

**SOURCE: Molecular Biometrics**



Dec 12, 2006 08:20 ET

# **Molecular Biometrics Secures Broad Patent Portfolio for Metabolomics Technology Platform in All Biomedical Applications**

## **Company Plans Pivotal U.S. Trial in 2007 for Lead Product in the IVF Market**

CHESTER, NJ -- (MARKET WIRE) -- December 12, 2006 -- Molecular Biometrics, a privately held metabolomics company, today announced the completion of a licensing agreement with McGill University, Montreal, Canada, that secures a broad patent portfolio for the company's metabolomics technology platform. The Company also announced that it is expediting the development of its lead indication of embryo selection for in-vitro fertilization (IVF) and plans to enter into a pivotal U.S. clinical trial early in 2007.

Under the licensing agreement with McGill University, Molecular Biometrics has licensed five broad patents relating to metabolomics and biospectroscopy of biomarkers for use in all biomedical applications, including molecular diagnostics, drug discovery and development and personalized medicine.

The Company's technology platform has broad application in numerous therapeutic categories. To date, Molecular Biometrics has validated its technology in IVF and in four additional therapeutic classes including, but not limited to, maternal fetal medicine, neurodegenerative diseases (such as Alzheimer's and Parkinson's disease), lactate metabolism and pulmonary metabolism. Molecular Biometrics is presently focused on pursuing its lead indication in IVF and is actively engaged in discussions with leading biotechnology and pharmaceutical firms to develop additional indications through partnership agreements.

James T. Posillico, Ph.D., Chief Executive Officer of Molecular Biometrics, commented, "The licensing agreement with McGill affords Molecular Biometrics five key patents and

a secure and broad intellectual property position that ensures the company's freedom to operate and leadership position in metabolomic profiling in numerous therapeutic areas."

Dr. Posillico continued, "Our metabolomic technology platform will initially be applied in the development of molecular diagnostics that can rapidly identify, predict and monitor disease, as well as in pharmacodiagnosics for drug discovery and development. Our lead product candidate, ViaTest-E, is a rapid, non-invasive method to accurately select viable embryos in IVF."

To date, the Company has tested ViaTest-E™ in 432 samples and has commenced a larger multi-national, multi-center clinical study in 16 IVF programs in the USA, Europe and Japan. Compared to other market opportunities, IVF represents the fastest, most direct commercialization path for the Company's technology. To this end, Molecular Biometrics is employing a focused regulatory strategy to achieve marketing approval for ViaTest-E™.

IVF currently requires three or more treatment cycles to achieve a live birth because only 15 percent of embryos transferred in IVF result in pregnancies. To overcome these limitations, IVF programs have widely adopted the clinical practice of multiple embryo transfer (MET) to achieve current pregnancy rates. This in turn, has led to an increased incidence of multiple births with associated neo-natal healthcare costs exceeding \$650 million annually.

Dr. Posillico added, "In its new guidelines, the American Society of Reproductive Medicine (ASRM) has clearly defined the need for a reduction in the number of embryos transferred to decrease the number of multiple births and complications associated with pre-term labor and delivery. In a recently presented, blinded clinical study at ASRM, researchers employing Molecular Biometrics' ViaTest-E accurately identified viable embryos that produced a pregnancy after transfer. We believe this technology offers significant potential for development as a tool to allow rapid, non-invasive assessment of embryo viability prior to transfer in IVF. Enhanced selection criteria by metabolomic profiling should allow a reduction in the number of embryos transferred with the desired effect of lowering multiple gestation rates while maintaining, or possibly increasing, pregnancy rates. A larger multi-national, multi-center study is now underway to further validate these clinical observations."

## Lead Product

Molecular Biometrics' lead product candidate, ViaTest-E™, is a rapid, non-invasive test for embryo viability for the IVF market, where embryo selection is a pivotal step in the treatment procedure. The Company's cost-effective platform enables identification and simultaneous analysis of multiple small molecule biomarkers, in a single sample of discarded culture media, leading to the accurate detection of viable embryos that are capable of producing a pregnancy versus those that are not. The technology is based on the metabolomic profile of specific oxidative stress (OS) biomarkers that distinguish metabolomic differences in viable versus non-viable embryos, so only the highest quality

embryos are identified and selected for transfer in IVF. This technology will also aid in the selection of embryos for cryopreservation. The test takes approximately one minute to complete and requires very small sample volumes (5-10µl).

OS has long been known to negatively affect gamete (egg and sperm) and embryo quality. Complex interactions between pro-oxidants and antioxidants are crucial to the maintenance of normal intracellular homeostasis. An imbalance in these interactions results in OS. Current analytical methods that assess OS rely primarily on biochemical methodologies that are cumbersome, costly and labor intensive. The advent of the Company's metabolomic profiling offers a more expeditious and sensitive means of studying mechanisms of OS.

### Technology Platform

Molecular Biometrics has developed a novel technology platform based on breakthrough metabolomic, bioinformatics and biospectroscopy sciences. These disciplines are used in concert to identify specific biomarkers of OS in a given sample that create novel "metabolomic profiles" of health or disease using highly specific and sensitive bioinformatics. The analysis is performed using a small, low cost and easy to use instrument that has been engineered to integrate the Company's proprietary technology platform. Single use, disposable sample cells are used to hold and analyze a given specimen. The same instrument can be used for multiple therapeutic applications.

### About Molecular Biometrics

Based in Chester, New Jersey, Molecular Biometrics, LLC is a privately held metabolomics company developing highly specific and sensitive analytical methodologies for molecular diagnostic and monitoring applications in medicine, and for drug discovery and development through pharmacodiagnosics based on its novel technology platform of metabolomics. For more information, please visit <http://www.molecularbiometrics.com/>.

### About McGill University

McGill is a top Canadian research-intensive university both in terms of sponsored research income per full-time faculty member and in peer-reviewed publications per full-time faculty member. For more information, please visit <http://www.mcgill.ca/>.

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