Atossa Genetics Receives Warning Letter From the Food and Drug Administration

The Associated Press

SEATTLE--(BUSINESS WIRE)--Feb 25, 2013--Atossa Genetics, Inc. (NASDAQ: ATOS) ("Atossa" or the "Company") received a Warning Letter ("Letter") from the FDA on February 21, 2013, regarding its Mammary Aspirate Specimen Cytology Test (MASCT) System and MASCT System Collection Test (together, the "System"). The Letter arises from certain FDA findings during a July 2012 inspection, to which the Company responded in August 2012, explaining why the Company believed it was in compliance with applicable regulations and/or was implementing changes responsive to the findings of the FDA inspection. The 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." At the time that the changes were made the Company determined that a new 510(k) was not required in accordance with the FDA's guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." 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.

The Company is committed to working with the FDA to resolve these issues in the best interests of patients and their doctors. 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.

The Company has until March 14, 2013 to respond to the Letter and is currently working to prepare that response. Among other things, the Company currently expects that the 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.

Management notes that the FDA could direct other compliance-verification activities or take other actions in connection with matters raised in the Letter and in connection with other matters that the FDA could identify in the future. Until these issues are resolved Atossa may be subject to additional regulatory action by the FDA, and any such actions could disrupt the Company's ongoing business and operations.

About Atossa Genetics, Inc.
Atossa Genetics, Inc. (NASDAQ: ATOS), The Breast Health Company™, is based in Seattle, WA, and is focused on preventing breast cancer through the commercialization of 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, and through research and development that will permit it to commercialize treatments for pre-cancerous lesions.