

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**

(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," "expects," "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-Dx<sup>TM</sup>*. 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-Dx<sup>TM</sup>* 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-Dx<sup>TM</sup>* 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-Dx<sup>TM</sup>* 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-Dx<sup>TM</sup>* 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-Dx<sup>TM</sup>* 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: /s/ Michael D. West  
Chief Executive Officer

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

**BioTime's Subsidiary OncoCyte Corporation Announces Plans for the Novel Pan-Cancer Diagnostic Product *PanC-Dx<sup>TM</sup>***

**- A novel blood-based screening method for the early detection of many common human cancers such as those of the breast, colon, and lung -**

ALAMEDA, Calif.--(BUSINESS WIRE)--December 16, 2011--BioTime, Inc. (NYSE Amex: BTX) and BioTime's subsidiary OncoCyte Corporation today announced plans for the development of *PanC-Dx<sup>TM</sup>*, a novel diagnostic device discovered at BioTime and OncoCyte to detect the presence of various human cancers, including cancers of the breast, lung, bladder, uterus, stomach, and colon, during routine check-ups. *PanC-Dx<sup>TM</sup>* would require only a simple antibody-based blood test similar to that commonly used to screen for prostate cancer. Initial studies performed by OncoCyte have indicated that *PanC-Dx<sup>TM</sup>* may be useful for detecting a much wider range of cancer types than that detected by blood tests currently available to clinicians. By facilitating early non-invasive detection, *PanC-Dx<sup>TM</sup>* could lead to more successful therapeutic outcomes while reducing the costs of cancer monitoring and increasing the availability of affordable cancer screening worldwide. BioTime's goal is to launch *PanC-Dx<sup>TM</sup>* 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 associated with cancer.

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 correctly identified people as cancer-free, which defines the test's specificity, was higher than that of commonly used tests such as the prostate-specific antigen test for prostate cancer. This finding, combined with initial evidence that this prospective screening device may be useful for diagnosing a broad range of cancer types, led BioTime and OncoCyte to prioritize the rapid commercialization of *PanC-Dx<sup>TM</sup>*. Another motivation for this product focus was the rapid growth of the oncology diagnostics market, which according to data from Business Insights, Ltd. is estimated to reach US \$8.14 billion by 2014, thus outpacing the growth of the general diagnostics market.

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OncoCyte intends to initially develop and market *PanC-Dx<sup>TM</sup>* 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-Dx<sup>TM</sup>* is classified as a General IVD under the IVD directive. The CE marking process is accomplished by a self-declaration of conformity with the requirements of the directive. Working with the British Standards Institute, OncoCyte will be pursuing full medical device quality system certification, which should be achieved by the fourth quarter of 2013.

“There is an opportunity for OncoCyte to rapidly meet the essential regulatory requirements to receive a European CE Mark for this new class of cancer diagnostics,” said Joseph Wagner, Ph.D., CEO of OncoCyte. “Our initial evidence of high sensitivity and specificity of the product, our aggressive filing for patent protection, the great unmet need in the field, and the tie-in of the molecules used in the diagnostic product with our stem cell-based therapeutic strategy give us an ideal ‘theragnostic’ model under which we are co-developing a diagnostic and an associated therapeutic that hinge on the same biology. All these factors led to our choice of *PanC-Dx<sup>TM</sup>* as OncoCyte’s lead diagnostic product.”

“There is a great need for rapidly deployed, effective screens to identify a wide array of human cancers at their earliest stages,” said Dr. Andrew von Eschenbach, former U.S. Food and Drug Administration Commissioner, former Director of the U.S. National Cancer Institute, and the newest member of the BioTime and OncoCyte boards of directors. “Early detection remains our current best hope for achieving cures, and therefore the development of more accurate diagnostics and screens for all major cancer types should be a national priority.”

### **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>TM</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>TM</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®, 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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## ***About OncoCyte Corporation***

OncoCyte Corporation is a majority-owned privately-held subsidiary of BioTime, Inc. OncoCyte's mission is to develop novel products for the diagnosis and treatment of cancer based on embryonic stem cell-derived technology in order to improve both the quality and length of life of cancer patients. OncoCyte's molecular diagnostics division is developing products that should provide for earlier detection and more effective treatment of numerous cancers. In addition to its diagnostic product line, OncoCyte is developing cellular therapies to treat cancer based on the unique biology of vascular precursor cells. The goal of OncoCyte's therapeutic research efforts is to derive vascular cells that can be engineered to deliver a toxic payload to the developing blood vessels of a malignant tumor to destroy the tumor without killing nearby normal tissues in the body. Additional information on OncoCyte can be found on the web at [www.oncocyte.com](http://www.oncocyte.com).

## ***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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