HONORABLE RICARDO S. MARTINEZ

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

IN RE ATOSSA GENETICS, INC. SECURITIES LITIGATION	**CASE NO: C13-1836-RSM** **AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs Miko Levi, Bandar Almosa, and Gregory Harrison ("Lead Plaintiffs") and Nicholas Cook (together with Lead Plaintiffs, "Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their Amended Complaint against Defendants, allege the following based upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Atossa Genetics, Inc. ("Atossa" or the "Company"), analysts' reports

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and advisories about the Company, and information readily obtainable on the Internet.[1] Plaintiffs believe that further evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants, who purchased or otherwise acquired Atossa shares between November 8, 2012 and October 4, 2013, both dates inclusive (the "Class Period"), and/or who acquired Atossa shares pursuant or traceable to Atossa's Registration Statement and Prospectus in connection with its November 8, 2012 initial public offering ("IPO"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under §§ 11 and 15 of the Securities Act of 1933 ("1933 Act"), and under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Defendants misrepresented that its sole product, the ForeCYTE Breast Health Test ("ForeCYTE Test"), had received all required clearances from the FDA for sale to the public, prior to its public offering of common stock on November 8, 2012. In fact, the ForeCYTE Test *had not* received the required FDA clearances. The FDA informed Defendants that ForeCYTE Test was not fully cleared by the FDA for sale to the public in a site meeting in July 2012 and throughout the Class Period. Defendants, however, misrepresented this information to its investors. On October 4, 2013, Atossa

[1] In addition, Plaintiffs' counsel has requested documents and information directly relevant to the allegations in this Complaint from the U.S. Food and Drug Administration ("FDA") pursuant to the Freedom of Information Act, 5 U.S.C. § 522, *et. seq*. The FDA's responses to these requests are still pending as of the date of this filing.

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acknowledged it did not possess the required FDA clearance to sell the ForeCYTE Test. Since that time, Atossa has generated *zero* revenue as public company as it cannot sell its only product or generate revenue from testing from its only product: the ForeCYTE Test.

INTRODUCTION

3. Atossa is a healthcare company that focuses on the development and marketing of cellular and molecular diagnostic risk assessment products for the detection of pre-cancerous conditions that could lead to breast cancer in the United States.

4. Atossa's only commercial product and sole revenue source is the ForeCYTE Test, which is a diagnostic test that purports to provide women with information regarding their individual risk of breast cancer. The ForeCYTE Test involves extracting and testing a specimen of nipple aspirate fluid ("NAF") from the breast milk duct, which is collected using Atossa's Mammary Aspirate Specimen Cytology Test ("MASCT") System – a patented breast pump (the "MASCT Device") and patient collection kit. Throughout Atossa's history, its operations have focused on the development of the MASCT System and the ForeCYTE Test, of which it is a part.

5. Indeed, prior to and during the Class Period, the success of the ForeCYTE Test was critical to Atossa's future. In 2010 and 2011 – prior to the marketing of the ForeCYTE Test – the Company generated total revenues of only $1,500. Indicative of its precarious financial predicament, after a failed attempt at a public offering in 2011, Atossa had merely $87,997 in cash and cash equivalents on hand to fund its operations in mid-2012 (just prior to the Class Period).

6. By the end of 2012, however, – after the initial, commercial rollout of the ForeCYTE Test – Atossa had generated $481,842 in total revenues, 98% ($475,402) of

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which came from the ForeCYTE Test, with the remaining 2% ($6,440) coming from sales of the related MASCT System.

7. Despite the revenue from the rollout of the ForeCYTE Test, Atossa remained in dire need of funding to stay afloat. The Company made another attempt at a public offering in November 2012 – this time touting the purported efficacy and huge commercial potential of its new ForeCYTE Test, which it claimed was FDA-cleared.

8. In the Offering Documents and throughout the Class Period, Atossa issued a series of false and misleading statements regarding the ForeCYTE Test, claiming that it and the MASCT System incorporated therein were "FDA-cleared" for breast cancer screening and equating the ForeCYTE Test with mammograms and Pap smears which are widely used for cancer screening. Defendants claimed that if the ForeCyte Test could gain market acceptance equal to that of mammograms or Pap smears, Atossa could reach a market of between 39.3 million and 55 million women per year in the United States alone. For example, as stated by Defendant Steven C. Quay, the Company's Chairman, President and Chief Executive Officer:

> The ForeCYTE Test . . . is literally a Pap smear for breast cancer. As you may know, the Pap smear is a test for cervical cancer and takes a small scraping from the cervix and looks at the changes under the microscope and can see pre-cancer changes up to 10-years before cervical cancer appears. That test is the most successful screening test in all of medicine . . . .
>
> * * *
>
> We've never had the opportunity for that kind of test with the breast until now, and we're really excited to be able to offer a similar test for breast health . . . . [The ForeCYTE Test] has gone through all the FDA clearance process, which is a multi-year, multi-million dollar process.[2]

[2] April Cashin-Garbutt, "Breast Cancer Tests: an Interview with Dr. Steven Quay, CEO of Atossa Genetics," *NewsMedical* (February 22, 2013); found at http://www.news-medical.net/news/20130222/Breast-cancer-tests-an-interview-with-Dr-Steven-Quay-CEO-of-Atossa-Genetics.aspx

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9. However, the diagnostic feature of the ForeCYTE Test and the MASCT System (which is a component of the ForeCYTE Test), had never been cleared by the FDA for any purpose, much less breast cancer screening and diagnosis. FDA clearance is mandatory before any device such as this can be marketed to doctors or patients. Indeed, there was no valid scientific data to show that ForeCYTE Test was an effective screening tool for any medical condition, including the detection of breast cancer or other breast disease.

10. Furthermore, Defendants knew prior to the Class Period that the ForeCYTE Test and MASCT System faced a significant risk of recall because these devices had not been FDA-cleared and were being illegally marketed. A July 2012 inspection report issued by the FDA following an inspection of Atossa's manufacturing facility warned the Company that neither product had been approved or cleared by the FDA as "safe and effective" and that the Company was in violation of numerous regulations for, among other things, its "misbranding" and illegal marketing of these "adulterated" products.

11. Although the Company learned of the significant likelihood of an FDA recall as early as July 2012, the market only began to get an inkling of the truth on February 25, 2013, when Atossa disclosed that on February 21, 2013, it had received a warning letter from the FDA regarding its MASCT System and the ForeCYTE Test. The Company, however, downplayed the significance of the warning letter, asserting that the primary concern of the FDA was simply a technical issue arising from a minor change to the MASCT System, which could be easily remedied. The Company misled the market by misrepresenting the seriousness of the FDA's findings regarding the Company's

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material alterations to the MASCT System which made it non-compliant with FDA regulations, and the Company's blatant violations of mandatory good manufacturing practices. In addition the Company misled the public regarding serious findings of illegal marketing of the ForeCYTE Test by dismissively describing these findings as raising "certain issues with respect to the Company's marketing of the System."

12. On this news, Atossa shares declined $0.3869 per share or nearly 5.6%, to close at $6.54 per share on February 25, 2013.

13. Over the next several months, the Company continued to publicly claim that the ForeCYTE Test was FDA-compliant, and proclaimed the great commercial potential of the ForeCYTE Test, and heralded smooth sailing through announcements of marketing and distribution agreements to sell the ForeCYTE Test and its components. Based on these representations, Atossa's stock price soared to $12.37.

14. Meanwhile, unbeknownst to investors and despite its repeated assurances that its products were in full compliance with FDA standard, the Company submitted an application for FDA clearance of the ForeCYTE Test, which it later withdrew from consideration after receiving a response from the FDA which indicated that the FDA would not likely provide clearance. The Company disclosed none of these facts to the market.

15. Investors were thus shocked when the Company announced, after the markets closed on October 4, 2013, that the FDA had not only rejected the Company's response to the February 2013 Warning Letter as sufficiently deficient, but had compelled a recall of all the ForeCYTE Test products sold to date. At that time, the Company admitted for the first time:

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> The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, ***the ForeCYTE [Test] has not been cleared or approved by the FDA for any indication***. The ForeCYTE [Test] and the MASCT device are not a replacement for screening mammograms, diagnostic imaging tests, or biopsies.

16. The FDA classified this recall as Class I, which means that the product is "dangerous or defective and has a reasonable chance of causing serious health problems or death."

17. On this news, Atossa shares declined $2.47 per share, or more than 46%, to close at $2.85 per share on October 7, 2013.

18. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock, Plaintiffs and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

19. The claims asserted herein arise under and pursuant to §§11 and 15 of the 1933 Act [15 U.S.C. §§77k and 77o], and §§10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. §240.10b-5].

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, §22 of the 1933 Act, and §27 of the Exchange Act.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because Defendants maintain their principal office in this District, and many of the acts and omissions complained of herein occurred in substantial part in this District.

22. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of

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interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange.

PARTIES

23. Lead Plaintiffs, as set forth in their previously-filed Certifications (Dkt. #8-2), purchased Atossa shares at artificially inflated prices during the Class Period and have been damaged upon the issuance of the alleged corrective disclosures.

24. Plaintiff Nicholas Cook, as set forth in his previously-filed Certification (Dkt. #1), purchased Atossa shares at artificially inflated prices during the Class Period and has been damaged upon the issuance of the alleged corrective disclosures.

25. Defendant Atossa is a Delaware corporation with principal executive offices located at 4105 East Madison Street, Suite 320, Seattle, Washington 98112. Atossa's common stock trades on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "ATOS."

26. Defendant Christopher Benjamin ("Benjamin") was the interim Chief Financial Officer of Atossa through January 3, 2013. Benjamin signed the false and misleading Registration Statements.

27. Defendant Kyle Guse ("Guse") has been the Company's Chief Financial Officer, General Counsel and Secretary at Atossa since January 4, 2013. Guse has over 20-years' experience counseling life science and other rapid growth companies through all aspects of finance, corporate governance, securities laws and commercialization.

28. Defendant Steven C. Quay ("Quay") is, and was at all relevant times, the Chairman, President, and Chief Executive Officer of Atossa. Quay oversaw the clinical

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testing and regulatory filing of the MASCT device with the FDA. Quay signed the false and misleading Registration Statements.

29. Quay, Guse and Benjamin are named as Defendants for violations of all Counts asserted herein, including violations of §§11 and 15 of the 1933 Act and §§10(b), 20(a) and Rule 10b-5 of the 1934 Act. Quay, Guse and Benjamin are sometimes referred to as the "Management Defendants."

30. Defendant Shu-Chih Chen ("Chen") serves as a director and Chief Scientific Officer of Atossa. Prior to joining Atossa, Chen served as President of Ensisheim Partners, LLC beginning in 2008 and was founder and President of SC2Q Consulting Company from 2006 to 2008. Chen signed or authorized the signing of the false and misleading Registration Statements.

31. Defendant John Barnhart ("Barnhart") served as a director of Atossa and was a member of the Atossa Board's Audit Committee and Corporate and Nominating & Corporate Governance Committees during the relevant period. On January 31, 2014, Barnhart announced his retirement from Atossa's Board so that he could "pursue other personal and professional activities." Barnhart signed or authorized the signing of the false and misleading Registration Statements.

32. Defendant Stephen J. Galli ("Galli") has served as a director of Atossa since July 2011 and is a member of the Atossa Board's Compensation Committee and Nominating & Corporate Governance Committees. Galli signed or authorized the signing of the false and misleading Registration Statements.

33. Defendant Alexander D. Cross ("Cross") served as a director of Atossa during the relevant period. Cross has also been an Independent Consultant in the fields of

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pharmaceuticals and biotechnology since January 1986. On December 18, 2013, Cross announced his retirement from the Atossa Board so that he "could pursue other personal and professional activities." Cross signed or authorized the signing of the false and misleading Registration Statements.

34. Defendant H. Lawrence Remmel ("Remmel") serves as a director of Atossa since February 2012. Remmel is a member of the Atossa Board's Audit and Nominating & Corporate Governance Committees. Remmel signed or authorized the signing of the false and misleading Registration Statements.

35. Defendants Chen, Barnhart, Galli, Cross and Remmel are named as Defendants for violations of §§11 and 15 of the 1933 Act.

Underwriter Defendants

36. Defendant Dawson James Securities, Inc. ("Dawson") was an underwriter of the Company's IPO and assisted in the preparation and dissemination of Atossa's IPO materials.

37. Defendant ViewTrade Securities, Inc. ("ViewTrade") was an underwriter of the Company's IPO and assisted in the preparation and dissemination of Atossa's IPO materials.

38. Defendant Paulson Investment Company, Inc. ("Paulson") was an underwriter of the Company's IPO and assisted in the preparation and dissemination of Atossa's IPO materials.

39. The Defendants named in ¶¶ 36–38 above are sometimes referred to herein as the "Underwriter Defendants" and are named as Defendants for violations of §§11 of the 1933 Act.

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SUBSTANTIVE ALLEGATIONS

A. BACKGROUND

1. The FDA's Regulatory Regime for the Clearance and Marketing of Medical Devices

40. The Food, Drug and Cosmetic Act (the "FDCA") and the U.S. Food and Drug Administration ("FDA") play a major role in ensuring that only medical devices cleared by the FDA as safe and effective are marketed to patients. Products classified as Class I and Class II devices are eligible for marketing through what is known as "premarket notification" or 510(k). Section 510(k) of the FDCA requires device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance. Medical device manufacturers are required to submit a 510(k) premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that has been significantly changed or modified to the extent that its safety or effectiveness could be affected.

41. To obtain 510(k) clearance for a medical device, an applicant must submit a 510(k) premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device legally marketed in the United States. A showing of substantial equivalence sometimes, but not always, requires clinical data. A company cannot market or distribute its device until it is "FDA-cleared" – that is, the company receives a letter from the FDA authorizing the company to do so. A company may market a device only for the purposes specifically identified by the FDA in its "clearance" of the device.

2. The Founding of Atossa Genetics, Inc. and the Development of the ForeCYTE Test and MASCT System.

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42. Defendant Quay is no stranger to controversy in the biotech industry. Prior to founding Atossa, he was CEO of Washington-based Sonus Pharmaceuticals, Inc. ("Sonus") in the 1990s, and the Washington-based Nastech Pharmaceutical Co. (now MDRNA) for most of the last decade. Sonus flamed out under Quay's successor a couple years ago, and was later absorbed by OncoGenex Pharmaceuticals (NASDAQ: OGXI). MDRNA is still alive, but has limited cash reserves, and its stock is currently priced and under $1.00 per share. Quay left MDRNA in the fall of 2008 with a severance package worth $1.7 million.

43. Quay's latest endeavor, Atossa, is a healthcare company focused on the prevention of breast cancer through the commercialization of diagnostic medical devices and tests related to breast cancer. The Company's leading diagnostic test, the ForeCYTE Test, involves the collection and testing of a specimen of nipple aspirate fluid ("NAF"), which is collected from the breast milk ducts using the Company's Mammary Aspirate Specimen Cytology Test ("MASCT") System. The MASCT System consists of a reusable hand-held pump (the "MASCT Device") and a patient collection kit. An illustration of the ForeCYTE Test and MASCT System is provided below:

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44. The MASCT System is a Class II medical "device" as defined by the FDCA. As such, it is regulated by the FDA and requires FDA clearance pursuant to a 510(k) premarket notification before it may be marketed in the United States. Defendant Quay oversaw the clinical testing and regulatory filing of the MASCT device with the FDA.

45. The ForeCYTE Test includes the processing of NAF samples (collected with the MASCT System) by Atossa's laboratory, which constitutes a Class II in-vitro diagnostic testing service. In-vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. As a Class II in-vitro diagnostic test service, the ForeCYTE Test is regulated by the FDA and requires premarket notification 510(k) before commercialization in the United States.

46. Atossa was formed for the purpose of developing and marketing the MASCT System. The Company's operations began in December 2008 with the acquisition of the MASCT System patent rights and assignments, which was completed in January 2009. The Company was incorporated in Delaware on April 30, 2009. Since its inception, its operations have consisted primarily of securing manufacturing and distribution for the MASCT System.

47. Prior to Atossa's acquisition of the MASCT System's patent rights, in 2003 the MASCT System received FDA clearance pursuant to 510(k). At that time, the MASCT System was cleared by the FDA for use only as a sample collection device, with

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the provision that the fluid collected using this device can be used to determine and/or differentiate between normal, pre-cancerous, and cancerous cells. The MASCT System was not cleared by the FDA for the screening or diagnosis of breast cancer.

48. After initial attempts to market the MASCT System, the Company recognized that there are a number of other companies within the medical device industry that have products used in NAF collection that are similar, if not superior, to the MASCT System. In 2010, the Company generated zero revenue. In 2011, it generated only $1,500.

49. The Company's cash position had diminished to the point where the founders of the Company were unable to finance the Company at the level needed for growth. Seeking to raise capital through a public offering, the Company filed a registration statement on Form S-1 with the SEC in October 2010, which it was forced to withdraw in February 2011. The withdrawal of the registration statement further weakened the company's position.

50. In dire straits, the Company sought to capitalize on the MASCT System by adding a cancer screening feature, the ForeCYTE diagnostic test, and marketing all the features as a single medical system/device – the ForeCYTE Test. However, the Company never sought FDA clearance through submission of a 510(k) premarket notification for either the ForeCYTE diagnostic test or the combined system that was the ForeCYTE Test.

51. During this time, the Company also significantly altered the MASCT System. As originally cleared by the FDA, the NAF specimen was to be washed from the collection membrane with fixative solution into the collection vial. Following its

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alteration, the user was instructed to apply one spray of the fixative to the collection membrane, which fixes the NAF specimen to the filter paper rather than washing it into a collection vial.

52. This change to the MASCT System significantly impacted the safety and effectiveness of the device and required the Company to seek FDA clearance through submission of a new 510(k) premarket notification. The Company never made such a submission.

53. In December 2011, the Company began limited-marketing of the ForeCYTE Test to physicians, primarily obstetric-gynecologists, as well as breast health and mammography clinics, for use in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. The Company marketed the ForeCYTE Test, as well as the MASCT System, as "FDA-cleared".

54. As a result, in 2012, Atossa's revenues jumped to $481,842, 98% ($475,402) of which came from the ForeCYTE diagnostic testing services, with the remaining 2% ($6,440) coming from sales of the related MASCT System (the MASCT Device and patient collection kits). The ForeCYTE Test was the Company's sole source of revenues. Indeed, as the Company itself recognized, the MASCT System would not have any market at all without the analytical services Atossa provided in the form of the ForeCYTE diagnostic test.

55. With the new, apparently lucrative ForeCYTE Test, the Company attempted another public offering. On or about February 14, 2012, Atossa filed with the

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SEC a Form S-1 Registration Statement (the "S-1 Registration Statement"), beginning the process toward what would be the Company's initial public offering in November 2012.

56. The S-1 Registration Statement described the MASCT System as FDA-cleared *more than 25 times* within its text. A successful offering was critical to the continued existence of Atossa. The Company had merely $87,997 in cash and cash equivalents on hand to fund its operations prior to the public offering and had been unable to identify any other alternative source of funding should the public offering be unsuccessful again.

57. In short, the success of the public offering and the existence of the Company itself hinged on investors' confidence in the MASCT System and the ForeCYTE Test.

58. In July 2012, while the Company was in the process of finalizing the Registration Statement, the FDA inspected Atossa's facilities. The inspection lasted from July 16, 2012 through July 25, 2012.

59. During the inspection, the FDA determined that the MASCT System was "adulterated" under Section 501(h) of the FDCA, and violated the Current Good Manufacturing Practices ("cGMP") requirements of the Quality System regulation found under Title 21, Code of Federal Regulations (CFR), Part 820. The inspection revealed numerous additional violations, including but not limited to those of 21 CFR 803.17; 807.81(a)(3)(i); 820.20(c); 820.20(d); 820.22; 820.30(a); 820.30(i); 820.50(a); 820.100(a); 820.184; 820.198(e).

60. Specifically, the FDA discovered what the Company already knew – that after the MASCT System received 510(k) clearance in 2003, Atossa had made substantial

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modifications to the NAF specimen collection process. The FDA determined that this change could significantly affect its safety or effectiveness and required the submission of another 510(k) to the FDA demonstrating that the new process/device is safe and effective. Because Atossa had never submitted a request for approval of the changes, , the MASCT System that Atossa had been marketing and selling was (1) not FDA-cleared, (2)"adulterated" under section 501(f)(1)(B) of the FDCA, [21 U.S.C § 351(f)(1)(B)], (3) "misbranded" under section 502(o) of the FDCA, [21 U.S.C. § 352(o)], and (4) being marketed illegally by the Company.

61. The FDA also determined that the ForeCYTE Test required independent approval or clearance before marketing, which had never been sought.[3] Thus the ForeCYTE Test was misbranded under Section 502(a) of the FDCA [21 U.S.C. 352(a)] (and 21 CFR 807.97). In particular, the FDA charged that Atossa's marketing literature that represented the MASCT System and the ForeCTYE Test as "FDA-approved" and/or "FDA-cleared" for breast cancer screening and diagnosis was misleading and illegal.

62. Of course, Defendants were well aware that neither the MASCT System nor the ForeCYTE Test had been cleared by the FDA because Atossa had never submitted the required 510(k) notification for either.

63. The Defendants also knew that without the ForeCYTE Test – Atossa's only current and potential source of revenue – the upcoming public offering would fail to raise the funding that Atossa needed to continue.

[3] See *http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm374600.htm*

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B. DEFENDANTS' MATERIALLY UNTRUE AND MISLEADING STATEMENTS REGARDING THE INITIAL PUBLIC OFFERING

64. On or about February 14, 2012, Atossa filed with the SEC a Form S-1 Registration Statement ("S-1 Registration Statement") beginning the process toward what would be the Company's initial public offering in November 2012.

65. The S-1 Registration Statement described the MASCT System as FDA-cleared *more than 25 times* within its text.

66. The S-1 Registration Statement was signed by Defendants Quay, Benjamin, Barnhart, Cross, Chen, Galli and Remmel.

67. On or about November 6, 2012, Atossa filed with the SEC a Form S-1/A Registration Statement ("S-1/A Registration Statement"), which would later be utilized for the IPO, and which incorporated a prospectus to be used in connection with the offer and sale of Atossa shares. The S-1/A Registration Statement contained substantially similar representations regarding FDA clearance of the ForeCYTE Test and MASCT System as those identified above in ¶¶ 65-66.

68. The S-1/A Registration Statement was signed by Defendants Quay, Benjamin, Barnhart, Cross, Chen, Galli and Remmel. Defendants Dawson, ViewTrade and Paulson served as the underwriters of the IPO.

69. On or about November 9, 2012, Atossa filed the final version of the public offering prospectus for the IPO, which forms part of the Registration Statement that became effective on November 8, 2012 (collectively, the "Offering Documents"). The Prospectus solicited investors for an IPO of 800,000 shares of Atossa common stock at a price of $5.00 to $7.00 per share, for proceeds – after expenses, underwriting discounts, commissions, and fees – to the Company of approximately $3,100,000.

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70. As with the S-1 and S-1A Registration Statements, the Prospectus describes the MASCT System as being FDA-cleared *more than 25 times*. Clearly, the selling point of the Prospectus was the commercialization of the MASCT System and ForeCYTE Test. For example, the Prospectus states that approximately $2.5 million of the approximately $3.1 million raised by the public offering would go toward the manufacturing of the MASCT System and to hire and train sales and marketing personnel for the national rollout of the ForeCYTE Test.

71. Rather than disclose to the market that neither of the two devices at the core of Atossa's business were FDA-cleared, the Prospectus touted the success of the MASCT System and ForeCYTE Test as FDA-compliant cancer screening and diagnostic devices.

72. The Prospectus represented that "The ForeCYTE Test uses the patented, ***FDA-cleared*** MASCT System medical device for the collection, shipment and clinical laboratory analysis of NAF" (emphasis added) and that "[t]he ForeCYTE [Test] . . . provides personalized information about the 10-year and lifetime risk of breast cancer for women between ages 18 and 65."

73. The Prospectus also repeatedly discussed the current marketing of the ForeCYTE Test as a diagnostic test for cancerous conditions, equating it to the mammogram and Pap smear. For example, the Prospectus states that:

> In December 2011, [the Company] began limited marketing of the ForeCYTE Test to physicians, primarily obstetric-gynecologists, as well as breast health and mammography clinics, for use in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms . . . .

* * *

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> 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 for breast cancer risk stratification would be between 39.3 million and 55 million women.

74. Moreover, under the heading "United States Market for ForeCYTE Test" the Prospectus stated: "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."

75. Indeed, the Prospectus even directly compared the ForeCYTE test to the mammogram in its ability to detect cancer, highlighting its convenience and inexpensiveness: "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." Under the heading "Alternative Diagnostic Tools" the Prospectus states "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."

76. The Prospectus also stated the following regarding compliance with FDA regulations, while remaining completely silent as to the numerous violations plaguing its sole revenue-generating ForeCYTE Test: (1) that Class II devices (such as the MASCT System and ForeCYTE Test) require 510(k) clearance, (2) that "[a]fter a device has

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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"; (3) that the Company is required to manufacture the MASCT Systems in compliance with current Good Manufacturing Practice requirements; (4) that failure to comply with regulations could result in the recall of the offending devices; and (5) that the "Company seeks to conduct its business in compliance with all statutes and regulations applicable to its operations".

77. The foregoing representations in ¶¶ 65 - 76 were materially untrue and/or misleading because they misrepresented and failed to disclose the following adverse facts, which were known to Defendants or recklessly disregarded by them, including that:

a) The ForeCYTE Test had never been clinically tested as a cancer screening device;

b) The ForeCYTE Test was required to be but never was approved or cleared by the FDA;

c) The original MASCT System had been cleared by the FDA for use only as a sample collection device, not for the screening or diagnosis of breast cancer;

d) the Company had altered the MASCT System's NAF specimen collection process from the design originally cleared by FDA without seeking, much less securing, required FDA clearance;

e) The FDA inspection in July 2012 had found that the Company's marketing of the ForeCYTE Test and the MASCT System violated FDA regulations due to the foregoing; and

f) The FDA inspection in July 2012 had found that the Company's facilities were in violation of, among other things, FDA mandated Good Manufacturing Practices (cGMP) regulations.

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C. ADDITIONAL FALSE AND MISLEADING STATEMENTS REGARDING THE FORECYTE TEST AND MASCT SYSTEM

1. The Q3 2012 Quarterly Statement and Press Release

78. On December 20, 2012, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2012. For the quarter, the Company reported a net loss of $1,143,382, or $0.10 diluted loss per share LPS and revenue of $105,576, as compared to net loss of $1,272,680, or $0.11 diluted LPS, for the same period the year prior. Discussing the success of the initial public offering, Defendant Quay stated that "[t]he proceeds from the IPO will enable us to accelerate the national roll-out of our first ***FDA-cleared and marketed product, the ForeCYTE [Test] for breast cancer risk assessment***." (emphasis added) The press release also described the ForeCYTE Test as a "patented, ***FDA-cleared diagnostic medical devices and patented, laboratory developed tests (LDT) that can detect precursors to breast cancer up to eight years before mammography***" that is "akin to the Pap Smear."

2. The Form 10-Q for the Period Ended September 30, 2012

79. On December 21, 2012, the Company filed a quarterly report for the period ended September 30, 2012 on a Form 10-Q with the SEC, which was signed by, Defendants Quay and Benjamin, and reiterated the Company's previously announced financial results and financial position. In addition, the Form 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Quay and Benjamin, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

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80. The foregoing representations in ¶¶ 78 - 79 were materially false and misleading for the reasons set forth in ¶ 77.

3. The February 2013 Interview With Defendant Quay

81. On February 2013, Defendant Quay was interviewed regarding the ForeCYTE Test and continued to insist that it was FDA-cleared. In addition, Quay continue to push the meme that the ForeCYTE Test was the equivalent of a Pap smear for breast cancer – and with the potential for similar wide-scale usage:

> The ForeCYTE Test . . . is literally a Pap smear for breast cancer. As you may know, the Pap smear is a test for cervical cancer and takes a small scraping from the cervix and looks at the changes under the microscope and can see pre-cancer changes up to 10-years before cervical cancer appears. That test is the most successful screening test in all of medicine….
>
> * * *
>
> We've never had the opportunity for that kind of test with the breast until now, and we're really excited to be able to offer a similar test for breast health . . . . [The ForeCYTE Test] has gone through all the FDA clearance process, which is a multi-year, multi-million dollar process.[4]

82. The foregoing representations in ¶ 81 were materially false and/or misleading for the reasons set forth in ¶ 77.

4. The Warning Letter Assurances

83. On February 25, 2013, the Company issued a press release announcing that it had received Warning Letter from the FDA dated February 20, 2013 (the "Warning Letter") regarding its MASCT System and the ForeCYTE Test of which it is a part. The press release described the Warning Letter as "aris[ing] from certain FDA findings during

[4] April Cashin-Garbutt, "Breast Cancer Tests: an Interview with Dr. Steven Quay, CEO of Atossa Genetics," *NewsMedical* (February 22, 2013); found at http://www.news-medical.net/news/20130222/Breast-cancer-tests-an-interview-with-Dr-Steven-Quay-CEO-of-Atossa-Genetics.aspx

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a July 2012 inspection," and characterized the thrust of the FDA's concerns as a technical violation relating to the modification to the MASCT System:

> FDA alleges in the Letter that following 510(k) clearance the Company changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA observes that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial."

84. The issues concerning the Company's misleading marketing of the ForeCYTE Test and MASCT System as FDA-cleared for cancer screening was relegated to a single dismissive statement: "The Letter also raises certain issues with respect to the Company's marketing of the System and the Company's compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters."

85. The Company downplayed the significance of the Warning Letter by assuring investors of the Company's full compliance with FDA regulations: "[Our] response will explain why the Company believes that the System in its current form has been and continues to be appropriately marketed under a cleared 510(k) premarket notification, and why it is in substantial compliance with applicable regulations, including cGMP." The Company also told investors that even if the FDA was unpersuaded by the Company's response, remedying the violation would simply require submitting new paperwork or reverting to the prior version of the MASCT System: "If the FDA does not agree with the Company's position concerning clearance of the System, Atossa may be required to submit and receive clearance of a new 510(k) notice for the current form of the System or revert to marketing the System using the prior NAF processing method."

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86. Despite disclosure of the FDA warning letter, Atossa's shares declined $0.3869 per share or only 5.6%, to close at $6.54 per share on February 25, 2013. The market believed and relied on Atossa's representations that the FDA warning letter would be readily resolved.

87. The foregoing representations in ¶¶ 83 - 85 were materially false and/or misleading for the reasons set forth in ¶ 77.

88. The same day as the Company's announcement of the Warning Letter, Defendant Dawson, an underwriter of the Company's initial public offering that also assisted in the preparation and dissemination of Atossa's offering documents, released an analyst report repeating the Company's misleading characterization of the FDA's position as being focused primarily on the technical changes to the MASCT System, adding that "[t]he new processing method simply provided an easier method for nurses and other healthcare providers to prepare the sample for laboratory testing, and the product benefits of the MASCT System are still evident under the original sample preparation method." Defendant Dawson concluded by asserting the following:

> We believe that Atossa will be able to suitably reply to the FDA's concerns as expressed in the Warning Letter and that even if a new 501(k) application is required for the new sample preparation method, Atossa will be able to continue marketing its MASCT system under the original method, thus we are maintaining our Buy rating on ATOS shares and $10.00 price target.

89. Following the FDA Warning Letter, the Company went on the offensive to assure investors that Atossa's business, which hinged on the ForeCYTE Test, would not be significantly impacted by the FDA's concerns. It did this by entering into marketing and distribution agreements, which the Company knew investors would take as a sign

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that the MASCT System and ForeCYTE Test were not in jeopardy of FDA suspension or recall.

5. The FedMed Announcement

90. For example, on March 13, 2013 Atossa announced that it entered into an agreement with FedMed, Inc., one of the largest proprietary Preferred Provider Organization networks in the U.S., for diagnostic laboratory testing. Upon the announcement, Defendant Quay stated: "There is a significant unmet clinical need in the medical community for more effective ways to identify women at high risk of breast cancer," and "Our agreement with FedMed will help ensure that more doctors and their patients have access to the ForeCYTE [Test]. . ."

91. On March 13, 2013, Atossa stock rose 17.3% to a high of $7.74 during the day, closing at $6.93, and was among NASDAQ stocks posting the largest percentage increases on that day. Also, approximately 451,700 shares changed hands, a 3,690.7 percent increase over its 65-day average volume.

92. The foregoing representations in ¶ 90 were materially false and misleading for the reasons set forth in ¶ 77.

6. The March 15, 2013 Interview with Defendant Quay

93. On Friday March 15, 2013, Defendant Quay gave an interview, which was also published on Monday March 18, 2013. Noting that the Company's stock "is up about 25% since the IPO", Quay emphasized the FDA clearance of its devices and downplayed the risk to the national rollout of the ForeCYTE Test: "I mean, 2013 and 2014 are execution years, where ***FDA clearance risk has been achieved***, patents have been obtained, clinical trials have been achieved, manufacturing has been achieved — ***so***

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now it's really a matter of going from less than 100 doctors doing our test to the expectation of thousands of doctors." (Emphasis added.)

94. On Friday March 15, 2013 Atossa stock rose 11.1% ($.74) to $7.40. It was among NASDAQ stocks posting the largest percentage increases in price and volume on that day. Approximately 513,500 shares changed hands, a 2,457.1 percent increase over its 65-day average volume. On Monday March 18, 2013, Atossa stock rose another 24.5% ($1.81) to $9.21, and was among NASDAQ stocks posting the largest percentage increases in price and volume on that day. Approximately 475,400 shares changed hands, a 1,595.3 percent increase over its 65-day average volume. On March 19, 2013, Atossa stock rose another 34.3% ($3.16) to $12.37, as it was the largest percentage price gainer on the NASDAQ and among those posting the largest volume increase. Approximately 921,500 shares changed hands, a 2,482.0 percent increase over its 65-day average volume.

95. The foregoing representations in ¶ 93 were materially false and misleading for the reasons set forth in ¶ 77.

7. The 2012 Annual Report

96. On March 28, 2013, the Company filed an annual report for the year ended December 31, 2012 on a Form 10-K with the SEC, which was signed by, Defendants Quay, Guse, Barnhart, Chen, Cross, Galli and Remmel. For the year, the Company reported net loss of $5,079,851, or $0.41 diluted LPS and revenue of $481,842, as compared to net loss of $3,442,269, or $0.38 diluted LPS and revenue of $1,500 for the prior year. In addition, the Form 10-K contained signed certifications pursuant to SOX by Defendants Quay and Guse, stating that the financial information contained in

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the Form 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting. Repeating many of the misleading statements identified in ¶¶ 65 – 93, the Company continued to mislead the market as to the truth regarding the ForeCYTE Test. In the accompanying press release, Defendant Quay stated: "We continue to make steady progress in the national rollout of our patented ForeCYTE [Test], advancing our ambition to arm women and their physicians with information that will enable improved breast health management and prevent breast cancer."

97. Regarding the FDA Warning Letter, the Form 10-Q stated: "We are reasonably confident in our responses to the FDA. Consequently, no provision or liability has been recorded as of December 31, 2012 as a result of the Letter."

98. The foregoing representations in ¶¶ 96 - 97 were materially false and misleading for the reasons set forth in ¶ 77.

99. Moreover, the representations in the Company's annual report for the year ended December 31, 2012 on a Form 10-K were materially false and misleading because the Company represented that Atossa had prepared its financial statements in compliance with GAAP. However, GAAP barred Atossa from recognizing its sales of the MASCT System and ForeCYTE diagnostic test as revenue (which it did) and required Atossa to reserve for the loss contingency of the inevitable recall (which it did not).

a. GAAP are those principles recognized by the accounting profession as the conventions, rules and procedures necessary to define accepted accounting practice at a particular time. Regulation S-X (17 C.F.R. §210.4-01(a)(1)) states that financial statements filed with the SEC which are not prepared in accordance

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with GAAP are presumed to be misleading and inaccurate. Regulation S-X also requires that interim financial statements comply with GAAP. 17 C.F.R. § 210.10-01 (a). GAAP, as described in Financial Accounting Standards Board ("FASB") Statement of Concepts No. 5 (FASB CON No. 5), provides the basic requirements for revenue to be recognizable: (i) revenue must have been earned; and (ii) revenue must be realizable (collectible).

b. SEC Staff Accounting Bulletin (SAB) Topic 13(A)(1) provides that revenue generally is realized or realizable and earned when all of the following criteria are met: (1) Persuasive evidence of an arrangement exists, (2) Delivery has occurred or services have been rendered, (3) The seller's price to the buyer is fixed or determinable, and (4) Collectability is reasonably assured.

c. GAAP does not permit the recognition of revenue where collectability is not reasonably assured. Collectability was not reasonable assured here because it was probable that the Company would be forced to recall the MASCT System and the ForeCYTE Test of which it was a part.

d. Even if the Company was entitled to book the proceeds from sales as revenues, which it was not, Atossa did not account for the probable recall of the products as a loss contingency in compliance with GAAP. GAAP for loss contingencies, is set forth in the Financial Accounting Standards Board's Statement of Financial Accounting Standards ("FAS") 5. "An estimated loss from a loss contingency shall be accrued by a charge to income if both of the following conditions are met: (a) information available prior to issuance of the financial statements that it is probable that

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an asset has been impaired or a liability has been incurred at the date of the financial statements [and] (b) the amount of loss can be reasonably estimated."

e. FAS 5, paragraph 26 is instructive: "Obligations other than warranties may arise with respect to products or services that have been sold, for example, claims resulting from injury or damage caused by product defects. If it is probable that claims will arise with respect to products or services that have been sold, accrual for losses may be appropriate. ***The condition in paragraph 8(a) would be met, for instance, with respect to a drug product or toys that have been sold if a health or safety hazard related to those products is discovered and as a result it is considered probable that liabilities have been incurred.*** The condition in paragraph 8(b) would be met if experience or other information enables the enterprise to make a reasonable estimate of the loss with respect to the drug product or the toys." (emphasis added)

100. The market bought into the assurances and posturing of the Company in the wake of the FDA Warning Letter. For example, a March 28, 2013 analyst report by Zack's Investment Research rated Atossa shares "Outperform" stating that "National rollout of ForeCYTE is on track" and that "[b]ased on the agreement with FedMed, we have raised our revenue forecast for 2013 and beyond." Addressing the FDA Warning Letter, the analyst report relied on representations received directly from the Company to conclude "We think the FDA letter won't impact Atossa's major business much", explaining, "***based on our conversation with the Company, we have reasons to believe that the new version of MASCT System is in compliance with the FDA regulations and not required for 510(K) clearance***." (emphasis added).

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101. Emboldened by the market's acceptance of its assertions that FDA clearance was not at risk, the Company ramped up its misleading and illegal marketing of the ForeCYTE Test.

8. The April 2013 Press Releases

102. On April 15, 2013, in a press release purporting to announce the launch of a new "Nationwide Awareness Program" for its "Breast Cancer Prevention Test", the Company proclaimed that the ForeCYTE Test was equivalent, and even superior, to the Pap smear and mammogram. The press release stated: (1) the ForeCYTE Test is the "'Pap smear for the breast' for early detection of cancerous cells"; (2) "[w]hile mammograms can detect cancer, Atossa's test detects treatable pre-cancerous conditions in the breast up to eight years before cancer arises"; and (3) "women with dense breasts, whom research shows may be at a higher risk for breast cancer and for whom mammograms are often less reliable, can be tested easily with the ForeCYTE test in their healthcare providers' office". Inexcusably capitalizing on women's fear of breast cancer, the Company represented that ***"[the ForeCYTE Test] can provide vital early detection of cancer*** or pre-cancerous conditions that may progress to cancer over an approximately eight year period and ***before cancer can be detected by mammography*** or other means and without the risks of radiation, especially in women younger than age 50. No invasive biopsy needles or open surgical incisions are used in the Atossa test and the test is painless." (Emphasis added.)

103. An April 23, 2013, press release similarly states that "the analysis in a woman with no family history may detect pre-cancerous changes -- up to eight years before a tumor is large enough to be spotted on a mammogram. ***That pinpoints a***

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woman's exact risk of developing cancer and allows any pre-cancer to be treated with drugs. . ." (emphasis added)

104. An April 29, 2013, press release states, "Unlike mammograms, which are commonly recommended for women starting at age 40 to 50, the ForeCYTE [Test] is more age agnostic, uses no radiation and does not require invasive biopsy needles or surgical incisions."

105. The foregoing representations in ¶¶ 102 - 104 were materially false and misleading for the reasons set forth in ¶¶ 77.

9. The Millennium HealthCare Announcement

106. On May 2, 2013, following on it prior announcement of an agreement with FedMed to expand access to the ForeCYTE Test, Atossa announced that it signed an agreement with Millennium HealthCare Inc. for the distribution of Atossa's MASCT System and that Millennium had submitted an initial order for 10,000 MASCT patient kits.

107. The foregoing representations in ¶ 106 were materially false and misleading for the reasons set forth in ¶ 77.

10. The Q1 2013 Quarterly Report and Press Release

108. On May 15, 2013, the Company announced the filing of a quarterly report for the first quarter ended March 31, 2013. In the press release, Defendant Quay stated: "The national rollout of our ForeCYTE [Test] is proceeding well and we are pleased with the response we are getting from the physician community and from patients." Defendant Quay continued: "We anticipate signing up additional distributors this year and continuing to build our internal sales and marketing team."

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109. On the same day, the Company filed a quarterly report for the first quarter ended March 31, 2013 on a Form 10-Q with the SEC, which contained many of the statements identified above from the Company's prior filings, and which was signed by, Defendants Quay and Guse. For the quarter, the Company reported a net loss of $1,941,440, or $0.14 diluted LPS and revenue of $182,670, as compared to a net loss of $1,062,918, or $0.09 diluted LPS and revenue of $54,713 for the same period a year ago. In addition, the Form 10-Q contained signed certifications pursuant to SOX by Defendants Quay and Guse, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting. Regarding the FDA Warning Letter, the Company continued to represent that "The Company is reasonably confident in its responses to the FDA. Consequently, no provision or liability has been recorded as of March 31, 2013 as a result of the Letter."

110. The foregoing representations in ¶¶ 1108 - 109 were materially false and misleading for the reasons set forth in ¶¶ 77 and 99 (a) – (e).

111. The market continued to rely on the Company's "confident" representations of smooth sailing. A May 22, 2013 analyst report titled "BUY Marketing blitz continues for Atossa" recounted the various marketing and distribution agreements entered into by the Company as well as the announcement that two leading breast centers in Texas would soon begin to offer the ForeCYTE test: "***with two approved products and an active and innovative marketing program*** in a very high-profile and large area of medical need, an improved balance sheet and recently added access to

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capital . . . ***there are many reasons for investors to hang onto their ATOS shares***. . .” (Emphasis added.)

11. The HealthSmart and Fisher HealthCare Announcements

112. On June 17, 2013, the Company announced that it had entered into a contractual agreement with HealthSmart, a PPO network serving clients in all 50 states. Defendant Quay stated: “The agreement with HealthSmart, our third agreement with a PPO organization, will help more doctors and patients access the ForeCYTE test.”

113. On June 20, 2013, the Company announced that it had signed another distribution agreement, this time with Fisher HealthCare Inc., for distribution of the ForeCYTE Test’s MASCT patient collection kit and the MASCT Device.

114. The foregoing representations in ¶¶ 112 - 113 were materially false and misleading for the reasons set forth in ¶¶ 77.

115. At the same time as the Company was assuring the market in its May second quarter Form 10-Q that the Company was “confident” in its response to the FDA that the ForeCYTE Test and MASCT System were appropriately marketed under a cleared 510(k) premarket notification, the Company was actually preparing and filing a new 510(k) premarket notification with the FDA.

116. In August 2013, the Company was forced to withdraw the new 510(k) premarket notification on the 89th day of the 90-day FDA review window. The withdrawal came after the Company received a response from the FDA which indicated that the FDA would likely not clear the 510(k) submission during the applicable time frame. None of these facts were disclosed to investors.

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12. The Quarterly Report for Q2 2013 and Press Release

117. On August 14, 2013, the Company filed a quarterly report for the second quarter ended June 30, 2013 on a Form 10-Q with the SEC, which contained many of the statements identified above from the Company's prior filings, and was signed by, Defendants Quay and Guse. For the quarter, the Company reported a net loss of $2,583,699, or $0.17 diluted LPS and revenue of $326,078, as compared to a net loss of $1,167,948, or $0.10 diluted LPS and revenue of $223,097 for the same period a year ago. In addition, the Form 10-Q contained signed certifications pursuant to SOX by Defendants Quay and Guse, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting. Regarding the FDA Warning Letter, the Form 10-Q continued to represent that "The Company is reasonably confident in its responses to the FDA. Consequently, no provision or liability has been recorded as of June 30, 2013 as a result of the Letter."

118. The foregoing representations in ¶ 117 were materially false and misleading for the reasons set forth in ¶¶ 77, 99 (a) – (e), as well as the failure to disclose the FDA's effective rejection of the Company's new 510(k) premarket notification.

119. In the August 14 press release Defendant Quay stated: "Interest in our ForeCYTE test continues to grow, as evidenced by the increasing numbers of doctors signing up to provide the test and the increasing number of doctors submitting specimens to our lab for analysis. . . . We will continue to sign up new doctors while focusing intently on driving volume from existing doctors through a comprehensive follow up program. In addition, we are working closely with our marketing partners to create

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awareness, interest and further adoption of the ForeCYTE test among general practitioners, OB/GYNs, breast clinics and hospitals."

120. The foregoing representations in ¶ 119 were materially false and misleading for the reasons set forth in ¶ 77, as well as the failure to disclose the filing of a new 510(k) premarket notification and the withdrawal of that premarket notification.

121. Based on these financial results – and left in the dark as to the true status of the MASCT System and ForeCYTE Test– analysts continued to rate Atossa stock "Outperform". For example, an August 15, 2013 analyst report with the headline "Record revenue reported in 2Q13 following national rollout of ForeCYTE" stated that "Sales will continue to grow due to focused market strategy":

> We are pleased to see that Atossa reported record revenue for the second quarter 2013. We believe as the Company continues to roll out its ForeCYTE tests nationally, revenue growth will accelerate in the coming quarters and years ***thanks to its focused marketing strategy*** and continued new products/services offering. . . . ***All these promotion efforts have created concrete effects for the Company***. Starting with 37 medical professionals offering the ForeCYTE test at the beginning of the year, there were 154 doctors offering the test at the end of the second quarter and 243 as of July 31, 2013. The number of tests received by Atossa s laboratory increased 50% sequentially in the second quarter 2013 compared to the first quarter. ***All these indicate that sales will continue to grow in the future***.
>
> (Emphasis added.)

13. The McKesson Announcement

122. On September 18, Atossa announced a nationwide distribution agreement with McKesson Medical-Surgical to sell and distribute the ForeCYTE Test's MASCT Device and patient collection kits, effectively completing the Company's nationwide rollout of the ForeCYTE Test. Defendant Quay lauded the agreement as "another important step forward in making the ForeCYTE test the standard of care in breast cancer

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risk assessment", and that "we look forward to providing physicians a much needed early warning system by detecting the earliest, reversible precursors of breast cancer."

123. On September 19, the shares of Atossa soared 21.0% ($1.04) on more than 37-times the normal daily trading volume, closing at $6.00. At its highest level, the stock had advanced 56.3%, touching $7.75 a share. Approximately 8,196,400 shares changed hands, a 10,262.2 percent increase over its 65-day average volume. Atossa shares were the second highest volume gainer on the NASDAQ that day.

124. The foregoing representations in ¶ 122 were materially false and misleading for the reasons set forth in ¶ 77, as well as the failure to disclose the filing of a new 510(k) premarket notification and the withdrawal of that premarket notification.

125. On the same day, September 19, the FDA contacted the Company, informing it that must recall the MASCT System and ForeCYTE Test because of the Company's continued marketing without FDA approval or clearance. Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.[5]

126. Continuing to encourage investors to believe that the Company's only products were viable, on September 25, 2013, Defendant Quay conducted a webinar via The Money Show, titled "How to Invest Ahead of Breast Cancer Awareness Month." Quay made no mention on this webinar of the FDA recall demand. The failure to promptly disclose the September 19, 2013 FDA recall demand was a material omission and operated as a fraud upon the market.

[5] *See* http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm374600.htm

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127. An October 3, 2013 Form 4 filing with the SEC reveals that Defendants Quay and Chen each sold 7,265 shares of Atossa stock on October 1, at a weighted average of $5.658 per share.

D. THE TRUTH EMERGES REGARDING DEFENDANTS' FRAUD

128. Three days after these October 1, 2013 insider sales, the Company disclosed that, consistent with the FDA demand, it was recalling the ForeCYTE Test and MASCT System from the market as a result of "concerns raised by the U.S. Food and Drug Administration (FDA) in a warning letter received by Atossa in February 2013." It was upon this announcement that the market learned for the first time that:

> The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, the ForeCYTE [Test] has not been cleared or approved by the FDA for any indication. The ForeCYTE [Test] and the MASCT device are not a replacement for screening mammograms, diagnostic imaging tests, or biopsies.

129. The market was shocked by this announcement. Investors finally realized that the Company's blitz marketing and national rollout of the ForeCYTE Test was a complete sham, perpetrated to dupe consumers and investors as to the safety, effectiveness and legality of Atossa's only product. Some analysts immediately suspended coverage of the Company, stating that prior estimates for the Company should not be relied upon. As a result, Atossa shares declined $2.47 per share, or more than 46%, to close at $2.85 per share on October 7, 2013, as shown on the chart below:

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130. It was only after the recall and the loss to investors that the market learned (i) that the FDA had previously warned the Company that the ForeCYTE Test did not have required FDA approval/clearance, (ii) that the Company had attempted and failed to gain FDA clearance in the summer of 2013, and (iii) that the recall of the MASCT System would cause the Company's distributors not to sell the MASCT System and ForeCYTE Test.

E. ADDITIONAL ALLEGATIONS

131. Subsequent to the recall of the ForeCYTE Test and MASCT System, there has been a changing of the guard at Atossa. On December 18, 2013, Defendant Cross announced his retirement from the Atossa Board so that he "could pursue other personal and professional activities." Similarly, on January 31, 2014, Defendant Barnhart announced his retirement from Atossa's Board, also for the purported purpose of "pursue[ing] other personal and professional activities."

132. On April 2, 2014, Atossa announced that Ben R. Chen joined the Company as Senior Vice President of Global Regulatory Affairs and Quality Assurance,

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a newly created position. Mr. Chen will now oversee all facets of Atossa's regulatory affairs, providing oversight for all U.S. and international regulatory matters, including filings and interactions with regulatory authorities, and all quality assurance matters.

133. In addition, Atossa has recently altered its website such that its product page, which previously made representations regarding the virtues of the ForeCYTE Test and the FDA-cleared MASCT System, is now "under construction" and contains no reference to these products.[6]

134. In perhaps a further effort to erase the past, Plaintiffs' private investigator, who has been attempting to contact former employees of Atossa, has advised that these former employees appear to have been contacted by Company officials and advised not to provide any information concerning Atossa.

135. Finally, in its 2013 Form 10-K, filed with the SEC, Atossa has admitted that "The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, our NAF cytology test has not been cleared or approved by the FDA for any indication . . ." Form 10-K at 6. Atossa further admitted that " as a result of the recall of the MASCT System in October 2013, our product revenue and service revenue have ceased. We do not anticipate generating revenue until and unless we receive an additional 510(k) clearance from the FDA for our ForeCYTE Breast Aspirator and re-launch the device." *Id* at 55.

[6] See http://www.atossagenetics.com/products/current-products/

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PLAINTIFFS' CLASS ACTION ALLEGATIONS

136. Plaintiffs brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons or entities who acquired Atossa shares during the Class Period and/or pursuant or traceable to the Company's false and misleading Registration Statement for its IPO, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Atossa, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Individual Defendants have or had a controlling interest.

137. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Atossa shares were actively traded on the Nasdaq. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds, if not thousands of members in the proposed Class.

138. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

139. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

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140. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the 1933 Act and/or the Exchange Act were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition, business, and prospects of Atossa;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading
- whether the Defendants caused Atossa to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Atossa shares during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

141. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

142. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

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- Atossa shares met the requirements for listing, and were listed and actively traded on the NASDAQ Global Select Market, a highly efficient and automated market;

- As a public issuer, Atossa filed periodic public reports with the SEC and the NASDAQ;

- Atossa regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

- Atossa was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

143. Based on the foregoing, the market for Atossa shares promptly digested current information regarding Atossa from all publicly available sources and reflected such information in the prices of the shares, and Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

COUNT I

For Violation of §11 of the 1933 Act
(Against All Defendants)

144. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein, except as set forth below in Paragraph 146.

145. This Count is brought pursuant to §11 of the 1933 Act, 15 U.S.C. §§77k, on behalf of the Class, against all Defendants.

146. This Count does not sound in fraud. All of the preceding allegations of fraud or fraudulent conduct and/or motive are specifically excluded from this Count. Plaintiffs do not allege that the Individual Defendants, or the Underwriter Defendants had

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scienter or fraudulent intent with respect to this Count, insofar as scienter or fraudulent intent are not elements of a §11 claim.

147. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary in order to make the statements not misleading, and omitted to state material facts required to be stated therein.

148. Atossa is the registrant for the IPO. The other Defendants named herein were responsible for the contents and dissemination of the Registration Statement.

149. As the issuer of the shares, Atossa is strictly liable to Plaintiffs and the Class for any misstatements or omissions in the Registration Statement.

150. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true, and/or without omissions of any material facts, were not misleading.

151. By reason of the conduct alleged herein, each defendant violated, and/or controlled a person who violated, §11 of the 1933 Act.

152. Plaintiffs acquired Atossa shares pursuant and/or traceable to the Registration Statement for the IPO.

153. Plaintiffs and the Class have sustained damages. The value of Atossa stock has declined substantially subsequent to and due to Defendants' violations.

154. At the time of their purchases of Atossa shares, Plaintiffs and the other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to

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October 4, 2013. Less than one year has elapsed from the time that Plaintiffs discovered or reasonably could have discovered the facts upon which this complaint is based, to the time that Plaintiffs filed this complaint. Less than three years elapsed between the time that the securities upon which this Count is brought were offered to the public, and the time Plaintiffs filed this complaint.

COUNT II

For Violation of §15 of the 1933 Act
(Against Atossa and the Individual Defendants)

155. Plaintiffs repeat and reallege each and every allegation contained above, excluding all allegations that contain facts necessary to prove any elements not required to state a Section 15 claim, including without limitation, scienter.

156. This Count is brought pursuant to §15 of the 1933 Act against Atossa and Individual Defendants.

157. This Count does not sound in fraud. All of the preceding allegations of fraud or fraudulent conduct and/or motive are specifically excluded from this Count. Plaintiffs do not allege that Individual Defendants had scienter or fraudulent intent with respect to this Count, insofar as scienter or fraudulent intent are not elements of a §15 claim.

158. The Individual Defendants each were control persons of Atossa by virtue of their positions as a director and/or senior officer of Atossa. The Individual Defendants each had a series of direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of Atossa. Atossa controlled the Individual Defendants.

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99. Defendants each were culpable participants in the violations of §11 of the 1933 Act alleged in the prior Count above, based on their having signed or authorized the signing of the Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.

COUNT III

For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder
(Against Atossa and Quay, Guse and Benjamin)

159. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

160. This Count is asserted against Atossa, Quay, Guse and Benjamin and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

161. During the Class Period, Atossa, Quay, Guse and Benjamin, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

162. Atossa, Quay, Guse and Benjamin violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

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- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiffs and others similarly situated in connection with their purchases of Atossa common stock during the Class Period.

163. Atossa, Quay, Guse and Benjamin acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of Atossa were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants by virtue of their receipt of information reflecting the true facts of Atossa, their control over, and/or receipt and/or modification of Atossa's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning Atossa, participated in the fraudulent scheme alleged herein.

164. Quay, Guse and Benjamin, who are the senior officers of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Atossa personnel to members of the investing public, including Plaintiffs and the Class.

165. As a result of the foregoing, the market price of Atossa common stock was artificially inflated during the Class Period. In ignorance of the falsity of the statements by Atossa, Quay, Guse and Benjamin, Plaintiffs and the other members of the Class relied on the statements described above and/or the integrity of the market price of Atossa

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securities during the Class Period in purchasing Atossa common stock at prices that were artificially inflated as a result of Atossa, Quay, Guse and Benjamin's false and misleading statements.

166. Had Plaintiffs and the other members of the Class been aware that the market price of Atossa common stock had been artificially and falsely inflated by Atossa, Quay, Guse and Benjamin's misleading statements and by the material adverse information which Atossa, Quay, Guse and Benjamin did not disclose, they would not have purchased Atossa common stock at the artificially inflated prices that they did, or at all.

167. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of the Class have suffered damages in an amount to be established at trial.

168. By reason of the foregoing, Atossa, Quay, Guse and Benjamin have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiffs and the other members of the Class for substantial damages which they suffered in connection with their purchase of Atossa common stock during the Class Period.

COUNT IV

Violations of Section 20(a) of the Exchange Act
(Against Quay, Guse and Benjamin)

169. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

170. During the Class Period, Defendants Quay, Guse and Benjamin participated in the operation and management of Atossa, and conducted and participated, directly and indirectly, in the conduct of Atossa's business affairs. Because of their

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senior positions, they knew the adverse non-public information about Atossa's misstatement of income and expenses and false financial statements.

171. As officers and/or directors of a publicly owned company, Defendants Quay, Guse and Benjamin had a duty to disseminate accurate and truthful information with respect to Atossa's financial condition and results of operations, and to correct promptly any public statements issued by Atossa which had become materially false or misleading.

172. Because of their positions of control and authority as senior officers, Defendants Quay, Guse and Benjamin were able to, and did, control the contents of the various reports, press releases and public filings which Atossa disseminated in the marketplace during the Class Period concerning Atossa's results of operations. Throughout the Class Period, Defendants Quay, Guse and Benjamin exercised their power and authority to cause Atossa to engage in the wrongful acts complained of herein. Defendants Quay, Guse and Benjamin therefore, were "controlling persons" of Atossa within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Atossa.

173. By reason of the above conduct, Defendants Quay, Guse and Benjamin are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Atossa.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and,

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury in this action on all issues so triable.

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Dated: April 15, 2014

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 15, 2014, the foregoing document was filed electronically using the Court's CM/ECF system. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing. Parties may access this filing through the Court's system.

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