BIOTIME INC
Form 8-K
August 27, 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): **August 21, 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))

Statements made in this Report that are not historical facts may constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those discussed. Such risks and uncertainties include but are not limited to those discussed in this report and in BioTime's other reports filed with the Securities and Exchange Commission. Words such as "expects," "may," "will," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions identify forward-looking statements.

Section 8 – Other Events

Item 8.01 Other Events

On August 21, 2014, our subsidiary, Asterias Biotherapeutics, Inc. ("Asterias") received notice from the United States Food and Drug Administration (FDA) of clearance to initiate a Phase 1/2a clinical trial of Asterias' product, AST-OPC1, in patients with complete cervical spinal cord injury. The approved trial follows the successful completion of the Phase 1 clinical study of the product, and is designed to assess safety and activity of escalating doses of AST-OPC1 in patients with complete cervical spinal cord injuries, the first targeted indication for AST-OPC1.

AST-OPC1 is a population of cells derived from human embryonic stem cells that contains oligodendrocyte progenitor cells ("OPCs"). OPCs and oligodendrocytes perform supportive functions for nerve cells in the central nervous system. The foundation for this newly cleared Phase 1/2a clinical trial comes from results from the Phase 1 clinical trial of AST-OPC1, which met its primary endpoints of safety and feasibility when administered to five patients with neurologically-complete, thoracic spinal cord injury. The five patients were administered a low dose of two million AST-OPC1 cells and have been followed to date for two to three years. No serious adverse events were observed associated with the delivery of the cells, the cells themselves, or the short-course immunosuppression regimen used. There was no evidence of expanding masses, expanding cysts, infections, cerebrospinal fluid leaks, increased inflammation, neural tissue deterioration or immune responses targeting AST-OPC1 in the patients. In four of the five subjects, serial MRI scans performed throughout the two to three year follow-up period indicate that reduced spinal cord cavitation may have occurred and that AST-OPC1 may have had some positive effects in reducing spinal cord tissue deterioration.

The new Phase 1/2a clinical trial will be an open-label, single-arm study testing three escalating doses of AST-OPC1 in 13 patients with subacute, C5-C7, neurologically-complete cervical spinal cord injury. These individuals will have essentially lost all sensation and movement below their injury site with severe paralysis of the upper and lower limbs. AST-OPC1 will be administered 14 to 30 days post-injury. Patients will be followed by neurological exams to assess the safety and activity of the product. Selection of the clinical trial sites is underway and Asterias expects to begin patient enrollment during the first quarter of 2015.

The new clinical trial differs from the original clinical study in that doses up to 10 times higher will be tested. In addition, the trial will focus on patients with neurologically-complete cervical spinal cord injuries. Because of the anatomy of the spinal cord and the existence of more sensitive outcomes measures to assess movement of the arms and hands, it is currently believed that detection of efficacy is much more likely to occur in patients with cervical injuries. It is this patient population that Asterias anticipates will be the target for the first registration clinical trials of AST-OPC1. Asterias expects that the results of the Phase 1/2a clinical trial will provide support for a Phase 2b expansion study that will be conducted to more thoroughly demonstrate safety and efficacy of the product.

There are currently no approved therapies for the treatment of spinal cord injury, and the complex pathology of the injury is unlikely to be addressed by a traditional small molecule or protein therapeutic. AST-OPC1, an oligodendrocyte progenitor population derived from human embryonic stem cells, has been shown to have three potentially reparative functions which address the complex pathologies observed at the spinal cord injury site. These activities of AST-OPC1 include production of neurotrophic factors, stimulation of vascularization, and induction of remyelination of denuded axons, all of which are critical for survival, regrowth and conduction of nerve impulses through axons at the injury site. In preclinical animal testing, AST-OPC1 administration led to remyelination of axons, improved hindlimb and forelimb locomotor function, dramatic reductions in injury-related cavitation and significant preservation of myelinated axons traversing the injury site.

Asterias has been awarded a $14.3 million Strategic Partnership III grant by the California Institute for Regenerative Medicine (CIRM) to help fund the clinical development of AST-OPC1. The grant will provide funding clinical development of AST-OPC1, including the dose escalation Phase 1/2a clinical trial. Asterias is in the process of negotiating with CIRM the funding agreement for the award, including the schedule for disbursement of the awarded funds and the pre-defined project milestones for continued funding. Asterias' ability to initiate the Phase 1/2a trial of AST-OPC1 on schedule will be dependent on the timely completion of these negotiations, and Asterias' ability to achieve adequate funds disbursements from CIRM during the early period of the award.

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: August 26, 2014 By /s/ Robert W. Peabody
Senior Vice President,
Chief Operating Officer,
and
Chief Financial Officer