

BIOTIME INC
Form 8-K
May 03, 2010
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): May 3, 2010

BioTime, Inc.
(Exact name of registrant as specified in its charter)

| | | |
|---|--------------------------|--------------------------------------|
| California | 1-12830 | 94-3127919 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

1301 Harbor Bay Parkway, Suite 100
Alameda, California 94502
(Address of principal executive offices)

(510) 521-3390
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Statements made in this Report that are not historical facts may constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those discussed. Such risks and uncertainties include but are not limited to those discussed in this report and in BioTime's other reports filed with the Securities and Exchange Commission. Words such as "expects," "may," "will," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions identify forward-looking statements.

Section 2 – Financial Information

Item 2.01 - Completion of Acquisition or Disposition of Assets.

On May 3, 2010, we completed the acquisition of all of the issued preferred shares and ordinary shares of ES Cell International Pte Ltd, a Singapore private limited company ("ESI"), and the secured promissory notes (the "Notes") in the amount of approximately \$35,000,000 of principal and accrued interest, issued by ESI to a former ESI shareholder (the "Acquisition"). We issued, in the aggregate, 1,383,400 BioTime common shares, and warrants to purchase an additional 300,000 common shares at an exercise price of \$10 per share (the "Warrants") to acquire all of the ESI shares and Notes.

Established in 2000, ESI has been at the forefront of advances in human embryonic stem cell ("hES") technology, being one of the earliest distributors of hES cell lines to the research community. More recently, ESI has produced an additional 6 new clinical-grade human embryonic stem cell lines that were derived following principles of good manufacturing practice ("GMP") and currently offers them for potential use in therapeutic product development. ESI's assets also include 20 patent families, including 50 issued patents, in the field of stem cell biology, and a significant equity position in the Israel-based stem cell company Cell Cure Neurosciences Ltd. BioTime plans to combine the newly-acquired assets with its ACTCellerate™ and ReCyte™ technologies to accelerate the development of numerous human therapeutic products.

Clinical-Grade Human Embryonic Stem Cell Master Cell Banks

The development of clinical-grade human therapeutic products requires high standards of quality control. The detailed procedures for all the aspects of production and testing of such products with the potential to impact the safety and quality of a product are commonly called "current good manufacturing practice" or "cGMP." In 2007, ESI scientists published a scientific report on the first derivation of six clinical-grade hES cell lines following principles of cGMP. Titled, "The Generation of Six Clinical-Grade Human Embryonic Stem Cell Lines (*Cell Stem Cell*. 2007 Nov 15;1(5):490-494)," the paper outlined the procedures used to document the production of clinical-grade hES cell lines derived on human feeder cells obtained from an FDA approved source, produced in a licensed cGMP facility, with donor consent and medical screening of donors. Combined with BioTime's ACTCellerate™ technology that allows the derivation of human embryonic progenitor clonal cell lines with high levels of purity and scalability, ESI's clinical-grade hES cell banks could potentially be used to generate clonal clinical-grade embryonic progenitor cell lines with a level of purity and quality unsurpassed in the industry. BioTime expects that the acquisition of ESI's clinical grade cell banks will save the Company years of development time and thereby accelerate the development of clinical grade progenitor cells for potential use in research products and therapeutic products. BioTime's research products are co-marketed worldwide by Millipore Corporation. If ESI is successful in commercializing products that utilize hES cells obtained from providers of hES cell banks, ESI will pay to the providers royalties on the sales of the products. If ESI develops certain human therapeutic products differentiated from an hES cell line provided by a third party, ESI will make milestone payments to the provider of the cell line upon filing investigational new drug applications and obtaining regulator approval of the therapeutic products.

Intellectual Property

ESI's patent portfolio includes 20 patent families covering various aspects of hES cell identification, propagation, genetic manipulation, storage, and directed differentiation of hES cells into other cell types (for example differentiating cells into neuronal progenitors, pancreatic progenitors, or cardiomyocytes). ESI currently holds or licenses from others more than 50 issued patents in various countries, including the United States, the UK, Australia, Israel, and Singapore.

Cell Cure Neurosciences, Ltd.

ESI holds over 49% of the shares of Cell Cure Neurosciences Ltd., an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders, including the development of retinal pigment epithelial cells for the treatment of macular degeneration, and treatments for multiple sclerosis. The other shareholders of Cell Cure are Hadasit BioHoldings Ltd. and Teva Pharmaceutical Industries. Cell Cure will need to raise additional capital to finance its research and development programs.

Singapore Laboratories and Operations

ESI currently has six employees and leases approximately 1,290 square feet of laboratory space and 590 square feet of office space in the Biopolis, a research and development park devoted to the biomedical sciences. Singapore has a long history as a hub for product distribution throughout Asia and India. BioTime will use this facility as a manufacturing and shipping point for sales in these territories.

ESI Financial Results

During its last three fiscal years, ending March 31, 2010, 2009, and 2008, respectively, ESI incurred net losses from operations of approximately S\$4.7 million (unaudited), S\$4.5 million, and S\$8.1 million, respectively, without adjustment to United States generally accepted accounting standards. However, financing costs related to the ESI promissory notes that BioTime will acquire contributed approximately S\$3.2 million (unaudited), S\$1.3 million, and S\$1.1 million to the net loss during each of those fiscal years. Interest on those notes will be eliminated in the consolidation of ESI's financial statements with those of BioTime. Total revenues for the fiscal year ended March 31, 2010 were approximately S\$295,000. At current exchange rates, a Singapore dollar is worth approximately \$0.73 in U.S. dollars.

We will file an amendment of this Report that will include audited financial statements of ESI for the past two fiscal years, and financial statements of BioTime prepared on a pro forma basis reflecting the Acquisition.

Background

Regenerative medicine refers to the development and use of therapies based on hES cell or induced pluripotent stem (“iPS”) cell technology. These therapies will be designed to regenerate tissues afflicted by degenerative diseases. The great scientific and public interest in regenerative medicine lies in the potential of hES and iPS cells to become all of the cell types of the human body. Many scientists therefore believe that hES and iPS cells have considerable potential as sources of new therapies for a host of currently incurable diseases such as diabetes, Parkinson’s disease, heart failure, arthritis, muscular dystrophy, spinal cord injury, macular degeneration, hearing loss, liver failure, and many other disorders where cells and tissues become dysfunctional and need to be replaced.

Since human embryonic stem cells are derived from discarded human embryos created in the process of *in vitro* fertilization, their use in research has been controversial. However, iPS stem cells can be created using noncontroversial adult cells, such as skin cells, rather than embryonic cells. The alteration of specific genes in adult cells allows them to be transformed into iPS cells that are very similar to hES. BioTime’s stem cell-based product development is in the preclinical stages and will require years of extensive testing prior to being used in an effort to treat humans.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOTIME, INC.

Date: May 3, 2010 By: /s/ Steven A. Seinberg
Chief Financial Officer