

BIOTIME INC
Form 8-K
December 16, 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 16, 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))
-

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 16, 2011, we and our subsidiary OncoCyte Corporation announced their plans for a novel diagnostic product designated *PanC-DxTM*. Stemming from original discovery research by us and our subsidiary OncoCyte Corporation, this prospective new antibody-based diagnostic product is designed to detect the presence of a wide array of human cancers during routine check-ups, using a simple blood test, similar to the commonly-used prostate-specific antigen (PSA) test for prostate cancer. Unlike the PSA test, however, initial studies performed by OncoCyte indicate *PanC-DxTM* may be useful in detecting a wide range of cancer types, including cancers of the breast, lung, bladder, uterus, stomach, colon, as well as others. BioTime believes that such a wide-ranging cancer screening tool would facilitate early detection, which could lead to more successful therapy, while reducing the costs of cancer monitoring, and would lead to the greater availability of affordable cancer detection worldwide. BioTime's goal is to launch *PanC-DxTM* in Europe in 2013.

Background

There are tens of thousands of genes in the human DNA code. The pattern of genes that are turned on or off determines the behavior of cells in the body. BioTime developed novel methods of accurately determining the pattern of over 40,000 gene sequences expressed in diverse types of cells arising from embryonic stem cells and induced pluripotent stem cells. Working together, BioTime and OncoCyte scientists discovered a large number of altered genes that appear to be newly discovered cancer-associated genes.

OncoCyte's scientists subsequently determined that the patterns of the proteins produced from a subset of these genes could be detected in the blood of cancer patients, but not in the blood of healthy people. The percentage of times that the test identified people as cancer-free, which defines the test's specificity, was higher than what is observed in commonly used tests such as the PSA test for prostate cancer. This finding, combined with initial evidence that the potential diagnostic may be useful in a broad array of cancer types, including breast, colon, lung, bladder, stomach, uterine cancer, led BioTime and OncoCyte to make the rapid commercialization of *PanC-DxTM* a priority. Another factor considered in choosing the product focus was the rapid growth of the oncology diagnostics market, which based on data published by Business Insights, Ltd. is estimated to reach US \$8.14 billion by 2014, outpacing the growth of the general diagnostics market.

OncoCyte intends to initially develop and market *PanC-DxTM* in Europe, before seeking regulatory approvals required to market the product in the United States and other countries. A blood screening test for cancer markers meets the definition of an *in vitro* diagnostic product as defined in the European Directive on *in vitro* diagnostic medical devices (IVD). Under this directive, IVD products placed into the European market must bear the CE mark, which indicates the product is in conformity with all applicable requirements of safety, performance, instructions, markings, and quality sufficient for the safe and effective use of the product. *PanC-DxTM* is a General IVD under the IVD directive. The CE marking process is accomplished with a self-declaration of Conformity to the requirements of the directive. OncoCyte will be pursuing a full Medical Device Quality System Certification, working with BSI, the British Standards Institute. Our goal is to complete the full quality assurance system certification by the fourth quarter of 2013.

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 16, 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 16, 2011 | By: <u>/s/</u> <u>Michael D.</u> <u>West</u> Chief Executive Officer |
|-------------------------|---|

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---------------------------------------|
| 99.1 | Press release dated December 16, 2011 |