

BIOTIME INC
Form 8-K
October 04, 2013

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

1-12830

94-3127919

(Commission File Number) (IRS Employer

(State or other jurisdiction
of incorporation)

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 filing is intended to simultaneously satisfy the filing obligation of the registrant 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," "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 *Renovia*[™].

The first of these new products is *ReGlyde*[™], 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*[™] 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*[™], is a *HyStem*[®] 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*[™] 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*[™] 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*[™] and *Premvia*[™] 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*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*TM may face a different level of regulatory approval for those uses.

The patented technology underlying our *HyStem*[®] hydrogels such as *ReGlyde*TM and *Premvia*TM 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*[®] 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*[®] family of unique, biocompatible resorbable hydrogels.

The building blocks for *HyStem*[®] hydrogels are hyaluronan and in some applications, gelatin, each of which has been thiol-modified by carbodiimide mediated hydrazide chemistry. *HyStem*[®] 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*[®] 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*[®] 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.

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|-------------------------------------|
| 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.

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

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|-------------------------------------|
| 99.1 | Press Release dated October 4, 2013 |