BIOTIME INC
Form 8-K
September 28, 2015

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-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 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