BIOTIME INC
Form 8-K
September 06, 2011
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): **August 30, 2011**

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

California	**1-12830**	**94-3127919**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1301 Harbor Bay Parkway, Suite 100
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 Annual Report on Form 10-K 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.

References to "we" or "us" are references to BioTime, Inc.

Section 1 - Registrant's Business and Operations

Item 1.01 - Entry into a Material Definitive Agreement.

On August 30, 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 human embryonic stem 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 subsidiary ReCyte Therapeutics, Inc. to treat age-related vascular disease, and products being developed at our subsidiary OncoCyte Corporation targeting the delivery of toxic payloads to the developing blood vessels of cancerous tumors.

Vascular endothelial cells form the tubular structure of the very small blood vessels, known as capillaries, and the innermost cells of larger arteries and veins in the body. They are believed to play a key role in numerous disease processes such as coronary heart disease and stroke, and the growth of cancerous tumors. The ability to manufacture young and healthy vascular endothelial cells may prove to be critically important for the future of certain therapeutic strategies in the emerging field of regenerative medicine. We have tested the technology licensed from Cornell University in combination with our ACTCellerate™ technology and have successfully generated highly purified monoclonal embryonic vascular endothelium which we plan to commercialize in our subsidiaries including OncoCyte Corporation and ReCyte Therapeutics.

In conjunction with the License Agreement, we also entered into a Sponsored Research Agreement under which scientists at Weill Cornell Medical College, led by Sina Y. Rabbany, Ph.D., will engage in research with the goals of (1) verifying the ability of progenitor cells, derived by our subsidiary ReCyte Therapeutics, Inc. using our ACTCellerate technology, to generate stable populations of vascular endothelial cells, (2) testing the functionality and transplantability of the vascular endothelial cells in animal models to see if the transplanted cells generate new vascular tissue, and (3) using Glycosan hydrogels, produced by our subsidiary OrthoCyte Corporation, and other materials as "scaffolds" for the three-dimensional propagation of vascular endothelial cells into vascular tissues suitable for transplantation.

The License Agreement

Fields of Use

Our license to use the technology and patent rights is worldwide and exclusive and permits us to use the licensed technology and patents rights for the fields of cell therapy for age- and diabetes-related vascular diseases and cancer therapy. The license also covers (i) products utilizing human vascular or vascular forming cells for the purpose of enhancing the viability of the graft of other human cells, and (ii) cell-based research products. We also have a non-exclusive right to use certain related technology provided by Cornell within the same fields of use, and non-exclusive rights with respect to certain non-cell-based products for the research market not covered by the licensed patent rights.

Sublicense Rights

We have the right to permit our subsidiaries and other affiliates to use the licensed patent rights and technology, and we have the right to grant sublicenses to others.

License Fees, Royalties and Other Payments

Cornell will be entitled to receive an initial license fee and annual license maintenance fees. The obligation to pay annual license maintenance fees will end when the first human therapeutic License Product is sold by us or by any of our affiliates or sublicensees. A Licensed Product includes any service, composition or product that uses the licensed technology, or is claimed in the licensed patent rights, or that is produced or enabled by any Licensed Method, or the manufacture, use, sale, offer for sale, or importation of which would constitute an infringement, an inducement to infringe, or contributory infringement of any pending or issued claim within the patent rights licensed to us. A Licensed Method means any method that uses the licensed technology, or is claimed in the patent rights licensed to us, the use of which would constitute an infringement, an inducement to infringe, or contributory infringement of any pending or issued claim within the patent rights licensed to us.

We will pay Cornell a milestone payment upon the achievement of a research product sales milestone amount, and we will make milestone payments upon the attainment of certain United States Food and Drug Administration (FDA) approval milestones, including (i) the first Phase II clinical trial dosing of a human therapeutic Licensed Product, (ii) the first Phase III clinical trial dosing of a human therapeutic Licensed Product; (iii) FDA approval of the first human therapeutic Licensed Product for age-related vascular disease; and (iv) FDA approval of the first human therapeutic Licensed Product for cancer.

We will pay Cornell royalties on sales of Licensed Products by ourselves and our affiliates and sublicensees, and we will share with Cornell a portion of any cash payments, other than royalties, that we receive for the grant of sublicenses to non-affiliates.

We will also reimburse Cornell for costs related to the patent applications and any patents that may issue that are covered by our license.

Reporting Requirements

We will provide Cornell with periodic reports of progress made in our research and development and product commercialization programs, and in those programs conducted by our affiliates and sublicensees, using the licensed patents and technology.

We and our affiliates and sublicensees will be required to keep accurate records of the use, manufacture, and sale of Licensed Products, and of sublicense fees received. Cornell with have the right to audit those records that we and our affiliates maintain.

Expiration and Termination of the License

Expiration

The license will expire on the later of (i) the expiration date of the longest-lived licensed patent, or (ii) on a country-by-country basis, the twenty-first anniversary of the first commercial sale of a Licensed Product.

Termination By Cornell

Cornell may terminate our license if we fail to perform, or if we violate, any term of the License Agreement, and we fail to cure that default within thirty (30) days after written notice from Cornell. Cornell also may terminate the license or convert the exclusive license to a non-exclusive license if we fail to meet any of the following requirements:

(i) diligently proceed with the development, manufacture and sale of Licensed Products;

(ii) annually spend certain specified dollar amounts for the development of Licensed Products;

(iii) submit an investigational new drug application covering at least one Licensed Product to the FDA within eight (8) years after the effective date of the License Agreement;

(iv) initiate preclinical toxicology studies for at least one Licensed Product within six (6) years after the effective date of the License Agreement;

(v) market at least one therapeutic Licensed Product in the United States within twelve (12) months after receiving regulatory approval to market the Licensed Product;

(vi) market at least one cell-based Licensed Product for the research market in the United States within twelve (12) months after the effective date of the License Agreement.

We may fulfill the obligations described in (i) through (vi) through our own efforts or through the efforts of our affiliates and sublicensees.

Our Right to Terminate

We have the right to terminate the License Agreement at any time and for any reason upon ninety (90) days written notice to Cornell.

Termination of the License Agreement by us or by Cornell or upon expiration will not relieve us of our obligations the make payments of fees owed at the time of termination, and certain provisions of the License Agreement, including the indemnification and confidentiality provisions, will survive termination. We may continue to sell all previously made or partially made Licensed Product for a period of one hundred and twenty (120) days after the License Agreement terminates, provided that the reporting and royalty payment provisions of the License Agreement will continue to apply to those sales.

Indemnification and Insurance

We have agreed to indemnify Cornell, Cornell Research Foundation, Inc., Howard Hughes Medical Institute, and their officers, trustees, employees, and agents, the sponsors of the research that led to the licensed patent rights, and the inventors and their employers, against any and all claims, suits, losses, damage, costs, fees, and expenses resulting from or arising out of exercise of the licenses and any sublicenses under the License Agreement. The indemnification will include, but not be limited to, patent infringement and product liability. We have also agreement to provide certain liability insurance coverage for Cornell and Howard Hughes Medical Institute.

Certain Retained Rights

Cornell and Howard Hughes Medical Institute will retain the right to use the licensed technology and patent rights for their own educational and research purposes. Cornell may also permit other nonprofit institutions to use the technology and patent rights for educational and research purposes.

The Sponsored Research Agreement

The Sponsored Research Agreement will have a term of three years, but we or Cornell can elect to terminate the agreement earlier by giving the other party thirty (30) days written notice.

If the researchers make any patentable discoveries or inventions in the course of the sponsored research program, we will have an option to negotiate an exclusive, royalty-bearing license to use the invention. If we do license the invention, Cornell would retain a right to use it on a non-exclusive royalty-free basis for its own internal research and teaching purposes.

Section 9 - Financial Statements and Exhibits

Item 9.01 - Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press release dated September 6, 2011

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: September 6, 2011 By: /s/ Robert W. Peabody
Senior Vice President,
Chief Operating Officer, and
Chief Financial Officer

Exhibit Number	Description
99.1	Press release dated September 6, 2011