

BIOTIME INC
Form 8-K
December 12, 2011
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 | 1-12830 | 94-3127919 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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," "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*[®]-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*[®]-Rx. *HyStem*[®]-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*[®] 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*[®] is compatible with a wide variety of tissue types including brain, bone, skin, neural, cartilage, and heart tissues.

In its first clinical application, *HyStem*[®]-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*[®]-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*[®]-Rx in the EU for reconstructive and cosmetic surgery in late 2013.

Our plan is to bring *HyStem*[®]-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*[®]-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

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---------------------------------------|
| 99.1 | Press release dated December 12, 2011 |