

BIOTIME INC
Form 8-K
December 30, 2004

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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): December 24, 2004.

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.)

**935 Pardee Street
Berkeley, California 94710**

(Address of principal executive offices)

(510) 845-9535

(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))
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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.

Section 1-Registrant's Business Operations

Item 1.01 Entry Into a Material Definitive Agreement

On December 24, 2004, BioTime, Inc. and Summit Pharmaceuticals International Corporation (Summit) entered into an agreement to develop Hextend and PentaLyte for the Japanese market. Hextend and PentaLyte are physiologically balanced blood plasma volume expanders designed for the treatment of hypovolemia. Hypovolemia is a condition caused by low blood volume, often from blood loss during surgery or from injury. Plasma volume expanders maintain circulatory system fluid volume and blood pressure and keep vital organs perfused during surgery. Hextend and PentaLyte are similar formulations, except that PentaLyte contains a lower molecular weight hydroxyethyl starch than Hextend, and is more quickly metabolized. PentaLyte is designed for use when shorter lasting volume expansion is desirable.

Under the terms of the agreement, Summit will apply for regulatory approval to manufacture and market Hextend and PentaLyte in Japan for use at body temperatures above 12 Centigrade. Summit will begin by preparing a development plan for Hextend. Summit will fund all laboratory, preclinical and clinical testing and developmental activities regarding the products, and will pay all application filing and similar fees for purposes of obtaining and maintaining regulatory approvals in Japan. Summit will not be obligated to begin to seek regulatory approval for PentaLyte until BioTime completes its Phase II clinical trial of PentaLyte in the United States and makes the results available to Summit. BioTime's Phase II clinical trial is now beginning and will take place at Duke University Medical Center.

Under the Agreement, Summit will make the following payments to BioTime:

\$300,000 within ten days after execution of the agreement;

\$450,000 by April 15, 2005; and

\$150,000 by October 31, 2005.

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A portion of the cash payments will be a partial reimbursement of BioTime's development costs of Hextend and a portion will be a partial reimbursement of BioTime's development costs of PentaLyte.

Within ten days after BioTime approves Summit's development plan for Hextend, BioTime will pay Summit a one-time fee of \$130,000 for Summit's services in preparing the development plan.

BioTime and Summit do not plan to manufacture and market Hextend and PentaLyte themselves. Instead, they will seek to license manufacturing and marketing rights to a third party such as a pharmaceutical company.

When Hextend and PentaLyte are licensed and sold in Japan, the revenues from licensing fees, royalties, and net sales, and any other payments made for co-development, manufacturing, or marketing rights, will be shared between BioTime and Summit as follows: 40% to BioTime and 60% to Summit. Net sales means the gross revenues from the sale of a product, less rebates, discounts, returns, transportation costs, sales taxes and import/export duties.

BioTime will pay to Summit 8% of all net royalties actually received by BioTime from the sale of PentaLyte in the United States plus 8% of any license fees that BioTime receives in consideration of granting a license to develop, manufacture and market PentaLyte in the United States. Net royalties means royalty payments received during a calendar year, minus the following costs and expenses incurred during such calendar year: (a) all taxes assessed (other than taxes determined with reference to BioTime net income) and credits given or owed by BioTime in connection with the receipt of royalties on the sale of PentaLyte in the United States, and (b) all fees and expenses payable by BioTime to the United States Food and Drug Administration (directly or as a reimbursement of any licensee) with respect to PentaLyte. In the case of license fees received from Hospira, Inc. based upon the combined sale of PentaLyte and Hextend, the portion of such license fee that will be deemed to be paid on account of the sale of PentaLyte will be determined by multiplying the total license fee paid by a fraction, the numerator of which will be the total net sales of PentaLyte in the United States for the applicable period and the denominator of which shall be the total net sales of Hextend and PentaLyte in the United States for the same period.

Either BioTime or Summit may terminate the agreement as follows:

By giving to the other party 60 days prior written notice following the bankruptcy or the insolvency of the other party; or

Upon the breach of any material provision of the agreement by the other party if the breach is not cured within 60 days after written notice thereof to the party in default.

BioTime may terminate the agreement upon 60 days prior written notice at any time following Summit's failure to use diligent efforts to achieve any one of the following milestones: (A) submitting to BioTime for approval a development plan that is substantially complete in all material respects within six months after the signing of the agreement, (B) initiating and conducting to

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completion clinical studies needed for regulatory approval of either Hextend or PentaLyte in accordance with the timetable included in the development plan approved by BioTime; or (C) obtaining regulatory approval of either Hextend or PentaLyte after the clinical studies are complete.

Summit may terminate the agreement at any time upon ninety 90 days prior written notice to BioTime if Summit determines that it no longer wishes to pursue obtaining regulatory approval of Hextend and PentaLyte.

If BioTime becomes bankrupt or insolvent or breaches a material provision of the agreement such that Summit would have the right to terminate the agreement, Summit may elect to keep the agreement in effect, and in lieu of any other remedy that Summit might have (1) if any of the cash installment payments are not yet payable Summit will be exempted from making those payments, and (2) BioTime's 40% share of revenues will be reduced to 20%.

The preceding discussion of the agreement is a summary only, does not purport to describe in full all provisions of the agreement, and is qualified in all respects by the full text of the agreement, a copy of which has been filed as an exhibit to this report and which is incorporated by reference herein.

Hextend® and PentaLyte® are registered trademarks of BioTime, Inc.

Section 9-Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

Exhibit Numbers	Description
99.1	Hextend and PentaLyte Collaboration Agreement Between BioTime, Inc. and Summit Pharmaceuticals International Corporation
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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: December 30, 2004

By /s/ Steven Seinberg
Steven Seinberg,
Chief Financial Officer

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99.1	Hextend and PentaLyte Collaboration Agreement Between BioTime, Inc. and Summit Pharmaceuticals International Corporation