

BIOTIME INC
Form DEFA14A
June 11, 2015

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

SCHEDULE 14A

(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement

Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

Definitive Proxy Statement

Definitive Additional Materials

Soliciting Material Pursuant to §240.14a-12

BioTime, Inc.

(Name of Registrant as Specified in Its Charter)

(Name of Person(s) Filing Proxy Statement if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

No fee required.

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Dear Fellow Shareholders,

Over the past year, BioTime has made significant progress in building a dominant company in the field of regenerative medicine. Our strategy is to lead in the development and application of pluripotent stem cell-based technologies targeted at the treatment of degenerative diseases that afflict large numbers of people worldwide. We have recently advanced some of our products into human clinical trials. As a result, we now have a number of products for which clinical data have been reported or for which the clinical data are forthcoming.

Some of the most significant unmet needs in medicine are related to degenerative diseases. More than 80% of the estimated \$3 trillion in health care expenditures in the United States can be attributed to the management of chronic and degenerative diseases. The demand for new and more effective therapies continues to grow with the aging of the U.S. baby boom population. It is well established that degenerative diseases are commonly associated with the loss or dysfunction of cell types that represent the building blocks of various tissues. Starting from these points of crossover between cell biology, socioeconomic need, and emerging technologies, the field of regenerative medicine extends the horizon line.

Degenerative diseases are often chronic and incurable because neither the body nor most currently available drugs can generate or repair the lost or damaged cells. The business opportunity before us requires that we harness the power of pluripotent stem cell technology to manufacture a wide array of first-in-class, cell-based therapeutics designed to replace those lost or damaged cells. Our goal is to be the principal developer of these products, which include not only the living cell types themselves, but also an innovative transplant matrix to create three-dimensional tissue within the body. The cells will be manufactured from renewable master cell banks of clinical-grade pluripotent stem cells. Our matrix for transplanting the cells, known as *HyStem*[®], is being developed in a number of applications. Among these applications is the product *Renevia*[™], which is currently in a pivotal trial in Europe to promote the engraftment of a single cell type. If we are successful in our endeavors, we may create a new standard of care for a number of these chronic and degenerative diseases.

Key Products and Programs

Our strategy for achieving the leadership role in regenerative medicine includes prioritizing applications with large unmet patient needs, leveraging sources of non-dilutive financing, and progressively unlocking shareholder value in our diverse disease-focused subsidiaries. Since the last Annual Meeting of Shareholders, the BioTime family of companies has made significant advances toward those goals, including in the following key programs.

Cell Therapies

OpRegen[®] is a therapy in development for the dry form of age-related macular degeneration (AMD). BioTime's subsidiary Cell Cure Neurosciences Ltd. is now in a Phase I/IIa dose escalation study of *OpRegen*[®] to evaluate its safety and efficacy in patients who have an advanced stage of the disease. There is currently no U.S. Food and Drug Administration-approved therapy for dry AMD, the most prevalent form of AMD and one of the major diseases of aging.

AST-OPCI is an oligodendrocyte progenitor cell-based therapy being developed by our majority-owned subsidiary Asterias Biotherapeutics, Inc. (NYSE MKT: AST). *AST-OPCI* is currently in a Phase I/IIa clinical trial in patients with complete cervical spinal cord injury. The *AST-OPCI* trial is funded in part through a \$14.5 million grant from the California Institute for Regenerative Medicine (CIRM). The primary goals of this clinical trial are to test the safety of the product in the cervical region of the spine and to escalate the dose in human patients to levels comparable to those already demonstrated as effective in an animal model of the disorder.

AST-VAC1 is Asterias's autologous telomerase-based cancer immunotherapy designed to target and destroy tumor cells. Telomerase is an unprecedented target, found to be abnormally expressed in approximately 95% of cancer types. Long-term follow-up data from a Phase II trial of *AST-VAC1* in acute myelogenous leukemia (AML) patients showed 58% of patients to be relapse-free after a median follow-up period of 52 weeks. These findings were selected for oral presentation at the annual meeting of the American Society of Clinical Oncology (ASCO) in May 2015. *AST-VAC2*, Asterias's next-generation, telomerase-based cancer immunotherapy is advancing toward clinical development for the treatment of non-small cell lung cancer (NSCLC). Asterias is working with Cancer Research UK (CRUK) to conduct the initial Phase I/IIa clinical trial of *AST-VAC2* using CRUK's non-dilutive funding. *Additional stem cell therapies* are in non-clinical development and include brown adipocyte progenitors for metabolic disorders and osteochondral progenitors for symptoms of low back pain being developed by BioTime's subsidiaries ReCyte Therapeutics, Inc. and OrthoCyte Corporation, respectively.

Cell Delivery Matrix

*Renovia*TM, our proprietary *HyStem*[®] based cell delivery matrix designed to facilitate the stable engraftment of transplanted cells, was used to treat the first patient in the above mentioned pivotal clinical trial in Europe earlier this year. This registration-enabling trial is designed to generate supportive data for the submission of *Renovia*TM for CE Mark approval in the European Union for the treatment of HIV-associated lipoatrophy. If CE Mark approval is successful, we may pursue other applications of the technology.

Cancer Diagnostics Platform

*PanC-Dx*TM is a class of proprietary low-cost tests being developed by BioTime's subsidiary OncoCyte Corporation for the non-invasive diagnosis of cancer. Clinical validation studies are currently underway for applications in bladder, breast, and lung cancers. We expect that the increasing demand for more frequent screening and monitoring for cancer recurrence will generate a growing market. Interim clinical validation study data for *PanC-Dx*TM, presented at the annual meeting of the American Association for Cancer Research in April 2015, demonstrated a high level of sensitivity and specificity in the detection of urothelial carcinoma, the most common type of bladder cancer. Interim clinical validation data for *PanC-Dx*TM for lung cancer were presented at the American Thoracic Society (ATS) international conference in May of 2015.

Other Products

BioTime subsidiary ES Cell International Pte Ltd (ESI) provides human embryonic stem cells for research and preclinical use. Recent agreements have been formalized with Beckman Research Institute of the City of Hope (BRICOH) for use of ESI's clinical-grade cells in the development of cell banks that will in turn be employed for the pre-clinical development of therapies to treat human disease. University of California at Irvine (UCI) scientist Dr. Leslie Thompson will be using ESI's stem cells to develop therapies for Huntington's disease under a \$5 million grant from CIRM.

BioTime subsidiary LifeMap Solutions, Inc. announced that the Icahn School of Medicine at Mount Sinai has launched a large-scale medical research study of asthma using the new ResearchKit software framework developed by Apple, Inc. for the iPhone. Developed by Mount Sinai in collaboration with LifeMap Solutions, the free Asthma Health App is designed to facilitate patient education and self-monitoring, promote positive behavioral changes, and reinforce adherence to treatment plans according to current asthma guidelines. An additional application for managing chronic obstructive pulmonary disease (COPD) is also in collaborative development by LifeMap Solutions.

Financial Structure for Growth

As of March 31, 2015, we had \$26 million of cash on hand, augmented by the \$24 million in marketable BioTime shares held by our subsidiaries. On the aforementioned date, BioTime also owned approximately 68% of publicly traded Asterias shares (NYSE MKT: AST). On May 28, 2015, the public market value of these Asterias shares was approximately \$251 million.

Building Commercial Expertise in Leadership

As we advance our clinical trials toward the goal of delivering regenerative therapies to patients, we have added professionals with extensive commercial experience at the levels of senior management and the Board of Directors. In December of last year, Adi Mohanty joined as Chief Operating Officer. A former executive of Shire plc, Adi has an extensive background in regenerative medicine and brings significant experience in biopharmaceutical product development, manufacturing, and commercialization. We have further plans to add to our leadership team to support our clinical and commercial efforts. We also strengthened our Board of Directors with the appointments of Angus Russell, former Chief Executive Officer of Shire plc; Stephen Cartt, former Chief Operating Officer of Questcor Pharmaceuticals, Inc.; and Michael Mulroy, former Executive Vice President of Strategic Affairs and General Counsel of Questcor and Mallinckrodt plc.

We enjoy leading what promises to be a revolutionary period in regenerative medicine by advancing clinical trials that execute on our strategic goals. We care deeply about our mission and the patients we serve. We appreciate the support of our stockholders; the passion and dedication of our scientists and employees; and the participation of clinicians, patients, and families that will enable us to bring our revolutionary new therapies to people with chronic and regenerative diseases.

Sincerely,

Michael D. West, Ph.D.
President & CEO

Alfred D.
Kingsley
Chairman of the
Board

June 10, 2015