

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**

BIO TIME, INC.

(Exact name of registrant as specified in its charter)

California

(State or other jurisdiction of
incorporation)

1-12830

(Commission File Number)

94-3127919

(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))
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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," "seeks," "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.

<u>Exhibit Number</u>	<u>Description</u>
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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated November 29, 2010

BioTime, Inc. and the California Institute for Regenerative Medicine Sign Distribution Agreement for GMP-Compliant Human Embryonic Stem Cell Lines

ALAMEDA, Calif.--(BUSINESS WIRE)--November 29, 2010--BioTime, Inc. (NYSE Amex: BTX) today announced 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 created when California voters supported a \$3 billion funding measure for stem cell-related research and clinical translation. Under the agreement, BioTime will initially provide research grade cell lines, and within one year, BioTime will also make available GMP-grade cell lines along with certain documentation and complete DNA sequence information. The parties anticipate that the use of the GMP grade cell lines may streamline the translation of basic science to human therapies. Should the users of the cell lines and BioTime eventually sign definitive license agreements for commercial use of the cell lines, BioTime will receive a royalty on net sales.

Background

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 United States Food and Drug Administration (FDA) and other regulators, the cell lines that are used to develop those therapies must fully comply with the strict current Good Manufacturing Practice (cGMP) quality standards that apply to all drugs and devices. The creation of such cell lines is a substantial undertaking.

BioTime's 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 (Crook et al, 2007 *The Generation of Six Clinical-Grade Human Embryonic Stem Cell Lines* *Cell Stem Cell* 2007 Nov;1:490-4) 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 (cGTPs and cGMPs), including potential compliance with guidelines provided by the U.S. FDA Center for Biologics Evaluation and Research regarding human cell-based products (HCT/Ps) intended for use in human therapeutics described in the Code of Federal Regulations parts 1270 and 1271 (Code of Federal Regulations, 2006a, 2006b). BioTime has agreed to make the following five cells lines available to CIRM grantees and California-based researchers: ESI-014, ESI-017, ESI-035, ESI-051 and ESI-053 described in greater detail in the above-mentioned article. 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.

The GMP grade versions of these 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 the complete genomic DNA sequence information on the cell lines, will be available to California-based researchers at a price approximating BioTime's cost of materials by November 22, 2011. Although no royalties will be payable to BioTime by researchers who acquire the cell lines for research use, entities that desire to use the GMP-compliant cell lines for therapeutic or other commercial purposes, may do so only after signing commercialization agreements acceptable to BioTime and entitling BioTime to receive royalties on net sales not to exceed 2.0% of net sales, reducible to 1.5% if the researcher must pay any other royalties in connection with the resulting product commercialization. The researchers will be responsible for obtaining any licenses that may be needed from third parties to use the GMP cell lines in their products. Lastly, the form of a material transfer agreement has been agreed to by CIRM and BioTime for research use. The pre-negotiation of terms will serve to help accelerate research by eliminating protracted negotiations.

“We believe this agreement is in the best interests of both the people of California and BioTime,” said Michael D. West, Ph.D., BioTime's President and CEO. “There are at least three potential benefits to the parties: First, access to cGMP-manufactured 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 improved medical outcomes for people with difficult to treat diseases. Second, the publication of the research results using these cell lines may benefit BioTime's own work to better understand the characteristics of the lines when used to manufacture human therapeutics. Lastly, BioTime may benefit from future commercial revenues from products developed as a result of this collaboration through a royalty-bearing license. The development of standards and open platforms often allows new fields of science and technology to move forward more quickly. We are grateful to the vision of CIRM in working with industry to advance this exciting science into the clinic.”

A sixth cell line designated ESI-049 is currently being evaluated by a large pharmaceutical company for exclusive use and was therefore not included in the collaborative agreement with CIRM. BioTime will retain the rights to manufacture its own research and therapeutic products from the cell lines. Additional information on the agreement is available on BioTime's website at www.biotimeinc.com.

About BioTime, Inc.

BioTime, headquartered in Alameda, California, is a biotechnology company focused on regenerative medicine and blood plasma volume expanders. Its broad platform of stem cell technologies is developed through subsidiaries focused on specific fields of applications. BioTime develops and markets research products in the field of stem cells and regenerative medicine through its wholly owned subsidiary Embryome Sciences, Inc. BioTime's therapeutic product development strategy is pursued through subsidiaries that focus on specific organ systems and related diseases for which there is a high unmet medical need. BioTime's majority owned subsidiary Cell Cure Neurosciences, Ltd. is developing therapeutic products derived from stem cells for the treatment of retinal and neural degenerative diseases. Cell Cure's minority shareholder Teva Pharmaceutical Industries has an option to clinically develop and commercialize Cell Cure's OpRegen™ retinal cell product for use in the treatment of age-related macular degeneration (AMD). BioTime's subsidiary OrthoCyte Corporation is developing therapeutic applications of stem cells to treat orthopedic diseases and injuries. Another subsidiary, OncoCyte Corporation, focuses on the therapeutic applications of stem cell technology in cancer. BioTime's Singapore subsidiary, ES Cell International Pte Ltd, has been at the forefront of advances in human embryonic stem ("hES") cell technology, having been one of the earliest distributors of hES cell lines to the research community. ESI has produced clinical-grade human embryonic stem cell lines that were derived following principles of Good Manufacturing Practice and currently offers them for potential use in therapeutic product development. In addition to its stem cell products, BioTime develops blood plasma volume expanders, blood replacement solutions for hypothermic (low temperature) surgery, and technology for use in surgery, emergency trauma treatment and other applications. BioTime's lead product, Hextend®, is a blood plasma volume expander manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ CheilJedang Corp. under exclusive licensing agreements. Additional information about BioTime, Embryome Sciences, Cell Cure, OrthoCyte, OncoCyte, BioTime Asia, and ESI can be found on the web at www.biotimeinc.com.

Forward-Looking Statements

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for the company and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the company's business, particularly those mentioned in the cautionary statements found in the company's Securities and Exchange Commission filings. The company disclaims any intent or obligation to update these forward-looking statements.

To receive ongoing BioTime corporate communications, please click on the following link to join our email alert list:
<http://www.b2i.us/irpass.asp?BzID=1152&to=ea&s=0>

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