BIOTIME INC
Form 8-K
November 03, 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 31, 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**

On October 31, 2014, the United States Food and Drug Administration (FDA) cleared the Investigational New Drug application submitted by our subsidiary Cell Cure Neurosciences Ltd. to initiate a Phase I/IIa clinical trial of its lead product *OpRegen*® in patients with the severe form of age-related macular degeneration (AMD) called geographic atrophy (GA). AMD is the leading cause of blindness in the aging US population and many other developed countries around the world. While treatment options exist for the treatment of the wet form of AMD, it amounts to only about 10% of the disease prevalence. There is currently no FDA-approved therapy for the dry form of the disease occurring in approximately 90% of all patients with AMD.

*OpRegen*® consists of animal product-free retinal pigment epithelial (RPE) cells with high purity and potency that were derived from human embryonic stem cells (hESCs). Cell Cure Neurosciences will conduct the trial in Israel where *OpRegen*® will be transplanted as a single dose into the subretinal space of the eye to test the safety and efficacy of the product. Patient enrollment is expected to begin in 2014 following approval of the trial by the Israel Ministry of Health.

***About the OpRegen® Clinical Trial***

The Phase I/IIa clinical trial is a dose escalation safety and preliminary efficacy study of hESC-derived RPE cells transplanted subretinally in patients with advanced dry-form AMD called geographic atrophy. The open-label, single center, nonrandomized trial will evaluate three different dose regimens of 50,000 to 500,000 cells. A total of 15 patients will be enrolled. The patients will be 55 years of age and older, with non-neovascular (dry-AMD) who have funduscopic findings of GA in the macula with absence of additional concomitant ocular disorders. The eye most affected by the disease will be treated with the contralateral eye being the control. Following transplantation, the patients will be followed for 12 months at specified intervals, to evaluate the safety and tolerability of *OpRegen*®. A secondary objective of the clinical trial will be to examine the ability of transplanted *OpRegen*® to engraft, survive, and induce changes in visual acuity. In addition to thorough characterization of visual function, a battery of defined ophthalmic imaging modalities will be used to quantify structural changes and rate of GA expansion. The study will be performed at Hadassah Ein Kerem Medical Center in Jerusalem, Israel.

Information about the trial will be made available at ClinicalTrials.gov website of the National Institutes of Health http://www.clinicaltrials.gov/ct2/home. Additional information will be made available on Cell Cure Neuroscience's website at http://www.cellcureneurosciences.com/.

***About Age-Related Macular Degeneration***

AMD is one of the major diseases of aging and is the leading eye disease responsible for visual impairment of older persons in the US, Europe and Australia. AMD affects the macula, which is the part of the retina responsible for sharp, central vision that is important for facial recognition, reading and driving. There are two forms of AMD. The dry form (dry-AMD) advances slowly and painlessly but may progress to geographic atrophy (GA) in which RPE cells and photoreceptors degenerate and are lost. Once the atrophy involves the fovea (the center of the macula), patients lose their central vision and may develop legal blindness. There are about 1.6 million new cases of dry-AMD in the US annually, and as yet there is no effective treatment for this condition. The market opportunity for a treatment for GA has been estimated at over $5 billion globally. About 10% of patients with dry-AMD develop wet (or neovascular) AMD, the second main form of this disease, which usually manifests acutely and can lead to severe visual loss in a matter of weeks. Wet-AMD can be treated with currently marketed VEGF inhibitors. However, such products typically require frequent repeated injections in the eye, and patients often continue to suffer from continued progression of the underlying dry-AMD disease process. Current annual sales of VEGF inhibitors for the treatment of the wet form of AMD are estimated to be about $7 billion worldwide.

The root cause of the larger problem of dry-AMD is believed to be the dysfunction of RPE cells. Therefore, one of the most exciting new therapeutic strategies for dry-AMD is the transplantation of healthy young RPE cells to support and replace those lost with age. Pluripotent stem cells, such as hESCs, can potentially provide a means of manufacturing such healthy RPE cells on an industrial scale.

***About OpRegen®***

*OpRegen®* consists of RPE cells that are produced using a proprietary process that drives the differentiation of human embryonic stem cells into high purity RPE cells. *OpRegen®* is also "xeno-free," meaning that no animal products were used either in the derivation and expansion of the human embryonic stem cells or in the directed differentiation process. The avoidance of the use of animal products eliminates some safety concerns. *OpRegen®* is formulated as a suspension of RPE cells. Preclinical studies in mice have shown that following a single subretinal injection of *OpRegen®* as a suspension of cells, the cells can rapidly organize into their natural monolayer structure and survive throughout the lifetime of the animal. *OpRegen®* is anticipated to be an "off-the-shelf" allogeneic product provided to retinal surgeons in a final formulation ready for transplantation. Unlike treatments for wet-AMD that require multiple, frequent injections into the eye, it is expected that *OpRegen®* would be administered in a single procedure.

**Section 9 – Financial Statements and Exhibits**

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated November 3, 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 3, 2014 By: /s/ Michael D. West
Chief Executive Officer

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated November 3, 2014 |

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