

BIOTIME INC
Form DEFA14A
May 03, 2017

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 ☒ [X]

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

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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)

Payment of Filing Fee (Check the appropriate box):

☒ No fee required.

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(4) Date filed:

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May 2, 2017

Dear Fellow Shareholders,

We would like to begin this letter with a word of thanks to you, the shareholders of BioTime, for your support of our mission to lead the world in the translation of the science of regenerative medicine from the lab bench to the bedside. Our goal is to build a powerful pipeline of high-value therapeutics targeting some of the greatest unmet needs in medicine. These products have the potential to be used to replace and repair cells and tissues of the body afflicted with chronic and degenerative disease. It is estimated that chronic diseases account for approximately 80% of the \$2.5 trillion health care expenditure in the United States. We at BioTime are acutely aware of the responsibility we have to patients around the world as well as the opportunity to our shareholders, to maximize value creation with this emerging technology.

We believe we are the technology leader with one of the largest intellectual property estates in the industry. Recently, we have reported on successful human clinical data, which show that our investigational products are well tolerated and have had no serious adverse events. In addition to our success, other cell-based therapies have generated considerable excitement with the efficacy reported in adaptive immuno-oncology products. These developments highlight the growing interest of pharma companies and the potential impact of cell-based therapies. There is also increasing appreciation of the competitive value of our pluripotency technology in not only the manufacture of any human cell type, but also in facilitating large-scale cost-effective scalability and uniformity of product.

The BioTime group of companies is focused on driving the clinical development of our key products toward commercialization. We have five such products in human trials and one more that is planned to enter the clinic during 2017. All the clinical data from our product trials have been positive and encouraging, which is unprecedented in the pharmaceutical industry that generally has product development failure rates between 80 and 90 percent. We believe this highlights another attractive feature of our cell therapies. Unlike drugs that can, and often do, show unexpected side effects and toxicities (think of the long list of side effects described in a typical drug television commercial), cells are the normal components of the human body. We anticipate that our cell therapies will have markedly lower safety risk profiles than most small molecule drug candidates.

In addition to demonstrating that a potential therapy is safe, it is necessary to show efficacy. Again cell therapies should, in our opinion, have a markedly lower risk of failure. When a patient has a failing kidney and they are lucky and can locate a kidney for transplantation, we know such transplants work even when we don't understand the detailed mechanism of how the original disease occurred. We also know that transplants now have a pretty high success rate of approximately 80 to 90 percent. The need we intend to meet is an industrially scalable source of cells or tissues for transplants that can be accepted by the body, engraft in its environment, and live and function to restore health as nature designed.

To date, the BioTime group of companies has products in the clinic successfully validating these assessments, and we are very encouraged by the data we have seen from the clinical trials. AST-OPC1 for spinal cord injury, OpRegen® for dry-AMD, and AST-VAC1 for AML all now have generated early safety data indicating that those cell or tissue transplants may be proven safe – based on results for a multiplicity of years in some cases. The trials show that the cells engraft appropriately and are even suggesting promising signs of positive biological activity.

The largest driver of chronic degenerative disease and therefore health care costs in the United States is the aging of our population. In a recent report published by Goldman Sachs titled: *A Healthcare Spotlight & The Coming Age of Regenerative Medicine*, it was stated that, “The advent of modern medicine has resulted in humans living longer, with age-related conditions representing a growing unmet need. Novel platforms and stem cell approaches are emerging as potentially promising therapy.” We have recognized that regenerative therapies for applications in the cardiovascular and type II diabetes markets are among the most valuable applications.

Cardiovascular disease has been the number one killer in the United States since 1920. In 2011, the American Heart Association predicted that by 2030, approximately 40% of Americans would have cardiovascular disease. However, by 2015, over 85 million Americans had at least some form of cardiovascular disease. New projections state that by 2035 over 130 million Americans will have cardiovascular disease and that will result in health care costs exceeding \$1 trillion a year. BioTime is seeking to address the need for new treatments by working to develop technology for the manufacture of vascular-forming cells to supply aging heart tissues.

BioTime has also begun to focus on diabetes. The Center for Disease Control has estimated that more than 25% of people over 65 years of age have diabetes and over 50% have prediabetes. Total direct and indirect costs associated with the disease exceeds \$250 billion annually in the US. Like cardiovascular disease, this surge in cases of the disease and the cost of treatment is being driven by an aging population.

Many scientists believe that type II diabetes and obesity could be addressed through the transplantation of brown adipocytes, and in response to recent research findings BioTime scientists have invented protocols for the manufacture of highly purified brown adipocytes. This recently-discovered type of cell in humans declines dramatically with age. Brown adipose tissue cells when injected into obese and diabetic animals have been reported to cause weight loss and a reversal of the symptoms of diabetes. These future products along with a new technology called “induced tissue regeneration” or “iTR” will be the focus of AgeX Therapeutics, Inc., a newly-formed subsidiary of BioTime intended to help us consolidate and simplify our corporate structure.

While we have a very solid scientific foundation, we have been evolving into a more mature company that is rapidly accumulating experience in moving products through clinical trials and preparing for the commercialization of our first cell transplant products in the field of facial aesthetics. To facilitate that process, our near term organizational focus has been on *Clinical Progress, Simplification, and Unlocking Value*.

Clinical Progress: Moving our product candidates successfully through the clinical trial process is our primary focus in building shareholder value. Each milestone achieved in the clinic reduces risk and increases value. So, for BioTime, advancing our lead programs like Renevia®, OpRegen® through clinical trials is critically important. At the same time, we are working with earlier stage programs like the bone grafting program and our three-dimensional *retinal restoration technology*, designed to be used in severe forms of retinal diseases, that are designed to address significant unmet medical needs.

Simplification: Simplifying our corporate, financial and organizational structure allows us to execute our strategies more efficiently and focus our resources on the core therapeutics in our pipeline first. Our aim is to make it much easier for key groups to better understand our company. A major step toward achieving our simplification goal was achieved in April 2017 when we announced the formation of AgeX Therapeutics, Inc. Our goal is to provide AgeX greater flexibility to explore external financing alternatives as well as strategic options to grow its technology platform.

Unlocking Value: We have been successful in unlocking the value of BioTime assets through the creation of companies and distributions, including Asterias Biotherapeutics, Inc., and OncoCyte Corporation, both of which are now stock exchange listed companies. We may develop and employ new or similar strategies in the future to unlock shareholder value. We have also added significant management depth in key areas such as business development and legal that we believe will further enable us to monetize the value of our products and patent estate within an industry landscape in which large pharma is becoming more active.

We remain committed to our aspirational goal of leading the regenerative medicine revolution by developing and commercializing products that address degenerative diseases with large unmet needs. Our current products each address potential multi-billion dollar markets and in some cases markets that could easily reach over 30 billion dollars worldwide. We anticipate that Main Street and Wall Street will soon recognize BioTime's ability to create significant value while making very meaningful contributions to society through our products and technology leadership.

We would like to thank our employees, the clinicians, patients and their families for the progress made in the last year. We look forward to further progress in the coming year in the development and commercialization of these next-generation therapies and changing the practice of medicine as we know it today.

Sincerely,

Adi Mohanty	Michael D. West, Ph.D.	Alfred D. Kingsley
Co-Chief Executive Officer	Co-Chief Executive Officer	Chairman of the Board

