

BIOTIME INC
Form 8-K
February 17, 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): **February 15, 2015**

BioTime, Inc.

(Exact name of registrant as specified in its charter)

California

1-12830

94-3127919

(Commission File Number) (IRS Employer

(State or other jurisdiction
of incorporation)

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 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 1 - Registrant’s Business and Operations

Item 1.01 - Entry into a Material Definitive Agreement.

On February 15, 2015, the option granted by our majority owned subsidiary Cell Cure Neurosciences Ltd. (“Cell Cure”) to Teva Pharmaceutical Industries Ltd. (“Teva”) under a Research and Exclusive Option Agreement (the “Option Agreement”), dated October 7, 2010, to license-in rights to complete the development and to commercialize Cell Cure’s *OpRegen*[®] product expired without having been exercised by Teva. As a result the Option Agreement has terminated. Cell Cure is continuing the clinical development of *OpRegen* and will be pursuing discussions with potential strategic partners, including those that have already indicated interest in participating in development and commercialization of the product.

See Item 8 below for additional recent developments concerning Cell Cure’s development of *OpRegen*.

Section 8 - Other Events

Item 8.01 - Other Events

On February 16, 2015, Cell Cure’s clinical trial of *OpRegen* opened at Hadassah University Medical Center in Jerusalem. The clinical trial is entitled “Phase I/IIa Dose Escalation Safety and Efficacy Study of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Patients with Advanced Dry-Form Age-Related Macular Degeneration with Geographic Atrophy.” Patient enrollment is expected to begin shortly. *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) using a proprietary directed differentiated method, for which a new US patent No. 8,956,866 is expected to issue on February 17, 2015.

The Phase I/IIa clinical trial, will evaluate three different dose regimens of *OpRegen*. Following transplantation, the patients will be followed for 12 months at specified intervals, to evaluate the safety and tolerability of the product. Following the initial 12 month period, patients will continue to be monitored at longer intervals for an additional period of time. A secondary objective of the clinical trial will be to examine the ability of transplanted *OpRegen* to engraft, survive, and moderate disease progression in the patients. In addition to thorough characterization of visual function, a battery of ophthalmic imaging modalities will be used to quantify structural changes and rate of geographic atrophy expansion.

The new U.S. patent, entitled “Retinal Pigment Epithelial Cells Differentiated from Embryonic Stem Cells With Nicotinamide and Activin A” claims a proprietary method of enhancing the yield of retinal pigment epithelial cells

which are the active ingredient of *OpRegen*.

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: February 17, 2015 By: s/Robert W. Peabody
Senior Vice President and
Chief Financial Officer