

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 8, 2014**

BioTime, Inc.

(Exact name of registrant as specified in its charter)

California

(State or other jurisdiction
of incorporation)

1-12830

(Commission File Number)

94-3127919

(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))
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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 September 8, 2014, Asterias Biotherapeutics, Inc. ("Asterias" or the "Company"), Cancer Research UK (the "Charity") and Cancer Research Technology Limited ("CRT"), a wholly owned subsidiary of the Charity, entered into a Clinical Trial and Option Agreement (the "Agreement") relating to the Company’s cell based therapeutic agent, AST-VAC2, pursuant to which the parties agreed that, upon completion by Asterias, at its own cost, of process development and manufacturing scale-up work to determine a product manufacturing process for AST-VAC2 (the "Development Work") and the demonstration that the Development Work meets criteria to be determined by the parties, the Charity shall, at its own cost, manufacture clinical grade AST-VAC2 and carry out AST-VAC2 clinical trials in the United Kingdom, subject to regulatory approval. The trial of AST-VAC2 will be a Phase 1/2 trial to evaluate the safety and toxicity of the vaccine, feasibility, stimulation of patient immune responses to telomerase and AST-VAC2, and clinical outcome after AST-VAC2 administration in patients with both resected early-stage, and advanced forms of lung cancer. The Charity is required to provide the Company with progress reports during the clinical trial, and a final report (the "Final Report") within 120 days after the completion of the clinical trial. Asterias granted Charity a license to use intellectual property relating to AST-VAC2 on a royalty-free basis for the purpose of preparing for and conducting the clinical trials.

Under the Agreement, CRT granted Asterias an exclusive first option (the "Asterias Option") to obtain a license to use the data from the clinical trial (the "Clinical Data License"), exercisable for three months commencing on the date it receives the Final Report. Under the form of license agreement (the "License Agreement") set forth in the Agreement, Asterias will be obligated to make payments to CRT upon the execution of the License Agreement, upon the achievement of various milestones and then royalties on sales of products. If Asterias declines to exercise the Asterias Option, CRT will then have an option (the "CRT Option") to obtain a license to use the Company’s intellectual property relating to AST-VAC2 to continue the development and commercialization of AST-VAC2 and related products for which Asterias will be entitled to receive a share of the revenue relating to development and partnering proceeds (the "AST-VAC2 License"). The CRT Option will be exercisable by CRT for four months from when the Asterias Option expires.

The Agreement will expire upon the earliest of (i) the date Asterias obtains the Clinical Data License pursuant to an exercise of the Asterias Option, (ii) the date CRT obtains the AST-VAC2 License pursuant to an exercise of the CRT Option and (iii) the expiration of both the Asterias Option and the CRT Option. Notwithstanding the foregoing, any party may terminate the agreement prior to its expiration for events including (i) a party materially breaches the agreement and such breach is not cured within 60 days after the non-breaching party delivers written notice, (ii) any party is insolvent or liquidated or (iii) if regulatory approval of the clinical trial is not obtained within 2 years after the parties complete the technology transfer phase of the Agreement, which is currently expected to be completed in the third quarter of 2015, or if regulatory approval is revoked, withdrawn or otherwise terminated, or if a regulatory authority orders a halt or hold on the clinical trial for more than 18 months. In addition, the Charity will have the right to terminate the Agreement under certain circumstances.

The Agreement contains customary representations, warranties and covenants from the Company and Charity, as well as customary provisions relating to indemnity, confidentiality and other matters.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, which Asterias expects to file as an exhibit to its Quarterly Report on Form 10-Q for the period ending September 30, 2014.

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 September 11, 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: September 11, 2014

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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release Dated September 11, 2014

BioTime Subsidiary, Asterias Biotherapeutics, and Cancer Research UK and Cancer Research Technology Partner for Clinical Trial of Immunotherapy Vaccine for Lung Cancer

ALAMEDA, Calif.--(BUSINESS WIRE)--September 11, 2014--BioTime, Inc. (NYSE MKT: BTX) announced that its subsidiary Asterias Biotherapeutics, Inc. (OTCBB: ASTY) has reached an agreement with Cancer Research UK and Cancer Research Technology (CRT), the charity's development and commercialization arm, to conduct a clinical trial of Asterias' novel immunotherapy treatment AST-VAC2 in subjects with non-small cell lung cancer.

AST-VAC2 is a non-patient specific (allogeneic) cancer vaccine designed to stimulate patients' immune systems to attack telomerase, a protein that is expressed in over 95 percent of cancers but is rarely expressed in normal adult cells.

The vaccine was developed following successful early phase clinical trials of a similar, patient specific (autologous) Asterias vaccine, called AST-VAC1, which was derived from patients' blood cells and tested in prostate cancer and acute myeloid leukemia.

Unlike AST-VAC1, and other autologous (patient specific) vaccines that are developed from a patient's own cells, AST-VAC2 is derived from human embryonic stem cells (hESCs), meaning it can be produced on a large scale and stored ready for use, rather than having to produce a specific version of the drug for each patient.

The trial of AST-VAC2 will evaluate the safety and toxicity of the vaccine, feasibility, stimulation of patient immune responses to telomerase and AST-VAC2, and clinical outcome after AST-VAC2 administration in patients with resected early-stage lung cancer and in patients with advanced forms of the disease.

Pedro Lichtinger, Asterias' chief executive officer, said: "The Asterias collaboration with Cancer Research UK's Drug Development Office and CRT represents a major step in advancing our proprietary dendritic cell platform for the potential benefit of patients.

"AST-VAC2 is based on a specific mode of action that is complementary and potentially synergistic to other immune therapies. We are delighted to partner with Cancer Research UK to advance this important platform through Phase 1/2 clinical trials. Cancer Research UK's Drug Development Office has the global recognition of having the quality, capability and track record of successfully advancing development programs. We are excited about the possibility of favorably impacting the lives of patients across multiple cancers and are proud to be working with Cancer Research UK."

Under the agreement, Asterias will complete development of the manufacturing process for AST-VAC2. Cancer Research UK will then produce the vaccine and conduct the phase 1/2 clinical trial in the United Kingdom. On completion of the clinical trial, Asterias will have an exclusive first option to acquire a license to the data from the trial on pre-agreed terms including an upfront payment, milestones and royalties on sales of products. If Asterias declines this option, CRT will then have an option to obtain a license to Asterias' intellectual property to continue the development and commercialization of AST-VAC2 and related products in exchange for a revenue share to Asterias of development and partnering proceeds.

Dr. Jane Lebkowski, president of research and development at Asterias, said: "The use of human embryonic stem cells to derive allogeneic dendritic cells for cancer immunotherapy has the potential to dramatically improve the scalability, consistency, and feasibility of cellular cancer vaccines. We believe this collaboration will enable the acceleration of clinical studies of AST-VAC2 and the collection of important proof-of-concept data for the entire human embryonic stem cell-derived dendritic cell immunotherapy platform."

About Lung Cancer

US:

Lung cancer is the leading cause of cancer death in the United States. More than 150,000 people in the US die from lung cancer annually. In the US five year survival rates remain only 25-50 percent for early stage disease and less than 20 percent for advanced disease. NSCLC is much more common than other types of lung cancer, and accounts for 85 percent of all lung cancer cases.

UK:

Lung cancer is the leading cause of cancer death in the UK, with more than 35,000 people dying from the disease each year. It has one of the lowest survival rates of any cancer and less than 10 per cent of people survive more than five years.

About Cancer Immunotherapy and Cancer Vaccines

Vaccines have the potential to act synergistically with immune checkpoint inhibitors by using the checkpoint inhibitor to activate, and the vaccine to direct, the immune response to cancer cells. One promising cancer vaccine approach uses dendritic cells, which normally serve this training function – known as antigen presentation – in the human immune system. However, first generation dendritic cell vaccines, such as Dendreon's Provenge® (sipuleucel-T) and Asterias' AST-VAC1, must be manufactured on a patient-by-patient (autologous) basis, which can result in higher costs of manufacture, variability in product performance, and delayed availability of such autologous products. Asterias' AST-VAC2 product represents a scalable platform for low cost, consistent manufacturing of a dendritic cell vaccine with on demand availability.

About AST-VAC2

AST-VAC2 is an immunotherapeutic product candidate consisting of human embryonic stem cell derived- mature dendritic cells (hESC-DCs) that are engineered to express telomerase. AST-VAC2 is designed as an “off-the-shelf” vaccine platform to stimulate an immune response against tumor cells expressing telomerase. Telomerase is expressed in most human cancers, and plays an important role in the prolonged proliferative lifespan of cancer cells. In contrast, telomerase expression is rare and transient in most normal adult tissues, making telomerase an attractive target for cancer immunotherapy.

Previous studies of a patient specific (autologous), peripheral blood-derived, dendritic cell vaccine targeting telomerase (AST-VAC1) in prostate cancer and acute myelogenous leukemia (AML) provided promising data supporting the safety and feasibility of dendritic cell-based telomerase immunotherapy, and showed telomerase-specific immune responses in 55% of AML and 95% of prostate cancer patients.

Additionally, in the AST-VAC1 prostate cancer trials, reductions in PSA velocity and circulating tumor cells which correlated with patient immune responses were observed. The use of human embryonic stem cells, as opposed to patient blood, as the starting material for production of AST-VAC2 provides a scalable system for the production of a large number of vaccine doses in a single production lot, enabling reduced costs of manufacturing, “off-the-shelf” availability, and improved product consistency compared to autologous dendritic cell immunotherapy products.

About BioTime

BioTime is a biotechnology company engaged in research and product development in the field of regenerative medicine. Regenerative medicine refers to therapies based on stem cell technology that are designed to rebuild cell and tissue function lost due to degenerative disease or injury. BioTime’s focus is on pluripotent stem cell technology based on human embryonic stem (“hES”) cells and induced pluripotent stem (“iPS”) cells. hES and iPS cells provide a means of manufacturing every cell type in the human body and therefore show considerable promise for the development of a number of new therapeutic products. BioTime’s therapeutic and research products include a wide array of proprietary *PureStem*[®] progenitors, *HyStem*[®] hydrogels, culture media, and differentiation kits. BioTime is developing *Renevia*[™] (a *HyStem*[®] product) as a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in human clinical applications, and is planning to initiate a pivotal clinical trial around *Renevia*[™], in 2014. In addition, BioTime has developed *Hextend*[®], a blood plasma volume expander for use in surgery, emergency trauma treatment and other applications. *Hextend*[®] is manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ HealthCare Corporation, under exclusive licensing agreements.

BioTime is also developing stem cell and other products for research, therapeutic, and diagnostic use through its subsidiaries:

- **Asterias Biotherapeutics**, Inc. is developing pluripotent stem-cell based therapies in neurology and oncology, including AST-OPC1 oligodendrocyte progenitor cells in spinal cord injury, multiple sclerosis and stroke, and AST-VAC2, an allogeneic dendritic cell-based cancer vaccine.
- **BioTime Asia**, Ltd., a Hong Kong company, may offer and sell products for research use for BioTime's ESI BIO Division.
- **Cell Cure Neurosciences** Ltd. is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders, including the development of retinal pigment epithelial cells for the treatment of macular degeneration, and treatments for multiple sclerosis.
- **ESI BIO** is the research and product marketing division of BioTime, providing stem cell researchers with products and technologies to enable them to translate their work into the clinic, including *PureStem*[®] progenitors and *HyStem*[®] hydrogels.
- **LifeMap Sciences**, Inc. markets, sells, and distributes *GeneCards*[®], the leading human gene database, as part of an integrated database suite that also includes the *LifeMap Discovery*[®] database of embryonic development, stem cell research, and regenerative medicine, and *MalaCards*, the human disease database.
- **LifeMap Solutions**, Inc. is a subsidiary of LifeMap Sciences focused on developing mobile health (mHealth) products.
- **OncoCyte** Corporation is developing products and technologies to diagnose and treat cancer, including *PanC-Dx*[™], with three clinical trials currently underway.
- **OrthoCyte** Corporation is developing therapies to treat orthopedic disorders, diseases and injuries.
- **ReCyte Therapeutics**, Inc. is developing therapies to treat a variety of cardiovascular and related ischemic disorders, as well as products for research using cell reprogramming technology.

BioTime stock is traded on the NYSE MKT, ticker BTX. For more information, please visit www.biotimeinc.com or connect with the company on Twitter, LinkedIn, Facebook, YouTube, and Google+.

About Asterias Biotherapeutics

Asterias' core technologies center on stem cells capable of becoming all of the cell types in the human body, a property called pluripotency. Asterias plans to develop therapies based on pluripotent stem cells to treat diseases or injuries in a variety of medical fields having major unmet needs and without adequate therapies available. Asterias initial focus is on two clinical stage programs including oligodendrocyte progenitor cells (AST-OPC1) for spinal cord injuries and antigen-presenting allogeneic dendritic cells (AST-VAC2) for lung cancer.

In October 2013, Asterias acquired the cell therapy assets of Geron Corporation. These assets included INDs for the clinical stage AST-OPC1 and AST-VAC1 programs, banks of cGMP-manufactured AST-OPC1 drug product, cGMP master and working cell banks of human embryonic stem cells, over 400 patents and patent applications filed worldwide including broad issued claims to fundamental platform technologies for the scalable growth of pluripotent stem cells and compositions of matter for several hESC-derived therapeutic cell types, research cell banks, customized reagents and equipment, and various assets relating to the AST-VAC2 program and preclinical programs in cardiology, and orthopedics.

Asterias is a member of the BioTime (NYSE MKT: BTX) family of companies. Asterias Series A Common Stock is traded on the OTC Bulletin Board under the symbol ASTY. Additional information about Asterias can be found at www.asteriasbiotherapeutics.com.

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 businesses of BioTime and its subsidiaries, including Asterias, particularly those mentioned in the cautionary statements found in BioTime's and Asterias' Securities and Exchange Commission filings. BioTime and Asterias disclaim 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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