

UNITED STATES  
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): **October 20, 2014**

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

Any statements that are not historical fact (including, but not limited to statements that contain words such as “may,” “will,” “believes,” “plans,” “intends,” “anticipates,” “expects,” “estimates”) should also be considered to be forward-looking statements. Additional factors that could cause actual results to differ materially from the results anticipated in these forward-looking statements are contained in BioTime’s periodic reports filed with the SEC under the heading “Risk Factors” and other filings that BioTime may make with the Securities and Exchange Commission. Undue reliance should not be placed on these forward-looking statements which speak only as of the date they are made, and the facts and assumptions underlying these statements may change. Except as required by law, BioTime disclaims any intent or obligation to update these forward-looking statements.

## **Section 8 – Other Events**

### **Item 8.01 Other Events**

We have received authorization from the Spanish Agency of Medicines and Medical Devices (AEMPS) to begin a pivotal human clinical trial of *Renovia*<sup>TM</sup> in Spain. In the trial, *Renovia* will be used in combination with the patient’s own fat-derived cells and injected into portions of the patient’s face where there has been a loss of fat from under the skin (lipoatrophy). Lipoatrophy is estimated to occur in 35-50% of the 10 million HIV patients on antiretroviral therapy.

#### ***About the Renovia Clinical Trial***

We will conduct a randomized, evaluator-blinded, delayed-treatment-controlled study of the effectiveness and safety of *Renovia*<sup>TM</sup> as a resorbable matrix for the delivery of autologous adipose-derived cells to treat subcutaneous facial lipoatrophy defects arising from HIV infection. The study will include a minimum of 56 and up to 92 HIV positive males and females between 18-65 years of age. Subjects will be randomized with half in the treatment group and half in a delayed-treatment cohort, each receiving a single treatment course of *Renovia*<sup>TM</sup> with autologous adipose cells harvested by liposuction and implanted in the mid-facial region. The primary effectiveness measure will be the comparison of the change in skin thickness between the treatment and delayed treatment groups. A secondary endpoint will be mid-face volume deficit and global aesthetic improvement scores. Patients will be monitored at one, three, and six-month intervals after treatment. Patient enrollment, which has begun, is expected to be completed in 2015. Additional information on the trial will be made available on BioTime’s website at [www.biotimeinc.com](http://www.biotimeinc.com).

The trial will be conducted at The Stem Center in Palma de Mallorca, Spain, an innovative patient therapy center, laboratory, and professional research facility located within the Clinica USP Palma Planas hospital in Palma. The Medical Director of The Stem Center and Principal Investigator for the *Renovia* studies, Ramon Llull, MD, PhD, is a leading expert on advanced regenerative therapies based on adipose technology.

## About Facial Lipoatrophy

Facial lipoatrophy is a condition characterized by localized loss of fat under the skin. It is common in HIV-infected patients on antiretroviral therapy (ART), and the resulting facial wasting ages the individual's appearance prematurely and, along with a thinning of the skin, allows musculature and vasculature to be easily seen, resulting in what is commonly known as "the face of AIDS." Treatment of the condition has been determined to be medically advisable to improve the individual's self esteem and quality of life.

While the use of highly active ART in the treatment of HIV-positive patients has greatly increased longevity, the reported incidence of HIV-associated lipoatrophy has correspondingly risen. According to statistics published by AVERT ([www.avert.org](http://www.avert.org)), worldwide there were 34 million people living with HIV/AIDS in 2011 with 900,000 of these in western and central Europe and 1.4 million in North America. UNICEF, UNAIDS, and the World Health Organization (WHO) reported in 2013 that the number of people receiving ART has tripled in five years to approximately 10 million people. A substantial effort is underway to reach a global target of 15 million people receiving ART by the end of 2015.

At present, commonly-used products for the treatment of HIV-related lipoatrophy include dermal fillers or products that trigger fibrotic reactions which create fibrous tissue that has an effect of bulking the skin, but not a restoration of natural subcutaneous fat with its associated texture and appearance. A full course of treatment of those products can require multiple injections over a period of several months. We expect that a single treatment of *Renevia* with adipose-derived cells when injected with a small gauge cannula will result in a reconstitution of normal subcutaneous fat and restoration of skin contour.

## 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 4, 2014

**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 4, 2014

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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated November 4, 2014

**BioTime Receives Authorization to Begin Pivotal Human Clinical Trial of *Renovia*<sup>TM</sup> in Europe**

- ***Renovia*<sup>TM</sup> to be utilized in the treatment of HIV-related lipoatrophy, a disorder estimated to afflict more than 3.5 million patients globally**
- **Patient enrollment initiated; expected to be completed in 2015**

ALAMEDA, Calif.--(BUSINESS WIRE)--November 4, 2014--BioTime, Inc. (NYSE MKT:BTX) today reported that it has received authorization to begin its pivotal human clinical trial of *Renovia*<sup>TM</sup> in Europe. In the trial, *Renovia* will be used in combination with the patient's own fat-derived cells and injected into portions of the patient's face where there has been a loss of fat from under the skin (lipoatrophy). Lipoatrophy is estimated to occur in 35-50% of the 10 million HIV patients on antiretroviral therapy. This pivotal trial follows the previous successful safety trial of *Renovia*, the completion of which was announced earlier in 2014.

"*Renovia* has the potential to be the first approved product that allows cells to be easily transplanted through a syringe and then safely polymerized into three-dimensional tissue constructs within the human body," said William Tew, Ph.D., BioTime's Chief Commercial Officer. "We are excited to enter this last phase of clinical trials for *Renovia* as well as by the promise of this technology for the transplantation of other types of cells to address unmet medical needs. BioTime considers *Renovia* a key strategic asset for its future regenerative medicine programs which are focused on the development of human embryonic stem cell-derived brown adipocytes, vascular, and osteochondral cells to treat tissues afflicted with degenerative disease. If the pivotal trial meets its primary end points, then we would expect to submit *Renovia* for CE Mark approval in 2016."

***About the Renovia Clinical Trial***

The Spanish Agency of Medicines and Medical Devices (AEMPS) authorized BioTime to conduct a randomized, evaluator-blinded, delayed-treatment-controlled study of the effectiveness and safety of *Renovia* as a resorbable matrix for the delivery of autologous adipose-derived cells to treat subcutaneous facial lipoatrophy defects arising from HIV infection. The study will include a minimum of 56 and up to 92 HIV positive males and females between 18-65 years of age. Subjects will be randomized with half in the treatment group and half in a delayed-treatment cohort, each receiving a single treatment course of *Renovia*<sup>TM</sup> with autologous adipose cells harvested by liposuction and implanted in the mid-facial region. The primary effectiveness measure will be the comparison of the change in skin thickness between the treatment and delayed treatment groups. A secondary endpoint will be mid-face volume deficit and global aesthetic improvement scores. Patients will be monitored at one, three, and six-month intervals after treatment. Patient enrollment, which has begun, is expected to be completed in 2015. Additional information on the trial will be made available on BioTime's website at [www.biotimeinc.com](http://www.biotimeinc.com).

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The trial will be conducted at The Stem Center in Palma de Mallorca, Spain, an innovative patient therapy center, laboratory, and professional research facility located within the Clinica USP Palma Planas hospital in Palma. The Medical Director of The Stem Center and Principal Investigator for the *Renevia* studies, Ramon Llull, MD, PhD, is a leading expert on advanced regenerative therapies based on adipose technology.

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While the use of highly active ART in the treatment of HIV-positive patients has greatly increased longevity, the reported incidence of HIV-associated lipoatrophy has correspondingly risen. According to statistics published by AVERT ([www.avert.org](http://www.avert.org)), worldwide there were 34 million people living with HIV/AIDS in 2011 with 900,000 of these in western and central Europe and 1.4 million in North America. UNICEF, UNAIDS, and the World Health Organization (WHO) reported in 2013 that the number of people receiving ART has tripled in five years to approximately 10 million people. A substantial effort is underway to reach a global target of 15 million people receiving ART by the end of 2015.

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## **HyStem<sup>®</sup> Technology and Renevia<sup>™</sup>**

BioTime's HyStem<sup>®</sup> hydrogels, including Renevia, are a family of unique and proprietary biomaterials that are designed to function as adhesion matrices for the stable attachment and survival of cells. The failure rate in many applications of cell grafts without such a matrix is high because of difficulties in achieving cell attachment and survival. The achievement of high success rates for cell grafts would create opportunities to develop cell therapies for many high unmet medical needs. A unique feature of the proprietary technology is that it allows the mixture of cells with the matrix in a liquid form such that the cells and matrix can be injected easily and safely through a small gauge syringe, and then the matrix can polymerize around the cells to create a three-dimensional tissue within the body. HyStem hydrogels are currently sold worldwide by BioTime and its distributors for pre-clinical research for a wide array of applications in regenerative medicine including the engraftment of cells in the brain, liver, cartilage and bone, heart, and vocal cords. Premvia,<sup>™</sup> a HyStem based hydrogel, is a recently FDA-cleared medical device indicated for the management of wounds. BioTime's HyStem technology is covered by two issued US patents with applications pending in the EU, Canada, Japan, and Australia.

### **About BioTime**

BioTime is a biotechnology company engaged in research and product development in the field of regenerative medicine. Regenerative medicine refers to therapies based on stem cell technology that are designed to rebuild cell and tissue function lost due to degenerative disease or injury. BioTime's focus is on pluripotent stem cell technology based on human embryonic stem ("hES") cells and induced pluripotent stem ("iPS") cells. hES and iPS cells provide a means of manufacturing every cell type in the human body and therefore show considerable promise for the development of a number of new therapeutic products. BioTime's therapeutic and research products include a wide array of proprietary PureStem<sup>®</sup> progenitors, HyStem hydrogels, culture media, and differentiation kits. Renevia<sup>™</sup> (a HyStem<sup>®</sup> product), is now in a pivotal trial in Europe as a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in the treatment of HIV-related lipodystrophy. In addition, BioTime has developed Hextend<sup>®</sup>, a blood plasma volume expander for use in surgery, emergency trauma treatment and other applications. Hextend<sup>®</sup> is manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ HealthCare Corporation, under exclusive licensing agreements.

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BioTime is also developing stem cell and other products for research, therapeutic, and diagnostic use through its subsidiaries:

- Asterias Biotherapeutics, Inc. is developing pluripotent stem-cell based therapies in neurology and oncology, including AST-OPC1 oligodendrocyte progenitor cells in spinal cord injury, multiple sclerosis and stroke, and AST-VAC2, an allogeneic dendritic cell-based cancer vaccine. Asterias trades publicly on the NYSE MKT under the symbol AST.
- BioTime Asia, Ltd., a Hong Kong company, may offer and sell products for research use for BioTime's ESI BIO Division.
- Cell Cure Neurosciences Ltd. is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders. *OpRegen<sup>TM</sup>* is currently in a Phase I/IIa clinical trial for the treatment of the dry-form of age-related macular degeneration. .
- ESI BIO is the research and product marketing division of BioTime, providing stem cell researchers with products and technologies to enable them to translate their work into the clinic, including *PureStem<sup>®</sup>* progenitors and *HyStem<sup>®</sup>* hydrogels.
- LifeMap Sciences, Inc. markets, sells, and distributes *GeneCards<sup>®</sup>*, the leading human gene database, as part of an integrated database suite that also includes the *LifeMap Discovery<sup>®</sup>* database of embryonic development, stem cell research, and regenerative medicine, and *MalaCards*, the human disease database.
- LifeMap Solutions, Inc. is a subsidiary of LifeMap Sciences focused on developing mobile health (mHealth) products.
- OncoCyte Corporation is developing products and technologies to diagnose and treat cancer, including *PanC-Dx<sup>TM</sup>*, with four clinical studies currently underway.
- OrthoCyte Corporation is developing therapies to treat orthopedic disorders, diseases and injuries.
- ReCyte Therapeutics, Inc. is developing therapies to treat a variety of cardiovascular and related ischemic disorders, as well as products for research using cell reprogramming technology.

BioTime stock is traded on the NYSE MKT, ticker BTX. For more information, please visit [www.biotimeinc.com](http://www.biotimeinc.com) or connect with the company on Twitter, LinkedIn, Facebook, YouTube, and Google+.

### **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://news.biotimeinc.com>

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