BIOTIME INC
Form DEFA14A
May 03, 2016
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:

o Preliminary Proxy Statement
o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
o Definitive Proxy Statement
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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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(2) Form, schedule or registration statement no.:

(3) Filing party:

(4) Date filed:

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May 2, 2016

Dear Fellow Shareholders,

We are entering an inflection point in the history of regenerative medicine. As demographic trends in much of the industrialized world are making age-related degenerative diseases a major societal concern, it is becoming increasingly clear to the pharmaceutical industry that one of the more powerful solutions may be found in pluripotent stem cell technology. At BioTime, we have several programs underway using this technology that, if successful in the clinic, could create a new standard of care for a number of these age-related chronic and degenerative diseases.

The increasing potential of cell therapy technology is made evident by the growing list of successful biotech and pharma industry leaders that have joined the management teams of BioTime and its family of companies, and by the increased business development activity of large pharmaceutical companies in the regenerative medicine field. Several companies, including BioTime and our subsidiaries, are moving products based on cell therapy technology through the clinical approval process. As an industry leader in terms of patents and patent applications as well as the number of cell therapy-based products in clinical trials, BioTime is well positioned to lead the push towards new therapeutic solutions in a variety of fields, including ophthalmology, medical aesthetics, and oncology. This means BioTime has many opportunities in 2016 and beyond to build substantial value for our shareholders.

Our therapeutic programs are based on our core pluripotent stem cells, *PureStem*® progenitor cells, and *HyStem*® biomaterial platforms. With these core technologies, we believe we have the foundation in place to lead in new product development in a number of important clinical areas that represent large market opportunities.

In order to align our resources appropriately we made three simple objectives the focus of our near term strategy.

- **Clinical progress**: In development-stage biotech companies, value is created when promising product candidates make progress in human clinical trials. Each milestone achievement reduces risk and increases value. So for us, advancing key programs like *Renevia*® and *OpRegen*® through clinical trials is critically important.
- **Simplification**: We are working to simplify BioTime's structure as we focus our operations and resources on therapeutic programs with the greatest potential value and fastest time to market.
- **Unlocking value**. As we focus on core therapeutic assets, we're also working with our non-core assets and subsidiaries to further create value for our shareholders.

Clinical Progress: The BioTime family of companies now have **four** therapeutic product candidates in human clinical trials.

Renevia® is in a pivotal clinical trial in Europe to assess its efficacy in delivering and engrafting transplanted cells to treat HIV-related facial lipoatrophy. *Renevia*® consists of our cell delivery matrix, *HyStem*®, combined with the patient s own adipose, or fat, cells. We expect *Renevia*® to lead to better, more natural outcomes by enabling higher cell survival and engraftment. If successful, this outcome could result in a more natural appearance and texture to the face leading to a clinically differentiated increased quality of life. We expect to complete patient enrollment by the second half of 2016 with top-line efficacy data expected in early 2017. If the data are positive, we expect to file for CE Mark approval in the European Union in the first half of 2017. We consider the *Renevia*® trial to be an important gateway trial that could serve as the basis for targeting *Renevia*® for broader use in medical aesthetics, such as age-related and trauma-related facial fat loss, which represent a multi-billion dollar market opportunity. We continue to believe there are many other potential applications for *Renevia*® and the *HyStem*® platform in combination with a diverse range of cell therapies and surgical applications.

The loss of retinal pigment epithelial, or RPE, cells in the eye can cause either wet AMD (age-related macular degeneration) or dry AMD, the latter being a condition for which there are no currently approved therapies. Therapeutics for the wet form of AMD currently generate around $8 billion in annual sales, while the unserved dry AMD market has about nine times as many potential patients. *OpRegen*® is designed to treat dry AMD by integrating new RPE cells into the subretinal space to replace missing RPE cells. *OpRegen*® has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of dry AMD.

Patients are currently being treated with *OpRegen*® in a Phase I/IIa dose-escalation clinical trial. We expect to report completion of the first cohort of this trial and clearance from the independent Data and Safety Monitoring Board (DSMB) to begin the second cohort in the second quarter of 2016. The second cohort is expected to be enrolled, and we anticipate approval from the DSMB to proceed to the third cohort, by the end of this year.

Last year, promising long-term data was reported from a Phase II study of AST-VAC1 as an immunotherapy for Acute Myeloid Leukemia, and a successful End-of-Phase II meeting was held with the FDA. The FDA indicated general agreement with a proposed development plan for registration of AST-VAC1 via an accelerated development pathway with a Phase III clinical trial and a potential Biologic License Application or BLA filing. This year, a Special Protocol Assessment, or SPA, with the FDA will be sought to confirm the primary endpoint and other design elements of the pivotal Phase III trial.

Another therapeutic product candidate, AST-OPC1, is currently in a Phase I/IIa clinical trial to treat spinal cord injuries. The clinical trial has completed enrolling the first two cohorts and continues to enroll patients. More than 12,000 people sustain spinal cord injuries in the U.S. each year, but there are no FDA-approved therapeutics or devices that can restore motor function in these individuals.

Simplification: We took several steps to simplify our structure last year and are committed to continuing this process.

Last fall, we combined our ESI BIO Division with the drug toxicity screening business of Hepregen Corporation to form a new company called Ascendance Biotechnology, Inc. This transaction provided an experienced leader for the business and enabled BioTime to eliminate its ESI BIO operating expenses, while providing key stem cell technologies and cell lines to Ascendance for use in strengthening the drug toxicity screening product lines that Ascendance acquired from Hepregen. Since December, Ascendance has generated meaningful revenue growth from customers that include Boehringer Ingelheim, Pfizer, and Merck.

Additionally, in February we completed a transaction with our subsidiary Asterias Biotherapeutics, Inc. that enabled us to further consolidate our ownership of two subsidiary companies holding the core assets, *OpRegen*® and our *PureStem*® orthopedic stem cell technologies, while providing Asterias with access to technologies that may help advance its product development programs.

Unlocking Value: The partial spin-off of OncoCyte Corporation, our subsidiary focused on liquid biopsy diagnostics for lung, breast, and bladder cancers, is an example of successfully unlocking value for our shareholders. We distributed shares of OncoCyte to our shareholders in December 2015. This distribution provided our shareholders with over $20 million worth of shares in a newly publicly traded company. BioTime still holds approximately 58% of OncoCyte s outstanding shares.

We are committed to reducing the complexity of our operations while progressively unlocking the value of our subsidiaries for BioTime shareholders. Our subsidiary LifeMap Solutions, Inc. has built innovative digital health apps in partnership with the Icahn School of Medicine at Mount Sinai, National Jewish Health, and other significant partners. LifeMap Solutions is also a commercial developer working with Apple on the innovative ResearchKit™ technology platform that enables medical researchers to gather medical and health data using a patient s iPhone. LifeMap Solutions Asthma Health app, which was co-developed with the Icahn School of Medicine at Mount Sinai, garnered worldwide attention when it enabled the first IRB-approved smartphone-based asthma study.

We believe the right strategic plan is in place to enhance long term shareholder value-based on our core clinical therapeutic product programs; unlocking the value of our non-core subsidiaries and assets; and our continued ownership of our publicly traded subsidiaries Asterias and OncoCyte that are advancing their own clinical programs.

We are passionate about what we do and appreciate the dedication of our team members across the BioTime family of companies. We would like to thank the clinicians and the patients and their families who are helping us in our journey. We would also like to thank our shareholders for their support as we work towards making revolutionary new therapies available to patients in need.

Sincerely,

Adi Mohanty	Michael D. West, Ph.D.
Co-Chief Executive Officer	Co-Chief Executive Officer