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): **September 25, 2015**

# 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-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 Securities and Exchange Commission ("SEC") under the heading "Risk Factors" and other filings that BioTime may make with the SEC. 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.*

*Item 7 of this Report and Exhibit 99.1 shall be deemed "furnished" and not "filed" under the Securities Exchange Act of 1934, as amended.*

## Section 8 – Other Events

## Item 8.01 – Other Events

On September 25, 2015, the U.S. Food and Drug Administration ("FDA") notified our subsidiary Cell Cure Neurosciences Ltd. ("Cell Cure") that the FDA has granted Fast Track designation for *OpRegen*®, a cell-based therapeutic product consisting of retinal pigment epithelial (RPE) cells designed to block the progression of the severe dry-form of age-related macular degeneration (AMD), a leading cause of blindness in an aging population.

Under an Investigational New Drug Application (IND) for "Retinal Pigment Epithelium (RPE) Cells derived from Allogenic Human Embryonic Stem Cells; Transplanted Subretinally" and after receiving approval from the Israel Ministry of Health, Cell Cure is now enrolling patients at Hadassah University Medical Center in Jerusalem, Israel, in a clinical Phase I/IIa dose-escalation study evaluating the safety and efficacy of *OpRegen*® for geographic atrophy (GA), the severe stage of the dry form of age-related macular degeneration (dry-AMD). The first patient was treated earlier this year and Cell Cure expects to provide interim data in early 2016.

The FDA grants Fast Track designation if it determines that a drug fills an unmet medical need in a serious condition. According to the FDA, a drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

Additional information about the FDA Fast Track Designation can be found on the FDA's website at www.fda.gov.

## Section 7 - Regulation FD

## Item 7.01 - Regulation FD Disclosure

The press release furnished as Exhibit 99.1 to this Report is incorporated by reference into this Item 7.01.

## Section 9 – Financial Statements and Exhibits

## Item 9.01 – Financial Statements and Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release, dated September 28, 2015 |

**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: September 28, 2015

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


| Exhibit Number | Description |
|---|---|
| 99.1 | Press release, dated September 28, 2015 |

**Exhibit 99.1**

**BioTime's Subsidiary Cell Cure Neurosciences Ltd. Receives FDA Fast-Track Designation for *OpRegen*® for the Treatment of the Dry Form of Age-Related Macular Degeneration**

ALAMEDA, Calif. & JERUSALEM--(BUSINESS WIRE)--September 28, 2015--BioTime, Inc. (NYSE MKT and TASE: BTX) and its subsidiary Cell Cure Neurosciences Ltd. ("Cell Cure") today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track designation for *OpRegen*®, a cell-based therapeutic product consisting of retinal pigment epithelial (RPE) cells designed to block the progression of the severe dry-form of age-related macular degeneration (AMD), a leading cause of blindness in an aging population.

Under an Investigational New Drug Application (IND) for "Retinal Pigment Epithelium (RPE) Cells derived from Allogenic Human Embryonic Stem Cells; Transplanted Subretinally" and after receiving approval from the Israel Ministry of Health, Cell Cure is now enrolling patients at Hadassah University Medical Center in Jerusalem, Israel, in a clinical Phase I/IIa dose-escalation study evaluating the safety and efficacy of *OpRegen*® for geographic atrophy (GA), the severe stage of the dry form of age-related macular degeneration (dry-AMD). The first patient was treated earlier this year and Cell Cure expects to provide interim data in early 2016.

The FDA grants Fast Track designation if it determines that a drug fills an unmet medical need in a serious condition. According to the FDA, a drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

Additional information about the FDA Fast Track Designation can be found on the FDA's website at www.fda.gov.

***About Dry Age-Related Macular Degeneration (Dry–AMD)***

Dry AMD is the most common type of macular degeneration and affects approximately 90% of people with the disorder. In the dry form, there is a loss or dysfunction of the layer of retinal pigment epithelial (RPE) cells, generally in the region of the eye called the macula. These RPE cells support the light detecting photoreceptor cells that are so critical to vision. When we look at something, the photoreceptors (rods and cones) detect the light and send the information to the brain allowing us to perceive our surroundings. The age-dependent loss of the RPE cells therefore leads to degeneration of nearby photoreceptors and this can lead to severe vision loss or even blindness. Generally, the damage caused by the "dry" form is not as severe or rapid as that of the "wet" form. However, over time, it can cause profound vision loss. The more advanced stage of dry macular degeneration is called geographic atrophy. While there are therapeutics available to treat the wet form of AMD, there are currently no FDA-approved therapies for dry-AMD.

***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. Cell Cure is located in Jerusalem, Israel on the campus of Hadassah University Hospital. Cell Cure's mission is to become a leading supplier of human embryonic stem 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) human embryonic stem cells. Its current focus is the development of retinal pigment epithelial (RPE) cells for the treatment of age-related macular degeneration. Cell Cure's major shareholders include BioTime, Inc., Hadasit BioHoldings Ltd. (Tel Aviv Stock Exchange: HDST), and Teva Pharmaceuticals Industries Ltd. (NYSE: TEVA). Additional information about Cell Cure can be found on the web at www.cellcureneurosciences.com.

***About BioTime***

BioTime, Inc., a pioneer in regenerative medicine, is a clinical-stage biotechnology company. BioTime and its subsidiaries are leveraging their industry-leading experience in pluripotent stem cell technology and a broad intellectual property portfolio to facilitate the development and use of cell-based therapies and gene marker-based molecular diagnostics for major diseases and degenerative conditions for which there presently are no cures. The lead clinical programs of BioTime and its subsidiaries include *OpRegen*®, currently in a Phase I/IIa trial for the treatment of the dry form of age-related macular degeneration; *AST-OPC1*, currently in a Phase I/IIa trial for spinal cord injuries; *Renevia*™, currently in a pivotal trial in Europe as an injectable matrix for the engraftment of transplanted cells to treat HIV-related lipoatrophy; and cancer diagnostics, nearing the completion of initial clinical studies for the detection of lung, bladder, and breast cancers. *AST-VAC2*, a cancer vaccine, is in the pre-clinical trial stage.

BioTime’s subsidiaries include the publicly traded Asterias Biotherapeutics, Inc. (NYSE MKT: AST), developing pluripotent stem cell-based therapies in neurology and oncology, including *AST-OPC1* and *AST-VAC2*; Cell Cure Neurosciences Ltd., developing stem cell-based therapies for retinal and neurological disorders, including *OpRegen*®; OncoCyte Corporation, developing cancer diagnostics; LifeMap Sciences, Inc., developing and marketing an integrated online database resource for biomedical and stem cell research; LifeMap Solutions, Inc., a subsidiary of LifeMap Sciences, developing mobile health (mHealth) products; ES Cell International Pte Ltd, which has developed cGMP-compliant human embryonic stem cell lines that are being marketed by BioTime for research purposes under the ESI BIO branding program; OrthoCyte Corporation, developing therapies to treat orthopedic disorders, diseases, and injuries; and ReCyte Therapeutics, Inc., developing therapies to treat a variety of cardiovascular and related ischemic disorders.

BioTime common stock is traded on the NYSE MKT and TASE under the symbol 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.

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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