BIOTIME INC
Form 10-K
March 14, 2012

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2011

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from_____ to _____

Commission file number 1-12830

BioTime, Inc.
(Exact name of registrant as specified in its charter)

California	94-3127919
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1301 Harbor Bay Parkway, Suite 100
Alameda, California 94502
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (510) 521-3390

Securities registered pursuant to Section 12(b) of the Act
Title of class Common Shares, no par value

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the

Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes o No x

The approximate aggregate market value of voting common shares held by non-affiliates computed by reference to the price at which common shares were last sold as of June 30, 2011 was $126,421,699. Shares held by each executive officer and director and by each person who beneficially owns more than 5% of the outstanding common shares have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of common shares outstanding as of March 5, 2012 was 50,321,962.

Documents Incorporated by Reference
Portions of Proxy Statement for 2012 Annual Meeting of Shareholders are incorporated by reference in Part III

BioTime, Inc.

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PART I

Statements made in this Form 10-K that are not historical facts may constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those discussed. Words such as “expects,” “may,” “will,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” and similar expressions identify forward-looking statements. See Note 1 to Financial Statements.

References to “we” means BioTime, Inc. and its subsidiaries unless the context otherwise indicates.

The description or discussion, in this Form 10-K, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.

Item 1. Business

Overview

We are a biotechnology company focused on the emerging field of regenerative medicine. Our core technologies center on stem cells capable of becoming all of the cell types in the human body,a property called pluripotency. Products made from these “pluripotent” stem cells are being developed by us and our subsidiaries, each of which concentrates on different medical specialties, including: neuroscience, oncology, orthopedics, and blood and vascular diseases. Our commercial strategy is heavily focused on near-term commercial opportunities including our current line of research products such as ACTCellerate™ cell lines and associated ESpan™ culture media, HyStem® hydrogels, human embryonic stem cell lines, and royalties from Hextend®. Potential near term therapeutic product opportunities include the launch of HyStem®-Rx as a cell delivery device expected in 2013, and the launch of PanC-Dx™ as a novel blood-based cancer screen, expected by 2014. Our long-term strategic focus is to provide regenerative therapies for age-related degenerative diseases.

“Regenerative medicine” refers to an emerging field of therapeutic product development that may allow all human cell and tissue types to be manufactured on an industrial scale. This new technology is made possible by the first isolation of human embryonic stem (“hES”) cells and by the development of “induced pluripotent stem (“iPS”) cells” which are created from regular cells of the human body using technology that allows adult cells to be “reprogrammed” into cells with pluripotency like young hES-like cells. These pluripotent hES and iPS cells have the unique property of being able to branch out into each and every kind of cell in the human body, including the cell types that make up the brain, the blood, the heart, the lungs, the liver, and other tissues. Unlike adult-derived stem cells that have limited potential to become different cell types, pluripotent stem cells may have vast potential to supply an array of new regenerative therapeutic products, especially those targeting the large and growing markets associated with age-related degenerative disease. Unlike pharmaceuticals that require a molecular target, therapeutic strategies in regenerative medicine are generally aimed at regenerating affected cells and tissues, and therefore may have broader applicability. Regenerative medicine represents a revolution in the field of biotechnology with the promise of providing therapies for diseases previously considered incurable.

Our commercial efforts in regenerative medicine include the development and sale of products designed for research applications in the near term as well as products designedfor diagnostic and therapeutic applications in the medium and long term. We offer advanced human stem cell products and technology that can be used by researchers at universities and at companies in the bioscience and biopharmaceutical industries. We have developed research and clinical grade hES cell lines that we market for both basic research and therapeutic product development. Our subsidiary, ES Cell International (“ESI”), has developed six hES cell lines that are among the best-characterized and documented lines available today. Developed using current Good Manufacturing Practices (“cGMP”) that facilitate transitions into the clinic, these hES cell lines are extensively characterized and five of the six cell lines currently have

documented and publicly-available genomic sequences. The ESI hES cell lines are now included in the Stem Cell Registry of the National Institutes of Health ("NIH"), making them eligible for use in federally funded research and all are available for purchase through www.biotimeinc.com. We also market human embryonic progenitor cell ("hEPCs") developed using ACTCellerate™ technology. These hEPCs are purified lineages of cells that are intermediate in the developmental process between embryonic stem cells and fully differentiated cells. We expect that hEPCs will simplify the scalable manufacture of highly purified and identified cell types and will possess the ability to become a wide array of cell types with potential applications in research, drug discovery, and human regenerative stem cell therapies. The ACTCellerate™ cell lines are also available for purchase through www.biotimeinc.com.

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Research products can be marketed without regulatory or other governmental approval, and thus offer relatively near-term business opportunities, especially when compared to therapeutic products. The medical devices that we and our subsidiaries are developing will require regulatory approval for marketing, but the clinical trial and approval process for medical devices is often faster and less expensive than the process for the approval of new drugs and biological therapeutics. Our current and near-term product opportunities, combined with expected long-term revenues from the potentially very large revenue cell-based therapeutic products under development at our subsidiaries, provide us with a balanced commercial strategy. The value of this balance is apparent in the commercial field of regenerative medicine as competitors whose sole focus is on long-term therapeutic products have found it challenging to raise the requisite capital to fund clinical development.

Our HyStem® hydrogel product line is one of the components in our near-term revenue strategy. HyStem® is a patented biomaterial that mimics the human extracellular matrix, which is the network of molecules surrounding cells in organs and tissues that is essential to cellular function. Many tissue engineering and regenerative cell-based therapies will require the delivery of therapeutic cells in a matrix or scaffold to sustain cell survival after transplantation and to maintain proper cellular function. HyStem® is a unique hydrogel that has been shown to support cellular attachment and proliferation in vivo and is currently being used by researchers at a number of leading medical schools in pre-clinical studies of stem cell therapies to facilitate wound healing, for the treatment of ischemic stroke, brain cancer, vocal fold scarring, and for, myocardial infarct repair. Our HyStem® hydrogels may have other applications when combined with the diverse and scalable cell types our scientists have isolated from hES cells.

HyStem®-Rx is a clinical grade formulation of HyStem-C®, a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in human clinical applications. As an injectable product, HyStem®-Rx may address an immediate need in cosmetic and reconstructive surgeries and other procedures by improving the process of transplanting adipose derived cells, mesenchymal stem cells, or other adult stem cells. We will need to obtain approval by the U.S. Food and Drug Administration (“FDA”) and comparable regulatory agencies in foreign countries in order to market HyStem®-Rx as a medical device. Our goal is to initiate clinical trials in the European Union by late 2012 for CE marking.

Our subsidiary, OncoCyte Corporation, is developing PanC-Dx™, a novel non-invasive blood-based cancer screening test designed to detect the presence of various human cancers, including cancers of the breast, lung, bladder, uterus, stomach, and colon, during routine check -ups. We intend to initially seek regulatory approval to market PanC-Dx™ in Europe before seeking regulatory approvals required to market the product in the U.S. and other countries.

Our subsidiaries focus on developing regenerative medicine products for diverse medical disciplines. OncoCyte Corporation (“OncoCyte”) is developing products and technologies to diagnose and treat cancer. ESI, a Singapore based private limited company, develops and sells hES products for research use. BioTime Asia, Limited (“BioTime Asia”), a Hong Kong based company, sells products for research use and may develop therapies to treat cancer and neurological and orthopedic diseases in Asia. OrthoCyte Corporation (“OrthoCyte”) is developing therapies to treat orthopedic disorders, diseases and injuries. ReCyte Therapeutics, Inc. (“ReCyte Therapeutics”), formerly known as Embryome Sciences, Inc., is developing therapies for age-related cardiovascular and blood disorders. Cell Cure Neurosciences Ltd. (“Cell Cure Neurosciences”), is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and other neurological disorders, including the development of retinal pigment epithelial (RPE) cells for the treatment of age-related macular degeneration. LifeMap Sciences, Inc. (“LifeMap”) is advancing the development and commercialization of our embryonic stem cell database and plans to make the database available for the marketing of research products and for use by stem cell researchers at pharmaceutical and biotechnology companies and other institutions via paid subscriptions or on a fee per use basis.

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We will partly or wholly fund our subsidiaries, recruit their management teams, assist them in acquiring technology, and provide general guidance for product development and business development. We may license our patents and technology to the subsidiaries that we do not wholly own; under agreements that will entitle us to receive royalty payments from the commercialization of products or technology they develop.

Initially, we developed blood plasma volume expanders and related technology for use in surgery, emergency trauma treatment, and other applications. Our lead blood plasma expander product, Hextend®, is a physiologically balanced intravenous solution used in the treatment of hypovolemia, a condition caused by low blood volume, often from blood loss during surgery or injury. Hextend® maintains circulatory system fluid volume and blood pressure, and keeps vital organs perfused during surgery and trauma care. Hextend® is manufactured and distributed in the U.S. by Hospira, Inc., and in South Korea by CJ CheilJedang ("CJ"), under license from us.

Key Accomplishments in 2011

During January 2011, we acquired the assets of Cell Targeting, Inc. ("CTI"), a biotechnology company focused on methods of "painting" molecules on the surface of cells, which in turn causes the cells to adhere to particular tissues, such as those afflicted with disease. CTI and its collaborators have produced several tissue-specific and disease-specific cell modification agents with the potential to elevate cell therapy products to a new level of performance. OncoCyte may utilize this technology in the development of genetically modified hES-derived vascular progenitors designed to target and destroy malignant tumors.

During 2011, we acquired Glycosan BioSystems, Inc. ("Glycosan") through a merger of Glycosan with OrthoCyte. Through the merger, OrthoCyte acquired all of Glycosan's assets, including Glycosan's Hystem® hydrogel product line. The HyStem® product line includes HyStem®-Rx, which we are developing as a medical device for the implantation of adipose derived cells and other adult stem cells in cosmetic and reconstructive surgery. Our subsidiary, OrthoCyte, is using HyStem® hydrogels in the development of therapeutic products for use in the treatment of osteoarthritis. Glycosan's hydrogels may have other applications when combined with the diverse and scalable cell types our scientists have isolated from hES cells. In January 2012, all Glycosan related activities were transferred to BioTime.

During March 2011, we entered into an agreement with XenneX, Inc., a privately-held company, pursuant to which we organized LifeMap Sciences, Inc., a new subsidiary formed to advance the development and commercialization of our hES cell data base. The new expanded data will address all known cellular branches in the mammalian developmental tree, including several thousand stem and progenitor cells, and related information such as that pertaining to anatomy, differentially-expressed gene signatures, and research reagents. Our plan is to make the data base available for use by stem cell researchers at pharmaceutical and biotechnology companies and other institutions via paid subscriptions or on a fee per use basis. The data base will permit users to follow the development of hES cell lines to the purified hEPC lines that we created using our proprietary ACTCellerateTM technology and is therefore expected to be useful in marketing the ACTCellerateTM cell lines.

During July 2011, we were awarded a $335,900 Small Business Innovation Research ("SBIR") grant from the National Institutes of Health to develop HyStem® microcarriers for the propagation of human stem cells and as a means of cell delivery for human clinical applications. The grant period is from September 30, 2011 to September 29, 2012.

During August 2011, we entered into a License Agreement with Cornell University for the worldwide development and commercialization of technology developed at Weill Cornell Medical College for the differentiation of hES cells into vascular endothelial cells. The technology may provide an improved means of generating vascular endothelial cells on an industrial scale, and will be utilized by us in diverse products, including those under development at our subsidiaries ReCyte Therapeutics and OncoCyte, to treat age-related vascular disease and to target the delivery of

toxic payloads to cancerous tumors, respectively.

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During August 2011, our subsidiary, OncoCyte sold 3,000,000 shares of common stock to a private investor who is also a BioTime shareholder for $3,000,000 in cash, and OncoCyte sold to us 7,000,000 shares of OncoCyte common stock for $1,000,000 in cash and 1,286,174 BioTime common shares having a market value of $6,000,000. These BioTime common shares are accounted for as treasury stock as of December 31, 2011. OncoCyte is using the funds raised from the sale of the shares for the expansion of its development of proprietary products and technologies for diagnosis and treatment of cancer in humans. OncoCyte's research has demonstrated that many of the same genes associated with the normal growth of embryonic stem cells are abnormally reactivated by cancer cells. Based on this finding, and utilizing its proprietary algorithms, OncoCyte has discovered and filed patent applications on over 100 novel cancer-associated genes. OncoCyte expects to use its new financing in part to expand its current patent portfolio of over twenty patent filings on these new genes and to advance the development and commercialization of resulting novel diagnostic and therapeutic products, including PanC-Dx™. In addition to advancing its new diagnostic product line, OncoCyte is continuing to develop cellular therapeutics for cancer therapy that will take advantage of the unique biology of vascular endothelial precursor cells.

During August 2011, four hES cell lines (ESI-035, ESI-049, ESI-051 and ESI-053) developed by our subsidiary ESI were approved by the NIH for inclusion in the NIH Human Embryonic Stem Cell Registry. This approval opens the door to the use of these cell lines in federally funded research. Two other ESI hES cell lines, ESI-014 and ESI-017, were previously included in the NIH Human Embryonic Stem Cell Registry. The ESI hES cell lines were derived using procedures and documentation that are in compliance with current Good Tissue Practices ("cGTP") and cGMP, are free of animal feeder cells and have been assessed for pluripotency and karyotypic stability. In collaboration with the California Institute of Regenerative Medicine ("CIRM"), we have supplied research grade versions of these lines to dozens of researchers throughout California, including those in the University of California system. We have also derived the complete genome sequence of five of the ESI hES cell lines to facilitate the development of products derived from these cell lines.

During December 2011, we announced the successful completion of ISO 10993 biocompatibility studies for our product HyStem®-Rx. These tests, as prescribed by the International Organization for Standardization for permanent implantable medical devices, are required by the United States Food and Drug Administration and European Union regulatory authorities prior to beginning clinical studies in humans. The results of these preclinical studies successfully demonstrated the safety and biocompatibility of HyStem®-Rx.

During December, 2011, we entered into two agreements with USCN Life Science, Inc. (USCN), a Chinese company. One agreement is a License Option Agreement that grants us the right, but not the obligation, to license from USCN certain technology and any related patents that may issue, and certain hybridoma cell lines for the purpose of deriving new products and technologies for use in diagnostic procedures and in therapeutics for the treatment of disease, as well as for products intended for research use only. A hybridoma cell line is an expandable culture of cells engineered to secrete a distinct antibody known as a monoclonal antibody that is directed to a specific protein. Certain antibodies distributed by USCN were tested by us and OncoCyte and were found to be effective as components of PanC-DxTM. The option to source USCN's existing hybridoma cell lines for the large-scale manufacture of OncoCyte's proprietary products may benefit OncoCyte by reducing the time required for the launch of PanC-DxTM in Europe, currently planned for 2013. The other agreement we entered into with USCN is an assay kit Supply Agreement under which we will purchase a wide array of assay kits designed for enzyme-linked immunosorbent assay (ELISA) and chemiluminescent immuno assay (CLIA) directed to the stem cell research community and for research use only.

Additional Information

Hextend® and PentaLyte® are registered trademarks of BioTime, Inc., and ESpan™, and ESpy™ are trademarks of BioTime, Inc. ReCyte™ is a trademark of ReCyte Therapeutics, Inc. ACTCellerate™ is a trademark licensed to us by

Advanced Cell Technology, Inc., PanC-Dx™ is a trademark of OncoCyte. HyStem® is a registered trademark of OrthoCyte Corporation.

We were incorporated in 1990 in the state of California. Our principal executive offices are located at 1301 Harbor Bay Parkway, Alameda, California 94502. Our telephone number is (510) 521-3390.

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Business Strategy

One of our goals is to develop cell-based regenerative therapies for age-related degenerative disease. The degenerative diseases of aging meet several criteria that make them an attractive business opportunity. First, the elderly comprise a large and growing segment of our population. Second, chronic degenerative diseases account for nearly 75% of health care costs. Third, because many age-related diseases appear to be caused by the inherent limited capacity of aged human cells to regenerate damaged tissues in the body, our cell replacement technologies may eliminate the high costs associated with years of palliative care addressing these large markets.

Our effort in regenerative medicine also includes research on more than 200 purified, scalable, and novel human embryonic progenitor cell types produced from hES and iPS cells. This research has included extensive gene expression studies of the unique properties of the cells, as well as conditions that cause the cells to differentiate into many of the cell types in the body. We have filed patent applications on the compositions of these cells, the media in which they can be expanded, and a variety of uses of the cells, including drug discovery and cell replacement therapies. This novel manufacturing technology may provide us with a competitive advantage in producing highly purified, identified, and scalable cell types for potential use in therapy.

We have organized several subsidiaries to undertake our cell replacement therapeutic programs. We will partly or wholly fund these subsidiaries, recruit their management teams, assist them in acquiring technology, and provide general guidance for building the subsidiary companies. We may license our patents and technology to the subsidiaries that we do not wholly own; under agreements that will entitle us to receive royalty payments from the commercialization of products or technology they develop. We believe that having subsidiaries that focus on particular disease applications or research products will facilitate the optimization of scientific and commercial collaborations, thereby improving the probability that a subsidiary company will eventually become an industry leader. We believe that high-quality executives are likely to be more attracted to managing subsidiary companies than to heading divisions within a larger company. The organization of our regenerative medicine business into subsidiaries has also facilitated our ability to obtain financing for our regenerative medicine programs at the subsidiary level.

The following table shows our subsidiaries, their respective principal fields of business, our percentage ownership, and the country where their principal business is located:

Subsidiary	Field of Business	BioTime Ownership	Country
ES Cell International Pte. Ltd.	Stem cell products for research, including clinical grade cell lines produced produced under cGMP	100%	Singapore
OncoCyte Corporation	Diagnosis and treatment of cancer	75.3%	USA
OrthoCyte Corporation	Orthopedic diseases, including osteoarthritis	100%	USA
Cell Cure Neurosciences, Ltd.	Age-related macular degeneration Multiple sclerosis Parkinson’s disease	53.6%	Israel
ReCyte Therapeutics, Inc. (formerly Embryome Sciences, Inc.)	Blood and vascular diseases including coronary artery disease Endothelial progenitor cells and iPS cell banking	95.15%	USA

BioTime Asia, Ltd.	Ophthalmologic, skin, musculo-skeletal system, and hematologic diseases for Asian markets. Stem cell products for research	81%	Hong Kong
LifeMap Sciences, Inc.	Stem cell data base	100%	USA
LifeMap Sciences, Ltd.	Stem cell data base	100% (1)	Israel

(1) LifeMap Sciences, Ltd. is a wholly-owned subsidiary of LifeMap Sciences, Inc