

BIOTIME INC
Form DEFA14A
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SCHEDULE 14A

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INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

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BioTime, Inc.

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Dear Fellow Shareholders,

The past year has been an historic one for BioTime and its subsidiary companies. Most notably, the acquisition of the stem cell assets of Geron Corporation and our approval to initiate clinical trials of *Renovia* in Europe, highlight the execution of our business strategy; namely:

- To lead the world in the development of high-value therapeutics from pluripotent stem cells; and
- To aggressively develop strategic near-term products.

Based on progress since last year's meeting, we believe that BioTime is well poised to be a formidable leader in the field of regenerative medicine. To put all this in perspective, let's begin with a bit of relevant history, delve into some of the specifics on our plans, and highlight some of our recent accomplishments.

Regenerative medicine: a new platform for treating degenerative disease

The field of regenerative medicine began at Geron Corporation in 1995 when I organized the world's first effort to isolate and characterize human embryonic stem cells. Based on the work we had previously done at Geron in the field of telomeres, telomerase, and cell aging, we believed these cells would have at least two unique properties that would allow them to fuel a new industry in medicine. First, they would be the ultimate stem cell, capable of changing into all the cell types in the human body. This is what is meant by the term pluripotent. Second, based on work with the immortalizing enzyme known as telomerase, we believed that these cells would differ from all the cell types of the body normally cultured in the laboratory, in that they could be replicated and scaled up indefinitely without aging. We believed this was because they would express the enzyme telomerase at high levels and that when body cell types were made from them, telomerase would turn off as it normally does in development, leading to young human cells of all types. Our vision, therefore, was that for the first time in the history of medicine, we could build an industrial scale manufacturing platform to make any of the cellular building blocks of the human body. We obviously saw this as a pretty exciting project.

Not only was the idea a novel and exciting one, the potential markets were extraordinary. Aging is the demographic trend of our time due to the aging post-World War II baby boomers. As President Obama said in his 2013 State of the Union Address, "the biggest driver of our long-term debt is the rising cost of health care for an aging population." The reason for this is simply that aging brings on chronic degenerative diseases that are difficult and expensive to treat, and often lead to continual care or rehabilitation over months or even years. Having the source of young cells of all types, and matrices to fashion those cells into novel regenerative therapies, could change those economics dramatically.

Back to the history. I left Geron in 1998 to pursue the possibility of turning any cell in the body into patient-specific embryonic stem cells using nuclear transfer technology. At around that time, Dr. Thomas Okarma joined the Geron team, and subsequently became Geron's CEO, overseeing some of the world's first commercial development of therapeutic cells from pluripotent stem cells. The first FDA-approved clinical trials were for the product designated OPC1, designed to improve outcomes following serious spinal cord injuries. Tom's group also turned the discoveries we had made regarding the widespread and abnormal expression of telomerase in malignant tumors, into two types of cancer vaccines. One called VAC1 was a vaccine designed to train the immune system to specifically attack the telomerase positive tumor cells. The other, called VAC2, was a more advanced version of the vaccine where the cells that carry these instructions to the patient's immune system are made from human pluripotent stem cells. VAC1 was also in human clinical trials at Geron. The telomerase vaccine was considered by many to also be very exciting because never in the history of cancer research has a target been identified that is abnormally expressed in over 90% of cancers.

Because of the importance of these clinical trials, as well as the mountain of materials and patents generated at Geron, Tom and I felt a deep sense of duty and opportunity in joining forces to acquire and reassemble the stem cell assets. The BioTime family of companies now hold patents and other stem cell assets of Geron, technology licensed to BioTime from Advanced Cell Technology, and technology developed by Singapore-based ES Cell International, Pte Ltd, making us a leader of this important sector.

Technology integration between BioTime's subsidiaries

In the last few years we have made enormous progress in our research of more than 200 diverse *PureStem* cell lines. These are scalable populations of cells but differ from those typically used in stem cell research in that, while made from a starting population of human pluripotent stem cells, they are purified lineages intermediate between pluripotent stem cells and the final cell types in the body. We have determined that many of these *PureStem* lines can be scaled to about 100 million doses of 100 million cells. This scalability combined with their high purity and identity may potentially greatly simplify the development of the cells as therapeutic products. In addition, the highly-defined *PureStem* cells when combined with our GMP-grade injectable matrix *Renevia* is a particularly exciting opportunity. Therefore our strategy is to integrate these and other advanced technologies through cross-licensing patents, know how, and cell lines between BioTime and its subsidiaries to build strong disease-focused subsidiaries that can build state-of-the-art products.

A continual focus on near-term commercialization

Since we see our principal duty to be that of building value for our shareholders, we continue to put a significant emphasis on products with a potential for near-term commercialization. A major challenge of biotechnology in general is the relatively long timelines to commercial launch of products compared to other technology sectors. This is due in part to the lengthy process of meeting FDA requirements for product launch.

To address these issues, our strategy is to aggressively develop and market products arising out of our stem cell platform with significant near-term potential, yet synergistic with the longer-term cellular therapies. Our *HyStem*[®] hydrogels like *Renevia* , are easily seen as such a product. While currently being tested by BioTime for the transfer of fat cells in the body, there is strong scientific support for the potential use of the product to engraft a wide array of other cell types into the body. Our subsidiary LifeMap Sciences has a trio of online databases called *GeneCards*[®], *MalaCards*, and *LifeMap Discovery* providing data on genes, diseases, and cells respectively. With over 2,000,000 unique visitors to the LifeMap Sciences databases, we believe there is considerable opportunity to monetize this important resource for the medical research community. Lastly, based on our stem cell expertise, our subsidiary OncoCyte has identified important new markers of cancer that are being developed as a blood test based diagnostic called *PanC-Dx* .

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.

Major Asset Acquisition

- Our subsidiary Asterias Biotherapeutics, Inc. recently acquired assets related to Geron Corporation's previous human embryonic stem (hES) cell programs, consisting primarily of patents and patent applications and other intellectual property, stem cell lines, and investigational new drug applications (IND) filed with the FDA for Geron's Phase I safety study of oligodendrocyte progenitor cells in patients with complete, subacute spinal cord injury, as well as its Phase I/II clinical trial of its autologous telomerase vaccine program in patients with acute myelogenous leukemia in complete remission. We believe that the hES assets that we and our subsidiaries have developed and acquired over the last several years, when coupled with the assets acquired by Asterias, will assemble within the BioTime group of companies the world's premier hES intellectual property, cell lines, development programs, and related technologies.

Advanced near-term and intermediate-term product development

- We have received approval from The Spanish Agency of Medicines and Medical Devices (AEMPS) to begin human clinical trials of *Renevia* , a unique biomaterial used as a delivery matrix for autologous adipose derived cells to treat the loss of subcutaneous adipose tissue (lipoatrophy) arising from trauma, surgical resection, and congenital defects and disease. This AEMPS approval follows the earlier approval this year from the Balearic Island Ethics Committee for the first of a multiphase clinical investigation of *Renevia* . Our goal is to complete the safety trial in 2013, and begin enrollment of the efficacy and pivotal trial in the first half of 2014.

- Our subsidiary OncoCyte Corporation made several key advances in the development of *PanC-Dx*, its novel diagnostic device to detect the presence of various human cancers. Our goal is to begin clinical studies of *PanC-Dx* before the end of 2013. The *PanC-Dx* products are designed to detect pan-cancer as well as tumor specific antigens in a low cost, but accurate manner.

Expanded research product offerings

- Our subsidiary LifeMap Sciences, Inc. released enhancements to its integrated database suite products *LifeMap BioReagents*[™], *LifeMap Discovery*[™], *GeneCards*[®] and *MalaCards* and entered into a value-added reseller agreement with Appistry, Inc., a company that provides big-data computing that supports life-science and medical analytics at hospitals and medical research centers and organizations. Appistry will market reports that include LifeMap Sciences' *GeneCards*[®] and *MalaCards* genetic information to clinicians and researchers under a revenue share arrangement with LifeMap Sciences, based on sales of such reports.
- LifeMap Sciences entered into a commercial relationship with ProSpec-Tany TechnoGene through which LifeMap Sciences has added 100 select recombinant proteins available for sale to researchers on its *LifeMap BioReagents* portal.

Advanced R&D collaborations and executed licensing agreements

- We have expanded the *HyStem*[®] field-of-use license from the University of Utah to an exclusive worldwide license for all human medical applications.
- We have entered into a worldwide license agreement with the University of California, Los Angeles (UCLA) for novel technology related to the treatment of stroke. The licensed technology developed at UCLA uses one of BioTime's *HyStem*[®] hydrogels to deliver locally released growth factors to improve recovery from stroke. Concurrent with the execution of this exclusive license agreement, BioTime has entered into a Sponsored Research Agreement with UCLA to support on-going pre-clinical work to advance the understanding of this technology and develop data in support for the potential filing of an IND for human clinical trials.
- We entered into an exclusive sublicense agreement with Jade Therapeutics, Inc., a Salt Lake City-based developer of ophthalmic sustained-release drug delivery platforms. This new agreement supersedes the previously announced sublicense and supply agreements and expands the scope of the license the use of BioTime's *HyStem*[®] hydrogel technology for the delivery of potential therapeutic molecules to the human eye. Jade's lead products in pre-clinical development utilize the licensed hydrogel technology to facilitate time-release, topical delivery of recombinant human growth hormone to help heal lesions on the ocular surface, as well as to enable local delivery of antibiotics to treat ocular infections.

Expanded and strengthened Board of Directors and management team

- We appointed three new members to our Board of Directors. The new directors are:
- Stephen C. Farrell, Chief Executive Officer and Director of Convey Health Solutions (formerly known as NationsHealth, Inc.), a healthcare business process outsourcing company headquartered in Sunrise, Florida. Mr. Farrell brings to our Board significant experience in finance, financial reporting, accounting and auditing, and in management as a senior executive of a public healthcare company during a period of significant growth.
- Henry L. Nordhoff, retired as Chairman of the Board of Gen-Probe Incorporated, a clinical diagnostic and blood screening company. Mr. Nordhoff brings to our Board a long record of experience and success in the pharmaceutical and biotech industries and provides our Board with valuable operational expertise and leadership skills during a period of significant growth.
- Franklin M. Berger, a consultant to biotechnology industry participants, including major biopharmaceutical firms, mid-capitalization biotechnology companies, specialist asset managers and venture capital companies, provides business development, strategic advisory, financing, partnering, and royalty acquisition advice.
- We expanded our senior management team with the appointment of Lesley Stolz, Ph.D. as Executive Vice President, Corporate Development. Dr. Stolz has more than 18 years of life science industry experience in corporate and business development.
- David Larocca, Ph.D. was hired as the Vice President Research and Development for BioTime's subsidiary ReCyte Therapeutics, Inc. Dr. Larocca has more than 25 years of experience in industry and academic research in the fields of immunotherapy, gene therapy, and pluripotent stem cell biology and reprogramming.

Key research publications and presentations

- We published in the peer-reviewed journal *Regenerative Medicine* the paper "Seven diverse human embryonic stem cell-derived chondrogenic clonal embryonic progenitor cell lines display site-specific cell fates comparing the cell lines with bone marrow-derived mesenchymal stem cells. It was determined that the confirmed purity and identify of the embryonic progenitor cells combined with the scalability of these lines could simplify manufacturing therapeutic products."
- We published in the peer-reviewed journal *Biomarkers in Medicine* a study that identified and characterized a highly specific breast cancer tumor marker. "Elevated expression of cancer/testis antigen *FSIP1* in ER-positive breast tumors finds that *FSIP1* is a highly attractive target for breast cancer immunotherapy and diagnostics due to its highly restricted expression in normal tissues and its uniformity of expression in breast tumors."

- Our subsidiary, LifeMap Sciences, Inc., announced the publication of two research studies showing that their products, *GeneCards*® and *MalaCards*, have added valuable information to ongoing disease study. *GeneCards*® now includes annotated ncRNA information that allowed the group to overcome the obstacles of the unification of ncRNA genes potentially leading to new discoveries in disease research. In addition, the same group published results of their research using the *MalaCards* disease database further validating the value of the information to biomedical research.
- We published a paper in a special edition of *Biomatter* focusing on the delivery, retention and engraftment of progenitor cells in cell therapy. This issue was devoted to research results using our *HyStem*® hydrogels in multiple applications including stroke, treatment after heart attack, neural applications, wound healing, and kidney damage.
- We made presentations of our products, technologies, and business strategies at the following scientific and investor meetings: Stem Cells USA & Regenerative Medicine Congress 2012, World Stem Cell Summit 2012, Scale-Up and Manufacturing of Cell-Based Therapies II, ROTH Conference, USC Minisymposium on Musculoskeletal Development and Repair, World Stem Cell & Regenerative Medicine Congress 2013, and the MSC 2013 Adult Stem Cell Therapy & Regenerative Medicine Conference.

In summary, we have made strategic strides this year in building the leading biotechnology company in regenerative medicine. Our focus has been specifically on technologies relating to pluripotent stem cells, cells which we believe have the most potential to serve the large markets in age-related degenerative disease. Our future success will now largely depend on advancing our product pipeline through laboratory development and into clinical development.

On a sad note, we lost two of our directors over the past year. Barry Cohen passed away last November and Arnold Burns, who resigned last May for health reasons, passed away very recently. Both provided us with wise counsel and will sorely be missed.

Thank you for supporting our efforts to develop these products and potentially improve the length and quality of life of millions of people around the world. We welcome you to join us again in New York City on October 28, 2013 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 a series of presentations from the principals of each of our subsidiaries.

Sincerely,

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

Alfred D. Kingsley
Chairman of the Board

October 2, 2013