BIOTIME INC
Form 8-K
November 04, 2014

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	**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))

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-looki 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 *Renevia*™ in Spain. In the trial, *Renevia* 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 Renevia Clinical Trial

We will conduct a randomized, evaluator-blinded, delayed-treatment-controlled study of the effectiveness and safety of *Renevia*™ 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 *Renevia*™ 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.

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.

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), 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.

Exhibit Number	Description
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

Exhibit Number	Description
99.1	Press Release dated November 4, 2014

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