

BIOTIME INC
Form DEFA14A
October 14, 2014

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

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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)

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Dear Fellow Shareholders,

Each year we look forward to writing this letter to you, a shareholder in BioTime. In this letter we will be summarizing a year of significant progress toward our goal of building the dominant biotechnology company in the emerging field of regenerative medicine by strengthening our management team and our financial resources, and by moving more products into clinical trials.

As we write this letter, our subsidiary Asterias Biotherapeutics (NYSE MKT: AST) is beginning its first day of trading on the NYSE MKT. Asterias, our first subsidiary to be publicly traded, acquired the entire stem cell estate of Geron Corporation in 2013. The rapid progress of Asterias in advancing its product development programs toward clinical trials is just one of numerous achievements within the BioTime family of companies which we will summarize below.

BioTime is focused on a new field called “regenerative medicine.” The term refers to a new method of treating diseases in which living cells are administered to a patient to replace missing or dysfunctional cells, the functional loss of which is the cause of the disease or disability. Stem cell technology may make it possible to create therapies for conditions such as spinal cord injury, macular degeneration, Parkinson’s disease, osteoarthritis, low back pain, blood cell disorders, and ischemic disease that cannot be treated at all, or only to a limited extent, with conventional drugs. The treatment of these degenerative disorders could open billion dollar markets in medicine. In practice, of course, these new cell therapies have to be demonstrated safe and effective in human clinical trials before they can be sold as therapeutics. Therefore, our goal is to lead both in the key intellectual property enabling this field, as well as in the clinical development and ultimate marketing of important new stem cell derived therapeutics.

The BioTime family of companies already leads the industry with over 600 key patents and patent applications worldwide. We are well-capitalized and have successfully leveraged significant non-dilutive sources of financing and collaborative agreements for clinical studies of some our product candidates. We now have seven clinical phase products including Asterias’ AST-OPC1 for spinal cord injury, for which the FDA has approved a phase 1/2a trial, Cell Cure Neurosciences’ OpRege[®] for macular degeneration, for which Cell Cure recently filed an investigational new drug (IND) application with the FDA, and our near-term products in ongoing trials, including Renevia[™] and OncoCyte’s cancer diagnostics.

We believe that a combination of factors -- namely, our strong potential to lead the regenerative medicine revolution, our broad base of product opportunities, our powerful IP portfolio, the absence of regulatory approval pathways for generic or biosimilar competitors for our cellular therapeutics, and our leveraging of non-dilutive third party financing -- give BioTime a winning strategy to maximize value creation for our shareholders.

Salient milestones from the past year

In the past year we announced numerous strategic advances in building the foundation of our company, including the following achievements.

Asterias Biotherapeutics, Inc.

Our subsidiary Asterias Biotherapeutics (NYSE MKT: AST) was formed to acquire the stem cell assets of Geron Corporation. Asterias owns or has licenses to over 400 patents and patent applications worldwide, and two leading therapeutic stem cell programs. The first product in development is AST-OPC1, which is composed of oligodendrocyte progenitor cells designed to treat patients with spinal cord injury. The second product in development is AST-VAC2, which is a cell-based vaccine designed to train the immune system to attack and destroy cancer cells. The unique potential advantage of AST-VAC2 is that it teaches the immune system to attack cells expressing telomerase, a protein abnormally expressed in over 95% of all cancer types.

In the last year Asterias' milestones included the following:

The California Institute for Regenerative Medicine ("CIRM") approved a \$14.3 million Strategic Partnership III grant to Asterias to provide funding for Asterias' Phase 1/2a clinical trial of AST-OPC1 in patients with complete cervical spinal cord injury, and for product development efforts to refine and scale manufacturing methods to support eventual commercialization. The FDA recently approved the initiation of the clinical trial.

Cancer Research UK agreed to fund a phase 1//2a clinical trial of Asterias' novel immunotherapy treatment AST-VAC2 in subjects with non-small cell lung cancer.

Asterias appointed Pedro Lichtinger as its President and Chief Executive Officer. Mr. Lichtinger, who served on the BioTime Board of Directors, has significant biopharma experience, having previously served as President, Chief Executive Officer, and a director of Optimer Pharmaceuticals, Inc., President of Pfizer's Global Primary Care Unit, and also as an executive of Smith Kline Beecham.

Asterias added Andrew Arno, Natale Ricciardi, and Richard LeBuhn to its Board of Directors. With these additions, the Asterias Board of Directors is now comprised of eight directors, three of whom are independent. Andy Arno has 30 years of experience working with emerging growth companies. He is currently Managing Director of Emerging Growth Equities, an investment bank, and Vice President of Sabr, Inc., a family investment group. Nat Ricciardi spent his entire 39-year biopharmaceutical career at Pfizer Inc, retiring in 2011 as a member of the Pfizer Executive Leadership Team after holding the positions of President, Pfizer Global Manufacturing, and Senior Vice President of Pfizer Inc. Richard LeBuhn is Senior Vice President of Broadwood Capital, Inc., the investment manager of Broadwood Partners, L.P., a private investment fund that is BioTime's largest shareholder.

Asterias raised \$12.5 million through the sale of a portion of its BioTime common shares with Asterias common stock purchase warrants.

Asterias Series A common stock began trading on the NYSE MKT under the ticker symbol "AST."

Cell Cure Neurosciences

Cell Cure Neurosciences filed an IND application with the FDA seeking to initiate a Phase I/IIa clinical trial of OpRegen® in patients with geographic atrophy, the severe stage of the dry form of age-related macular degeneration (dry-AMD). OpRegen® consists of retinal pigment epithelial 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.

LifeMap Sciences

LifeMap Solutions, Inc., a newly formed subsidiary of BioTime's subsidiary LifeMap Sciences, Inc., entered into a Co-Development and Option Agreement with the Icahn School of Medicine at Mount Sinai to cooperatively develop internet, web-based, mobile user or consumer software products to provide users with information that may potentially aid them in improving lifestyle and healthcare decisions and outcomes. The planned products are envisioned to provide information based on interpretations of one or more components of clinical, genetic, wearable device, and other data relating to human disease, health or wellness.

OncoCyte Corporation

OncoCyte initiated clinical development of PanC-Dx™, its family of cancer diagnostic products, for the detection of bladder cancer, breast cancer and lung cancer. The goal of these clinical development initiatives is to determine the overall relative performance of OncoCyte's PanC-Dx™ markers in detecting those types of cancer.

Some of OncoCyte's bladder cancer trials are being conducted at a leading medical institution with an international reputation for excellence and discovery, and in China, through a contract research organization serving nine major medical institutions, including top-ranked university hospitals in Shanghai and Wuhan. More recently, OncoCyte initiated a multi-site clinical trial of its urine-based bladder cancer diagnostic test that will involve up to 1,200 patient samples from at least four large urology clinics in the U.S. The goal of the current clinical trial is to compare the performance of OncoCyte's proprietary PanC-Dx™ bladder cancer markers to the performance of cystoscopy. Investigators in the trial are collecting urine samples from patients undergoing cystoscopy for the diagnosis of either primary or recurrent bladder cancer. Cystoscopy and biopsy results will be compared with the results of OncoCyte's proprietary diagnostic test panel in determining the overall performance of the PanC-Dx™ markers.

In lung cancer diagnostics, OncoCyte is working collaboratively with two major medical research institutions. The Wistar Institute is providing OncoCyte with blood samples obtained from patients in a Wistar clinical study to determine levels of tumor-associated proteins found in the blood samples. The Weill Cornell Medical College also will provide OncoCyte blood samples derived from healthy people and lung cancer patients for comparative analysis using PanC-Dx™ gene markers for cancer detection. The results of these analyses will be combined to produce a data set from over 700 patients. This data will be used by OncoCyte to assess the performance of potential cancer markers for the purpose of developing a multi-marker test for the detection of lung cancer.

ReCyte Therapeutics

BioTime's scientists in ReCyte Therapeutics wrote and were awarded three SBIR Phase 1 Small Business Grants totaling \$787,434 from the National Institute of General Medical Sciences at the National Institutes of Health. ReCyte will use the grant support to strengthen its cell manufacturing technology.

HyStem[®] Product Development

BioTime successfully completed its Renevia[™]-01 safety study. Renevia[™] is being developed as a platform product with a wide array of potential therapeutic applications. The product is a biocompatible and injectable hyaluronan and collagen-based matrix designed to promote the stable engraftment of cells into the body. Completion of the initial safety trial paves the way for a pivotal clinical efficacy trial in which Renevia[™] will be tested in combination with adipose stromal fraction for the treatment of subcutaneous facial lipoatrophy commonly manifested in patients treated for human immunodeficiency virus (HIV) infection. The pivotal trial is expected to commence later this year and, if successful, could lead to an application for CE Mark approval for marketing in Europe and other markets outside the United States.

BioTime received ISO 13485:2003 certification from BSI (British Standards Institution) for design, development, manufacture, and distribution of BioTime HyStem[®] hydrogels for cell delivery applications. BSI is currently one of the world's largest independent certification bodies for quality management systems and ISO 13485:2003 is the world's most recognized standard for quality management systems for medical devices, and is the most commonly chosen path for companies to meet the quality system requirements in Europe, Canada, Japan, Australia, and certain other countries. This certification is an important milestone also in BioTime's development program for Renevia[™].

BioTime has received notification from the FDA of a premarket clearance of BioTime's 510(k) application for Premvia[™]. Premvia[™] is a HyStem[®]-based product indicated for the management of a variety of wounds. BioTime's next step is to identify market segments and build its marketing capability for Premvia[™] which will take some time.

BioTime entered into a collaboration with Susan Thibeault, Ph.D., of the University of Wisconsin and Marc Remacle, M.D. of Louvain University to evaluate BioTime's proprietary HyStem[®]-based hydrogel for the treatment of vocal fold scarring. Upon completion of preclinical studies, an investigator-initiated clinical trial in patients with vocal fold scarring due to disease or prior surgical interventions is planned, under the direction of Dr. Remacle, at the Cliniques Universitaires UCL Mont-Godinne in Belgium, subject to institutional and regulatory approval.

ESI BIO

BioTime consolidated its research products business into a new ESI BIO division and a new ESI BIO branding program. The ESI BIO brand and US-based operating division will now be BioTime's primary developer, manufacturer and distributor of a growing portfolio of stem cell based research products.

Building our Patent Portfolio

The BioTime family of companies own or have license to what is likely the largest patent estate in pluripotent stem cell-based therapy in the world including over 600 patents and patent applications worldwide. In the past year we announced the issuance of 14 new patents covering a wide range of core technologies foundational to BioTime's business. These patents include:

United States patent 8,685,386 – This patent is based on work performed at BioTime on the PureStem[®] cell lines capable of becoming cell types useful in the repair of cartilage and bone. The claims cover certain PureStem[®] cell types as well as certain products made from them used in patients. Titled “Methods and Compositions for In Vitro and In Vivo Chondrogenesis,” this patent is one of numerous patents useful to BioTime's subsidiary OrthoCyte Corporation.

United States patent 8,691,793 – Certain claims in this patent relate to chemical modifications of glycosaminoglycans such as hyaluronic acid, one of the components of some of the HyStem[®]- products being developed by BioTime.

Japan patent 2011-047716 – Oligodendrocytes derived from human embryonic stem cells for re-myelination and treatment of spinal cord injury are described. The patent relates to methods of making oligodendrocytes from human embryonic stem cells. The patent is useful to Asterias for its AST-OPC1 product development.

Australia patent 2012203810 – Methods and Compositions for the Treatment and Diagnosis of Bladder Cancer. The patent relates to methods of detecting bladder cancer by contacting a sample from a subject with agents that bind certain proprietary markers expressed in patients with bladder cancer. The patent is useful to OncoCyte for its cancer diagnostic product development.

Strengthening BioTime's Balance Sheet

So far, during 2014, BioTime, and certain of its subsidiaries, have successfully raised over \$60 million in new financing for clinical trials of products under development, for research and development programs, and for general working capital purposes.

Expanded and Strengthened Board of Directors

We have appointed four seasoned executives to our Board of Directors. David Schlachet, Deborah Andrews, and Michael H. Mulroy have already joined our Board and Stephen L. Cartt has been nominated for election to the Board at the Company's upcoming Annual Meeting of Shareholders, which will be held on November 4. Information about these new directors as well as the other members of our Board can be found in the accompanying proxy statement.

In summary, it has been a strong year for BioTime and its subsidiaries. Our focus continues to be one of leading the regenerative medicine revolution while maximizing shareholder value through a balanced product portfolio.

Thank you for your investment in BioTime. We welcome you to join us in San Francisco on November 4, 2014 for our Annual Meeting of Shareholders, and shareholders of record that attend the shareholder's meeting will also be invited to attend a later meeting featuring presentations from some of our subsidiaries.

Sincerely,

Michael D. West, Ph.D.

Alfred D.
Kingsley

President & CEO

Chairman of the
Board

October 8, 2014