

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

(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

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](http://www.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.

<u>Exhibit Number</u>	<u>Description</u>
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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated November 3, 2014

BioTime's Subsidiary Cell Cure Neurosciences Receives FDA Authorization to Initiate Phase I/IIa Trial of Embryonic Stem Cell-Derived *OpRegen*[®] for the Treatment of the Dry Form of Age-Related Macular Degeneration

- **IND cleared for Phase I/IIa dose escalation trial in patients with the dry form of age-related macular degeneration (AMD) called geographic atrophy (GA)**
- **No approved therapy exists for dry-AMD, the leading cause of visual impairment in an aging population in the US and other developed countries**
- ***OpRegen*[®] will be the first preparation of xeno-free human embryonic stem cell-derived RPE cells evaluated for transplant therapy of dry-AMD**

ALAMEDA, Calif. & JERUSALEM--(BUSINESS WIRE)--November 3, 2014--BioTime, Inc. (NYSE MKT:BTX) and Cell Cure Neurosciences Ltd. (Cell Cure) today announced that the U.S. Food and Drug Administration (FDA) has cleared Cell Cure's Investigational New Drug (IND) application to initiate a Phase I/IIa clinical trial of *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.

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***About the OpRegen*[®] Clinical Trial**

Cell Cure's Phase I/IIa clinical trial is a dose escalation safety and preliminary efficacy study of hESC-derived Retinal Pigment Epithelial (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 fundoscopic 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.

“The FDA’s acceptance of our IND for the Phase I/IIa trial of *OpRegen*[®] is a significant milestone for our company, and in the broader development of therapies based on human embryonic stem cells for the treatment of major diseases,” said Benjamin Reubinoff, MD, PhD, Chief Scientific Officer of Cell Cure and Chairman of Obstetrics and Gynecology and Director of the Hadassah Human Embryonic Stem Cell Research Center at Hadassah Medical Center, Jerusalem, Israel. “We look forward to initiating this first-of-its-kind study, and to continuing the clinical development of *OpRegen*.”

“Cell Cure’s Phase I/IIa study of *OpRegen*[®] has been designed to provide preliminary, objective functional and structural data on the ability of hESC-RPE cell transplantation to slow the progression of geographic atrophy, in addition to safety data,” added Prof. Eyal Banin, Head of the Center for Retinal and Macular Degenerations at the Department of Ophthalmology of Hadassah University Medical Center, Jerusalem, Israel who together with Prof. Reubinoff helped develop this novel treatment over the last decade. “We are truly excited that this unique, hESC-based therapy will finally be tested in patients with dry-AMD which severely impacts the quality of life of the elderly, and for which no approved therapy yet exists,” Dr. Banin stated.

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’s website at <http://www.cellcureneurosciences.com/>.

About Age-Related Macular Degeneration

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About Cell Cure Neurosciences Ltd.

Cell Cure Neurosciences Ltd. was established in 2005 as a subsidiary of ES Cell International Pte. Ltd. (ESI), now a subsidiary of BioTime, Inc. (NYSE MKT: BTX). BioTime directly and indirectly through its subsidiaries owns approximately 62.5% of Cell Cure. Cell Cure's second largest shareholder is HBL- Hadasit Bio-Holdings, (TASE: HDST, OTC: HADSY) followed by Teva Pharmaceuticals Industries Ltd. (NYSE: TEVA). Cell Cure is located in Jerusalem, Israel on the campus of Hadassah Medical Center. Cell Cure's mission is to become a leading supplier of human cell-based therapies for the treatment of retinal and neural degenerative diseases. Its technology platform is based on the manufacture of diverse cell products sourced from clinical-grade (GMP-compatible) human embryonic stem cells. Its current focus is the development of retinal pigment epithelial (RPE) cells for the treatment of age-related macular degeneration. Additional information about Cell Cure can be found on the web at www.cellcureneurosciences.com. A video of a presentation by Cell Cure's CEO Dr. Charles Irving is available on BioTime's website.

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[®]* progenitors, *HyStem[®]* hydrogels, culture media, and differentiation kits. BioTime is developing *Renovia[™]* (a *HyStem[®]* product) as a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in human clinical applications, and is planning to initiate a pivotal clinical trial around *Renovia[™]*, in 2014. In addition, BioTime has developed *Hextend[®]*, a blood plasma volume expander for use in surgery, emergency trauma treatment and other applications. *Hextend[®]* is manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ HealthCare Corporation, under exclusive licensing agreements.

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, including the development of retinal pigment epithelial cells for the treatment of macular degeneration, and treatments for multiple sclerosis.
- 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*[®] progenitors and *HyStem*[®] hydrogels.
- LifeMap Sciences, Inc. markets, sells, and distributes *GeneCards*[®], the leading human gene database, as part of an integrated database suite that also includes the *LifeMap Discovery*[®] 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*[™], 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 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.

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<http://news.biotimeinc.com>

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