

BIOTIME INC
Form 8-K
October 06, 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 2, 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-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.

The information contained in Item 7 of this Report and Exhibit 99.2 shall be deemed “furnished” and not “filed” under the Securities Exchange Act of 1934, as amended.

Section 5 - Corporate Governance and Management

Item 5.02 - Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

Election of Director to Fill Vacancy

On October 4, 2014, our Board of Directors appointed Michael H. Mulroy to the Board of Directors to fill a vacancy on the Board.

Mr. Mulroy, 48, is a business consultant. Mr. Mulroy served until September 2014 as Executive Vice President – Strategic Affairs and General Counsel of the Autoimmune and Rare Diseases Business Unit of Mallinckrodt plc following its acquisition of Questcor Pharmaceuticals, Inc. in August 2014. Mr. Mulroy was appointed Executive Vice President, Strategic Affairs and General Counsel and Corporate Secretary of Questcor during February 2014, having previously served as Senior Vice President, Chief Financial Officer, General Counsel and Corporate Secretary since January 2011. From July 2011 to August 2014, Mr. Mulroy served as a member of the Board of Directors of Comarco, Inc., which developed and designed innovative technologies and intellectual property used in power adapters. From 2003 to 2011, Mr. Mulroy was employed by the law firm of Stradling Yocca Carlson & Rauth, where he served as a partner from 2004, and represented Questcor and other publicly-traded companies. From 1997 to 2003, Mr. Mulroy was an investment banker at Merrill Lynch and Citigroup. Mr. Mulroy earned his J.D. degree from the University of California, Los Angeles and his B.A. (Economics) from the University of Chicago.

Mr. Mulroy brings to our Board his experience as a strategic planner and as legal counsel to a growing biopharmaceutical company, and his experience in corporate finance.

Compensation as Director

For serving as a non-employee director of BioTime, Mr. Mulroy will receive an annual cash fee of \$30,000. The annual fee for serving on the Board is payable in four equal quarterly installments, with each payment conditioned upon Mr. Mulroy serving on the Board for the entire calendar quarter.

In addition to the annual fees, Mr. Mulroy will be entitled to receive \$2,000 for meetings of the Board of Directors attended in person, and \$1,000 for meetings attended by telephone conference. In addition to cash fees, Mr. Mulroy will receive an annual grant of options to purchase 20,000 common shares under our Equity Incentive Plan. The options will vest and thereby become exercisable in four equal quarterly installments, with quarterly vesting conditioned upon the director serving on the Board of Directors for the entire quarter.

Nomination of New Director for Election at Annual Meeting

Our Board of Directors has nominated Stephen L. Cartt for election as a director at our annual meeting of shareholders to be held on November 4, 2014.

Mr. Cartt, 51, has served on a transitional basis as Chief Operating Officer of the Autoimmune and Rare Diseases Business Unit of Mallinckrodt plc since August 2014 when it acquired Questcor Pharmaceuticals, Inc. Mr. Cartt had previously served as Questcor's Chief Operating Officer. Mr. Cartt joined Questcor as Executive Vice President, Corporate Development, during March 2005. He was later appointed Chief Business Officer and in February 2012 was appointed Chief Operating Officer of Questcor. Mr. Cartt was a private consultant from August 2002 until March 2005. From March 2000 through August 2002, Mr. Cartt was the Senior Director of Strategic Marketing for Elan Pharmaceuticals. Prior to that, Mr. Cartt held a variety of R&D and Commercial positions at ALZA Corporation during the period July 1985 to March 2000. Mr. Cartt holds a B.S. degree from the University of California at Davis in biochemistry, and an M.B.A. from Santa Clara University.

Mr. Cartt will bring to our Board his many years of experience in the pharmaceutical industry, including experience in senior management of a growing biopharmaceutical company.

Section 7 - Regulation FD

Item 7.01 - Regulation FD Disclosure

On October 6, 2014, we issued the press release furnished as Exhibit 99.2 to this report, which is incorporated by reference.

Section 8 - Other Events

Item 8.01 - Other Events

On October 2, 2014, our subsidiary Cell Cure Neurosciences Ltd. (Cell Cure) filed an Investigational New Drug ("IND") application with the United States Food and Drug Administration seeking to initiate a Phase I/IIa clinical trial of *OpRegen*[®] in patients with geographic atrophy ("GA"), the severe stage of the dry form of age-related macular degeneration ("dry-AMD"). *OpRegen* consists of retinal pigment epithelial ("RPE") cells derived from human embryonic stem cells and is intended to be administered as a single dose into the subretinal space of patients' eyes in order to treat this leading cause of blindness.

OpRegen[®] is “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.

The design of the proposed clinical trial, “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,” is based on a pre-IND meeting and a series of earlier interactions with the FDA. Patients will undergo a single transplantation and the study will explore three different doses of *OpRegen*[®]. Following transplantation the patients will be followed over 12 months at specified intervals and then at longer time periods, to evaluate the safety and tolerability of the product. A secondary objective of the clinical trial will be to explore the ability of transplanted *OpRegen*[®] to engraft, survive, and moderate the disease progression.

About Age-Related Macular Degeneration

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 until it progresses to the GA stage. Once the atrophy reaches the fovea (the center of the macula), patients lose their central vision and may develop legal blindness.

There is currently no effective treatment for dry-AMD. There are about 1.6 million new cases of dry-AMD in the US annually. The market opportunity for a treatment for GA has been estimated at over \$5 billion globally.

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 October 6, 2014 |
| 99.2 | Press Release dated October 6, 2014 |
| 99.3 | Press Release dated October 6, 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: October 6, 2014 By: /s/ Michael D. West
Chief Executive
Officer

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|-------------------------------------|
| 99.1 | Press Release dated October 6, 2014 |
| 99.2 | Press Release dated October 6, 2014 |
| 99.3 | Press Release dated October 6, 2014 |