information to the IRS. U.S. Holders should consult their own tax advisors regarding the applicability of backup withholding.

## Non-U.S. Holders

## Common Stock

Distributions. Dividends paid to a Non-U.S. Holder, if any, with respect to shares of common stock will be subject to withholding tax at a 30% rate (or lower applicable income tax treaty rate) unless the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business in the United States. If a Non-U.S. Holder is engaged in a trade or business in the United States and dividends with respect to the common stock are effectively connected with the conduct of that trade or business and, if required by an applicable income tax treaty, are attributable to a U.S. permanent establishment, then the Non-U.S. Holder will be subject to U.S. federal income tax on those dividends on a net income basis (although the dividends will be exempt from the 30% U.S. federal withholding tax, provided the certification requirements are satisfied) in the same manner as if received by a U.S. person as defined under the Code. Any such effectively connected income received by a foreign corporation may be subject to an additional branch profits tax at a 30% rate (or lower applicable income tax treaty rate).

Subject to the discussion below under "— New Legislation Relating to Foreign Accounts," in order to obtain a reduced rate of withholding, you will be required to timely provide a properly executed IRS Form W-8BEN (or other applicable IRS form) certifying your entitlement to benefits under a treaty. If a Non-U.S. Holder is eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty, it can obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the Internal Revenue Service.

Dispositions . A Non-U.S. Holder may recognize gain upon the sale, exchange, redemption or other taxable disposition of common stock. Subject to the discussion below concerning backup withholding and the newly-enacted legislation relating to foreign accounts, such gain generally will not be subject to U.S. federal income tax unless: (i) that gain is effectively connected with conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment) by a Non-U.S. Holder; (ii) the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and other conditions are met; or (iii) the Company is or has been a "U.S. real property holding corporation" for U.S. federal income tax purposes.

If a Non-U.S. Holder is an individual described in clause (i) of the last sentence of the preceding paragraph, the Non-U.S. Holder will be subject to tax on the net gain at regular graduated U.S. federal income tax rates. If the Non-U.S. holder is an individual described in clause (ii) of the preceding paragraph, the Non-U.S. holder will be subject to a flat 30% tax on the gain, which may be offset by U.S. source capital losses even though the non-U.S. holder is not considered a resident of the United States. If a Non-U.S. Holder is a foreign corporation that is described in clause (i) of the last sentence of the preceding paragraph, it will be subject to tax on its net gain in the same manner as if it were a U.S. person as defined under the Code and, in addition, the Non-U.S. Holder may be subject to the branch profits tax at a rate equal to 30% of its effectively connected earnings and profits or at such lower rate as may be specified by an applicable income tax treaty.

The Company believes that it is not and does not anticipate becoming a "U.S. real property holding corporation" for U.S. federal income tax purposes. However, because the determination depends on the fair market value of our U.S. real property interests and the fair market value of our other assets, no assurance can be provided that we currently are not, or in the future will not become, a U.S. real property holding corporation. The tax relating to stock in a "U.S. real property holding corporation" will not apply to a Non-U.S. Holder whose holdings (taking into account actual ownership and the constructive ownership rules as modified by Treasury Regulations) at all times during the applicable period, constitute 5% or less of our common stock, provided that our common stock is regularly traded on an established securities market. If your holdings (taking into account actual ownership and the constructive ownership rules as modified by Treasury Regulations) at all times during the applicable period, constituted 5% or less of our common stock and provided our common stock is regularly traded on an established securities market, you will not be subject to U.S. federal income tax on the disposition of your common stock.

#### Warrants

Dispositions. A Non-U.S. Holder may recognize gain upon the sale, exchange, redemption, exercise or other taxable disposition of a warrant. Subject to the discussion below concerning backup withholding and the newly-enacted legislation relating to foreign accounts, such gain generally will not be subject to U.S. federal income tax unless: (i) that gain is effectively connected with conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment) by a Non-U.S. Holder; (ii) the Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or (iii) the Company is or has been a "U.S. real property holding corporation" for U.S. federal income tax purposes.

If a Non-U.S. Holder is an individual described in clause (i) of the last sentence of the preceding paragraph, the Non-U.S. Holder will be subject to tax on the net gain at regular graduated U.S. federal income tax rates. If the Non-U.S. holder is an individual described in clause (ii) of the preceding paragraph, the Non-U.S. holder will be subject to a flat 30% tax on the gain, which may be offset by U.S. source capital losses even though the non-U.S. holder is not considered a resident of the United States. If a Non-U.S. Holder is a foreign corporation that is described in clause (i) of the last sentence of the preceding paragraph, it will be subject to tax on its net gain in the same manner as if it were a U.S. person as defined under the Code and, in addition, the Non-U.S. Holder may be subject to the branch profits tax at a rate equal to 30% of its effectively connected earnings and profits or at such lower rate as may be specified by an applicable income tax treaty.

The Company believes that it is not and does not anticipate becoming a "U.S. real property holding corporation" for U.S. federal income tax purposes. However, because the determination depends on the fair market value of our U.S. real property interests and the fair market value of our other assets, no assurance can be provided that we currently are not, or in the future will not become, a U.S. real property holding corporation. If we are a U.S. real property holding corporation and our warrants are treated as a U.S. real property interest, you will be subject to U.S. federal income tax on a net income basis on any gain realized on a sale or other disposition of the warrants and a purchaser may be required to withhold a portion of the proceeds payable to you from the disposition. However, provided our common stock is regularly traded on an established securities market and your holdings (taking into account actual ownership and the constructive ownership rules as modified by Treasury Regulations) on the date of the acquisition of your warrants have a fair market value of 5% or less of the value of our publicly traded common stock, you will not be subject to U.S. federal income tax on the disposition of your warrants. If any subsequent acquisitions cause your interests to exceed the applicable limitation described above, then all such interests shall be treated as U.S. real property interests, regardless of when acquired.

Constructive Distributions. A shareholder may be deemed to receive a constructive distribution pursuant to Section 305 of the Code. Such a constructive distribution could occur if at any time during the period you hold warrants, we pay a taxable dividend to our stockholders and, in accordance with the anti-dilution provisions of the warrants, we adjust the exercise price of the warrant. That adjustment will be taxable as a dividend, return of capital, or capital gain in accordance with the earnings and profits rules under the Code, notwithstanding that you will not receive a cash payment. In addition, the occurrence of, or failure to make, adjustments to either the number of shares of common stock to be issued upon exercise of a warrant or to the warrant's exercise price in connection with a stock split, combination, recapitalization or other similar transaction affecting the common stock, could result in a constructive distribution. See "Description of Securities."

Any deemed dividends that are not effectively connected with the conduct of a trade or business in the United States generally will be subject to withholding tax at a 30% rate (or lower applicable income tax treaty rate). Subject to the discussion below under "— New Legislation Relating to Foreign Accounts," in order to obtain a reduced rate of withholding, you will be required to timely provide a properly executed IRS Form W-8BEN (or other applicable IRS form) certifying your entitlement to benefits under a treaty. Because any constructive dividend would not give rise to any cash from which any applicable withholding tax could be satisfied, it is possible that this tax would be withheld from any amount owed to you, including, but not limited to, cash or shares of common stock otherwise due on exercise, dividends or sales proceeds subsequently paid or credited to you.

Constructive dividends that are effectively connected with the conduct of a trade or business within the United States and, where a tax treaty applies, are attributable to a U.S. permanent establishment, are not subject to withholding tax, but instead are subject to U.S. federal income tax on a net income basis at applicable graduated U.S. federal income tax rates in the same manner as if you were a resident of the United States. In such cases, we generally will not be required to withhold U.S. federal income tax if you comply with applicable certification and disclosure requirements, generally on a properly executed IRS Form W-8ECI (or other applicable IRS Form). Any such effectively connected income received by a Non-U.S. Holder that is classified as corporation for U.S. tax purposes may also be subject to an additional branch profits tax at a 30% rate (or lower applicable income tax treaty rate).

A Non-U.S. Holder of warrants that wishes to claim the benefit of an applicable treaty rate is required to satisfy applicable certification and other requirements. If you are eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty, you may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS. You should consult your tax advisor regarding the certification and disclosure requirements applicable to you.

In certain situations, we may be obligated to adjust the conversion rate of the warrants or, in lieu of such adjustment, to provide for the conversion of warrants into warrants or shares of an acquirer. Depending on the circumstances, such modification could result in a deemed exchange of your warrant for a new warrant, potentially resulting in the recognition of taxable gain (See "Warrants – Dispositions" above). You should consult your tax advisor regarding the proper treatment of any adjustments to the warrants.

# New Legislation Relating to Foreign Accounts

Newly enacted legislation imposes withholding taxes on certain types of payments made to "foreign financial institutions" and certain other non-U.S. entities where information reporting requirements are not satisfied. The legislation imposes a 30% withholding tax on dividends on, and gross proceeds from the sale or other disposition of, common stock or paid to a foreign financial institution or to a foreign non-financial entity, unless (i) the foreign financial institution undertakes required diligence and reporting obligations or (ii) the foreign non-financial entity either certifies it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner. If the payee is a foreign financial institution, it must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. The legislation would apply to payments made after December 31, 2012. Prospective investors should consult their tax advisors regarding this legislation.

# Information Reporting and Backup Withholding

We must report to the IRS and to you the amount of dividends paid (or deemed paid) to you and the amount of tax, if any, withheld with respect to those payments. Copies of the information returns reporting such interest payments and any withholding may also be made available to the tax authorities in the country in which you reside under the provisions of an applicable income tax treaty.

In general, you will not be subject to backup withholding with respect to payments of dividends (or deemed dividends) that we make to you provided that we do not have actual knowledge or reason to know that you are a U.S. person, as defined under the Code, and (a) we have a properly executed IRS Form W-8BEN (or other applicable IRS form) on which you certify, under penalties of perjury, that you are not a U.S. person or (b) you hold your common stock or warrants through certain foreign intermediaries and satisfy the certification requirements of applicable U.S. Treasury regulations. Special rules apply to non-U.S. holders that are pass-through entities rather than corporations or individuals.

In addition, no information reporting or backup withholding will be required regarding the proceeds of the sale of common stock or a warrant made within the U.S. or conducted through certain U.S.-related financial intermediaries, if the payor receives the statement described above and does not have actual knowledge or reason to know that you are a U.S. person, as defined under the Code, or you otherwise establish an exemption.

Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against your U.S. federal income tax liability provided the required information is timely furnished to the IRS.

## **UNDERWRITING**

Subject to the terms and conditions of the underwriting agreement, the underwriters named below, through their representative, Dawson James Securities, Inc., who is acting as the sole book-running manager and sole representative of the underwriters of this offering, each underwriter named below has severally agreed to purchase from us on a firm commitment basis the following respective number of Units at a public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus:

Number of Underwriter Shares

Dawson James Securities, Inc.

Total

The underwriting agreement provides that the obligation of the underwriters to purchase all of the 3,000,000 Units being offered to the public (assuming a \$6.00 per Unit public offering price) is subject to specific conditions, including the absence of any material adverse change in our business or in the financial markets and the receipt of certain legal opinions, certificates and letters from us, our counsel and the independent auditors. Subject to the terms of the underwriting agreement, the underwriters will purchase all of the 3,000,000 Units being offered to the public, other than those covered by the over-allotment option described below, if any of these Units are purchased.

# **Over-Allotment Option**

We have granted to the underwriters an option, exercisable not later than 45 days after the effective date of the registration statement, to purchase up to 450,000 additional Units at the public offering price less the underwriting discounts and commissions set forth on the cover of this prospectus. The underwriters may exercise this option only to cover over-allotments made in connection with the sale of the Units offered by this prospectus. The overallotment option will only be used to cover the net syndicate short position resulting from the initial distribution. To the extent that the underwriters exercise this option, each of the underwriters will become obligated, subject to conditions, to purchase approximately the same percentage of these additional Units as the number of Units to be purchased by it in the above table bears to the total number of Units offered by this prospectus. We will be obligated, pursuant to the option, to sell these additional Units to the underwriters to the extent the option is exercised. If any additional Units are purchased, the underwriters will offer the additional Units on the same terms as those on which the other Units are being offered hereunder.

## **Commissions and Discounts**

The underwriting discounts and commissions are 6% of the initial public offering price. We have agreed to pay the underwriters the discounts and commissions set forth below, assuming either no exercise or full exercise by the underwriters of the underwriters' over-allotment option. In addition, we have agreed to pay to Dawson James Securities, Inc. a non-accountable expense allowance of up to 2% of the gross proceeds of this offering.

Additionally, Dawson James Securities, Inc. will receive a warrant exercisable for the purchase of Units in an amount up to 8% of the aggregate number of Units sold in this offering. The Dawson James warrant will be exercisable, at an exercise price of 110% of the public Unit offering price, commencing one year from the effective date of the registration statement of which this prospectus forms a part and will expire four years from such effective date. The Dawson James warrant will contain a cashless, net exercise feature. Each of the Units issuable upon exercise of the Dawson James warrant will consist of (i) one share of common stock, (ii) one Class A Warrants, exercisable for one share of common stock at an exercise price of \$0.05 per share and (iv) one Class C Warrant, exercisable for one share of common stock at an exercise price equal to 55% of the Unit price in this offering. The Class A Warrants and Class B Warrants issuable upon exercise of the Dawson James warrant will be exercisable only on a cashless basis and will be exercisable for a period of 10 days from the date the Dawson James Unit warrant is exercised; the Class C Warrants issuable upon exercise of the Dawson James warrant will be exercisable for a period of five years following the exercise of the Dawson James Unit warrant. In compliance with the lock-up restrictions set forth in FINRA Rule 5110(g)(1), neither the Dawson James warrants nor the underlying securities may be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of at least 180 days immediately following the date of effectiveness or commencement of sales of the offering, except to any member participating in the offering and the officers or partners thereof, and only if all securities so transferred remain subject to the one-year lock-up restriction for the remainder of the lock-up period.

The representative has advised us that the underwriters propose to offer the Units directly to the public at the public offering price set forth on the cover of this prospectus. In addition, the representative may offer some of the Units to other securities dealers at such price less a concession of \$\_\_\_\_ per Unit. The underwriters may also allow, and such dealers may reallow, a concession not in excess of \$\_\_\_\_ per Unit to other dealers. After the common stock is released for sale to the public, the representative may change the offering price and other selling terms at various times.

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. The underwriting discounts and commissions are equal to the public offering price per share less the amount per share the underwriters pay us for the shares.

	Per Unit	Total without Over-Allotment	Total with Over-Allotment
Public offering price			
Underwriting discount (1)			
Proceeds, before expenses, to us			
(1) Does not include the non-accountable expense reimbursement fee in the amount of up to 2% of	the gross proceed	ls of this offering.	
We estimate that the total expenses of the offering, including registration, filing and listing fees, prin	nting fees and lega	al and accounting exp	enses, but

# Lock-Up Agreements

excluding underwriting discounts and commissions, will be approximately \$\_\_\_

We and each of our officers, directors, and existing stockholders are bound by agreements providing that we and these stockholders may not offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of 12 months from the effective date of the registration statement of which this prospectus is a part without the prior written consent of Dawson James.

Dawson James may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the representative will consider, among other factors, the securityholder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

# **Pricing of this Offering**

Prior to this offering there has been no public market for any of our securities. The public offering price of the Units and the terms of the warrants, including the exercise prices of the warrants, were negotiated between us and Dawson James. Factors considered in determining the prices and terms of the Units, including the common stock and warrants underlying the Units, include:

- the history and prospects of companies in our industry;
- · prior offerings of those companies;
- · our prospects for developing and commercializing our products;
- · our capital structure;
- · an assessment of our management and their experience;
- · general conditions of the securities markets at the time of the offering; and
- · other factors as were deemed relevant.

However, although these factors were considered, the determination of our offering price is more arbitrary than the pricing of securities for an operating company in a particular industry since the underwriters are unable to compare our financial results and prospects with those of public companies operating in the same industry.

## Price Stabilization, Short Positions and Penalty Bids

The underwriters may engage in over-allotment, stabilizing transactions, short positions, syndicate covering transactions, and penalty bids or purchasers for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- · Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. In connection with the offering, the underwriters may make short sales of the Company's shares. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- · Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- · Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- · Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, short positions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make representation that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

## Other Terms

We have engaged Dawson James, on a non-exclusive basis, as our agent for the solicitation of the exercise of the Class C Warrants. To the extent not inconsistent with the guidelines of the Financial Industry Regulatory Authority, or FINRA, and the rules and regulations of the SEC, we have agreed to pay the underwriter for bona fide services rendered a commission equal to 5% of the exercise price for each warrant exercised more than one year after the date of this prospectus if the exercise was solicited by Dawson James. No compensation will be paid to the underwriter upon the exercise of the warrants if:

- the market price of the underlying shares of common stock is lower than the exercise price;
- · the holder of the warrants has not confirmed in writing that the underwriter solicited his, her or its exercise;
- · the warrants are held in a discretionary account, unless prior specific written approval for the exercise is received from the holder;
- · the warrants are exercised in an unsolicited transaction; or
- the arrangement to pay the commission is not disclosed in the prospectus provided to warrant holders at the time of exercise.

In addition, we have agreed to reimburse the underwriters for up to \$150,000 of the legal fees incurred by the underwriters in connection with the offering, plus up to an additional \$25,000 in legal fees for blue sky matters and up to \$15,000 for legal fees related to filings with FINRA. These expenses, which are in addition to the 2% non-accountable expense reimbursement fee described above, will be paid from the proceeds of this offering.

## Indemnification

We have agreed to indemnify the underwriters against liabilities relating to the offering arising under the Securities Act, liabilities arising from breaches of some or all of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriters may be required to make for these liabilities.

## **Electronic Distribution**

A prospectus in electronic format may be made available on a website maintained by the representatives of the underwriters and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives of the underwriters to underwriters that may make Internet distributions on the same basis as other allocations. In connection with the offering, the underwriters or syndicate members may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

The underwriters have informed us that they do not expect to confirm sales of Units offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

## Relationships

Certain of the underwriters or their affiliates have provided from time to time and may in the future provide investment banking, lending, financial advisory and other related services to us and our affiliates for which they have received and may continue to receive customary fees and commissions.

## Foreign Regulatory Restrictions on Purchase of Units

We have not taken any action to permit a public offering of the Units outside the United States or to permit the possession or distribution of this prospectus outside the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to this offering of Units and the distribution of the prospectus outside the United States.

## **LEGAL MATTERS**

The validity of the securities offered by this prospectus will be passed upon for us by Goodwin Procter LLP, San Francisco, California. Certain legal matters relating to this offering will be passed upon for the underwriter by McDermott Will & Emery LLP, Menlo Park, California.

## **EXPERTS**

KCCW Accountancy Corp., an independent PCAOB registered public accounting firm, has audited the Company's balance sheets as of December 31, 2009 and the related statements of operations, stockholders' equity, and cash flows, which are included in this prospectus. The financial statements are included in reliance on the report of KCCW Accountancy Corp., given their authority as experts in accounting and auditing.

## ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933 with respect to the Units offered by this prospectus. This prospectus does not contain all of the information included in the registration statement, portions of which are omitted as permitted by the rules and regulations of the SEC. For further information pertaining to us and the Units to be sold in this offering, you should refer to the registration statement and its exhibits.

In this prospectus, whenever reference is made to contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document filed as an exhibit to the registration statement or such other document, each such statement being qualified in all respects by such reference.

Upon the completion of this offering, we will be subject to the informational requirements of the Securities Exchange Act of 1934 and will be required to file annual, quarterly and current reports, proxy statements and other information with the SEC. We anticipate making these documents publicly available, free of charge, on its website as soon as reasonably practicable after filing such documents with the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

You can read the registration statement and future filings, as they are filed with the SEC, over the Internet at the SEC's website at *www.sec.gov*. Copies of filings may be requested, at no cost, from us. You may also read and copy any document filed with the SEC at its public reference facility at 100 F Street, N.E., Washington, D.C. 20549 and copies may be requested at prescribed rates at such address or at 1-800-SEC-0330.

# ATOSSA GENETICS, INC. (A Development Stage Company) INDEX TO FINANCIAL STATEMENTS

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# ATOSSA GENETICS, INC. (A DEVELOPMENT STAGE COMPANY) BALANCE SHEETS

	September 30, 2010		December 31, 2009		
	(U	naudited)	(Audited)		
<u>Assets</u>					
Current Assets					
Cash and cash equivalents	\$	29,531	\$	84,364	
Other receivable		1,622		-	
Total Current Assets		31,153		84,364	
Other Assets					
Security deposit - related parties		1,100		1,100	
Total Other Assets		1,100		1,100	
Total Assets	\$	32,253	\$	85,464	
<u>Liabilities and Stockholders' (Deficit) Equity</u>					
Current Liabilities					
Accrued payroll	\$	166,071	\$	-	
Accrued expenses		285,811		36,281	
Note payable - related party		107,000		5,000	
Accrued royalty payable - related party		_		12,500	
Total Current Liabilities		558,882	_	53,781	
Stockholders' (Deficit) Equity					
Preferred stock - \$.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding		-		-	
Common stock - \$.001 par value, 75,000,000 shares authorized, 6,000,067 and 4,899,882 shares issued and					
outstanding, respectively		6,000		4,900	
Additional paid-in capital		334,585		149,640	
Accumulated deficit		(867,214)		(122,857)	
Total Stockholders' (Deficit) Equity		(526,629)		31,683	
Total Liabilities and Stockholders' (Deficit) Equity	\$	32,253	\$	85,464	

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

# ATOSSA GENETICS, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF OPERATIONS (UNAUDITED)

	Mo	r The Three onths Ended otember 30, 2010	Moı	The Three oths Ended tember 30, 2009	M	or The Nine Conths Ended eptember 30, 2010	200	om April 30, 9 (Inception) Through ptember 30, 2009	200	om April 30, 09 (Inception) Through eptember 30, 2010
Net Revenue	\$	-	\$	-	\$	-	\$	-	\$	-
Operating Expenses										
Legal and professional expenses		237,249		70,804		331,863		70,804		416,480
Compensation expenses		140,545		-		194,116		-		194,116
Consulting expenses		46,449		-		90,614		-		90,614
Research and development expenses		1,306		17,500		1,306		17,500		22,556
Website and internet expenses		-		-		52,500		-		55,538
Advertising and promotion expenses		-		-		12,204		-		12,204
Other operating expenses		51,760		4,277		56,953		4,801		70,906
Total operating expenses		477,309		92,581		739,557		93,105		862,414
Operating Loss		(477,309)		(92,581)		(739,557)		(93,105)		(862,414)
Interest Income		2		-		455		-		455
Interest Expense		(5,129)			_	(5,129)			_	(5,129)
Net Loss before Income Taxes		(482,436)		(92,581)		(744,231)		(93,105)		(867,089)
Income Taxes	_			<u>-</u>	_	125			_	125
Net Loss	\$	(482,436)	\$	(92,581)	\$	(744,356)	\$	(93,105)	\$	(867,214)
Loss per common share - basic and diluted	\$	(80.0)	\$	(0.02)	\$	(0.13)	\$	(0.02)	\$	(0.17)
Weighted average shares outstanding, basic and diluted		6,000,035		4,004,426		5,914,204		3,993,093		5,024,779

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

# ATOSSA GENETICS, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF CASH FLOWS (UNAUDITED)

	For The Nine Months Ended September 30, 2010		From April 30, 2009 (Inception) Through September 30, 2009		2009	m April 30, O (Inception) Fhrough otember 30, 2010
CASH FLOWS FROM OPERATING ACTIVITIES						
Net loss	\$	(744,356)	\$	(93,105)	\$	(867,214)
Common shares issued for services		71,000		-		71,000
Compensation cost for stock options granted to executives		13,045		-		13,045
Loan initiation fee accrued for notes payable		2,000		-		2,000
Adjustments to reconcile net loss to net cash provided by operating activities:						
Increase in other receivable		(1,622)		-		(1,622)
Increase in security deposits		-		-		(1,100)
Increase in accrued payroll		166,071		-		166,071
Increase in accrued expenses		237,030		51,250		285,811
Net cash used in operating activities		(256,833)		(41,855)		(332,009)
CASH FLOWS FROM FINANCING ACTIVITIES						
Proceeds from issuance of common stocks		102,000		54,540		256,540
Proceeds from loans from related parties		100,000		5,000		105,000
Net cash provided by financing activities		202,000		59,540	_	361,540
The cash provided by immemig activates		202,000		55,510		301,310
NET (DECREASE) INCREASE IN CASH & CASH EQUIVALENTS		(54,833)		17,686		29,531
CASH & CASH EQUIVALENTS, BEGINNING BALANCE		84,364		-		-
CASH & CASH EQUIVALENTS, ENDING BALANCE	\$	29,531	\$	17,686	\$	29,531
SUPPLEMENTAL DISCLOSURES:						
Interest paid	\$	_	\$	_	\$	_
Income taxes paid	\$	125	\$	-	\$	125

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

## NOTE 1: NATURE OF OPERATIONS

Atossa Genetics, Inc., (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was formed to develop and market the Mammary Aspirate Specimen Cytology Test, or the MASCT System, a cellular and molecular diagnostic risk assessment product for the detection of precancerous changes that could lead to breast cancer. The Company's fiscal year ends on December 31 st ..

## **Development Stage Risk**

To date, the Company has not earned any revenues from operations. Accordingly, the Company's activities have been accounted for as those of a "Development Stage Enterprise" as set forth in Accounting Standards Codification ("ASC") 915 "Development Stage Entities", which was previously Statement of Financial Accounting Standards No. 7 ("SFAS 7"). Among the disclosures required by ASC 915 are that the Company's financial statements be identified as those of a development stage company, and that the statements of operations, stockholders' equity and cash flows disclose activity since the date of the Company's inception.

Since its inception, the Company has been dependent upon the receipt of capital investment to fund its continuing activities. In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's business plan will be successfully executed. The Company's ability to execute its business plan will depend on its ability to obtain additional financing and achieve a profitable level of operations. There can be no assurance that sufficient financing will be obtained. Further, the Company cannot give any assurance that it will generate substantial revenues or that its business operations will prove to be profitable.

# **NOTE 2: GOING CONCERN**

The Company's financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

# Management's Plan to Continue as a Going Concern

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management's plans to obtain such resources for the Company include (1) obtaining capital from the sale of its securities, (2) sales of the MASCT System and (3) short-term borrowings from stockholders or other related party(ies) when needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

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

## NOTE 3: SUMMARY OF ACCOUNTING POLICIES

## **Revenue Recognition:**

Although the Company has yet to generate any revenues, it expects that it will recognize product and service revenue when the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or the service has been performed, (iii) the Company's price to the customer is fixed or determinable and (iv) collection of the resulting accounts receivable is reasonably assured. The Company will recognize revenue for product sales upon transfer of title to the customer. The Company will recognize revenue for services upon performance of the service. Customer purchase orders and/or contracts will generally be used to determine the existence of an arrangement. Shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery or that services have been rendered. The Company will assess whether a price is fixed or determinable based upon the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. The Company will record reductions to revenue for estimated product returns and pricing adjustments in the same period that the related revenue is recorded. These estimates will be based on industry-based historical data, historical sales returns, if any, analysis of credit memo data, and other factors known at the time.

## **Interim Financial Statements:**

The unaudited financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States of America for annual audited financial statements. However, the information included in these interim financial statements reflects all adjustments (consisting solely of normal recurring adjustments) which are, in the opinion of management, necessary for the fair presentation of the financial position and the results of operations of the Company. Results shown for interim periods are not necessarily indicative of the results to be obtained for a full year. These interim financial statements should be read in conjunction with the Company's audited financial statements as of December 31, 2009 and related notes included therein.

# **Cash and Cash Equivalents:**

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

## **Use of Estimates:**

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

## **Research and Development Expenses:**

Research and development costs are generally expensed as incurred. The Company's research and development expenses consist of costs incurred for internal and external research and development.

# **Share Based Payments:**

In December 2004, the Financial Accounting Standard Board, or the FASB, issued the Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share-Based Payment", which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in the FASB's ASC Topic 718, "Compensation – Stock Compensation." Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees or independent contractors are required to provide services. Share-based compensation arrangements include stock options and warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or SAB 107, which expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for SFAS No. 123(R). Companies may elect to apply this statement either prospectively, or on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123.

The Company has fully adopted the provisions of FASB ASC 718 and related interpretations as provided by SAB 107. As such, compensation cost is measured on the date of grant as the fair value of the share-based payments. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

## **Recently Issued Accounting Pronouncements:**

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company. The adoption of these accounting pronouncements, including those not yet effective, is not anticipated to have a material effect on the financial position or results of operations of the Company.

# NOTE 4: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of Common Stock, par value \$.001 per share, and 10,000,000 shares of Preferred Stock, par value \$.001 per share.

# Reverse Stock-Split

On September 28, 2010, the Board of Directors approved a 1-for-2.26332 reverse share split for all issued and outstanding shares of Common Stock, with no change to the par value of the common stock.

## Prior Issuances of Common Stock

On April 30, 2009 (inception), the Company issued 1,767,315 shares (or 4,000,000 shares prior to the reverse stock-split on September 28, 2010) to Ensisheim Partners LLC, a related party to the Company through common ownership, for cash in the amount of \$24,000, or \$.014 per share (or \$.006 per share prior to the reverse stock-split on September 28, 2010); 1,325,487 shares (or 3,000,000 shares prior to the reverse stock-split on September 28, 2010) to Manistee Ventures LLC, a related party to the Company through common ownership, for cash in the amount of \$18,000, or \$.014 per share (or \$.006 per share prior to the reverse stock-split on September 28, 2010); and 883,658 shares (or 2,000,000 shares prior to the reverse stock-split on September 28, 2010) to the Chairman, CEO and President of the Company at that time for cash in the amount of \$12,000, or \$.014 per share (or \$.006 per share prior to the reverse stock-split on September 28, 2010).

On July 28, 2009, the Company issued 39,765 shares (or 90,000 shares prior to the reverse stock-split on September 28, 2010) to a director of the Company for cash in the amount of \$540, or \$.014 per share (or \$.006 per share prior to the reverse stock-split on September 28, 2010).

On December 28, 2009, the Company issued 883,658 shares (or 2,000,000 shares prior to the reverse stock-split on September 28, 2010) to Ensisheim Partners LLC for cash in the amount of \$100,000, or \$.11 per share (or \$.05 per share prior to the reverse stock-split on September 28, 2010).

On January 21, 2010, the Company issued 865,984 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) to forty-four (44) investors for cash in the amount of \$98,000, or .11 per share (or \$.05 per share prior to the reverse stock-split on September 28, 2010).

On January 21, 2010, the Company issued 132,549 shares (or 300,000 shares prior to the reverse stock-split on September 28, 2010) to a servicer for effecting transactions intended to cause the Company to become a public company and to have its securities traded in the United States. The shares were issued at a value of \$15,000, or \$.11 per share (or \$.05 per share prior to the reverse stock-split on September 28, 2010), the same price as the issuance of the 865,984 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date.

On January 21, 2010, the Company issued an additional 53,019 shares (or 120,000 shares prior to the reverse stock-split on September 28, 2010) to a shareholder who acquired 13,255 shares (or 30,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date as one of the forty-four (44) investors. Those shares were issued to the shareholder for services to be performed, including investor relations, media relations, and corporate communications. Those shares were issued at a value of \$6,000, or \$.11 per share (or \$.05 per share prior to the reverse stock-split on September 28, 2010), the same price as the issuance of the 865,984 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date.

On January 23, 2010, the Company issued 35,346 shares (or 80,000 shares prior to the reverse stock-split on September 28, 2010) to an investor for cash in the amount of \$4,000, or \$.11 per share (or \$.05 per share prior to the reverse stock-split on September 28, 2010).

On April 27, 2010, the Company issued 13,255 shares (or 30,000 shares prior to the reverse stock-split on September 28, 2010) at \$3.77 per share (or \$1.67 per share prior to the reverse stock-split on September 28, 2010) to a service provider for website development services pursuant to an original agreement between the Company and the web site developer executed on December 14, 2009, where it was agreed at that time \$50,000 or 30,000 shares of common stock would be issued to the developer in exchange for his services.

## Letter of Intent for Proposed Initial Public Offering

On May 25, 2010, the Company executed a Letter of Intent with Dawson James Securities, Inc. relating to a proposed public initial public offering of the Company's securities (the "Letter Agreement"). Pursuant to the Letter Agreement, the Company paid a \$25,000 deposit upon signing for out-of-pocket expenses and will reimburse Dawson James for up to \$150,000 in expenses incurred in connection with the offering. If the offering is successful, Dawson James will receive compensation in an amount equal to 7% of the gross proceeds received by the Company in the offering, plus an expense allowance of 3% of the gross proceeds. Dawson James will also receive a warrant to purchase Units equal to 15% of the total Units sold in the offering, exercisable at 110% of the public offering price of the Units.

## Stock Option and Incentive Plan

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, subject to stockholder approval, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 1,000,000 shares (or 2,263,320 shares prior to the reverse stock-split on September 28, 2010) are reserved for issuance in connection with awards granted under the 2010 Plan, such number of shares to be subject to adjustment as provided in the plan and in any award agreements entered into by the Company under the plan, and upon the exercise or conversion of any awards granted under the plan. As of September 30, 2010, no award agreement or award had been entered into or granted by the Company under the plan.

## **NOTE 5: INCOME TAXES**

The Company accounts for income taxes as outlined in ASC 740, "Income Taxes", which was previously Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS 109"). Under the asset and liability method of SFAS 109, deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

The provision for income taxes differs from the amounts which would be provided by applying the statutory federal income tax rate of 34% to the net loss before provision for income taxes for the following reasons:

	Peri	ne Month od Ended ember 30, 2010	2009 T	m April 30, (Inception) Through tember 30, 2009	200	om April 30, 9 (Inception) Through ptember 30, 2010
Income tax benefit at statutory rate (34%)	\$	(251,277)	\$	(31,656)	\$	(292,937)
Valuation allowance		251,277		31,656		292,937
Delaware state tax		125		-		125
Income taxes	\$	125	\$	-	\$	125

The tax effect of temporary difference that gave rise to the Company's deferred tax asset as of September 30, 2010 and December 31, 2009 is as follows:

	Sept	tember 30, 2010	December 31, 2009		
NOL carryover	\$	292,937	\$	46,871	
Valuation allowance		(292,937)		(46,871)	
Net deferred tax asset	\$	-	\$	-	

## NOTE 6: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. At June 30, 2010 and December 31, 2009, the Company had no amounts in excess of the FDIC insured limit.

## NOTE 7: RELATED PARTY TRANSACTIONS

# Loans from Officer

The Company had borrowed \$5,000 as of December 31, 2009 from its Chairman of the Board and Chief Executive Officer. This amount was borrowed on May 26, 2009 as a short-term, unsecured loan via verbal agreement and did not bear any interest. Commencing June 30, 2010, the loan was converted into a written Promissory Note bearing an annual interest rate of 10%, with a maturity date of December 31, 2010.

On June 30, 2010, the Company borrowed an additional \$100,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The note bears a 10% interest rate per annum and carries a \$4,000 loan origination fee which is accreted to the loan balance throughout the life of the loan. The loan under the note was funded to the Company on July 12, 2010. This note matured and became callable on December 31, 2010. To date, Dr. Quay has not demanded repayment of this note.

## **Exclusive License Agreement**

On July 27, 2009, the Company entered into an exclusive license agreement with Ensisheim Partners LLC ("Ensisheim"), an entity solely owned by the Chairman and Chief Executive Officer of the Company and the Chief Technology Officer of the Company, who is also the Company's Chairman and CEO's wife. Pursuant to that agreement, Ensisheim granted the Company an exclusive, worldwide, perpetual, irrevocable, royalty-bearing, license to the MASCT System, with the right to grant and authorize sublicenses. The license agreement provided that the Company would pay Ensisheim a royalty equal to 2% of net sales revenues, with a minimum royalty of \$12,500 per fiscal quarter during the term of the agreement, which would have increased to a minimum royalty of \$25,000 per fiscal quarter beginning in the quarter in which the first commercial sale of a licensed product would have taken place. As of December 31, 2009, a total of \$12,500 was payable to Ensisheim under the minimum royalty provisions. From inception through September 30, 2010, the Company had incurred \$16,250 in patent-related expenses under the license agreement with Ensisheim.

On June 17, 2010, the Company and Ensisheim entered into an Assignment Agreement, whereby Ensisheim assigned to the Company all rights to the patents and patent applications underlying the MASCT System. Pursuant to the assignment, the Company will have all responsibility for prosecution, maintenance, and enforcement and will indemnify Ensisheim from any and all claims against the patent estate. Ensisheim retained no residual rights with respect to the patents and patent applications. In conjunction with the assignment, the Company terminated the exclusive license agreement between the Company and Ensisheim dated July 27, 2009. As a result of the termination, the Company has no further obligations with respect to royalty payments to Ensisheim due under the old licensing agreement. As a result, the \$12,500 of patent royalty payable to Ensisheim recorded as accrued royalty payable at December 31, 2009 has been reversed through royalty expense during the second quarter of 2010.

## Commercial Lease Agreement

On December 24, 2009, the Company entered into a commercial lease agreement with Ensisheim for office space located in Seattle, Washington. The lease provided for annual rent of \$13,200, plus applicable sales tax. From inception through December 31, 2009, the Company incurred \$248 of rent expense for the lease. As of December 31, 2009, security deposit for the lease amounted to \$1,100. For the period of January 1, 2010 through June 30, 2010, the Company incurred \$6,600 of rent expense for the lease. On July 15, 2010 the Company and Ensisheim terminated the lease, effective July 1, 2010 and the Company commenced use of the facility rent free.

On September 29, 2010, the Company entered into a commercial lease agreement with CompleGen, Inc. for laboratory space located in Seattle, Washington. The lease provides for monthly rent of \$3,657.05 and a security deposit of \$3,657.50. The lease terms are from September 29, 2010 through March 31, 2011, at which time the lease will convert to month to month unless two months written notice of the intent to terminate the agreement is given prior.

# **Executive Compensation**

On May 19, 2010, the Company entered into employment agreements with three executives, including its Chief Executive Officer, its former President, and its Chief Technology Officer. The annual base salaries under each agreement were calculated based on combined consideration of the success of capital raise and the operating results of the Company, and capped at \$360,000, \$350,000, and \$250,000, respectively for the three executives.

On July 22, 2010, in connection with the resignation and departure of Robert L. Kelly, the President and a director, the Company entered into a consulting agreement with a limited liability company controlled by Mr. Kelly. Under the agreement, the Company was to receive consulting services relating to capital raising and investor relations. The agreement was terminated by the Company in September 2010, through which time a total of \$30,000 consulting expense had been paid.

On July 22, 2010, the Company restated and amended the employment agreements with its CEO and CTO. The agreements modified the base annual salary amounts to \$250,000 and \$200,000, respectively, effective retroactively to May 19, 2010. These salaries were accrued and amounted to \$166,071 as of September 30, 2010.

## **Share-Based Compensation**

The amended employment agreement with the CEO granted options to purchase 250,000 shares (or 565,830 shares prior to the reverse stock-split on September 28, 2010) at a price of \$5.00 per share, in consideration of their services to the Company. Of these options, 25% (or 62,500 shares) will vest on December 31, 2010 with the remaining 75% (or 187,500 shares) will vest in equal quarterly installments over the next three years so long as the executives remain employed with the company.

The amended employment agreement with the CTO granted options to purchase 100,000 shares (or 226,332 shares prior to the reverse stock-split on September 28, 2010) at a price of \$5.00 per share in consideration of their services to the Company. Of these options, 25% (or 25,000 shares) will vest on December 31, 2010 with the remaining 75% (or 75,000 shares) will vest in equal quarterly installments over the next three years so long as the executives remain employed with the company.

In accordance with the guidance provided in ASC Topic 718, Stock Compensation (formerly SFAS 123R), the compensation costs associated with these options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized a compensation expense of \$13,045 for the nine-month period ended September 30, 2010.

The Company estimates the fair value of these options using the Black-Scholes-Merton option pricing model based on the following weighted-average assumptions:

Date of grant	July 22, 2010	)
Fair value of common stock on date of grant	\$ 2.756	;
Exercise price of the options	\$ 5.00	)
Expected life of the options (years)	3.33	}
Dividend yield	-	
Expected volatility	58.59	)%
Risk-free interest rate	1.03	3%
Weighted-average fair value of the options (per unit)	\$ 0.6744	ļ

Management determined that it is not possible to reasonably estimate the grant-date fair value of the options because the Company's stock had not been publicly traded as of the date of grant. Accordingly, as required by ASC 718-10-30, the Company has accounted for the options using the calculated value method. The Company identified seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the options.

Options issued and outstanding as of September 30, 2010 and their activities during the period are as follows:

	Number of Underlying Shares	Exe	/eighted- Average rcise Price er Share	Weighted- Average Contractual Life Remaining in Years
Outstanding as of January 1, 2010	-		-	
Granted	350,000	\$	5.00	
Expired	-		-	
Forfeited	-		-	
Outstanding as of September 30, 2010	350,000	\$	5.00	3.25
Exercisable as of September 30, 2010	-		-	-

# NOTE 8: SUBSEQUENT EVENTS

On November 3, 2010, the Company issued a promissory note to its Chairman of the Board and Chief Executive Officer in connection with a \$500,000 line of credit extended to the Company by the officer. Pursuant to the terms of the note, all principal amounts borrowed under the line of credit bear interest at a rate of 10% per annum, and all principal and accrued interest will be due and payable in full on December 31, 2011. As of January 31, 2011, the Company has borrowed \$80,000 under the line of credit.

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Atossa Genetics, Inc.:

We have audited the accompanying balance sheet of Atossa Genetics, Inc. (a development stage company) (the "Company") as of December 31, 2009, and the related statement of operations, changes in stockholders' equity, and cash flows for the period from April 30, 2009 (inception) through December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Atossa Genetics, Inc. (a development stage company) as of December 31, 2009 and the results of their operations and their cash flows for the period from April 30, 2009 (inception) through December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 of the financial statements, the Company has been in the development stage since its inception (April 30, 2009) and continues to incur expenses. The Company's viability is dependent upon its ability to obtain future financing and the success of its future operations. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plan in regard to these matters is also described in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KCCW Accountancy Corp.

Diamond Bar, California February 20, 2010

## ATOSSA GENETICS, INC. (A DEVELOPMENT STAGE COMPANY) BALANCE SHEET December 31, 2009

<u>Assets</u>		
Current Assets	Φ.	0.4.00.4
Cash and cash equivalents	\$	84,364
Total Current Assets		84,364
Other Assets		
Security deposit - related parties		1,100
Total Other Assets		1,100
Total Assets	\$	85,464
Liabilities and Stockholders' Equity		
<u> </u>		
Current Liabilities		
Accrued expenses	\$	36,281
Accrued expenses - related parties		12,500
Loan from officer		5,000
Total Current Liabilities		53,781
Stockholders' Equity		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, 0 shares		
issued and outstanding		-
Common stock - \$.001 par value; 75,000,000 shares authorized,		4.000
4,899,882 shares issued and outstanding		4,900
Additional paid-in capital  Accumulated deficit		149,640
		(122,857)
Total Stockholders' Equity	_	31,683
Total Liabilities and Stockholders' Equity	\$	85,464
The accompanying notes are an integral part of financial statements.		
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# ATOSSA GENETICS, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENT OF OPERATIONS

# From April 30, 2009 (Inception) through December 31, 2009

Net Revenue	\$ -
General and Administrative Expenses	
Legal and professional expenses	88,522
Other general and administrative expenses	13,085
Total general, selling and administrative expenses	101,607
Research and Development Expenses	21,250
Net Loss before Income Taxes	(122,857)
Income Tax Expense	
Net Loss	<u>\$ (122,857)</u>
Loss per common share - basic and diluted	\$ (0.03)
Weighted average shares outstanding, basic and diluted	4,037,847

The accompanying notes are an integral part of financial statements.

# ATOSSA GENETICS, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock		Additional				Total		
	Shares		Amount	_	Paid-in Capital	A	ccumulated Deficit	St	ockholders' Equity
Balance at April 30, 2009, Founders' shares	3,976,459	\$	3,976	\$	50,024	\$	-	\$	54,000
Issuance of shares for cash, July 28, 2009	39,765		40		500		-		540
Issuance of shares for cash, December 28, 2009	883,658		884		99,116		-		100,000
Net loss for the period ended December 31, 2009	-		-		-		(122,857)		(122,857)
Balance at December 31, 2009	4,899,882	\$	4,900	\$	149,640	\$	(122,857)	\$	31,683

The accompanying notes are an integral part of financial statements.

# ATOSSA GENETICS, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENT OF CASH FLOWS

# From April 30, 2009 (Inception) through December 31, 2009

\$	(122,857)
	(1,100)
	48,781
	(75,176)
	154,540
	5,000
	159,540
	84,364
	-
ф	04.004
\$	84,364
\$	<u>-</u> _
\$	
	\$ \$ \$ \$

#### NOTE 1: NATURE OF OPERATIONS

Atossa Genetics, Inc., (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company specializes in the molecular diagnostic industry to develop and market a patented, FDA-approved cellular and molecular diagnostic risk assessment product for breast cancer, the Mammary Aspirate Cytology Specimen Test (MASCT) system. The Company's fiscal year ends on December 31 st ...

#### **Development Stage Risk**

The Company has not earned revenues from operations. Accordingly, the Company's activities have been accounted for as those of a "Development Stage Enterprise" as set forth in Accounting Standards Codification ("ASC") 915 "Development Stage Entities", which was previously Statement of Financial Accounting Standards No. 7 ("SFAS 7"). Among the disclosures required by ASC 915 are that the Company's financial statements be identified as those of a development stage company, and that the statements of operations, stockholders' equity and cash flows disclose activity since the date of the Company's inception.

Since its inception, the Company has been dependent upon the receipt of capital investment to fund its continuing activities. In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's business plan will be successfully executed. Our ability to execute our business plan will depend on our ability to obtain additional financing and achieve a profitable level of operations. There can be no assurance that sufficient financing will be obtained. Further, we cannot give any assurance that we will generate substantial revenues or that our business operations will prove to be profitable.

#### **NOTE 2: GOING CONCERN**

The Company's financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

### Management's Plan to Continue as a Going Concern

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management's plans to obtain such resources for the Company include (1) obtaining capital from the sale of its securities, (2) the sale of the MASCT Systems, and (3) short-term borrowings from shareholders or related party when needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

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

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

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

The accompanying financial statements have been prepared by the Company. The Company's financial statements are prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP").

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

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

#### **Use of Estimates:**

The preparation of financial statements in conformity with generally accepted accounting principles in the Unites States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

#### **Research and Development Expenses:**

Research and Development costs are generally expensed as incurred. The Company's Research and Development expenses consist of costs incurred for internal and external research and development.

#### **Share Based Payments:**

In December, 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment", which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in ASC 718 "Compensation – Stock Compensation". Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees or independent contractors are required to provide services. Share-based compensation arrangements include stock options and warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March, 2005, the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107") which expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for SFAS No. 123(R). Companies may elect to apply this statement either prospectively, or on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123.

The Company has fully adopted the provisions of SFAS No. 123(R) and related interpretations as provided by SAB 107. As such, compensation cost is measured on the date of grant as the fair value of the share-based payments. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

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

The Company has adopted all recently issued accounting pronouncements. The adoption of the accounting pronouncements, including those not yet effective, is not anticipated to have a material effect on the financial position or results of operations of the Company.

### **NOTE 4: STOCKHOLDERS' EQUITY**

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of Common Stock, par value \$.001 per share, and 10,000,000 shares of Preferred Stock, par value \$.001 per share.

On April 30, 2009 (inception), the Company issued 1,767,315 shares (or 4,000,000 before giving effect to the September 2010 reverse stock split) to Ensisheim Partners LLC, a related party to the Company through common ownership, for cash in the amount of \$24,000, or \$.014 per share (or \$.006 per share before giving effect to the September 2010 reverse stock split); 1,325,487 shares (or 3,000,000 shares before giving effect to the September 2010 reverse stock split) to Manistee Ventures LLC, a related party to the Company through common ownership, for cash in the amount of \$18,000, or \$.014 per share (or \$.006 per share before giving effect to the September 2010 reverse stock split); and 883,658 shares (or 2,000,000 shares before giving effect to the September 2010 reverse stock split) to the Chairman, CEO and President of the Company at that time for cash in the amount of \$12,000, or \$.014 per share (or \$.006 per share before giving effect to the September 2010 reverse stock split).

On July 28, 2009, the Company issued 39,765 shares (or 90,000 shares before giving effect to the September 2010 reverse stock split) to a director of the Company for cash in the amount of \$540, or \$.014 per share (or \$.006 per share before giving effect to the September 2010 reverse stock split).

On December 28, 2009, the Company issued 883,658 shares (or 2,000,000 shares before giving effect to the September 2010 reverse stock split) to Ensisheim Partners LLC for cash in the amount of \$100,000, or \$.11 per share (or \$.05 per share before giving effect to the September 2010 reverse stock split).

#### **NOTE 5: INCOME TAXES**

The Company accounts for income taxes as outlined in ASC 740, "Income Taxes", which was previously Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS 109"). Under the asset and liability method of SFAS 109, deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

The provision for income taxes differs from the amounts which would be provided by applying the statutory federal income tax rate of 34% to the net loss before provision for income taxes for the following reasons:

	De	ecember 31, 2009
Income tax benefit at statutory rate (34%)	\$	(46,871)
Valuation allowance		46,871
Net income tax benefit	\$	-

The tax effect of temporary difference that gave rise to the Company's deferred tax asset as of December 31, 2009 is as follows:

	December 31,
	2009
NOL carryover	\$ 46,871
Valuation allowance	(46,871)
Net deferred tax asset	\$ -

#### NOTE 6: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. At December 31, 2009, the Company had no amounts in excess of FDIC insured limit.

### NOTE 7: RELATED PARTY TRANSACTIONS

The parties primarily refer to the shareholders and officers of the Company and corporate entities related to the Company through common ownership.

# Loan from Officer

Loan from officer amounted to \$5,000 as of December 31, 2009. The loan was borrowed from the CEO and President of the Company on May 26, 2009 for short-term with verbal agreement, unsecured, and bearing no interest.

### **Exclusive License Agreement**

On July 27, 2009, the Company entered into an exclusive license agreement with Ensisheim Partners LLC ("Ensisheim"), solely owned by the CEO and President of the Company and the COO of the Company, the Company's CEO's wife. Pursuant to the agreement, Ensisheim grants to the Company an exclusive, worldwide, perpetual, irrevocable, royalty-bearing, license, with the right to grant and authorize sublicenses. The Company will pay Ensisheim a royalty equal to two percent (2%) of net sales revenues derived from such licensing, with a minimum royalty of \$12,500 per fiscal quarter during the term of this agreement, which will increase to a minimum royalty of \$25,000 per fiscal quarter beginning in the quarter in which the first commercial sale of a licensed product takes place. This agreement will continue in effect, on a country-by-country basis, until the date on which no further licensing royalty would be due in such country, unless terminated earlier in accordance with the terms of this agreement. From inception through December 31, 2009, the Company incurred \$16,250 of patent royalty with Ensisheim which was recorded as research and development expense. As of December 31, 2009, \$12,500 of patent royalty payable to Ensisheim was recorded as accrued expense whereas \$4,000 was paid during the period from inception through December 31, 2009.

#### Commercial Lease Agreement

On December 24, 2009, the Company entered into a commercial lease agreement with Ensisheim for an office space located in Seattle, Washington. The term of the lease shall terminate on December 31, 2010, with annual rent of \$13,200 plus applicable sales tax. From inception through December 31, 2009, the Company incurred \$248 of rent expense for the lease. As of December 31, 2009, security deposit for the lease amounted to \$1,100.

#### **NOTE 8: SUBSEQUENT EVENTS**

On January 21, 2010, the Company issued 865,984 shares (or 1,960,000 shares before giving effect to the September 2010 reverse stock split) to forty-four (44) investors for cash in the amount of \$98,000, or \$0.11 per share (or \$.05 per share before giving effect to the September 2010 reverse stock split).

On January 21, 2010, the Company issued 132,549 shares (or 300,000 shares before giving effect to the September 2010 reverse stock split) to a service provider for effecting transactions intended to cause the Company to become a public company and to have its securities traded on a national exchange in the United States. The shares were issued at a value of \$15,000, or \$0.11 per share (or \$.05 per share before giving effect to the September 2010 reverse stock split), the same price as the 865,984 shares (or 1,960,000 shares before giving effect to the September 2010 reverse stock split) issued for cash on the same date.

On January 21, 2010, the Company issued an additional 53,019 shares (or 120,000 shares before giving effect to the September 2010 reverse stock split) to a shareholder who acquired 13,255 shares (or 30,000 shares before giving effect to the September 2010 reverse stock split) for cash on the same date as one of the forty-four (44) investors. Those shares were issued to the shareholder for services to be performed, including investor relations, media relations, and corporate communications. Those shares were issued at a value of \$6,000, or \$0.11 per share (or \$.05 per share before giving effect to the September 2010 reverse stock split), the same price as the issuance of the 865,984 shares (or 1,960,000 shares before giving effect to the September 2010 reverse stock split) for cash on the same date.

On January 23, 2010, the Company issued 35,346 shares (or 80,000 shares before giving effect to the September 2010 reverse stock split) to an investor for cash in the amount of \$4,000, or \$0.11 per share (or \$.05 per share before giving effect to the September 2010 reverse stock split).



tossa genetics, inc.
3,000,000 Units
PROSPECTUS
DAWSON JAMES SECURITIES, INC.
Until, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

#### PART II

#### Item 13. Other Expenses of Issuance and Distribution

The expenses (other than underwriting discounts and commissions) payable by us in connection with this offering are as follows:

	A	mount
SEC registration fee	\$	1,255
Financial Industry Regulatory Authority, Inc. fee		3,000
NYSE Amex listing fee		*
Accountants' fees and expenses		*
Legal fees and expenses		250,000
Transfer Agent's fees and expenses		25,000
Printing and engraving expenses		*
Miscellaneous		*
Total Expenses	\$	*

to be completed by amendment

All expenses are estimated except for the SEC registration fee and the Financial Industry Regulatory Authority, Inc. fee.

#### Item 14. Indemnification of Directors and Officers

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

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

- · any breach of the director's duty of loyalty to us or our stockholders;
- · any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- · any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- $\cdot$  any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws to be in effect at the completion of this offering will provide that:

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

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

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

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Exchange Act.

## Item 15. Recent Sales of Unregistered Securities

The Company has sold the following securities within the past three years which were not registered under the Securities Act of 1933:

Pursuant to an exemption from registration under Section 4(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering as founder shares in connection with the formation of the Company, the Company issued 4,899,884 shares of its common stock as follows:

	Shares	Date		sideration
Steven Quay	883,658	April 30, 2009	\$	12,000
Ensisheim Partners LLC	1,767,316	April 30, 2009		(1)
Ensisheim Partners LLC	883,658	December 28, 2009	\$	100,000
Manistee Ventures, Inc.	1,325,487	April 30, 2009	\$	18,000
John Barnhart	39,765	July 28, 2009	\$	540

(1) The 1,767,316 shares of common stock issued to Ensisheim Partners LLC at the Company's inception were issued in consideration for \$24,000 in cash and this entity's contribution to the Company of intellectual property rights and FDA marketing authorization for the MASCT System.

In January 2010, pursuant to an exemption from registration under Rule 504 pursuant to the Securities Act of 1933 (the "Securities Act"), the Company issued an aggregate of 901,354 shares of its common stock to 45 investors for aggregate cash proceeds of \$102,000. Of these 45 investors, 13 are accredited investors and 4 are citizens and residents of Taiwan, Republic of China.

In January 2010, the Company issued 185,569 shares in consideration for services performed by two consultants, with an aggregate value of \$21,000. This offering was exempt from registration under Rule 504 under the Securities Act.

On April 23, 2010, the Company issued 13,256 shares of common stock for services performed by a consultant with an aggregate value of \$50,000. This offering was exempt from registration under Section 4(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

# Item 16. Exhibits and Financial Statement Schedules.

# **EXHIBITS**

1.1*	Form of Underwriting Agreement
3.1+	Certificate of Incorporation, as currently in effect
3.2+	Certificate of Incorporation (to be effective immediately prior to completion of this offering)
3.3+	By-laws, as currently in effect
3.4+	By-laws (to be effective immediately prior to completion of this offering)
4.1*	Specimen common stock certificate
4.2*	Form of Warrant Agent Agreement
4.3*	Form of Class A Warrant Certificate
4.4*	Form of Class B Warrant Certificate
4.5*	Form of Class C Warrant Certificate
4.6*	Form of Unit Certificate
5.1*	Opinion of Goodwin Procter LLP
10.1+	License Agreement with Ensisheim Partners, LLC
10.2+	Termination of Exclusive Patent License Agreement, dated June 17, 2010
10.3#+	Amended and Restated Employment Agreement with Steven Quay
10.4#+	Amended and Restated Employment Agreement with Shu-Chih Chen
10.5*	Form of Indemnification Agreement
10.6#+	2010 Stock Option and Incentive Plan
10.7*#	Form of Incentive Stock Option Agreement
10.8*#	Form of Non-Qualified Stock Option Agreement for Employees
10.9*#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors
10.10+	Form of Subscription Agreement
10.11+	Promissory Note issued by the Company to Steven Quay on January 2, 2010.
10.12+	Promissory Note issued by the Company to Steven Quay on June 30, 2010.
10.13+	Sublease Agreement with CompleGen, Inc, dated September 29, 2010
10.14*	Patent Assignment Agreement by and between Atossa Genetics, Inc. and Ensisheim Partners, LLC
10.15*#	Form of Restricted Stock Award Agreement
10.16+	Form of Lock-Up Agreement
10.17+	Consulting Agreement with Christopher Benjamin
10.18	Consulting Agreement with Edward Sauter
10.19+	Promissory Note – Line of Credit issued by the Company to Steven Quay on November 3, 2010.
10.20+	Prototype Development Proposal and Terms and Conditions, dated July 22, 2010, between the Company and HLB, LLC.
23.1	Consent of KCCW Accountancy Corp.
23.2*	Consent of Goodwin Procter LLP (filed as part of Exhibit 5.1)
24.1+	Power of Attorney (contained on signature page)
99.1	Reserved.
99.2+	Consent of Prospective Director Stephen Galli, M.D.
99.3+	Consent of Prospective Director Alexander Cross, Ph.D.

+ Previously filed.

\* To be filed by amendment.

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

### Item 17. Undertakings

Request for acceleration of effective date or filing of registration statement becoming effective upon filing,

The undersigned registrant hereby undertakes:

- 1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

# **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 4 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Seattle, State of Washington, on February 4, 2011.

ATOSSA GENETICS INC.

By: /s/ Steven C. Quay

Name: Steven C. Quay, M.D., Ph.D. Title: President and Chief Executive Officer

# **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 3 to Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Capacity	Date
President, Chief Executive Officer and Chairman of the Board of Directors	February 4, 2011
(Principal Executive Officer)	
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 4, 2011
Director	February 4, 2011
Director	February 4, 2011
	February 4, 2011
II-5	
	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)  Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)  Director

### Exhibit 23.1

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 4 to the Registration Statement on Form S-1 of Atossa Genetics Inc. (a development stage company) of our report dated February 20, 2010 relating to the financial statements as of December 31, 2009 and for the period from April 30, 2009 (date of inception) to December 31, 2009 appearing in the Prospectus, which is part of this Registration Statement. We also consent to the reference to us under the heading "Experts" in such Prospectus.

/s/ KCCW Accountancy Corp.

Diamond Bar, California February 4, 2011