BIOTIME INC
Form DEFA14A
March 29, 2018

**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

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[ ] 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):

[X] No fee required.

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(1) Title of each class of securities to which transaction applies:

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March 29, 2018

Dear Fellow Shareholders,

At the turn of the millennium, Malcolm Gladwell published a book called *The Tipping Point: How Little Things Can Make a Big Difference.* He defined the tipping point as, "the moment of critical mass, the threshold, the boiling point." We at BioTime, with your support, have been laboring diligently in recent years to develop a powerful pipeline of high-value therapeutics. We believe that this platform may be approaching such a Gladwell tipping point. We are pleased to update you, our shareholders, on our product development, in particular, the anticipated regulatory approval in Europe for *Renevia*®, advances in the clinical trials of *OpRegen*® for age-related macular degeneration, and our planned distribution of shares of our subsidiary AgeX Therapeutics, Inc. ("AgeX"), events that we believe will be perceived as meaningful milestones in the coming year.

Our core technology relates to our master cell banks of human pluripotent cells that are a renewable source of potentially all of the cellular building blocks of the body. The platform allows, for the first time in the history of medicine, the ability to manufacture on an industrial scale previously rare and valuable human cell types. These, in turn, can potentially be developed as therapeutics to rebuild or regenerate function in tissue afflicted with degenerative disease. It is estimated that chronic diseases account for approximately 80% of the $2.5 trillion health care expenditure in the United States, and these numbers are now growing rapidly as a result of the aging baby boom generation. The impact of this important demographic shift is only now really impacting strategic planning in the pharmaceutical industry, and, as a result, our technology platform in regenerative medicine is attracting the attention of the sector.

In addition to our broad human cell manufacturing capability, we have incorporated our matrix technology, *HyStem*®, in much of our product development plans. If one thinks of tissues in the body being composed of cells, sort of like bricks making up a wall, then *HyStem* is the mortar that holds the cells in place. Through this proprietary technology, cells can be mixed with *HyStem* in a liquid suspension. Upon injection, the matrix cross-links in the presence of living cells to stabilize and maintain them in a specific anatomical site.

Our products are tissue-specific and, as such, are more similar to transplant medicine than body-wide systemic drug therapies. We believe this may reduce the risk profile of the products during clinical trials. As you know, many systemic product candidates have failure rates in excess of 80% due to their unexpected results and/or side effects on tissues in the body other than the targeted disease process. We have shown through clinical trials that our products can be locally administered and remain at the intended target site. Supporting this belief, the products used in our clinical

trials have historically been well tolerated with no unexpected serious adverse events noted to date.

Our relentless focus on clinical progress, simplification and unlocking value, have laid the foundation for years to come. In 2017 the BioTime group of companies presented transformational clinical data from human clinical trials. BioTime's lead cell delivery program, *Renevia* (a formulation of *HyStem* together with the patient's own adipose-derived cells), met its primary endpoint in a European clinical trial in HIV-associated facial lipoatrophy. In the first quarter of 2018, we submitted our design dossier for CE Mark approval in Europe and expect approval later this year.

Additional *Renevia* data were presented from the successful pivotal trial at the International Federation for Adipose Therapeutics and Science conference. As well as successfully meeting the primary endpoint, treated patients retained an average 70% of the transplanted volume at 12 months and 64% at 18 months. This observed retention of the product could translate into an improved and long-lasting effect on cosmetic appearance.

In addition to *Renevia*, we presented positive interim data from our lead cell replacement therapy program, *OpRegen*. Images presented in scientific meetings appeared to indicate that the transplanted product engrafted in the appropriate location within the retina and survived over time. There were also some areas that appeared to show structural improvement suggesting possible evidence of a biological response. As with *Renevia*, we have seen no unexpected serious adverse events in the trial to date.

More specifically, we completed enrollment of the third cohort of the *OpRegen* clinical trial. The Independent Data Safety Monitoring Board (DSMB) approved, in parallel, three additional patients in the third cohort and the initiation of the fourth cohort. The approval of the fourth cohort is of particular importance because we will evaluate *OpRegen* in patients with vision of approximately 20/70 who are likely in a much earlier stage of the disease. Treating patients with better vision at an earlier stage of the disease process will allow us the opportunity to potentially demonstrate a potential treatment effect in our eventual target patient population. This will also provide us the ability to perform a broader spectrum of functional assessments to quantify and objectively evaluate the potential benefit of this therapy.

We continue to hold a significant equity position in Asterias Biotherapeutics, Inc. ("Asterias"), a previous subsidiary of BioTime, now trading publicly under the ticker symbol (NYSE American: AST). Over the past year, Asterias has announced continued progress in the Phase II SciStar trial of *AST-OPC1* for subacute spinal cord injury. In addition, Asterias expects to soon begin enrollment of patients in the Phase I trial of *AST-VAC2*, a cancer immunotherapy training the immune system to target and destroy cells expressing telomerase, a gene abnormally expressed in the majority of all human cancer types. We also hold a large equity stake in OncoCyte Corporation (NYSE American: OCX), which is developing novel cancer diagnostics.

The formation of AgeX in 2017 reflects the continued implementation of our strategy to simplify our corporate structure and thereby dedicate more resources to the clinical development of *Renevia* and *OpRegen.* Our Board of Directors and management have agreed in principle to distribute some or all of the AgeX shares to BioTime

shareholders. On final approval, the distribution could take place in the next few months. We are actively working with investment banks and other financial institutions to finalize and implement the strategy for taking AgeX public.

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 worldwide. We are closer to making very meaningful contributions to society through our products and technology leadership and along with that creating significant value for our shareholders. We look forward to changing the practice of medicine as we know it today.

We would like to thank our shareholders, employees, the clinicians, patients and their families for the progress made in the last year. With the progress we have made so far, we enter 2018 with significant momentum and confidence.

Sincerely,