Form
Unknown document format
"margin-left:20px; text-indent:-10px">Borrowings 1,000,000
Issuance of preferred shares for cash
600,000
Preferred shares placement costs
(125,700)
Issuance of common shares for cash
4,184,420 29,961,271
Exercise of Options
18,307 86,896 5,116,792
Common shares placement costs
(162,453) (2,689,399)
Contributed capital cash
77,547
Dividends paid on preferred shares
(24,831)
Repurchase Common Shares
(202,722)

Net cash provided by financing activities 2,190,274 86,896 34,212,958

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS 851,661 (102,897) 1,568,845 Cash and cash equivalents at beginning of period 717,184 1,284,432 Cash and cash equivalents at end of period \$1,568,845 \$1,181,535 \$1,568,845

# **BIOTIME, INC.** (A Development Stage Company)

# CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended September 30,		Period from Inception (November 30, 1990) to September 30, 2004		
		2004	2003		
NONCASH FINANCING AND INVESTING ACTIVITIES:					
Issuance of common shares in exchange for shares of common stock of Cryomedical Sciences, Inc. in a stock-for-stock transaction	\$			\$	197,400
Conversion of Line of Credit to debentures	φ			ֆ \$	840,878
Issuance of warrants for private placement costs				ֆ \$	403,312
Issuance of warrants rol private placement costs				φ	405,512
and Line of Credit agreement			\$ 239,729	\$	1,911,106
Conversion of debentures to Common shares	\$	1,500,000		\$	1,500,000
Issuance of warrants to Guarantors for participation in the Rights Offer SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:	\$	82,500		\$	82,500
Cash paid for interest	\$	175,552	\$ 335,000		
Cash paid for income taxes		49,518	\$ 82,520		
See notes to condensed financial statements.	5				(Concluded)

# **BIOTIME, INC.** (A Development Stage Company)

## NOTES TO FINANCIAL STATEMENTS

#### 1. Organization

*General* - BioTime, Inc. (the Company) was organized November 30, 1990 as a California corporation. The Company is a biomedical organization, currently in the development stage, which is engaged in the research and development of synthetic plasma expanders, blood volume substitute solutions, and organ preservation solutions, for use in surgery, trauma care, organ transplant procedures, and other areas of medicine.

The condensed balance sheet as of September 30, 2004, the condensed statements of operations for the three month and nine month periods ended September 30, 2004 and 2003 and the period from inception (November 30, 1990) to September 30, 2004, and the statements of cash flows for the nine month periods ended September 30, 2004 and 2003 and the period from inception (November 30, 1990) to September 30, 2004 have been prepared by the Company without audit. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at September 30, 2004 and for all periods presented have been made. The balance sheet as of December 31, 2003 is derived from the Company s audited financial statements as of that date. The results of operations for the three month and nine month periods ended September 30, 2004 are not necessarily indicative of the operating results anticipated for the full year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted as permitted by regulations of the Securities and Exchange Commission. Certain previously furnished amounts have been reclassified to conform with presentations made during the current periods. It is suggested that these interim condensed financial statements be read in conjunction with the annual audited financial statements and notes thereto included in the Company s Form 10-K for the year ended December 31, 2003.

*Development Stage Enterprise* - Since inception, the Company has been engaged in research and development activities in connection with the development of synthetic plasma expanders, blood volume substitute solutions and organ preservation products. The Company has limited operating revenues and has incurred net losses of \$37,894,514 from inception to September 30, 2004. The successful completion of the Company s product development program and, ultimately, achieving profitable operations is dependent upon future events including maintaining adequate capital to finance its future development activities, obtaining regulatory approvals for the products it develops and achieving a level of revenues adequate to support the Company s cost structure.

The Company s operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include but are not limited to the following: the results of clinical trials of the Company s products; the Company s ability to obtain United States Food and Drug Administration and foreign regulatory approval to market its products; competition from products manufactured and sold or being developed by other companies; the price of and demand for Company products; the Company s ability to obtain additional financing and the terms of any such financing that may be obtained; the Company s ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; the availability of ingredients used in the Company s products; and the availability of reimbursement for the cost of the Company s products (and related treatment) from government health administration authorities, private health coverage insurers and other organizations.

*Liquidity* - At September 30, 2004, BioTime had \$1,568,845 cash on hand, which includes funds raised in a Rights Offer completed in January 2004. However, the Company needs additional capital and greater revenues to continue its current operations, to complete clinical trials of PentaLyte®, and to conduct its planned product development and research programs. Sales of additional equity securities could result in the dilution of the interests of present shareholders. The Company is also continuing to seek new agreements with pharmaceutical companies to provide product and technology licensing fees and royalties. The availability and terms of equity financing and new license agreements are uncertain. The unavailability or inadequacy of additional financing or future revenues to meet capital needs could force the Company to modify, curtail, delay, suspend, or possibly discontinue some or all aspects of its planned operations. Management believes its existing cash, along with license fees receivable and anticipated royalties, is sufficient to allow the Company to operate through June 30, 2005.

# 2. Significant Accounting Policies

*Financial Statement Estimates* - The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Such management estimates include certain accruals. Actual results could differ from those estimates.

*Revenue recognition* - In April 1997, BioTime and Abbott Laboratories (Abbott) entered into an Exclusive License Agreement (the License Agreement) under which BioTime granted to Abbott an exclusive license to manufacture and sell BioTime s proprietary blood plasma volume expander solution Hextend® in the United States and Canada for certain therapeutic uses. During the second quarter of 2004, Abbott completed the spin-off of a substantial portion of its hospital products division as a new company called Hospira, Inc. Abbott has assigned the BioTime License Agreement to Hospira.

Under the License Agreement, Abbott paid the Company \$2,500,000 of license fees based upon achievement of specified milestones. Such fees have been recognized as revenue as the milestones were achieved. Up to \$37,500,000 of additional license fees will be payable

based upon Hospira s annual net sales of Hextend® at the rate of 10% of annual net sales if annual net sales exceed \$30,000,000 or 5% if annual net sales are between \$15,000,000 and \$30,000,000.

Hospira s obligation to pay license fees on sales of Hextend® will expire on the earlier of January 1, 2007 or, on a country by country basis, when all patents protecting Hextend® in the applicable country expire or any third party obtains certain regulatory approvals to market a generic equivalent product in that country.

In addition to the license fees, the Company will receive a royalty on Hospira s annual net sales of Hextend®. The royalty rate will be 5% plus an additional .22% for each increment of \$1,000,000 of annual net sales, up to a maximum royalty rate of 36%. The obligation to pay royalties on sales of Hextend® will expire in the United States or Canada when all patents protecting Hextend® in the applicable country expire and any third party obtains certain regulatory approvals to market a generic equivalent product in that country.

The Company recognizes such revenues in the quarter in which the sales report is received, rather than the quarter in which the sales took place, as the Company does not have sufficient sales history to accurately predict quarterly sales. Revenues for the three months ended September 30, 2004 include royalties on sales made by Hospira during the three months ended June 30, 2004. Royalties on sales made during the third quarter of 2004 will not be recognized by the Company until the fourth quarter of fiscal year 2004.

Under the License Agreement, the Company may convert the exclusive license to a non-exclusive license or may terminate the license outright if certain minimum sales and royalty payments are not met. In order to terminate the license outright, BioTime would pay a termination fee in an amount ranging from the milestone payments made by Abbott to an amount equal to three times prior year net sales, depending upon when termination occurs. Management believes that the probability of payments of any termination fee by the Company is remote.

Research and product license fees are generally deferred and recognized over the life of the contract unless the license periods commenced, the technology has been delivered, and all other performance conditions have been met. If all of these conditions are met, any remaining deferred revenue would then be recognized.

During March 2003, BioTime granted to CJ Corp. (CJ) an exclusive license to manufacture and sell Hextend® and PentaLyte® in South Korea (the CJ Agreement). Under the CJ Agreement, CJ agreed to pay the Company a license fee of \$800,000, payable in two installments. The first installment of \$500,000, less \$80,000 of Korean taxes withheld, was paid to the Company during April 2003, and the second installment of \$300,000, less \$49,500 of Korean taxes withheld, was paid during July 2004. In connection with this agreement, the Company paid a finder s fee of \$50,000 to an unrelated third party in April 2003, and another finder s fee of \$30,000 in July 2004. In addition to the license fees, CJ will pay the Company a royalty on sales of the licensed products. The royalty will range from \$1.30 to \$2.60 per 500 ml unit of product sold, depending upon the price approved by Korea s National Health Insurance. CJ has obtained regulatory approval to manufacture and market Hextend but will have to obtain

Korean Health Insurance pricing before sales can begin. CJ is also responsible for obtaining the regulatory approvals required to manufacture and market PentaLyte®, including conducting any clinical trials that may be required, and will bear all related costs and expenses.

The Company has not yet completed the development of PentaLyte, for which additional clinical trials in the United States are being planned. As the expected completion date is uncertain, the license fee of \$800,000, net of the finder s fees, has been deferred and will be recognized as revenue over the life of the contract, which has been estimated to be approximately eight years based on the current expected life of the governing patent covering the Company s products in Korea. If the development of PentaLyte is discontinued, BioTime will grant CJ an exclusive license to use, manufacture, or sell another BioTime product in South Korea.

*Indemnification* The following is a summary of the Company s agreements that the Company has determined are within the scope of the Financial Accounting Standards Board (the FASB ) interpretation No. 45 (FIN 45), Guarantor s Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others an interpretation of FASB Statements No. 5, 57 and 107 and rescission of FIN 34.

Under its bylaws, the Company has agreed to indemnify its officers and directors for certain events or occurrences arising as a result of the officer or director s serving in such capacity. The term of the indemnification period is for the officer s or director s lifetime. The maximum potential amount of future payments the Company could be required to make under the indemnification provisions contained in its bylaws is unlimited. However, the Company has a directors and officers liability insurance policy that limits its exposure and enables it to recover a portion of any future amounts paid. As a result of its insurance policy coverage, the Company believes the estimated fair value of these indemnification agreements is minimal and has no liabilities recorded for these agreements as of September 30, 2004.

Under the License Agreement and the CJ Agreement, BioTime shall indemnify Abbott, Hospira, and/or CJ for any cost or expense resulting from any third party claim or lawsuit arising from alleged patent infringement, as defined, by Abbott, Hospira, or CJ relating to actions covered by the License Agreement or the CJ Agreement, respectively. Management believes that the possibility of payments under the indemnification clauses by the Company is remote. Therefore, the Company has not recorded a provision for potential claims as of September 30, 2004.

The Company enters into indemnification provisions under (i) its agreements with other companies in its ordinary course of business, typically with business partners, licensees, contractors, hospitals at which clinical studies are conducted, and landlords and (ii) its agreements with investors, investment bankers and financial advisers. Under these provisions the Company generally indemnifies and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company s activities or, in some cases, as a result of the indemnified party s activities under the agreement. These indemnification provisions often include indemnifications relating to representations made by the Company with regard to intellectual property rights. These indemnification provisions generally survive termination of the underlying agreement. In some cases, the Company has obtained liability insurance providing

coverage that limits its exposure for indemnified matters. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of September 30, 2004.

*Comprehensive Income (Loss)* - Statement of Financial Accounting Standards (SFAS) No. 130, Reporting Comprehensive Income, establishes standards for reporting and displaying comprehensive income and its components (revenues, expenses, gains, and losses) in a full set of general-purpose financial statements. Comprehensive loss was the same as net loss for all periods presented.

*Stock-based Compensation* - In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, which amended SFAS No. 123, Accounting for Stock-Based Compensation. The new standard provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. Additionally, the statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in the annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The Company has elected to continue to follow the intrinsic value method in accounting for its stock-based employee compensation arrangement as defined by Accounting Principles Board Opinion (APB) No. 25, Accounting for Stock Issued to Employees.

Had compensation cost for employee options granted under the Company s option plans been determined based on the fair value at the grant dates, as prescribed in SFAS No. 123, the Company s net loss and pro forma net loss per share would have been as follows:

	Three Months Ended September 30,			ths Ended 1ber 30,
	2004	2003	2004	2003
Net income (loss) as reported Deduct: Stock-based compensation determined under fair value method	\$(452,060)	\$362,020	\$(2,537,270)	\$(1,143,981)
for awards, net of applicable tax effects	(38,639)	(34,252)	(153,828)	(200,610)
Pro forma net income	¢ (100, C00)	<b>\$227</b> 7 (0)	¢ (2, (01, 000))	¢(1,244,501)
(loss)	\$(490,699)	\$327,768	\$(2,691,098)	\$(1,344,591)

	Three Months Ended September 30,			nths Ended 1ber 30,
	2004	2003	2004	2003
Basic income (loss) per common share as reported	\$(0.03)	\$0.03	\$(0.15)	\$(0.08)
Diluted income (loss) per common share as reported	\$(0.03)	\$0.03	\$(0.15)	\$(0.08)
Pro forma basic income (loss) per common share	\$(0.03)	\$0.02	\$(0.16)	\$(0.10)
Pro forma diluted income (loss) per common share	\$(0.03)	\$0.02	\$(0.16)	\$(0.10)

# 3. Debentures

In August 2001, the Company issued \$3,350,000 of debentures to an investor group. Interest on the debentures was payable at an annual rate of 10% and was payable semi-annually. Investors who purchased the debentures also received warrants to purchase a total of 515,385 common shares at an exercise price of \$6.50. The warrants expired on August 1, 2004.

During April 2003, holders of \$2,750,000 principal amount of the debentures granted BioTime a pay in kind right allowing (but not requiring) BioTime to make interest payments in common shares instead of cash for the interest payments due during August 2003 and February 2004 (the PIK Right ). BioTime retained the right to pay the interest due in cash. Each debenture holder who agreed to grant BioTime the PIK Right received a three-year warrant entitling the holder to purchase BioTime common shares for \$1.50 per share. The number of shares covered by the warrants is the amount of debenture interest due in August 2003 and February 2004 divided by the \$1.50 exercise price. Warrants to purchase a total of 223,331 common shares inclusive of the 39,999 warrants granted to Alfred Kingsley discussed below were issued.

The warrants will expire on April 1, 2006, and will not be exercisable thereafter. The warrants will be redeemable by BioTime at \$0.05 per warrant share if the closing price of the common shares on the American Stock Exchange exceeds 200% of the exercise price for 20 consecutive trading days. All prices and share amounts will be adjusted for any stock splits, reverse splits, recapitalization, or similar changes to the common shares.

During April 2003, Mr. Kingsley agreed with BioTime that if BioTime exercised the PIK right, he would have provided BioTime with the cash required to pay the interest due on any debentures held by persons who did not grant BioTime the PIK Right. In consideration of his agreement to do so, BioTime issued to Mr. Kingsley a warrant for 39,999 additional common

shares, which is the amount of warrants that would have been issued had the debenture holders who did not grant BioTime the PIK Right, instead agreed to do so. BioTime, Inc., chose not to exercise the right to pay interest in stock and paid all interest on the debentures in cash.

During February 2004, the Company eliminated its \$3,350,000 of debenture indebtedness by using a portion of the proceeds of its recently completed Rights Offer (see Note 4) to repay \$1,850,000 of debentures in cash, and by issuing a total of 1,071,428 common shares and 535,712 common share purchase warrants in exchange for \$1,500,000 of debentures held by certain persons who acted as Participating Debenture Holders under the Standby Purchase Agreement described in Note 4. As the fair value of the consideration of \$3,781,786 given to the debenture holders exceeded the carrying value of the debentures. BioTime recognized interest expense of \$1,106,786 relative to the cost incurred on the extinguishment of the debentures. The components of this charge are as follows: (1) a \$664,606 charge for unamortized discount of the warrants issued to the debenture holders at the time they acquired the debentures; (2) a \$265,000 charge for fees consisting of \$100,000 of cash and 500,000 common share purchase warrants, bearing the same terms as those sold in the Rights Offer described in Note 4 and determined to have a fair value of \$0.33 per warrant, received by the Participating Debenture Holders under the Standby Purchase Agreement; and (3) a \$177,180 charge for the excess of the fair value of the 1,071,428 common shares and 535,712 warrants over the \$1,500,000 face value of debentures exchanged. The common shares and warrants were valued at the AMEX closing prices on February 4, 2004. BioTime now has no long-term debt.

# 4. Shareholders Equity (Deficit)

During January 2004, BioTime completed a subscription rights offer (the Rights Offer ) through which the Company raised gross proceeds of \$3,584,420 through the sale of 2,560,303 common shares and 1,280,073 warrants. Following the completion of the Rights Offer, the Company raised an additional \$600,000 by selling an additional 428,571 common shares and 214,284 warrants under a Standby Purchase Agreement to certain persons who acted as Guarantors of the Rights Offer. The common shares and warrants were sold as units for \$1.40 per unit. Each unit consisted of one common share and one-half of a warrant. Each full warrant entitles the holder to purchase one common share for \$2.00 per share and will expire on January 14, 2007. BioTime may redeem the warrants by paying \$.05 per warrant if the closing price of the common shares on the AMEX or any other national securities exchange or the Nasdaq Stock Market exceeds 200% of the exercise price of the warrants for any 20 consecutive trading days.

In consideration for their agreement to purchase up to \$2,250,000 of units if the subscription rights were not fully exercised, under the Standby Purchase Agreement the Company paid the Guarantors \$50,000 in cash and issued to them warrants to purchase 250,000 common shares, which were accounted for as costs of the equity financing. Total estimated cash costs of the Rights Offer, which were recorded as a reduction of the proceeds received, were \$351,516. Also, the Company paid the Participating Debenture Holders \$100,000 in cash and issued to them warrants to purchase 500,000 common shares, which were included in the computation of the cost on extinguishments of the debentures (See Note 3). The warrants issued to the Guarantors and Participating Debenture Holders have the same terms as the warrants the Company sold in the Rights Offer.

Additionally, the Company issued a total of 1,071,428 common shares and 535,712 common share purchase warrants in exchange for \$1,500,000 of debentures held by the Participating Debenture Holders (See Note 3).

The Rights Offer triggered the anti-dilution provisions contained in various warrants previously issued by the Company. The resulting change in the exercise prices of the warrants was small, and did not significantly change the fair market value of the warrants. Under these anti-dilution provisions, the number of shares issuable upon the exercise of the warrants increased by a total of 15,169 shares. The Company recognized a total charge to interest expense of \$6,135 relative to the adjustments of the exercise prices and the number of shares issuable upon the exercise of the warrants.

Options to purchase 60,000 common shares were granted to consultants in 1999, and vest upon achievement of certain milestones. During the first quarter of 2004, the Company accelerated the vesting of these options so that all were fully vested as of March 31, 2004. During the three months ended March 31, 2004, expense of \$8,276 was incurred for these options and recorded as a research and development expense. No further expense was recorded after March 31, 2004. Reductions in expense of \$3,982 and \$4,780 were recorded during the three and nine months, ended September 30, 2003, respectively, related to the change in fair value of these awards.

During April 1998, the company entered into a financial advisory services agreement with Greenbelt Corp., a corporation controlled by Alfred D. Kingsley and Gary K. Duberstein, who are also shareholders of the Company. The agreement has been renewed each subsequent year ending March 31. For the twelve months ended March 31, 2003, the Company agreed to pay Greenbelt \$60,000 in cash and issue 100,000 common shares. For the twelve months ended March 31, 2005, the Company agreed to pay Greenbelt \$90,000 in cash and issue 80,000 common shares. For the twelve months ending March 31, 2005, the Company agreed to pay Greenbelt \$90,000 in cash and issue 60,000 common shares. Expenses of \$29,550 and \$50,500 relating to the current term of the agreement were recognized during the three months ended September 30, 2004 and September 30, 2003, respectively. The common shares relating to the twelve months ended March 31, 2004 were issued during April 2004.

Activity related to the Greenbelt agreement is presented in the table below:

	Balance included in Accounts Payable at January 1	Add: Cash- based expense accrued	Add: Stock- based expense accrued	Less: Cash payments	Less: Value of stock- based payments	Balance included in Accounts Payable at September 30,
2004	\$105,300	67,500	72,400	(67,500)	(122,800)	\$ 54,900
2003	\$131,250	60,000	106,750	(30,000)	(155,000)	\$113,000
			13			

During the nine months ended September 30, 2004 and 2003, the Company issued to Greenbelt 80,000 and 100,000 common shares, respectively, valued at \$122,800 and \$155,000. The 60,000 common shares related to the current agreement have not been issued.

During the three months ended September 30, 2004, no options were exercised.

During the three months ended June 30, 2004, the Company issued to an outside consultant an option to purchase 200,000 common shares. The option vests over a two-year period. An expense of \$17,350 was recorded in general and administrative expenses for the nine months ended September 30, 2004. A reduction of expense of \$718 was recorded during the three months ended September 30, 2004, related to the change in fair value of this award. The fair value of the option was determined using the Black-Scholes option pricing model with the following assumptions: contractual life of 3 years; risk-free interest rate of 3.24%; volatility of 77.23%; and no dividends during the expected term.

#### 5. Net Income (Loss) Per Share

Basic earnings (loss) per share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share reflect the potential dilution from securities and other contracts which are exercisable or convertible into common shares. For the three and nine months ended September 30, 2004, options to purchase 1,273,832 common shares, and warrants to purchase 3,153,191 common shares were excluded from the computation of earnings (loss) per share as their inclusion would be antidilutive. For the three months ended September 30, 2003, options to purchase 22,742 common shares, and warrants to purchase 42,892 common shares were included in the computation of diluted earnings per share based on the treasury stock method. For the nine months ended September 30, 2003, options to purchase 881,367 common shares, and warrants to purchase 883,561 common shares were excluded from the computation of earnings (loss) per share 3, 2003 per share as their inclusion would be antidilutive. As a result, there is no difference between basic and diluted calculations of loss per share for the three and nine months ended September 30, 2004 and the nine months ended September 30, 2003.

#### Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

# MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Overview

Since its inception in November 1990, BioTime has been engaged primarily in research and development activities, which have culminated in the commercial launch of Hextend, our lead product, and a clinical trial of PentaLyte. Our operating revenues have been generated primarily from licensing fees and from royalties on the sale of Hextend®. As a result of the developmental nature of our business and the limited sales of our products, since BioTime s inception in November 1990 we have incurred \$37,894,514 of losses. Our ability to generate substantial operating revenue depends upon our success in developing and marketing or licensing our plasma volume expanders and organ preservation solutions and technology for medical use.

Most of our research and development efforts have been devoted to our first three blood volume replacement products: Hextend, PentaLyte, and HetaCool. By testing and bringing all three products to the market, we can increase our market share by providing the medical community with solutions to match patients needs. By developing technology for the use of HetaCool in low temperature surgery, trauma care, and organ transplant surgery, we may also create new market segments for our product line.

Our first product, Hextend, is a physiologically balanced blood plasma volume expander, for the treatment of hypovolemia. During 1997 we granted Abbott an exclusive license to sell Hextend in the United States and Canada, along with a right to obtain licenses to manufacture and sell other BioTime products. Abbott has completed a spin-off of a substantial portion of its hospital products business into a new company called Hospira, Inc. Abbott has assigned to Hospira its license to manufacture and market Hextend. According to information disclosed by Abbott, Abbott had global sales of approximately \$19.7 billion during 2003, and has over 70,000 employees. According to information disclosed by Hospira, it employs approximately 14,000 people worldwide, and had the spin-off occurred on January 1, 2003, Hospira would have had net sales of approximately \$2.5 billion for the year ended December 31, 2003.

Under our License Agreement, Hospira will report sales of Hextend and pay us the royalties and license fees due on account of such sales within 90 days after the end of each calendar quarter. We recognize such revenues in the quarter in which the sales report is received, rather than the quarter in which the sales took place, as we do not have sufficient sales history to accurately predict quarterly sales. Hextend sales are still in the ramp-up phase.

During March 2003, we granted to CJ Corp. an exclusive license to manufacture and sell Hextend and PentaLyte in South Korea (the CJ Agreement ). CJ has obtained regulatory approval to manufacture and market Hextend but will have to obtain Korean Health Insurance pricing before sales can begin. CJ is also responsible for obtaining the regulatory approvals

required to manufacture and market PentaLyte®, including conducting any clinical trials that may be required, and will bear all related costs and expenses.

We have retained all rights to manufacture, sell or license Hextend, PentaLyte, HetaCool, and other products in all other countries, and we are negotiating potential manufacturing, distributing and marketing agreements for our products in certain overseas markets.

Revenues for the three months ended September 30, 2004 consist of royalties on sales made by Hospira during the period beginning April 1, 2004 and ending June 30, 2004. Royalty revenues recognized for that three-month period were \$145,208, a 52% increase over the \$95,807 of royalty revenue during the same period last year. A significant portion of the increase in royalties is attributable to an increase in sales to the United States Armed Forces, and the balance of the increase is due to increases in hospital sales. The Armed Forces purchase Hextend through intermittent, large volume orders, which makes it difficult to predict sales to them in subsequent quarters.

We received \$147,148 in royalties from Hospira in October 2004, based on Hextend sales during the three months ended September 30, 2004. This represents an increase of 48% from the \$99,674 in royalties received during the same period last year. This revenue will be reflected in our financial statements for the fourth quarter of 2004. During the same period last year, we received \$238,571 in total revenues from Abbott Laboratories, Hospira s former parent, which included \$138,897 royalties due at that time to preserve certain rights under their license.

Hextend has become the standard plasma volume expander at a number of prominent teaching hospitals and leading medical centers. We believe that as Hextend use proliferates within the leading US hospitals, other smaller hospitals will follow their lead and accelerate sales growth.

We have completed a Phase I clinical trial of PentaLyte and we are planning the next phase of clinical trials in which PentaLyte will be used to treat hypovolemia in surgery. We have spent approximately \$2,133,548 in direct costs through September 30, 2004 developing PentaLyte. Our ability to commence and complete additional clinical studies of PentaLyte depends on our cash resources and the costs involved, which are not presently determinable. Clinical trials of PentaLyte in the United States may take longer and may be more costly than the Hextend clinical trials, which cost approximately \$3,000,000. The FDA permitted us to proceed directly into a Phase III clinical trial of Hextend involving only 120 patients because the active ingredients in Hextend had already been approved for use in plasma expanders by the FDA in other products. Because PentaLyte contains a starch (pentastarch) that has not been approved by the FDA for use in a plasma volume expander (although pentastarch is approved in the US for use in certain intravenous solutions used to collect certain blood cell fractions), we had to complete a Phase I clinical trial of PentaLyte, and we are commencing a Phase II clinical trial. We estimate that the Phase II trial will cost approximately \$1,000,000. A subsequent Phase III trial may involve more patients than the Hextend trials, and we do not know yet the actual scope or cost of the clinical trials that the FDA will require for PentaLyte or the other products we are developing.

If Hospira obtains a license to manufacture and market PentaLyte under our License Agreement with them, they would reimburse us for our direct costs incurred in developing

PentaLyte. Hospira s decision whether to license PentaLyte would follow the completion of our Phase II trial.

Plasma volume expanders containing pentastarch have been approved for use in certain foreign countries including Canada and those of the European Union and Japan. The regulatory agencies in those countries may be more willing to accept applications for regulatory approval of PentaLyte based upon clinical trials smaller in scope than those that may be required by the FDA. This would permit us to bring PentaLyte to market overseas more quickly than in the United States, provided that suitable licensing arrangements can be made with multinational or foreign pharmaceutical companies to obtain financing for clinical trials and manufacturing and marketing arrangements.

We are also continuing to develop solutions for low temperature surgery. Once a sufficient amount of data from successful low temperature surgery has been compiled, we plan to seek permission to use Hextend as a complete replacement for blood under near-freezing conditions. We currently plan to market Hextend for complete blood volume replacement at very low temperatures under the registered trademark HetaCool® after FDA approval is obtained.

We have spent approximately \$1,723,917 through September 30, 2004 developing HetaCool. These costs do not include the cost of developing Hextend, upon which HetaCool is based. During April 2004, we were awarded a research grant by the National Heart, Lung, and Blood Institute division of the National Institutes of Health (NIH) for use in the development of HetaCool. The grant will be used to fund a project entitled Resuscitating Blood-Substituted Hypothermic Dogs at the Texas Heart Institute in Houston under the guidance of Dr. George V. Letsou. Dr. Letsou is Associate Professor of Surgery and Director of the Heart Failure Center at the University of Texas Medical School in Houston, Texas. We may receive up to \$299,990 through the grant, including \$149,994 during 2004 and subject to availability of funds and satisfactory progress on the project an additional \$149,996 during 2005. We have received no funds to date.

BioTime scientists believe the HetaCool program has the potential to produce a product that could be used in very high fluid volumes (50 liters or more per procedure if HetaCool were used as an multi-organ donor preservation solution or to temporarily replace substantially all of the patient s circulating blood volume) in cardiovascular surgery, trauma treatment, and organ transplantation. However, the cost and time to complete the development of HetaCool, including clinical trials, cannot presently be determined.

Until such time as we are able to complete the development of PentaLyte and HetaCool and enter into commercial license agreements for those products and foreign commercial license agreements for Hextend, we will depend upon royalties from the sale of Hextend by Hospira, and from CJ once product sales commence in Korea, as our principal source of revenues.

The amount and pace of research and development work that we can do or sponsor, and our ability to commence and complete clinical trials required to obtain FDA and foreign regulatory approval of products, depends upon the amount of money we have. Future research and clinical study costs are not presently determinable due to many factors, including the



inherent uncertainty of these costs and the uncertainty as to timing, source, and amount of capital that will become available for these projects. We have already curtailed the pace of our product development efforts due to the limited amount of funds available, and we may have to postpone further laboratory and clinical studies, unless our cash resources increase through growth in revenues, the completion of licensing agreements, additional equity investment, borrowing or third party sponsorship.

Because our research and development expenses, clinical trial expenses, and production and marketing expenses will be charged against earnings for financial reporting purposes, management expects that there will be losses from operations in the near term.

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

# **Results of Operations**

## Revenues

From inception through September 30, 2004, we recognized \$2,596,236 of license fee revenues, including \$25,173 and \$54,049 of license fees from CJ Corp recognized during the three and nine months ended September 30, 2004, respectively. The license fees based upon milestones under the License Agreement with Abbott were earned prior to the quarter ended September 30, 2004. See Note 2 to the accompanying condensed financial statements.

From inception through September 30, 2004, we have recognized \$1,513,654 in royalty revenue based on product sales. For the three and nine months ended September 30, 2004, we recognized \$145,208 and \$442,369, respectively in royalty revenue, whereas we recognized \$95,807 and \$275,663 for the three and nine months ended September 30, 2003, respectively. These increases of 52% and 60% in royalties are attributable to an increase in product sales by Hospira.

During the three months ended September 30, 2004 and 2003 we recognized \$25,173 and \$14,063, respectively, of license fee revenue from CJ Corp. During the nine months ended September 30, 2004 and 2003, we recognized \$54,049 and \$28,125, respectively; the increase is due to the fact that we did not begin recognizing revenue from CJ until April 2003.

# **Operating Expenses**

From inception (November 30, 1990) through September 30, 2004, we incurred \$24,447,405 of research and development expenses. Research and development expenses were \$305,626 for the three months ended September 30, 2004, compared to \$239,760 for the three months ended September 30, 2003. This increase is chiefly attributable to a \$5,750 increase in expenditures for research performed off-site at locations other than the BioTime facility ( outside research ), an increase of \$29,118 in fees paid to scientific consultants, an increase of \$18,341 in salaries allocated to research and development, a \$5,802 increase in insurance costs allocated to research and development, and a minor increase in other research and development expenses. For the nine months ended September 30, 2004, research and development expenses

increased to \$810,379 from the \$675,900 during the nine months ended September 30, 2003. The primary components of this increase were a \$51,364 increase in fees paid to scientific consultants, a \$72,530 increase in expenses for outside research, and a \$13,532 increase in salaries allocated to research and development. Research and development expenses include laboratory study expenses, salaries, ongoing prosecution of regulatory applications in the United States and Europe, and consultants fees. We expect that research and development expenses will increase now that we are preparing to commence new clinical trials of PentaLyte.

From inception (November 30, 1990) through September 30, 2004, we incurred \$17,062,036 of general and administrative expenses. General and administrative expenses increased to \$280,712 for the three months ended September 30, 2004 from \$227,432 for the three months ended September 30, 2003. This increase is chiefly attributable to an increase of \$25,871 in investor relations expenses, a \$31,632 increase in legal fees, and an increase of \$25,616 in general and administrative salaries; these increases were offset by a decrease of \$20,534 in general and administrative consulting fees and a decrease of \$9,336 in accounting fees. For the nine months ended September 30, 2004, general and administrative expenses increased to \$1,055,438 from the \$943,767 spent on general and administrative expenses for the nine months ended September 30, 2003. The primary components of this increase were a \$21,364 increase in fees paid to general and administrative consultants, a \$49,881 increase in investor relations expenses, and a \$47,079 increase in salaries allocated to general and administrative costs.

#### Interest and Other Income

From inception (November 30, 1990) through September 30, 2004, we generated \$2,951,724 of interest and other income and incurred \$3,349,028 of interest expense. For the three months ended September 30, 2004, we generated a total of \$13,415 of net interest and other income with no offsetting interest expense, compared to net interest and other income of \$1,007,945, which was offset by an interest expense of \$288,603 for the three months ended September 30, 2003. The differences are attributable to the fact that we have now paid off our debenture debt, and we are no longer making the associated interest payments; also, \$1,000,000 of the interest and other income generated in 2003 was attributable to proceeds from a key man life insurance policy collected after the death of former CEO, Paul Segall. In February 2004, we recognized interest expense of \$1,106,392 based on the excess of the fair value of consideration given to the Participating Debenture Holders over the carrying amount of the debentures at the time the debenture holders exchanged \$1,500,000 of debentures for common shares and warrants. (See Note 3 to the condensed financial statements).

#### Income Taxes

During the three months ended March 31, 2003, we incurred Korean withholding taxes of \$82,520 related to the receipt of license fees from CJ Corp., and during the three months ended September 30, 2004, we incurred Korean withholding taxes of \$49,518 related to the receipt of additional license fees from CJ Corp. With respect to Federal and state income taxes, our effective income tax rate differs from the statutory rate due to the 100% valuation allowance established for our deferred tax assets, which relate primarily to net operating loss carryforwards, as realization of such benefits is not deemed to be likely.

# Liquidity and Capital Resources

Since inception, we have primarily financed our operations through the sale of equity securities, licensing fees, and borrowings. During January 2004, we completed a Rights Offer (the Rights Offer ) through which we raised gross proceeds of \$3,584,420 through the sale of 2,560,303 common shares and 1,280,073 warrants. Following the completion of the Rights Offer, we raised an additional \$600,000 by selling an additional 428,571 common shares and 214,284 warrants under a Standby Purchase Agreement. During February 2004, we eliminated \$3,350,000 of debenture indebtedness by using a portion of the proceeds of the Rights Offer to repay \$1,850,000 of debentures in cash, and by issuing a total of 1,071,428 common shares and 535,712 common share purchase warrants in exchange for \$1,500,000 of debentures held by certain persons who acted as Participating Debenture Holders under the Standby Purchase Agreement. See Note 4 to the condensed financial statements.

During April 2003, we received the initial \$500,000 license fee payment, less \$80,000 of Korean taxes withheld, from CJ under the CJ Agreement. During July 2004 we received the balance of the license fee of \$300,000 less \$49,500 of Korean taxes withheld, in connection with CJ Corp. filing its application for regulatory approval of Hextend in South Korea.

At September 30, 2004, we had \$1,568,845 of cash on hand. We will need to obtain additional equity capital from time to time in the future, as long as the fees we receive from licensing our products to pharmaceutical companies, profits from sales of our products, and royalty revenues are not sufficient to fund our operations. We need additional capital and greater revenues to continue our current operations, to complete clinical trials of PentaLyte®, and to conduct our planned product development and research programs. Sales of additional equity securities could result in the dilution of the interests of present shareholders. We are also continuing to seek new agreements with pharmaceutical companies to provide us with additional product and technology licensing fees and royalties. The amount of license fees and royalties that may be earned through the licensing and sale of our products and technology, the timing of the receipt of license fee payments, and the future availability and terms of equity financing, are uncertain. The unavailability or inadequacy of financing or revenues to meet future capital needs could force us to modify, curtail, delay or suspend some or all aspects of our planned operations. Management believes our existing cash and anticipated royalties are sufficient to allow us to operate through June 30, 2005.

# Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company did not hold any market risk sensitive instruments as of September 30, 2004, December 31, 2003, or September 30, 2003.



# **Item 4. Controls and Procedures**

# Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officers and our principal financial officer, have reviewed and evaluated our disclosure controls and procedures as of a date within ninety (90) days of the filing date of this Form 10-Q quarterly report. Following this review and evaluation, management has collectively determined that our disclosure controls and procedures are sufficient to ensure that material information relating to BioTime with respect to the period covered by this report was made known to them.

# Changes in Internal Controls

There were no significant changes to our internal controls or in other factors that could significantly affect these controls subsequent to the date of the review by our Chief Executive Officers and Chief Financial Officer.

# PART II OTHER INFORMATION

# Item 6. Exhibits and Reports of Form 8-K

(a) Exhibits.

Exhibit Numbers	Description
3.1	Articles of Incorporation, as Amended
3.2	By-Laws, As Amended.#
4.1	Specimen of Common Share Certificate.+
4.2	Form of Warrant++
4.3	Form of Warrant Agreement between BioTime, Inc. and American Stock Transfer & Trust Company++
10.1	Lease Agreement dated July 1, 1994 between the Registrant and Robert and Norah Brower, relating to principal executive offices of the Registrant.*
10.2	Intellectual Property Agreement between BioTime, Inc. and Hal Sternberg.+
10.3	Intellectual Property Agreement between BioTime, Inc. and Harold Waitz.+
10.4	Intellectual Property Agreement between BioTime, Inc. and Judith Segall.+
10.5	Intellectual Property Agreement between BioTime, Inc. and Steven Seinberg.**
10.6	Agreement between CMSI and BioTime Officers Releasing Employment Agreements, Selling Shares, and Transferring Non-Exclusive License.+
10.7	Agreement for Trans Time, Inc. to Exchange CMSI Common Stock for BioTime, Inc. Common Shares.+
10.8	2002 Stock Option Plan, as amended.##
10.9	Addenda to Lease Agreement between BioTime, Inc. and Donn Logan.
10.10	Exclusive License Agreement between Abbott Laboratories and BioTime, Inc. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment).###

Exhibit Numbers	Description		
10.11	Modification of Exclusive License Agreement between Abbott Laboratories and BioTime, Inc. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment).^^^		
10.12	Warrant Agreement, dated March 27, 2001, between BioTime, Inc. and Alfred D. Kingsley		
10.13	Form of Series 2001-A 10% Debenture due August 1, 2004		
10.14	Warrant Agreement between BioTime, Inc. and Purchasers of Series 2001-A Debentures		
10.15	Warrant Agreement, dated March 27, 2002, between BioTime, Inc. and Alfred D. Kingsley**		
10.16	Warrant for the Purchase of Common Shares, dated August 12, 2002, issued to Ladenburg Thalmann & Co. Inc.***		
10.17	Exclusive License Agreement between BioTime, Inc. and CJ Corp.****		
10.18	Warrant Agreement, dated April 9, 2003, between BioTime, Inc. and certain holders of Series 2001-A Debentures****		
10.19	Addendum to Lease, dated March 12, 2004, between BioTime, Inc. as lessee, and Donn Logan and Marcy Li Wong as lessor		
31	Rule 13a-14(a)/15d-14(a) Certification		
32 Incorpor	Section 1350 Certification ated by reference to BioTime s Form 10-K for the fiscal year ended June 30, 1998.		
+ Incorporated by reference to Registration Statement on Form S-1, File Number 33-44549 filed with the Securities and Exchange Commission on December 18, 1991, and Amendment No. 1 and Amendment No. 2 thereto filed with the Securities and Exchange Commission on February 6, 1992 and March 7, 1992, respectively.			
# Incorporated by reference to Registration Statement on Form S-1, File Number 33-48717 and Post-Effective Amendment No. 1 thereto filed with the Securities and Exchange Commission on June 22, 1992, and August 27, 1992, respectively.			

++ Incorporated by reference to Registration Statement on Form S-2, File Number 333-109442, filed with the Securities and Exchange Commission on October 3, 2003, and Amendment No.1 thereto filed with the Securities and Exchange Commission on November 13, 2003.

\* Incorporated by reference to BioTime s Form 10-K for the fiscal year ended June 30, 1994.

^ Incorporated by reference to BioTime s Form 10-Q for the quarter ended March 31, 1997.

## Incorporated by reference to Registration Statement on Form S-8, File Number 333-101651 filed with the Securities and Exchange Commission on December 4, 2002.

^ ^ Incorporated by reference to BioTime s Form 10-Q for the quarter ended March 31, 1999.

### Incorporated by reference to BioTime s Form 8-K, filed April 24, 1997.

^^^ Incorporated by reference to BioTime s Form 10-Q for the quarter ended June 30, 1999.

Incorporated by reference to BioTime s Form 10-K for the year ended December 31, 1999.

Incorporated by reference to the Company s Form 10-K for the year ended December 31, 2000.

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Incorporated by reference to BioTime s Form 10-K for the year ended December 31, 2003

Filed herewith

## (b) Reports on Form 8-K

BioTime filed reports on Form 8-K on July 7, 2004 and August 13, 2004.

BIOTIME INC

# 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, thereunto duly authorized.

/s/ Judith Segall
Judith Segall Vice-President Operations Member, Office of the President*
/s/ Hal Sternberg
Hal Sternberg Vice-President Research Member, Office of the President*
/s/ Harold Waitz
Harold Waitz Vice-President Regulatory Affairs Member, Office of the President*
/s/ Steven Seinberg
Steven Seinberg Chief Financial Officer

\* The Office of the President is comprised of the three above-referenced executive officers of the Company who collectively exercise the powers of the Chief Executive Officer

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Filed herewith