

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

DIVISION OF CORPORATION FINANCE

March 12, 2012

<u>Via E-Mail</u> Steven C. Quay, M.D., Ph.D. Chairman, Chief Executive Officer and President Atossa Genetics Inc. 4105 E. Madison Street, Suite 320 Seattle, Washington 98112

> Re: Atossa Genetics Inc. Registration Statement on Form S-1 Filed February 14, 2012 File No. 333-179500

Dear Dr. Quay:

We have reviewed your registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

# **Prospectus**

1. Please provide objective support for any unsubstantiated claims contained in the prospectus. With regard to third party data referenced throughout, please provide copies of these industry publications, studies, surveys, and other sources of statistics, clearly marking the relevant sections of these reports. Please also tell us whether any of this market data was commissioned by the company.

# Prospectus Summary, page 1

2. Please revise this section to include the substance of your risk factor entitled "Currently Medicare and certain insurance carriers will not reimburse for the NAF collection procedure..." on page 9.

3. We note that your summary emphasizes the positive aspects of your products. Please revise the prospectus to provide appropriate balancing disclosure regarding your products' weaknesses and potential obstacles to acceptance. Note that the list of risk factors appearing on page 4 does not provide sufficient balance. Make similar revision in the Business section, as well.

# The Company, page 1

- 4. We note your statement in the last sentence in this section. Please specify the revenues generated. Please also revise this section to highlight the going concern language in your auditor's report and to disclose the amount of your accumulated deficit since inception.
- 5. We note your statement on page 1 that you launched your commercial operations in late 2011. Please clarify the extent to which you have launched your commercial operations. For example, we note the discussion under "Growth Strategy" on page 33 that you are currently conducting a field experience trial. Please discuss the number of MASCT Systems you have sold and how many diagnostic tests your laboratory has completed.
- 6. Please revise to define "CLIA" and disclose whether a laboratory must be "CLIAregistered" in order to operate. Additionally, please revise here and under "State Laboratory Licensure" on page 43 to clarify the states from which you may currently accept testing samples.

# Our Diagnostic Tests, page 1

7. Please revise to clarify when your diagnostic tests and related medical devices received FDA approval. In addition, please clarify which diagnostic tests have received FDA approval. For example, clarify if all of the diagnostic tests discussed on pages 1 and 2 have received FDA approval and if you have begun the process of applying for FDA approval for your Intraductal Treatment Research. Please also specify the current stage of development of the FullCYTE and NextCYTE tests.

# Currently, Medicare and certain billing providers..., page 9

8. We note your disclosure in the first sentence under the heading "Discriminatory Billing Prohibition" on page 42. Please expand your risk factor disclosure to more fully address the risk of discounted pricing arrangements and its effects on your profit margins and income.

# Use of Proceeds, page 16

9. We note your estimated use of proceeds appears to include considerable discretion. To the extent that you are reserving the right to change the uses of proceeds identified, please

include a specific discussion of contingencies and alternatives. For guidance, please refer to Instruction 7 to Item 504 of Regulation S-K.

# Funding Requirements, page 23

10. We note your statement that you would need between \$5 million and \$7 million of additional capital to fund your operations for at least the next 12 months under your current business plan. Please clarify how the amount of capital raised in this offering would affect the amount of capital needed to fund your operations for at least the next 12 months.

### Billing and Reimbursement, page 33

11. We note your statement here that Medicare and certain insurance carriers do not currently cover the cost of collecting the NAF sample. However, we also note your disclosure in the penultimate paragraph on page 2 and throughout the registration statement regarding applicable Medicare reimbursement rates. Please revise to reconcile. For example, revise the section "Reimbursement" on page 34 to clarify for which products and services the company expects to bill Medicare.

#### Competition, page 36

12. We note your discussion of the competitive position of your MASCT System. However, it appears that your ArgusCYTE Breast Health Test does not involve use of your MASCT System. Please revise to include a discussion of the competitive position of your ArgusCYTE diagnostic test.

# Property, page 44

13. We note your disclosure here regarding your office and laboratory space in Seattle, Washington. However, please tell us why you have not described the additional properties discussed under "Commercial Lease Agreements" on page 20.

#### Management, page 45

14. Please revise Dr. Quay's business description to describe the principal business of MDRNA, Inc. Please also revise Mr. Benjamin's business description to describe the principal businesses of Quantum Materials Corporation, Paradise Publishers, NexTec Group, Redfin Corporation and Bsquare Corporation and the dates Mr. Benjamin served in these positions. In addition, revise Dr. Cross's business description to describe the principal businesses of Cytopharm, Inc. and NDA Partners, LLC and the dates Dr. Cross served on the boards of Marina Biotech, Inc. and Nastech Pharmaceutical Company, Inc.

### Scientific Advisory Board, page 47

- 15. Please revise the business descriptions of Dr. Sauter and Dr. Hunkapiller to provide the dates in which they served in the positions described.
- 16. With a view to disclosure, please provide additional detail regarding the compensation paid to the advisory board (including annual compensation, if any). Please also tell us the role of the advisory board as well as the frequency of its meetings.

### Remuneration of Officers, page 50

17. Please clarify how the amounts of the salary accruals paid in July 2011 were calculated. Add appropriate footnote disclosure to your summary compensation table as appropriate.

# Certain Relationships and Related Transactions, page 55

18. Please tell us why you have not discussed in this section the sales of unregistered securities to related parties, as described in Item 15.

### Loans from Officer, page 55

19. Please revise to clarify the dollar amount of interest paid to Dr. Quay on the loan entered into on May 26, 2009 and June 30, 2010. With regard to the loan entered into on November 3, 2010, please revise to clarify the amount of the loan outstanding as of the latest practicable date and the amount of interest paid.

# Exclusive License Agreement, page 56

20. Please revise to describe the \$16,250 in patent-related expenses the company incurred under the license agreement with Ensisheim and clarify whether the company paid these expenses. Please also revise to clarify the consideration Ensisheim Partners LLC and the company's Chief Executive Officer and Chief Scientific Officer received pursuant to the Assignment Agreement. We note for example the receipt of shares of common stock of the company noted in the penultimate paragraph on page 55.

# Commercial Lease Agreement, page 56

21. Please revise to describe the basis upon which CompleGen, Inc. is a related party.

# Shares Eligible for Future Sale, page 63

22. Please revise to fill in the aggregate number of shares in the table.

Financial Statements, page F-1

23. Please update the financial statements as required by Rule 8-03 of Regulation S-X.

Unaudited financial statements for the nine months ended September 30, 2011 Note 10. Stockholder's Equity, page F-9

- 24. We see that you issued stock and warrants in a private placement in April through June 2011 for \$1.25 per share. Please revise to disclose the significant assumptions, including stock price assumptions, for the valuation of the warrants at \$0.906 per share.
- 25. Please tell us why you classify expected volatility using the calculated value method as a Level 2 input in the fair value hierarchy. Under FASB ASC 820-10-35-37 the level in the fair value hierarchy should be determined based upon the lowest level input that is significant to the fair value measurement in its entirety. Please refer you to FASB ASC 820-10-55-22 which states that a Level 3 input would include historical volatility. We also note that you use the historical volatility of comparable public companies to calculate your expected volatility. Please also apply to the disclosure in Note 14.

Note 14. Related Party Transactions, page F-13 Share Based Compensation, page F-15

- 26. Please revise to disclose how you determined the fair value of common stock at each stock option issue date. In addition, provide a specific discussion of each significant factor contributing to the significant difference between the estimated fair value of your stock and the estimated IPO price range of \$5 \$7 for the 12 months prior to the contemplated IPO. Please also explain the factors that contributed to the decrease in the fair value of your stock from \$2.756 in June 2010 to \$0.906 during 2011.
- 27. Please tell us when you obtained estimated pricing information from the underwriters and indicate whether this was considered in determining the estimated fair value of the underlying stock during 2010 or 2011. We note that you previously filed registration statements on Form S-1 in March and October 2010.

Audited Financial Statements for the year ended December 31, 2010 Statement of Stockholder's Equity, page F-23

28. Please revise to show for each stock issuance, the date and number of shares of stock issued, the dollar amount assigned to the consideration received for equity, the nature of any noncash consideration and the basis for assigning such amounts to the consideration. Refer to FASB ASC 915-215 for development stage entities.

# Note 4. Stockholder's Equity, page F-26

- 29. We see that you issued 13,256 shares of stock at \$3.77 per share in April 2010 to a service provider for website development pursuant to an agreement executed on December 14, 2009. Under FASB ASC 505-50-30-2, share-based transactions with nonemployees should be measured at fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. Please tell us why you believe that the \$50,000 agreed upon value of services received was more reliably measurable than the fair value of your stock.
- 30. Please also tell us how you considered FASB ASC 505-50-30-11 in determining the date that you should value the equity instruments issued to the website developer. Under that guidance, the fair value of the equity issued is determined on the earlier of the date that a commitment for performance is reached or the date that the counterparty's performance is complete.

Note 7. Related Party Transactions, page F-28 Share-Based Compensation, page F-29

31. Please revise to disclose how you determined the fair value of common stock as of July 22, 2010. We see that you valued the shares issued to the website developer at \$3.77 per share in April 2010 and that you issued shares in a private placement in April 2011 at \$1.25 per share.

# Exhibits

- 32. We note your discussion of your third-party suppliers on page 8 and your statement that you currently source the NAF collection device, patient collection kits and Microcatheter Systems from sole suppliers. We also note your disclosure that if your sole suppliers cannot produce these products in sufficient quantities, you will be unable to commercialize your products and services and generate revenues from their sales as planned. Please tell us why you have not filed the agreements with your third-party suppliers as exhibits, or alternatively, file these agreements as exhibits.
- 33. We note that it does not appear that you have filed all material agreements. As examples, please tell us why you have not filed all consulting agreements and why you have not filed all the lease agreements described on page 20 as exhibits. Note that these examples are not intended to be exhaustive.

# Exhibit 23.1. Consent of Independent Registered Public Accounting Firm

34. To the extent there is a delay in requesting effectiveness of your registration statement, or there is any change, other than typographical, made to the financial statements, or there

have been intervening events since the prior filing that are material to the company, please provide a currently dated and signed consent from your independent accountant with your next amendment.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Kristin Lochhead at (202) 551-3664 or Brian Cascio, Accounting Branch Chief, at (202) 551-3676 if you have questions regarding comments on the financial

statements and related matters. Please contact Allicia Lam at (202) 551-3316 or Daniel Morris, Special Counsel, at (202) 551-3314 with any other questions.

Sincerely,

/s/ Daniel Morris for

Amanda Ravitz Assistant Director

cc (by e-mail):

Ryan Murr Ropes & Gray LLP