#### 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): October 4, 2013

# 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))

Statements made in this Report 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. Such risks and uncertainties include but are not limited to those discussed in this report and in BioTime's other reports filed with the Securities and Exchange Commission. Words such as "expects," "may," "will," "anticipates," "intends," "plans," "believes," "seeks," "estimates," and similar expressions identify forward-looking statements.

#### **Section 8 - Other Events**

#### Item 8.01 - Other Events.

We have commenced development of two new products based on our  $HyStem^{@}$  technology platform. The new products are unique formulations utilizing some of the same cGMP components that will be used in our clinical trials of  $Renevia^{TM}$ .

The first of these new products is  $ReGlyde^{TM}$ , a cross-linked thiol-modified hyaluronan hydrogel for the management and protection of tendon injuries following surgical repair of the digital flexor or extensor tendons of the hand. The product is intended to be applied to the repaired tendon area via a syringe or similar device immediately prior to closing of the surgical area. Separation of the tendon from surrounding tissue has been shown to significantly reduce post-surgical adhesions that can lead to complications such as restricted finger mobility and flexibility. We believe that the flowable and in-situ gelling capability of  $ReGlyde^{TM}$  could provide an advantage over the existing technology which is in the form of a sheet causing difficulty in application in what is often a small compartment after surgery.

The second new product,  $Premvia^{TM}$ , is a  $HyStem^{\circledast}$  hydrogel formulation of cross-linked thiol-modified hyaluronan and thiol-modified gelatin for the management of wounds including partial and full-thickness wounds, ulcers, tunneled/undermined wounds, surgical wounds, and burns. Due to its high water content,  $Premvia^{TM}$  is able to donate water molecules to the wound surface and to maintain a moist environment at the wound bed, which is critical for wound healing. Additionally, the biodegradable matrix provides a scaffold for the cellular infiltration and proliferation as well as capillary growth needed to promote healing. There is significant competition in the wound healing dressing space, however, one advantage that  $Premvia^{TM}$  appears to have over most other technologies is the ability to flow into the wound and cross-link, or change from a flowing liquid to a semi-solid gel consistency, in-situ, thereby providing a moist environment to every part of a wound which a traditional covering cannot.

Both  $ReGlyde^{TM}$  and  $Premvia^{TM}$  are expected to be regulated as medical devices in the United States, and we believe that they are each eligible for 510(k) market approvals. We have initiated for these development-stage products the requisite studies for marketing approval, including ISO 10993 biocompatibility studies and animal studies to demonstrate safety and efficacy. If these requisite studies do not show biocompatibility and efficacy, we will have to reconsider our development plans. We may be required to provide human clinical data demonstrating safety and efficacy for approval as a medical device if the Food and Drug Administration determines that marketing approval should not be granted on the basis of a 510(k) application.

 $Premvia^{\mathrm{TM}}$  is also intended to serve as a foundation for the further development of bioactive wound healing products that could deliver biological factors or cells to accelerate wound healing.  $Premvia^{\mathrm{TM}}$  may face a different level of regulatory approval for those uses.

The patented technology underlying our *HyStem*<sup>®</sup> hydrogels such as *ReGlyde* <sup>TM</sup> and *Premvia* <sup>TM</sup> was developed at the University of Utah and has been licensed to us for human therapeutic uses. Published animal studies conducted by Glenn Prestwich, PhD, Presidential Professor of Medicinal Chemistry, University of Utah, who invented the technology, suggest that the hydrogels may be efficacious in the treatment of wound healing and tendon adhesions.

The *HyStem*<sup>®</sup> technology is based on a unique thiol cross-linking strategy to prepare hyaluronan-based hydrogels from thiol-modified hyaluronan. Since the first published report in 2002, there have been over 120 academic scientific publications supporting the biocompatibility of thiol cross-linked hyaluronan based hydrogels and their applications as medical devices and in cell culture, tissue engineering, and animal models of cell based therapies. Building upon this platform, we have developed the *HyStem*<sup>®</sup> family of unique, biocompatible resorbable hydrogels.

The building blocks for  $HyStem^{\mathbb{R}}$  hydrogels are hyaluronan and in some applications, gelatin, each of which has been thiol-modified by carbodiimide mediated hydrazide chemistry.  $HyStem^{\mathbb{R}}$  hydrogels are formed by cross-linking mixtures of these thiolated macromolecules with polyethylene glycol diacrylate (PEGDA). This unique cross-linking chemistry works through an elegant chemical reaction between the acrylate groups on the PEGDA and the sulfhydryl groups on the thiolated macromolecules, that does not generate any toxic by-products, pH change or heat. The rate of the cross-linking reaction turning the liquid mixture into a hydrogel (gelation rate) as well as hydrogel stiffness can be controlled by varying the amount of the PEGDA cross-linker. Due to the unique cross-linking chemistry,  $HyStem^{\mathbb{R}}$  hydrogels can be injected or applied as a liquid which allows the hydrogel to conform to the cavity or space, and gelation occurs in situ without harming the recipient tissue. This property of  $HyStem^{\mathbb{R}}$  hydrogels offers several distinct advantages over other hydrogels, including the possibility of mixing bioactive materials with the hydrogel at the point of use and the ability to inject or otherwise apply the material in its liquid state with precision at surgical or wound sites.

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

## Item 9.01 - Financial Statements and Exhibits.

Exhibit Number **Description** 

99.1 Press release dated October 4, 2013

## **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.

By: /s/ Michael D. West
Chief Executive Officer Date: October 4, 2013

Exhibit Number Description

99.1 Press Release dated October 4, 2013

# BioTime Announces Additional Products in Development Based on HyStem® Technology

ALAMEDA, Calif.--(BUSINESS WIRE)--October 4, 2013--BioTime, Inc. (NYSE MKT: BTX), today announced that it has initiated the development of two new products based on its *HvStem*<sup>®</sup> hydrogel technology platform.

The first of these new products is  $ReGlyde^{TM}$ , a cross-linked thiol-modified hyaluronan hydrogel for the management and protection of tendon injuries following surgical repair of the digital flexor or extensor tendons of the hand. The product is intended to be applied in the vicinity of the repaired tendon via a syringe or similar device immediately prior to closing of the surgical area. Separation of the tendon from surrounding tissue has been shown to significantly reduce post-surgical adhesions that can lead to complications such as restricted finger mobility and flexibility. BioTime believes that the flowable and in-situ gelling capability of  $ReGlyde^{TM}$  could provide an advantage over the existing technology which is in the form of a sheet causing difficulty in application in what is often a small compartment after surgery.

The second new product,  $Premvia^{TM}$ , is a  $HyStem^{\circledast}$  hydrogel formulation of cross-linked thiol-modified hyaluronan and thiol-modified gelatin for the management of wounds including partial and full-thickness wounds, ulcers, tunneled/undermined wounds, surgical wounds, and burns. Due to its high water content,  $Premvia^{TM}$  is able to donate water molecules to the wound surface and to maintain a moist environment at the wound bed, which is critical for wound healing. Additionally, the biodegradable matrix provides a scaffold for the cellular infiltration and proliferation as well as capillary growth needed to promote healing. There is significant competition in the wound healing dressing space, however, one advantage that  $Premvia^{TM}$  appears to have over most other technologies is the ability to flow into the wound and cross-link, or change from a flowing liquid to a semi-solid gel consistency, in-situ, thereby providing a moist environment to every part of a wound which a traditional covering cannot.

Both  $ReGlyde^{TM}$  and  $Premvia^{TM}$  are expected to be regulated as medical devices in the United States. BioTime has initiated for these development-stage products the requisite studies for marketing approval, including ISO 10993 biocompatibility studies and animal studies to demonstrate safety and efficacy for a 510(k) application to the Food and Drug Administration. BioTime may be required to provide human clinical data demonstrating safety and efficacy for approval as a medical device if the FDA determines that marketing approval should not be granted on the basis of a 510(k) application.

 $Premvia^{\mathrm{TM}}$  is also intended to serve as a foundation for the further development of bioactive wound healing products that could deliver biological factors or cells to accelerate wound healing.  $Premvia^{\mathrm{TM}}$  may face a different level of regulatory approval for those uses.

Significant quantities of the components common to  $ReGlyde^{TM}$  and  $Premvia^{TM}$  have been manufactured under cGMP conditions, therefore, BioTime will have cGMP quantities of both products available for its pre-clinical investigations and the initiation of human clinical use if FDA approval for marketing is obtained.

#### About BioTime, Inc.

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  $PureStem^{TM}$  progenitors,  $HyStem^{(\!R)}$  hydrogels, culture media, and differentiation kits. BioTime is developing  $Renevia^{TM}$  (a  $HyStem^{(\!R)}$  product) as a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in human clinical applications. In addition, BioTime has developed  $Hextend^{(\!R)}$ , a blood plasma volume expander for use in surgery, emergency trauma treatment and other applications. Hextend is manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ CheilJedang Corporation under exclusive licensing agreements.

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

- OncoCyte Corporation is developing products and technologies to diagnose and treat cancer.
- ES Cell International Pte Ltd., a Singapore private limited company, develops hES products for research use.
- OrthoCyte Corporation is developing therapies to treat orthopedic disorders, diseases and injuries.
- ReCyte Therapeutics, Inc. is developing therapies to treat a variety of blood and lymphatic vascular disorders, as well as products for research using iPS and other cell reprogramming technology.
- Cell Cure Neurosciences Ltd. is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological degenerative diseases. Its lead product is *OpRegen*<sup>®</sup> for the treatment of macular degeneration.
- LifeMap Sciences, Inc. markets, sells and distributes *GeneCards*<sup>®</sup>, the leading human gene database, the leading human gene database, as part of an integrated database suite that also includes the *LifeMap Discovery*<sup>TM</sup> database of embryonic development, stem cell research and regenerative medicine, and *MalaCards*, the human disease database. LifeMap Sciences also markets BioTime research products and *PanDaTox*, an innovative, recently developed, searchable database that can aid in the discovery of new antibiotics and biotechnologically beneficial products.
- Asterias Biotherapeutics, Inc. is a newly formed subsidiary whose first acquisition was 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.

Additional information about BioTime can be found on the web at www.biotimeinc.com.

#### **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:
BioTime, Inc.
Lesley Stolz, Ph.D., 510-521-3390, ext. 367
Executive Vice President, Corporate Development <a href="mailto:lstolz@biotimemail.com">lstolz@biotimemail.com</a>
or
Judith Segall, 510-521-3390, ext. 301
isegall@biotimemail.com