BIOTIME INC
Form 8-K
November 29, 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): **November 23, 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 8 – Other Events

Item 8.01 – Other Events

On November 23, 2010, we entered into an agreement with the California Institute for Regenerative Medicine (CIRM) to make five clinical-grade human embryonic stem (hES) cell lines available to California-based researchers. CIRM is the stem cell agency that was created when California voters supported a $3 billion funding measure for stem cell-related research and clinical translation. Under the agreement, we will initially provide research-grade cell lines, and within one year we will also make available GMP-compliant grade cell lines along with certain documentation and complete DNA sequence information. GMP-compliant cell lines are hES cell lines that have been produced under conditions intended to comply with current Good Manufacturing Practice (cGMP) quality standards that are required by regulatory authorities, such as the United States Food and Drug Administration, to be used in the manufacture of drugs, therapeutic biological products, and medical devices. The use of the GMP-compliant grade cell lines may streamline the translation of basic science to human therapies. Should the users of our cell lines eventually sign definitive license agreements with us for commercial use of the cell lines or products derived from those cell lines, we anticipate that we will receive a royalty on net sales.

Research grade versions of the cell lines will be provided to CIRM grantees and California-based institutions free of charge until April 30, 2011 for research use only. After that date, the research grade cell lines will be priced at $2,500 per ampoule. The GMP-compliant grade versions of the cell lines along with a letter of cross-reference to a biologics master file containing manufacturing and controls information and additional documentation needed to establish GMP compliance, and complete genomic DNA sequence information on the cell lines, will be available to California-based researchers, at a price approximating our cost of producing and supplying the cell lines, by November 22, 2011. Although no royalties will be payable to us by researchers who acquire the cell lines for research use, researchers that desire to use the GMP cell lines for therapeutic or diagnostic products or for other commercial purposes may do so only after signing commercialization agreements acceptable to us and entitling us to receive royalties on net sales not to exceed 2% of net sales, reducible to 1.5% if the researcher must pay any other royalties in connection with the resulting product commercialization.

We believe that access to our GMP-compliant cell lines may help CIRM-funded researchers accelerate their work in a wide array of new cell-based therapies and drugs, and more quickly translate the research into products to treat diseases. We may benefit, through a royalty-bearing license, from future commercial revenues from any new products developed from our cell lines. The publication of the research results using our cell lines may also benefit our own work to better understand the characteristics of the cell lines when used to manufacture human therapeutics.

Human embryonic stem cell lines are expandable populations of cells with the potential to generate all human cell types. However, there are many scientific and technological steps that are necessary in order to turn this potential into a reality. In recent years, research conducted around the world has shown promising results for hES cell-based therapies for a wide range of diseases. But in order to develop effective therapies for use in humans that will meet the regulatory standards of the FDA and other regulators, the cell lines that are used to develop those therapies must fully comply with the strict clinical GMP quality standards. The creation of such cell lines is a substantial undertaking.

Our Singapore-based subsidiary ES Cell International Pte Ltd. (ESI) has been at the forefront of advances in hES technology since 2000 and created the first cell bank of clinical-grade hES cell lines that were derived following cGMP principles for research use. These cell lines were created under conditions intended to be compliant with international standards of oocyte procurement and embryo donation. In addition, protocols were used in the derivation of the cell lines intended to lead to their conformity to regulations controlling clinical-grade cell and tissue product development, including compliance with current good tissue and manufacturing practices, including potential compliance with guidelines provided by the FDA Center for Biologics Evaluation and Research regarding human cell-based products.

We have agreed to make the following five cell lines available to CIRM grantees and California-based researchers: ESI-014, ESI-017, ESI-035, ESI-051 and ESI-053, which are described in greater detail in an article entitled The Generation of Six Clinical-Grade Human Embryonic Stem Cell Lines by Crook et al, published in *Cell Stem Cell* 2007 Nov 1:490-4.

Section 9 – Financial Statements and Exhibits

Item 9.01 – Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press release dated November 29, 2010

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: November 29, 2010	By:	/s/ Robert W. Peabody
		Senior Vice President, Chief Operating Officer, and Chief Financial Officer

Exhibit Number	Description
99.1	Press release dated November 29, 2010