

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): **December 12, 2011**

**BioTime, 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  
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," "foresees" and similar expressions identify forward-looking statements.

## Section 8 – Other Events

### Item 8.01 – Other Events.

On December 12, 2011, we announced the successful completion of ISO 10993 biocompatibility studies for our product *HyStem*<sup>®</sup>-*Rx*. These tests, as prescribed by the International Organization for Standardization for permanent implantable medical devices, are required by the United States Food and Drug Administration and European Union regulatory authorities prior to beginning clinical studies in humans. The results of these preclinical studies successfully demonstrated the safety and biocompatibility of *HyStem*<sup>®</sup>-*Rx*. *HyStem*<sup>®</sup>-*Rx* is a proprietary biocompatible hydrogel that mimics the human extracellular matrix (ECM), a web of molecules surrounding cells that is essential to cellular function. When cells lacking the ECM or an ECM substitute are introduced into the body, they commonly die or fail to function correctly after transplantation.

We foresee *HyStem*<sup>®</sup> technology as the foundation for the development of unique, injectable cell delivery platforms with applications in a wide variety of tissue engineering and cell-based therapies. Current research at leading medical institutions has shown that *HyStem*<sup>®</sup> is compatible with a wide variety of tissue types including brain, bone, skin, neural, cartilage, and heart tissues.

In its first clinical application, *HyStem*<sup>®</sup>-*Rx* will be used with autologous adipose cells to restore subcutaneous tissue lost as a result of injury, oncologic resection, or congenital defects. Restoration of the normal skin contour is an important quality-of-life issue, not only in elective cosmetic procedures, but also in reconstructive surgeries needed to repair deformities and traumatic injuries to the face and upper extremities.

Our next milestone in the development of *HyStem*<sup>®</sup>-*Rx* will be the completion of manufacture of clinical lots under current good manufacturing practices, and an ISO 13485 certification audit by mid-2012, which will enable the initiation of clinical trials in the European Union by late 2012. Our near term goal is to receive approval to market *HyStem*<sup>®</sup>-*Rx* in the EU for reconstructive and cosmetic surgery in late 2013.

Our plan is to bring *HyStem*<sup>®</sup>-*Rx* to the medical market first in the European Union, where the anticipated cost of the clinical trials would be relatively low. Once the use of *HyStem*<sup>®</sup>-*Rx* in surgery is established in the EU, we plan to seek FDA approval in the United States to address an even larger American market where there are approximately 4 million surgical reconstructive procedures performed per year.

## 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 December 12, 2011

#### 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: December 12, 2011

By: /s/ Michael D. West  
Chief Executive Officer

Exhibit Number

99.1

Description

Press release dated December 12, 2011

## BioTime Successfully Completes *HyStem*<sup>®</sup>-Rx Preclinical ISO 10993 Studies

ALAMEDA, Calif.--(BUSINESS WIRE)--December 12, 2011--BioTime, Inc. (NYSE Amex: BTX), a biotechnology company that develops and markets products in the field of regenerative medicine, today announced the successful completion of ISO 10993 biocompatibility studies for *HyStem*<sup>®</sup>-Rx. These tests, as prescribed by the International Organization for Standardization for permanent implantable medical devices, are required by the United States Food and Drug Administration and European Union regulatory authorities prior to the initiation of clinical studies in humans. The results of these preclinical studies successfully demonstrated the safety and biocompatibility of *HyStem*<sup>®</sup>-Rx.

“This is an important milestone in our commercialization effort and brings us closer to offering much-needed products to clinicians and patients around the world, beginning with the large markets in reconstructive and cosmetic surgery,” stated William P. Tew, Ph.D., Chief Commercialization Officer of BioTime, Inc. “Our *HyStem*<sup>®</sup> technology forms the foundation for unique stem cell delivery products in both the adult and embryonic stem cell marketplace, including products manufactured using BioTime’s ACTCellerate<sup>™</sup> technology. Current research at leading medical institutions has shown that *HyStem*<sup>®</sup> is compatible with a wide variety of tissue types including brain, bone, skin, neural, cartilage, and heart tissues. Our next milestone will be the completion of manufacture of clinical lots under current good manufacturing practices, and an ISO 13485 certification audit by mid-2012, which will enable the initiation of clinical trials in the European Union by late 2012 with the goal of receiving approval to market *HyStem*<sup>®</sup>-Rx in the EU for reconstructive and cosmetic surgery in late 2013.”

In its first clinical application, *HyStem*<sup>®</sup>-Rx will be used with autologous adipose cells to restore subcutaneous tissue lost as a result of injury, oncologic resection, or congenital defects. Restoration of the normal skin contour is an important quality-of-life issue, not only in elective cosmetic procedures, but also in reconstructive surgeries needed to repair deformities and traumatic injuries to the face and upper extremities. BioTime’s plan is to bring *HyStem*<sup>®</sup>-Rx to the medical market first in the EU, where the anticipated cost of the clinical trials would be relatively low. Once the use of *HyStem*<sup>®</sup>-Rx in surgery is established in the EU, BioTime would address an even larger American market where there are approximately 4 million surgical reconstructive procedures performed per year.

*HyStem*<sup>®</sup>-Rx is a proprietary biocompatible hydrogel that mimics the human extracellular matrix (ECM), a web of molecules surrounding cells that is essential to cellular function. When cells lacking the ECM or an ECM substitute are introduced into the body, they commonly die or fail to function correctly after transplantation. *HyStem*<sup>®</sup> hydrogels are currently being used by researchers at a number of leading medical schools in laboratory studies of stem cell therapies to facilitate wound healing and for the treatment of ischemic stroke, brain cancer, vocal fold scarring, and cardiac infarct.

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“BioTime’s *HyStem*<sup>®</sup> product line is one of four components in our near-term revenue strategy, which also includes Hextend<sup>®</sup> revenues, sales of stem cell research products (including the ACTCellerate cell lines and associated products), and planned near-term products being developed by our subsidiary OncoCyte Corporation,” said Michael West, Ph.D., BioTime’s CEO. “These, combined with expected long-term revenues from the potentially very large revenue cell-based therapeutic products that are under development at our subsidiaries, provide BioTime with a balanced commercial strategy. The value of this balance is becoming apparent in the regenerative medicine community as competitors whose sole focus is on long-term therapeutic products find it challenging to raise the requisite capital to fund clinical development.”

### ***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, including a wide array of proprietary ACTCellerate<sup>™</sup> cell lines, culture media, and differentiation kits. BioTime's wholly owned subsidiary ES Cell International Pte. Ltd. has produced clinical-grade human embryonic stem cell lines that were derived following principles of Good Manufacturing Practice and currently offers them for use in research. 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<sup>™</sup> retinal cell product for use in the treatment of age-related macular degeneration. 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 diagnostic and therapeutic applications of stem cell technology in cancer, including using vascular progenitor cells engineered to destroy malignant tumors. ReCyte Therapeutics, Inc. is developing applications of BioTime's proprietary induced pluripotent stem cell technology to reverse the developmental aging of human cells to treat cardiovascular and blood cell diseases. BioTime's newest subsidiary, LifeMap Sciences, Inc., is developing an online database of the complex cell lineages arising from stem cells to guide basic research and to market BioTime's research products. 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<sup>®</sup>, 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, ReCyte Therapeutics, Cell Cure, OrthoCyte, OncoCyte, BioTime Asia, LifeMap Sciences, and ESI can be found on the web at [www.biotimeinc.com](http://www.biotimeinc.com).

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## ***Forward-Looking Statements***

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for BioTime 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 business of BioTime and its subsidiaries, particularly those mentioned in the cautionary statements found in BioTime's Securities and Exchange Commission filings. BioTime 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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