### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

# Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): May 28, 2014

# BioTime, Inc.

(Exact name of registrant as specified in its charter)

California

(State or other jurisdiction of incorporation)

1-12830

(Commission File Number)

94-3127919

(IRS Employer Identification No.)

1301 Harbor Bay Parkway Alameda, California 94502 (Address of principal executive offices)

(510) 521-3390

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K fil	ling is intended to simultaneously satisfy	y the filing obligation of the registrar	it under any of the following
provisions:			

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Any statements that are not historical fact (including, but not limited to statements that contain words such as "may, "will," "believes," "plans," "intends," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Additional factors that could cause actual results to differ materially from the results anticipated in these forward-looking statements are contained in BioTime's periodic reports filed with the SEC under the heading "Risk Factors" and other filings that BioTime may make with the Securities and Exchange Commission. Undue reliance should not be placed on these forward-looking statements which speak only as of the date they are made, and the facts and assumptions underlying these statements may change. Except as required by law, BioTime disclaims any intent or obligation to update these forward-looking statements.

This Report and any accompanying exhibits shall be deemed "furnished" and not "filed" under the Securities Exchange Act of 1934, as amended.

# **Section 7 - Regulation FD**

## **Item 7.01 - Regulation FD Disclosure**

On May 28, 2014, BioTime, Inc. issued the press release furnished as Exhibit 99.1, which is incorporated by reference.

# **Section 9 - Financial Statements and Exhibits**

### Item 9.01 - Financial Statements and Exhibits.

Exhibit Number Description

99.1 Press Release Dated May 28, 2014.

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOTIME, INC.

Date: May 28, 2014 By: /s/ Michael D. West

**Chief Executive Officer** 

Exhibit Number

**Description** 

99.1

Press Release Dated May 28, 2014.

#### **BioTime Receives ISO 13485 Certification for Medical Devices**

ALAMEDA, Calif.--(BUSINESS WIRE)--May 28, 2014--BioTime, Inc. (NYSE MKT: BTX) today announced that it has received ISO 13485:2003 certification from BSI (British Standards Institution) for design, development, manufacture, and distribution of BioTime *HyStem*<sup>®</sup> hydrogels for cell delivery applications.

BSI is currently one of the world's largest independent certification bodies for quality management systems and ISO 13485:2003 is the world's most recognized standard for quality management systems for medical devices, and is the most commonly chosen path for companies to meet the quality system requirements in Europe, Canada, Japan, Australia, and other countries.

ISO certification is a prerequisite for CE marking of medical devices within the European Union and this certification is an important milestone in BioTime's development program for *Renevia*<sup>TM</sup>, a cell delivery matrix scheduled to begin pivotal human clinical trials in 2014 at the Stem Center in Palma de Mallorca, Spain. In this first clinical application, *Renevia*<sup>TM</sup> will be used as a delivery matrix for autologous adipose cells to treat the facial lipoatrophy associated with HIV. Restoration of normal skin contour is an important quality-of-life issue with this chronic condition and BioTime believes that this cell-based therapy will offer fewer complications and a more natural like appearance compared to products currently available. It has been estimated that worldwide over 40% of individuals receiving long-term antiretroviral therapies suffer from this disfiguring condition. According to <a href="https://www.avert.org">www.avert.org</a> in 2011 there were approximately 800,000 persons living with HIV/AIDS in Western Europe. Globally the number exceeds 30 million.

If  $Renevia^{\text{TM}}$  is approved for the treatment of HIV-related facial lipoatrophy, BioTime plans to seek to expand its uses into other cell-based applications in reconstructive surgeries, traumatic injuries, and age-related lipoatrophy. BioTime's plan is to bring  $Renevia^{\text{TM}}$  to the medical market first in the European Union, where the regulatory pathway will allow for faster approval than in the United States. Once the use of  $Renevia^{\text{TM}}$  is established in Europe, BioTime will address an even larger potential market in Asia and the United States.

William P. Tew, Ph.D., BioTime's Chief Commercial Officer stated, "We are very pleased with our ISO Certification and BSI's acknowledgement of our on-going commitment to quality. Our quality management systems will provide a solid foundation for our clinical, regulatory, manufacturing, and future commercial activities. While this present certification focuses on  $HyStem^{(\!R)}$  hydrogels for cell delivery applications, should BioTime decide to pursue CE marks for other applications of its hydrogel technology we will expand the scope of our ISO certification."

# About HyStem®

BioTime's *HyStem*<sup>®</sup> family of hydrogels are unique biomaterials that are designed as matrices and scaffolds in medical device, tissue engineering, and regenerative medicine applications. *HyStem*<sup>®</sup> hydrogels are distributed and sold worldwide by BioTime and its distributors for pre-clinical research. Clinical grade hydrogels are also available to support translational research and investigator initiated clinical studies. BioTime's *HyStem*<sup>®</sup> technology is covered by two issued US patents with applications pending in the EU, Canada, Japan, and Australia.

### About BioTime

BioTime is a biotechnology company engaged in research and product development in the field of regenerative medicine. Regenerative medicine refers to therapies based on stem cell technology that are designed to rebuild cell and tissue function lost due to degenerative disease or injury. BioTime's focus is on pluripotent stem cell technology based on human embryonic stem ("hES") cells and induced pluripotent stem ("iPS") cells. hES and iPS cells provide a means of manufacturing every cell type in the human body and therefore show considerable promise for the development of a number of new therapeutic products. BioTime's therapeutic and research products include a wide array of proprietary  $PureStem^{\mathbb{R}}$  progenitors,  $HyStem^{\mathbb{R}}$  hydrogels, culture media, and differentiation kits. BioTime is developing  $Renevia^{TM}$  (a  $HyStem^{\mathbb{R}}$  product) as a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in human clinical applications, and is planning to initiate a pivotal clinical trial around  $Renevia^{TM}$ , in 2014. In addition, BioTime has developed  $Hextend^{\mathbb{R}}$ , a blood plasma volume expander for use in surgery, emergency trauma treatment and other applications.  $Hextend^{\mathbb{R}}$  is manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ HealthCare Corporation, under exclusive licensing agreements.

BioTime is also developing stem cell and other products for research, therapeutic, and diagnostic use through its subsidiaries:

- Asterias Biotherapeutics, Inc. is a new subsidiary which has acquired the stem cell assets of Geron Corporation, including patents and other intellectual property, biological materials, reagents and equipment for the development of new therapeutic products for regenerative medicine.
- BioTime Asia, Ltd., a Hong Kong company, may offer and sell products for research use for BioTime's ESI BIO Division.
- Cell Cure Neurosciences Ltd. is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders, including the development of retinal pigment epithelial cells for the treatment of macular degeneration, and treatments for multiple sclerosis.
- ESI BIO is the research and product marketing division of BioTime, providing stem cell researchers with products and technologies to enable them to translate their work into the clinic, including *PureStem*® progenitors and *HyStem*® hydrogels.
- LifeMap Sciences, Inc. markets, sells, and distributes *GeneCards*<sup>®</sup>, the leading human gene database, as part of an integrated database suite that also includes the *LifeMap Discovery*<sup>®</sup> database of embryonic development, stem cell research, and regenerative medicine, and *MalaCards*, the human disease database.
- LifeMap Solutions, Inc. is a subsidiary of LifeMap Sciences focused on developing mobile health (mHealth) products.
- OncoCyte Corporation is developing products and technologies to diagnose and treat cancer, including *PanC-Dx*<sup>TM</sup>, with three clinical trials currently underway.
- OrthoCyte Corporation is developing therapies to treat orthopedic disorders, diseases and injuries.
- ReCyte Therapeutics, Inc. is developing therapies to treat a variety of cardiovascular and related ischemic disorders, as well as products for research using cell reprogramming technology.

BioTime stock is traded on the NYSE MKT, ticker BTX. For more information, please visit <u>www.biotimeinc.com</u> or connect with the company on Twitter, LinkedIn, Facebook, YouTube, and Google+.

### FORWARD-LOOKING STATEMENTS

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for BioTime and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of BioTime and its subsidiaries, particularly those mentioned in the cautionary statements found in BioTime's Securities and Exchange Commission filings. BioTime disclaims any intent or obligation to update these forward-looking statements.

To receive ongoing BioTime corporate communications, please click on the following link to join our email alert list: <a href="http://news.biotimeinc.com">http://news.biotimeinc.com</a>.

CONTACT:
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