

BIOTRANSPLANT INC  
Form 10-Q  
November 19, 2002

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

**For the Quarterly Period Ended September 30, 2002**

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 000-28324**

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**BIOTRANSPLANT INCORPORATED**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**04-3119555**  
(IRS Employer Identification No.)

**Charlestown Navy Yard, Building 75, Third Avenue,  
Charlestown, Massachusetts 02129**

(Address of Principal Executive Offices) (Zip Code)

**(617) 241-5200**

(Registrant's Telephone Number, Including Area Code)

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

The number of shares outstanding of the Registrant's Common Stock as of November 14, 2002: 25,385,998 shares.

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**BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES**  
**FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002**  
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**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS.**

**BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

	<b>September 30, 2002</b>	<b>December 31, 2001</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,025,762	\$ 5,698,609
Restricted cash	118,860	411,470
Short-term investments	6,617,431	8,546,726
Accounts receivable, trade, net	64,098	242,045

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	September 30, 2002	December 31, 2001
Accounts receivable from Immerge	424,290	662,783
Inventory, net	516,451	975,423
Prepaid expenses and other current assets	246,385	654,878
<b>Total current assets</b>	<b>10,013,277</b>	<b>17,191,934</b>
Property and equipment, net	3,767,978	4,341,007
Other long-term assets	128,000	128,000
Intangible assets, net	6,428,572	10,017,856
Goodwill, net	2,621,188	18,060,188
<b>TOTAL ASSETS</b>	<b>\$ 22,959,015</b>	<b>\$ 49,738,985</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 508,013	\$ 1,257,256
Current obligation under capital lease	40,819	45,215
Accounts payable	411,081	1,270,787
Accrued expenses	2,377,188	2,326,520
Current portion of deferred revenue	858,864	858,864
<b>Total current liabilities</b>	<b>4,195,965</b>	<b>5,758,642</b>
Long-term debt, net of current portion		261,640
Long-term obligation under capital leases, net of current portion		32,746
Deferred revenue, net of current portion	4,163,225	4,807,373
Stockholders' equity:		
Preferred stock, \$.01 par value, authorized 2,000,000 shares; issued and outstanding no shares		
Common stock, \$.01 par value, authorized 50,000,000 shares; issued and outstanding 25,349,616 shares at September 30, 2002 and 21,272,672 shares at December 31, 2001	253,497	212,728
Additional paid-in capital	162,874,651	152,088,879
Deferred compensation	(1,186,313)	(1,951,838)
Accumulated deficit	(147,342,010)	(111,471,185)
<b>Total stockholders' equity</b>	<b>14,599,825</b>	<b>38,878,584</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 22,959,015</b>	<b>\$ 49,738,985</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
<b>Revenues:</b>				
License fees	\$ 214,716	\$ 119,047	\$ 644,148	\$ 119,047
Product revenues	129,872	92,950	569,787	92,950
<b>Total revenues</b>	<b>344,588</b>	<b>211,997</b>	<b>1,213,935</b>	<b>211,997</b>
<b>Expenses:</b>				
Cost of product revenues	289,374	58,270	574,472	58,270
Research and development	2,994,317	2,986,706	11,552,859	7,877,876
Selling, general and administrative	1,730,632	1,282,942	3,960,820	2,646,794
Amortization of intangible assets	285,714	1,011,303	1,071,426	1,514,323
Stock-based compensation (1)	232,637	1,748,264	1,979,997	3,098,293
In-process research and development				20,000,000
Loss from impairment			17,956,858	
<b>Total expenses</b>	<b>5,532,674</b>	<b>7,087,485</b>	<b>37,096,432</b>	<b>35,195,556</b>
<b>Operating loss</b>	<b>(5,188,086)</b>	<b>(6,875,488)</b>	<b>(35,882,497)</b>	<b>(34,983,559)</b>
Interest income	40,096	160,040	115,341	441,451
Interest expense	(21,572)	(50,657)	(103,669)	(92,350)
<b>Net loss</b>	<b>\$ (5,169,562)</b>	<b>\$ (6,766,105)</b>	<b>\$ (35,870,825)</b>	<b>\$ (34,634,458)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.20)</b>	<b>\$ (0.35)</b>	<b>\$ (1.56)</b>	<b>\$ (2.28)</b>
<b>Weighted average common shares outstanding, basic and diluted</b>	<b>25,341,306</b>	<b>19,278,229</b>	<b>22,962,841</b>	<b>15,168,519</b>

(1)

The following summarizes the departmental allocation of the stock-based compensation charge:

Research and development	\$ 176,436	\$ 1,912,246
General and administrative	56,201	67,751
<b>Total stock-based compensation</b>	<b>\$ 232,637</b>	<b>\$ 1,979,997</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

## BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2002	2001
Cash flows from operating activities:		
Net loss	\$ (35,870,825)	\$ (34,634,458)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	880,239	524,950
Amortization of intangible assets	1,071,426	1,514,322
Stock-based compensation	1,979,997	3,098,293
In-process research and development		20,000,000
Loss from impairment	17,956,858	
Changes in current assets and liabilities:		
Accounts receivable, trade	177,947	(3,666,949)
Accounts receivable from Immerge	238,493	
Prepaid expenses and other current assets	408,493	1,031,951
Inventories	458,972	(361,311)
Accounts payable	(859,706)	(950,731)
Accrued expenses	50,668	(2,615,344)
Deferred revenue	(644,148)	5,880,953
Net cash (used) in operating activities	(14,151,586)	(10,178,324)
Cash flows from investing activities:		
Purchases of property and equipment	(347,210)	(394,036)
Proceeds from sale of property and equipment	40,000	
Purchases of short-term investments		(1,044,223)
Proceeds from maturities of short-term investments	1,929,295	3,395,000
Decrease in investment in Stem Cell Sciences		105,000
Cash paid for transaction costs, net of cash received in acquisition of Eligix, Inc.		(3,488,716)
Net cash provided by (used in) investing activities	1,622,085	(1,426,975)
Cash flows from financing activities:		
Payments of long-term debt	(1,010,883)	(426,704)
Release of restricted funds	292,610	
Payments of obligations under capital leases	(37,142)	(33,721)
Proceeds from sale of common stock	9,612,069	18,153,676
Net cash provided by financing activities	8,856,654	17,693,251
Net increase/(decrease) in cash and cash equivalents	(3,672,847)	6,087,952
Cash and cash equivalents, beginning of period	5,698,609	11,481,297

	Nine Months Ended September 30,	
	_____	_____
Cash and cash equivalents, end of period	\$ 2,025,762	\$ 17,569,249
<b>Supplemental disclosures and noncash transactions:</b>		
Interest paid during the period	\$ 98,341	\$ 96,132

The accompanying notes are an integral part of these condensed consolidated financial statements.

## BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

#### 1. OPERATIONS AND BASIS OF PRESENTATION

BioTransplant Incorporated ("BioTransplant" or the "Company") was incorporated on March 20, 1990 in the state of Delaware. The Company discovers, develops and commercializes therapeutics, therapeutic devices and therapeutic regimens designed to suppress undesired immune responses and enhance the body's ability to accept donor cells, tissues and organs. The Company believes that its patented therapeutic regimens, either alone, in combination or with modified conventional therapies, have the potential to address significant unmet medical needs in autoimmune diseases, cancer and transplantation.

During the third quarter of 2001, the Company emerged from the development stage with sales of the Eligix HDM Cell Separation Systems, which received CE mark approval in Europe. However, the Company is still devoting extensive efforts toward product research and development and raising capital. The Company is subject to a number of risks similar to those of other emerging biotechnology companies, including risks related to: collaborative research and distribution partners, competition from substitute products and larger companies, its ability to develop and market commercially usable products and obtain regulatory approval for its products under development, and its ability to obtain the substantial additional financing necessary to adequately fund the development, commercialization and marketing of its product candidates. As described more fully in Note 8, the Company recorded a loss from impairment of \$18.0 million in the accompanying statement of operations for the nine months ended September 30, 2002 related to the Eligix reporting unit.

The accompanying unaudited condensed consolidated interim financial statements herein have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and include, in the opinion of management, all adjustments, consisting of normal, recurring adjustments, necessary for a fair representation of the Company's financial position and its interim period results. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States, have been condensed or omitted pursuant to such rules and regulations. The results for the interim periods presented are not necessarily indicative of results to be expected for the fiscal year or any future period. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001, as filed with the SEC.

The Company incurred a net loss of approximately \$35.9 million and \$42.6 million for the nine months ended September 30, 2002 and year ended December 31, 2001, respectively, and had an accumulated deficit of approximately \$147.3 million and \$111.5 million as of September 30, 2002 and December 31, 2001, respectively. The Company has funded these losses principally through equity financings. At September 30, 2002, the Company had approximately \$8.6 million in cash, cash equivalents and short-term investments. Management believes that these resources will be adequate to fund operations into the second quarter of 2003. (See Note 12 for further discussion.)

Certain prior period amounts have been reclassified to be consistent with the current period's presentation.

## 2. NET LOSS PER COMMON SHARE

Net loss per common share is based on the weighted average number of common shares outstanding during the periods presented, in accordance with Financial Accounting Standards Board ("FASB") Statement No. 128, "Earnings Per Share". Diluted net loss per common share is the same as basic net loss per common share as the inclusion of common stock issuable pursuant to options and warrants would be antidilutive.

## 3. IMMERGE BIOTHERAPEUTICS, INC.

In September 2000, the Company and Novartis Pharma AG entered into an agreement to combine their respective expertise in the field of xenotransplantation into a newly-formed, independently-run company named Immerge BioTherapeutics AG ("Immerge"). Immerge began operations in January 2001. In return for contributing its technology and an aggregate of \$30.0 million in funding over three years beginning January 1, 2001, Novartis obtained a 67% ownership share of Immerge and the exclusive worldwide, royalty-bearing rights to the development and commercialization of any xenotransplantation products resulting from Immerge's research. In return for contributing its technology, BioTransplant obtained a 33% share of Immerge and will receive royalty payments from Novartis sales of xenotransplantation products, if any.

In December 2000, Immerge formed a wholly-owned Delaware operating subsidiary, Immerge BioTherapeutics, Inc. Effective January 1, 2001, BioTransplant entered into a contract research agreement with the Delaware subsidiary, under which BioTransplant has committed approximately 20 full-time employees to perform specified research activities exclusively for the Delaware subsidiary and has agreed to provide administrative services and support at agreed upon rates. Amounts due BioTransplant under this agreement are being recorded as offsets to the relevant BioTransplant expenses incurred. For the three months ended September 30, 2002 and 2001, BioTransplant recorded offsets to its expenses of approximately \$0.8 million and \$1.2 million, respectively for research and development services, and approximately \$245,000 and \$245,000, respectively, for general and administrative services and support, provided under the agreement. For the nine months ended September 30, 2002 and 2001, BioTransplant recorded offsets to its expenses of approximately \$3.4 million and \$4.2 million, respectively for research and development services, and approximately \$733,000 and \$733,000, respectively, for general and administrative services and support, provided under the agreement. Of these amounts, approximately \$424,000 is included as accounts receivable from Immerge on September 30, 2002.

## 4. REVENUE RECOGNITION

Beginning in the third quarter of 2001, the Company generated product revenues in connection with the development and sale of the Company's Eligix HDM Cell Separation System product line. Product revenues are recognized upon shipment provided there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collectibility of the related receivable is reasonably assured. During the third quarter of 2001, the Company also received license fees and milestone payments in connection with the Gambro BCT distribution agreement (see Note 9 and Note 12). The Company recognizes these payments as revenue on a straight line basis over the term of the distribution agreement in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition" ("SAB 101"). SAB 101 requires companies to recognize certain upfront non-refundable

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fees and milestone payments over the life of the related alliance when such fees are received in conjunction with alliances that have multiple elements.

## 5. DEBT

In September 1997, the Company entered into a term note with a bank, whereby the Company could borrow up to \$500,000 for certain equipment and fixtures during a specified drawdown period, after which time the outstanding balance will become payable in 36 equal monthly principal installments plus interest. During 1999, the Company amended the term note to extend the drawdown period and increase its availability to \$1.0 million under the same conditions of the original term note. Borrowings under the term note bear annual floating interest at the bank's prime rate (4.75% at September 30, 2002) during the drawdown period. Borrowings under the term note are secured by equipment and fixtures purchased using the proceeds of the note. There were \$58,000 in borrowings outstanding under this term note at September 30, 2002. In order to provide its consent to the Eligix acquisition (see Note 7), a bank has required the Company to secure the term note with cash funds until the date the loan is paid off. The Company transferred \$540,000 into a restricted cash account during April 2001 in order to meet this requirement. As September 30, 2002, approximately \$119,000 of this amount is still restricted.

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In connection with the acquisition of Eligix, Inc. (see Note 7), the Company has become a co-borrower on two loan and security agreements. The first loan and security agreement was entered into by Eligix in September 1997 and allows the Company to borrow up to \$750,000. The minimum funding amount is \$100,000 with a maximum of five loans. Loans under the agreement bear interest at a fixed rate equal to the yield to maturity for the U.S. Treasury note having a term equivalent with the loan's term on the date of funding plus 300 basis points. The loans are collateralized by certain equipment. There were \$97,000 in borrowings outstanding under this term note at September 30, 2002. The second loan and security agreement was entered into by Eligix in June 1999 and allowed Eligix to borrow up to \$2,700,000. This agreement expired in January of 2001 with Eligix drawing down approximately the entire loan commitment amount. Each note had a fixed term of 42 months. Loans under the agreement bear interest at a fixed rate equal to the prime rate on the date of commencement plus the average interest rate of a similar term U.S Treasury note for the week preceding the date of commencement. The loans are collateralized by certain equipment. There were \$353,000 in borrowings outstanding under this term note at September 30, 2002. The weighted average interest rate on these Eligix loan and security agreements outstanding was 13.36% at September 30, 2002.

### 6. COMPREHENSIVE INCOME

Statement of Financial Accounting Standards ("SFAS") No. 130, "Reporting Comprehensive Income," establishes standards for reporting and display of comprehensive income and its components (revenues, expenses, gains and losses) in a full set of general-purpose financial statements. There are no material differences between the Company's reported income and comprehensive income for all periods presented.

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### 7. ELIGIX ACQUISITION

On May 15, 2001, the Company completed its acquisition of Eligix. The transaction was accounted for as a purchase and, accordingly, the purchase price of \$48.0 million for the acquisition of Eligix was allocated to the assets and liabilities of Eligix based upon their respective fair values with the excess of the purchase price over the fair value of identified intangible and tangible net assets of \$19.7 million allocated to goodwill. During the three months ended June 30, 2002, the Company recorded \$1.07 million in amortization expense related to intangible assets acquired in the purchase. Amortization of goodwill and intangible assets was \$2.6 million for period ending December 31, 2001. As described in Note 8, the Company has recorded a loss from impairment of \$18.0 million for the nine months ended September 30, 2002 related to the goodwill and intangible assets acquired in the Eligix acquisition.

Of the 5,610,000 shares of BioTransplant common stock issuable to Eligix securityholders in the merger, 493,327 shares issued to Eligix stockholders were deposited in an escrow account to satisfy indemnification claims made by the Company within 15 months after the closing of the merger. Because no indemnification escrow shares were required to be used to satisfy indemnification claims made by BioTransplant within 15 months following the completion of the merger, these shares were distributed to former Eligix stockholders on August 15, 2002.

Additionally, BioTransplant assumed all outstanding Eligix stock options at the time of the merger and for the three and nine months ended September 30, 2002, the Company recorded \$31,000 and \$100,000, respectively, in stock-based compensation related to the vesting of stock options held by former employees and consultants of Eligix who became employees or consultants of BioTransplant.

Additionally, certain employees of Eligix received an aggregate of 990,000 shares of BioTransplant common stock under the Eligix management equity incentive plan. These shares vested over a 365-day period following the closing of the merger. Accordingly, at the merger date, \$6,094,000 was recorded as deferred compensation. These management equity incentive plan shares were expensed over the vesting period of the shares. These shares were fully amortized during the three months ended June 30, 2002. During the nine months ended September 30, 2002, the Company amortized approximately \$1,680,000 of deferred compensation related to research and development, in connection with the vesting of these shares.

### 8. IMPAIRMENT OF GOODWILL AND OTHER INTANGIBLE ASSETS

In July 2001, the FASB issued SFAS No. 141, "Business Combinations" and No. 142, "Goodwill and Other Intangible Assets" (the "Statements"). Under the new rules, goodwill and intangible assets deemed to have indefinite lives are no longer amortized but are subject to annual impairment tests in accordance with the Statements.

For the Eligix acquisition, which was completed prior to June 30, 2001, the Company has applied the Statements beginning in the first quarter of 2002. The Company performed the first of the required impairment tests of goodwill and intangible assets as of January 1, 2002 and determined that as of that date there was no impairment and no effect on earnings and financial position of the Company. The adoption of the Statements did not impact the comparability of the financial results for the three months ended March 31, 2002 as no goodwill amortization was recorded during that period. Goodwill subject to such impairment testing was \$18,060,188 at January 1, 2002.



At the end of the second quarter of 2002, management concluded that certain conditions and events were such that impairment testing was required to be performed again with respect to the goodwill and intangible assets acquired in the Eligix acquisition. These conditions and events included continued unfavorable economic conditions and sales of the Company's Eligix HDM Cell Separation Systems that were significantly below expectations, including quarter-to-quarter declines in sales. In addition, the Company had undergone two reductions in force to help reduce spending and conserve cash as these negative events adversely affected the cash flow projections used to determine the fair value of the Eligix reporting unit and related intangible assets.

Fair value measurements of the Eligix reporting unit and related intangible assets were estimated with the assistance of a third-party specialist utilizing an income approach, which was finalized during the third quarter of 2002. Based on this analysis, BioTransplant recorded a loss from impairment related to goodwill and acquired technology of \$18.0 million in the accompanying statement of operations for the nine months ended September 30, 2002.

The following table presents the changes in the carrying amounts of goodwill and intangible assets for the nine months ended September 30, 2002:

	<u>Goodwill</u>	<u>Intangible Assets</u>	<u>Total</u>
Balances as of December 31, 2001	\$ 18,060,188	\$ 10,017,856	\$ 28,078,044
Amortization expense, March 31, 2002		(392,856)	(392,856)
Amortization expense, June 30, 2002		(392,856)	(392,856)
Loss from impairment	(15,439,000)	(2,517,858)	(17,956,858)
Amortization expense, September 30, 2002		(285,714)	(285,714)
Balances as of September 30, 2002	\$ 2,621,188	\$ 6,428,572	\$ 9,049,760

At June 30, 2002 and September 30, 2002, acquired intangible assets subject to amortization consisted of capitalized acquired technology of \$6.7 million and \$6.4 million, respectively, with an estimated useful life of six years, related to the Eligix acquisition (see Note 7). As of September 30, 2002, accumulated amortization on acquired technology and goodwill was \$2.1 million and \$1.6 million, respectively. For the nine months ended September 30, 2002, amortization expense for intangible assets subject to amortization was \$1.07 million. The estimated annual amortization expense for intangible assets subject to amortization is \$1.4 million for fiscal year 2002 and \$1.1 million for each of the next five years. The Company will perform its annual impairment test in accordance with SFAS No. 142 in the fourth quarter of 2002.

The following table presents prior year reported amounts adjusted to eliminate the effect of goodwill amortization in accordance with SFAS No. 142 (in thousands, except per share amounts):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2002</u>	<u>2001</u>	<u>2002</u>	<u>2001</u>
Reported net loss	\$ (5,170)	\$ (6,766)	\$ (35,871)	\$ (34,634)
Add back goodwill amortization		703		937
Adjusted net loss	\$ (5,170)	\$ (6,063)	\$ (35,871)	\$ (33,697)
Basic and diluted net loss per share:				
Reported net loss	\$ (0.20)	\$ (0.35)	\$ (1.56)	\$ (2.28)
Goodwill amortization		0.04		0.06

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	Three Months Ended September 30,		Nine Months Ended September 30,	
Adjusted net loss	\$ (0.20)	\$ (0.31)	\$ (1.56)	\$ (2.22)

### 9. GAMBRO BCT DISTRIBUTION AGREEMENT

In August 2001, BioTransplant entered into an exclusive distribution agreement with Gambro BCT, Inc., a wholly-owned subsidiary of Gambro AB, for the distribution of its Eligix HDM Cell Separation Systems. BioTransplant granted Gambro the exclusive right to distribute these products worldwide, with the exception of the United States and Japan, and the non-exclusive right to distribute these products in Canada. Gambro also has the option to negotiate the terms of an exclusive arrangement for Canada. If BioTransplant is unable to negotiate an exclusive arrangement in Canada with Gambro and subsequently reaches an agreement with a third party, then Gambro's non-exclusive rights in Canada will terminate. Gambro has the exclusive option for a limited period of time to negotiate for the exclusive right to distribute products in the United States by making a one-time payment to the Company. Thereafter, Gambro has the option, without payment of a fee, to negotiate on a non-exclusive basis for United States distribution rights. Gambro also has a right of prior notice and first negotiation with respect to any third-party discussions BioTransplant may seek to engage in with respect to distribution of the Eligix HDM Cell Separation Systems in Japan.

Under the terms of the agreement, BioTransplant is responsible for developing, manufacturing and seeking to obtain CE mark approval for the Company's Eligix HDM Cell Separation Systems. Three of these products, the Eligix BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems, have received CE mark approval, permitting their sale in the European Union. Gambro will be responsible for clinical market development and all other aspects of marketing, sales and distribution (See Note 12). In August and September 2001, the Company received an upfront licensing fee of \$4.0 million, plus milestone payments of \$2.0 million for obtaining CE mark approval for the Company's Eligix BCell-SC and CD8-DLI Cell Separation Systems. The Company has been recognizing these amounts as revenue ratably over the seven-year term of the distribution agreement. During the three and nine month periods ended September 30, 2002, the Company recognized \$215,000 and \$644,000, respectively, as license fee revenues, and \$129,000 and \$570,000 in product revenues, respectively, all of which were sold to Gambro BCT in the United States, and as of September 30, 2002, \$5.0 million is included as deferred revenue in the accompanying consolidated balance sheet. BioTransplant may receive future

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milestone payments for the commissioning by Gambro of other new products, if any, and upon the receipt of CE mark approval for other new products, if any.

### 10. SALE OF COMMON STOCK

On June 10, 2002, the Company sold four million shares of common stock pursuant to its shelf registration statement filed in December 2001. The net proceeds of approximately \$9.5 million will be used for working capital and other general corporate purposes.

### 11. EMPLOYEE RETENTION PLAN

On August 1, 2002, the Company awarded to its employees stock options at below market prices. These awards were comprised of two segments. The stock options granted with the first segment of the program vest evenly every four months over a 12 month period. The stock options granted with the second segment of the program vest in increments of fifty percent at the one year anniversary date and the remaining fifty percent at the earlier to occur of the one year anniversary of the date of grant or upon the Company securing additional financing. The Company recorded \$1.2 million as deferred compensation related to these stock options of which \$201,000 was amortized for the three months ended September 30, 2002.

### 12. SUBSEQUENT EVENTS

On November 15, 2002, the Company implemented a restructuring plan intended to preserve its rights to MEDI-507 while reducing its cash burn rate. The Company intends to evaluate possible partnering agreements, divestitures or closures of all programs and assets other than MEDI-507. In conjunction with the restructuring, the Company has given all employees a tentative notice of termination at a future date. If the partnering efforts are successful by that date, the Company will reevaluate this proposed reduction in force. At this point, the Company cannot reasonably estimate the financial statement impact of this restructuring plan on the Company.

Also on November 15, 2002, the Company notified Gambro BCT, Inc. that it believes that Gambro is in material breach of the distribution agreement between the parties relating to the distribution of the Eligix HDM Cell Separation Systems (See Note 9). Under the terms of the agreement, unless Gambro cures its breach within the cure period specified in the agreement, the agreement will terminate. Gambro has separately informed BioTransplant that it intends to seek dispute resolution under the terms of the agreement with respect to certain issues, including whether or not it has breached the agreement. If Gambro is unable to cure its breach and, accordingly, the agreement is terminated, the Company plans to seek a partner or licensee for its Eligix HDM Cell Separation Systems, in accordance with the restructuring plan announced on November 15, 2002.

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## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### OVERVIEW

Since commencement of our operations in 1990, we have been engaged primarily in the discovery, development and commercialization of therapeutics, therapeutic devices and therapeutic regimens designed to suppress undesired immune responses and enhance the body's ability to accept donor cells, tissues and organs. The major sources of our working capital have been the proceeds from sales of equity securities, sponsored research funding and license fees, capital lease financings and borrowings under term loans. Although we commenced initial sales of our Eligix HDM Cell Separation Systems in Europe during the fourth quarter of 2001 through a distribution partner, we have not generated substantial product revenues from our sales of products to date.

We are a party to a number of collaborations and strategic relationships. Since 1995, we have had a collaborative agreement with MedImmune, Inc. Currently, the main focus of this relationship is the development of Siplizumab, which we also refer to as MEDI-507, a humanized monoclonal antibody we exclusively licensed to MedImmune for stand-alone indications. MedImmune is currently completing multiple Phase II trials of Siplizumab for the treatment of psoriasis. We will be entitled to receive royalties on any sales of Siplizumab and future generation products. In 2001, we entered into a distribution agreement with Gambro BCT for the distribution of our Eligix HDM Cell Separation Systems. Since 1993, we have been involved in collaborations with Novartis to research, develop and commercialize xenotransplantation products. In 2001, Immerge BioTherapeutics AG, the joint venture we formed with Novartis to research xenotransplantation products, began operations as an independently run company. Novartis will fund the joint venture through 2003.

#### *Restructuring*

On November 15, 2002, we implemented a restructuring plan intended to preserve our rights to MEDI-507 while reducing our cash burn rate. We intend to evaluate possible partnering or licensing agreements, divestitures or closures of all programs and assets other than MEDI-507. In conjunction with the restructuring, we have given all employees a tentative notice of termination at a future date. In the event we are able to conclude a partnering deal in the near term, we will reevaluate our plans to eliminate our work force. At this point, we cannot reasonably estimate the financial statement impact of this restructuring plan on us.

#### *Gambro Distribution Eligix HDM Cell Separation Systems*

In August 2001, we entered into an exclusive distribution agreement with Gambro BCT, Inc. a wholly-owned subsidiary of Gambro AB, for the distribution of our Eligix HDM Cell Separation Systems. Under this agreement, as amended, we granted Gambro the right to distribute these products worldwide, with the exception of the United States and Japan, and the non-exclusive right to distribute these products in Canada. Under the agreement, Gambro may exercise specified rights and options to become our exclusive distribution partner in Canada, Japan and the United States.

The agreement requires us and Gambro to share revenues under the distribution agreement based upon a specific formula. Under the terms of the agreement, we are responsible for developing, manufacturing and seeking to obtain CE Mark approval for our Eligix HDM Cell Separation Systems. Three of these products, the BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems, have received CE Mark approval, permitting their sale in the European Union. Gambro is responsible for clinical market development and all other aspects of marketing, sales and distribution. In August and September 2001, we received an upfront licensing fee of \$4.0 million, as well as milestone payments of \$2.0 million for obtaining CE Mark approval for our BCell-SC and CD8-DLI Cell Separation Systems.

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On November 15, 2002, we notified Gambro that we believe that Gambro is in material breach of the distribution agreement between us (See Note 12 of the notes to condensed consolidated financial statements). Under the terms of the agreement, unless Gambro cures its breach within the cure period specified in the agreement, the agreement will terminate. Gambro has separately informed us that it intends to seek dispute resolution under the terms of the agreement with respect to certain issues, including whether or not it has breached the agreement. If Gambro is unable to cure its breach and, accordingly, the agreement is terminated, we plan to seek a partner or licensee for our Eligix HDM Cell Separation Systems, in accordance with the restructuring plan we announced on November 15, 2002. However, we can not assure you that we will be able to enter into any such arrangement.

### *MedImmune*

Under our collaborative agreement with MedImmune, MedImmune paid us a \$2.0 million license fee at the time of execution of the agreement, and agreed to fund and assume responsibility for clinical testing and commercialization of the BTI-322 monoclonal antibody and other related products developed by us, including Siplizumab, which is the name given by MedImmune to MEDI-507, the humanized version of BTI-322. MedImmune has provided \$2.0 million of non-refundable research support and has agreed to make milestone payments of up to an additional \$11.0 million. All milestone payments which are received by BioTranplant are repayable from royalties, if any, on future sales of the BTI-322 monoclonal antibody and other related products by MedImmune. In October 2002, MedImmune announced preliminary results from its partial analysis of three Phase II clinical trials for MEDI-507 for the treatment of psoriasis. MedImmune has indicated that it expects to initiate Phase II retreatment trials for psoriasis in early 2003 to further investigate a laboratory-only observation of immunogenicity to MEDI-507 in certain patient data analyzed so far. Pending successful retreatment studies, MedImmune has stated that it expects to initiate a pivotal Phase III trial in late 2003.

### *Eligix Acquisition*

On May 15, 2001, we completed our acquisition of Eligix, Inc. (See Note 7 of the notes to condensed consolidated financial statements). Upon consummation of the merger, Eligix became our wholly-owned subsidiary. Under the terms of the merger, we issued 4,939,200 shares of common stock in exchange for the outstanding common stock of Eligix and 990,000 shares of common stock to certain former employees of Eligix. The 990,000 shares issued to Eligix employees were subject to a repurchase option which lapsed on May 15, 2002.

We accounted for the acquisition as a purchase. In accordance with the requirements of accounting principles generally accepted in the United States, we allocated the purchase price for the acquisition to the assets acquired, including intangible assets consisting of in-process research and development, acquired technology and goodwill. The allocations among the intangible assets were based upon an independent third-party valuation of the intangible assets acquired. As a result of a preliminary valuation, performed in December 2000, we allocated \$20.0 million to in-process research and development, or IPR&D, and \$25.0 million to acquired technology. The excess of the purchase price over the fair value of identified intangible and tangible assets of \$5.7 million was allocated to goodwill. During 2001, the intangible assets, including acquired technology and goodwill, were amortized over their estimated useful lives of seven years. The fair value of the IPR&D was recorded as an expense as of the acquisition date. In connection with our year-end audit, the third-party valuation firm finalized its valuation as of May 15, 2001 based upon revised estimates of expected cash flows from the developed portion of the technology acquired from Eligix and other variables. As a result of the final valuation report, we reallocated \$14.0 million from acquired technology to goodwill. As a result, we continued to allocate \$20.0 million to IPR&D, and allocated \$11.0 million to acquired technology and \$19.7 million to goodwill. Finally, we performed a review of our intangible assets as of December 31, 2001 and determined that no impairment existed. The reallocation had no impact on our statement of operations for the year ended December 31, 2001.

At the end of the second quarter of 2002, management concluded that certain conditions and events were such that impairment testing was required to be performed again with respect to the goodwill and intangible assets acquired in the Eligix acquisition. These conditions and events included continued unfavorable economic conditions and sales of our Eligix HDM Cell Separation Systems that were significantly below expectations, including quarter-to-quarter declines in sales. In addition, we had undergone two reductions in force to help reduce spending and conserve cash as these negative events adversely affected the cash flow projections used to determine the fair value of the Eligix reporting unit and related intangible assets.

Fair value measurements of the Eligix reporting unit and related intangible assets were estimated with the assistance of a third-party specialist utilizing an income approach. Based on this analysis, we recorded a loss from impairment of \$18.0 million in the accompanying statement of operations for the nine months ended September 30, 2002.

The following table presents the changes in the carrying amounts of goodwill and intangible assets for the three months ended September 30, 2002:

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	Goodwill	Intangible Assets	Total
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Balances as of December 31, 2001	\$ 18,060,188	\$ 10,017,856	\$ 28,078,044
Amortization expense, March 31, 2002		(392,856)	(392,856)
Amortization expense, June 30, 2002		(392,856)	(392,856)
Loss from impairment	(15,439,000)	(2,517,858)	(17,956,858)
Amortization expense, September 30, 2002		(285,714)	(285,714)
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Balances as of September 30, 2002	\$ 2,621,188	\$ 6,428,572	\$ 9,049,760
	<u>                    </u>	<u>                    </u>	<u>                    </u>

At June 30, 2002 and September 30, 2002, acquired intangible assets subject to amortization consisted of capitalized acquired technology of \$6.7 million and \$6.4 million, respectively, related to the Eligix acquisition. As of September 30, 2002, accumulated amortization on acquired technology and goodwill was approximately \$2.1 million and \$1.6 million, respectively. For the nine months ended September 30, 2002, amortization expense for intangible assets was \$1.07 million. The estimated annual amortization expense for intangible assets subject to amortization is \$1.4 million for fiscal year 2002 and \$1.1 million for each of the next five fiscal years.

*Novartis/Immerge BioTherapeutics*

From 1993 through October 2000, we were a party to two collaboration agreements with Novartis to research, develop and commercialize xenotransplantation products. During these collaborations, we received and recognized as revenue an aggregate of \$33.5 million in research funding and \$16.5 million in license fees and milestone payments from Novartis. In September 2000, we entered into an arrangement with Novartis to terminate the prior collaborations and combine our respective expertise in the field of xenotransplantation into a newly formed, independently run Swiss company, Immerge BioTherapeutics AG, which began operations in January 2001.

Novartis has committed to provide an aggregate of \$30.0 million in research funding over three years to the joint venture, \$20.0 million of which has been received to date by Immerge BioTherapeutics, Inc., a Delaware subsidiary of Immerge BioTherapeutics AG, to cover Novartis's funding obligation through 2002. Both we and Novartis have exclusively licensed to the joint venture patent rights and technology in the field of xenotransplantation. The joint venture has granted to Novartis an exclusive, worldwide, royalty-bearing license to develop and commercialize any xenotransplantation products resulting from the joint venture's research. We will receive royalties from the sale of xenotransplantation products by Novartis, if any.

We entered into a contract research agreement with Immerge BioTherapeutics, Inc. under which we have committed approximately 20 full-time employees to perform research and are providing

administrative services at rates specified in the agreement. We are recognizing the expense reimbursement received from Immerge BioTherapeutics, Inc. as an offset to the expenses we incur. For the nine months ended September 30, 2002 and 2001, we recorded approximately \$3.4 million and \$4.2 million in research and development services and support, respectively, and approximately \$733,000 and \$733,000 in general and administrative services and support reimbursement. As part of the restructuring program we implemented on November 15, 2002 (see Note 12 of notes to condensed consolidated financial statements), we and Immerge have entered into discussions regarding proposed changes to the contract research agreement to eliminate our ongoing obligation to commit employees, provide administrative services, and otherwise incur direct expenses, reimbursable or otherwise, relating to the joint venture.

Novartis holds 67% of the shares of Immerge BioTherapeutics AG and we hold the remaining 33%. All income, gain, profit or loss of the joint venture, if any, will be allocated to us and Novartis pro rata based upon our respective equity ownership of the joint venture in effect in the period in which these items accrue. We will accrue losses up to the amount of our investment balance in Immerge BioTherapeutics AG. Because we have not invested any amount, or committed to invest any amounts, in the joint venture, our investment balance is zero. Accordingly, we have not recognized any losses related to the joint venture during 2002 or 2001. Initially, the board of directors of Immerge BioTherapeutics, Inc. will consist of four directors: one selected by us, one selected by Novartis and two additional directors, one each designated by us and Novartis, who are experts in the field of xenotransplantation. Immerge BioTherapeutics AG has agreed not to undertake, or permit its subsidiaries to undertake, specified fundamental corporate actions without the consent of both shareholders.

**RESULTS OF OPERATIONS**

*Three Months Ended September 30, 2002 and 2001*

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Revenues for the three months ended September 30, 2002 and 2001 were \$345,000 and \$212,000, respectively. Revenues for the three months ended September 30, 2002 were due to product sales of \$130,000 and \$215,000 in Gambro milestone payments and upfront license fees. Revenues for the three months ended September 30, 2001 were due to product sales of \$93,000 and Gambro upfront license fees of \$119,000. The increase in product sales and upfront license fees during the three months ended September 30, 2002, as compared to the same period last year, is mainly due to the fact that the Company entered into the agreement with Gambro in August of 2001. The Gambro milestone payments and upfront license fees have been recognized ratably over the remaining life of the Gambro distribution agreement, as described in Note 9 of the notes to condensed consolidated financial statements.

Product revenue for the three months ended September 30, 2002 decreased from each of the prior two quarters of 2002. The decline in product revenues, together with the other factors described more fully in Note 8 to the notes to condensed consolidated financial statements, led to a loss from impairment of \$18.0 million being recorded during the three months ended June 30, 2002.

Cost of product revenues for the three months ended September 30, 2002 and 2001 were \$289,000 and \$58,000, respectively. The increase in cost of product revenues during the three months ended September 30, 2002 was due to an increase in product sales and overhead charges compared to the same period for 2001 and an additional reserve applied against existing inventory due to a decrease in forecasted sales.

Research and development expenses primarily consist of salaries and related expenses for personnel, sponsored research, consulting, clinical development costs, facilities related costs and depreciation. Research and development expenses for the three months ended September 30, 2002 and 2001 were \$3.0 million and \$3.0 million, respectively. An increase due to inclusion of Eligix expenses

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during the three months ended September 30, 2002 was offset by the cost reduction efforts implemented during 2002.

General and administrative expenses primarily consist of salaries and related expenses for personnel, facilities related costs, depreciation and professional fees. General and administrative expenses increased to \$1.7 million for the three months ended September 30, 2002, compared to \$1.3 million for the three months ended September 30, 2001. This increase was primarily due to the accrual of future severance benefits and the inclusion of Eligix expenses for the three months ended September 30, 2002, offset by the cost reduction efforts implemented during 2002.

Interest income decreased to \$40,000 for the three months ended September 30, 2002 from \$160,000 for the three months ended September 30, 2001. The decrease was due primarily to lower cash balances available for investment purposes and lower interest rates in the three months ended September 30, 2002.

Interest expense decreased to \$22,000 for the three months ended September 30, 2002 from \$51,000 for the three months ended September 30, 2001. The decrease was due primarily to repayment of debt and other obligations.

On August 1, 2002, the Company awarded to its employees stock options at below market price. These awards were comprised of two segments. The stock options granted with the first segment of the program vest evenly every four months over a 12 month period. The stock options granted with the second segment of the program vest in increments of fifty percent at the one year anniversary date and the remaining fifty percent at either the earlier of the one year anniversary of the date of grant or upon the Company securing additional financing. The Company recorded \$1.2 million as deferred compensation related to the stock options, of which \$201,000 was amortized during the three months ended September 30, 2002.

As a result of the above factors and approximately \$317,000 of non-cash Eligix merger-related expenses and \$201,000 of non-cash compensation expense related to the employee retention plan (see Notes 7 and 11 to the notes to condensed consolidated financial statements) we generated a net loss for the three months ended September 30, 2002 of \$5.2 million or \$0.20 per share. During the third quarter of 2001, we generated a net loss of \$6.8 million, or \$0.35 per share.

### ***Nine Months Ended September 30, 2002 and 2001***

Revenues for the nine months ended September 30, 2002 and 2001 were \$1,214,000 and \$212,000, respectively. Revenues for the nine months ended September 30, 2002 were due to product sales of \$570,000 and \$644,000 in Gambro milestone payments and upfront license fees, respectively. Revenues for the nine months ended September 30, 2001 were due to product sales of \$93,000 and Gambro upfront license fees of \$119,000, respectively. The increase in product sales and upfront license fees during the nine months ended September 30, 2002 as compared to the same period last year, is mainly due to the fact that the Company entered into an agreement with Gambro in August of 2001. The Gambro milestone payments and upfront license fees have been recognized ratably over the remaining life of the Gambro distribution agreement, as described in Note 9 of the notes to condensed consolidated financial statements.

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Cost of product revenues for the nine months ended September 30, 2002 and 2001 were \$574,000 and \$58,000, respectively. The increase in cost of product revenues during the the nine months ended September 30, 2002 was due to an increase in product sales and overhead charges compared to the same period of 2001 and an additional reserve applied against existing inventory due to a decrease in forecasted sales.

Research and development expenses increased to \$11.6 million for the nine months ended September 30, 2002 from \$7.9 million for the nine months ended September 30, 2001. This increase

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was primarily due to the inclusion of Eligix expenses for the nine months ended September 30, 2002 offset by the cost reduction efforts implemented during 2002.

General and administrative expenses increased to \$4.0 million for the nine months ended September 30, 2002, compared to \$2.6 million for the nine months ended September 30, 2001. This increase was primarily due to the inclusion of Eligix expenses and the accrual of future severance benefits for the nine months ended September 30, 2002, offset by the cost reduction efforts implemented during 2002.

Interest income decreased to \$115,000 for the nine months ended September 30, 2002 from \$441,000 for the nine months ended September 30, 2001. The decrease was due primarily to lower cash balances available for investment purposes and lower interest rates in the nine months ended September 30, 2002.

Interest expense increased to \$104,000 for the nine months ended September 30, 2002 from \$92,000 for the nine months ended September 30, 2001. The increase was due primarily to inclusion of Eligix expenses for the nine months ended September 30, 2002.

On August 1, 2002, the Company awarded to its employees stock options at below market price. These awards were comprised of two segments. The stock options granted with the first segment of the program vest evenly every four months over a 12 month period. The stock options granted with the second segment of the program vest in increments of fifty percent at the one year anniversary date and the remaining fifty percent at the earlier to occur of the one year anniversary of the date of grant or upon the Company securing additional financing. The Company recorded \$1.2 million as deferred compensation related to these stock options, of which \$201,000 was amortized for the nine months ended September 30, 2002.

As a result of the above factors and approximately \$2.9 million of non-cash Eligix merger-related expenses and \$201,000 of non-cash compensation expense related to the employee retention plan (see Notes 7 and 11 to the notes to condensed consolidated financial statements) and a \$18.0 million loss from impairment (see Note 8 to the notes to condensed consolidated financial statements) recognized during the nine months ended September 30, 2002, we generated a net loss for the nine months ended September 30, 2002 of \$35.9 million, or \$1.56 per share. During the nine months ended September 30, 2001, we generated a net loss of \$34.6 million, or \$2.28 per share, mainly due to our recording of \$20.0 million for in-process research and development and \$3.0 million of non-cash Eligix merger-related expenses.

### **LIQUIDITY AND CAPITAL RESOURCES**

#### ***Background***

Since our inception, our operations have been funded principally through the net proceeds of an aggregate of \$109.3 million from sales of equity securities. We have also received \$50.0 million from research and development and collaboration agreements with Novartis, \$4.0 million from an alliance agreement with MedImmune, \$6.0 million in up-front licensing fees and milestone payments from our distribution agreement with Gambro and \$2.9 million in equipment financing. The proceeds of the sales of equity securities, equipment financing and cash generated from the corporate collaborations with Novartis and MedImmune and our distribution agreement with Gambro have been used to fund operating losses of approximately \$146.2 million and the investment of approximately \$9.8 million in equipment and leasehold improvements through September 30, 2002.

During the nine months ended September 30, 2002 and September 30, 2001, we used cash from operating activities of \$14.2 million and \$10.2 million, respectively. The cash used in operations during the nine months ended September 30, 2002 resulted primarily from our operating loss, changes in our working capital and adjustments for non-cash expenses relating to amortization of intangible assets, stock based compensation and loss from impairment charges.

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During the nine months ended September 30, 2002, we generated cash from investing activities of \$1.6 million. This was primarily due to \$1.9 million of net proceeds from investing activities, which consisted of maturities of short-term investments and was offset by the \$347,000 cash paid for purchase of property and equipment. During the nine months ended September 30, 2001, we used \$1.4 million of cash from investing activities. This was primarily due to a net increase in short-term investments of \$2.3 million, which was offset by the \$394,000 cash paid for purchase of property and equipment additions, and \$3.5 million of cash paid for transaction costs in connection with the acquisition of Eligix.

During the nine months ended September 30, 2002 and 2001, we generated cash of \$8.9 million and \$17.7 million from financing activities, respectively. Our financing activities in both periods consisted principally of issuances of our common stock, which were offset by payments on long-term debt.

On November 15, 2002, we notified Gambro BCT, Inc. that we believe that Gambro is in material breach of the distribution agreement between the parties pursuant to which Gambro is distributing our Eligix HDM Cell Separation Systems in Europe (see Note 9 and Note 12 of notes to condensed consolidated financial statements). Under the terms of the agreement, unless Gambro cures its breach within the cure period specified in the agreement, the agreement will terminate. Gambro has informed us that it intends to seek dispute resolution under the terms of the agreement with respect to certain issues, including whether it has breached the agreement. If the agreement is terminated, we will no longer receive product revenue from sales of the Eligix HDM Cell Separation Systems.

On November 15, 2002, we implemented a restructuring plan intended to preserve our rights to MEDI-507 while reducing our cash burn rate. We intend to evaluate possible partnering agreements, divestitures or closures of all programs and assets other than MEDI-507. In conjunction with the restructuring, we have given all employees a tentative notice of termination at a future date. If the partnering efforts are successful by that date, we will reevaluate this proposed reduction in force.

We recorded a charge of approximately \$210,000 in the third quarter of 2002 for employee termination costs related to a headcount reduction of 13 full-time employees which was announced on July 29, 2002.

On May 8, 2002, we implemented a cost reduction program, including a reduction in the workforce of approximately 15 full-time employees, and other measures to reduce overall spending in subsequent quarters. We recorded a charge of approximately \$260,000 in the second quarter of 2002 for employee termination costs.

As of September 30, 2002, we had approximately \$58,000 in borrowings outstanding under a term note with a bank for certain equipment and fixture borrowings. The bank has required us to secure the term note with a cash balance until the loan is paid off. In connection with the acquisition of Eligix, we assumed the obligations under two outstanding loans to which Eligix was a party at the time of the acquisition. As of September 30, 2002, the aggregate amount outstanding under these two loans was approximately \$450,000.

We have entered into sponsored research and consulting agreements with certain hospitals, academic institutions and consultants, requiring periodic payments by us. Our aggregate minimum funding obligations under these agreements is approximately \$3.4 million, of which approximately \$950,000 remains to be payable in 2002. We lease our facilities under operating leases that expire between 2003 and 2009. Aggregate minimum rental payments, excluding taxes and operating costs, under these arrangements is \$8.3 million of which \$457,000 is payable in 2002.

### ***Current Resources***

We had cash, cash equivalents and short-term investments of \$8.6 million as of September 30, 2002, as compared to \$14.2 million as of December 31, 2001.

As announced on November 15, 2002, we have implemented a restructuring plan to preserve our rights to MEDI-507 while partnering, licensing, divesting or closing all other programs and assets in an effort to reduce our cash burn rate. In conjunction with the restructuring, we have given all of our employees a tentative notice of termination at a future date. We anticipate that our existing cash, cash equivalents and short-term investments, in conjunction with this restructuring plan, will be sufficient to fund our operating and capital requirements as currently planned into the second quarter of 2003.



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Assuming the termination of our employees, our primary remaining expenses are our facility leases and related expenses. We will seek to renegotiate the facility leases in order to further reduce our cash burn rate. In addition, we anticipate that if we are able to successfully enter into partnering, licensing, divestiture or similar arrangements for any or all of our programs other than MEDI-507 we may raise additional funds through the receipt of milestone payments, license fees or the support of the expenses related to all or a portion of our employees. If we are able to successfully renegotiate our facility leases and/or enter into partnering, licensing or divestiture arrangements, we may be able to extend the date through which our existing cash will be sufficient to fund our operating requirements. However, we can not assure you that we can successfully renegotiate our facility leases and/or enter into these arrangements on terms that are acceptable to us, if at all.

### CRITICAL ACCOUNTING POLICIES

While our significant accounting policies are summarized in Note 2 to our condensed consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2001, as filed with the SEC, we believe that certain of these accounting policies are critical to a portrayal of our financial position and results and require the application of the most significant judgment by our management. In applying these policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of estimates. Those estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our strategic partners and information available from other outside sources, as appropriate. Actual results may differ significantly from the estimates contained in our financial statements. Our critical accounting policies include:

*Impairment of long-lived assets.* Our long-lived assets include intangible assets and goodwill. At September 30, 2002, we had \$9.05 million of intangible assets and goodwill, net, which accounted for approximately 39% of our total assets. In assessing the recoverability of our intangible assets and goodwill, we must make assumptions in determining the fair value of the asset by estimating future cash flows and considering other factors, including significant changes in the manner or use of the assets, or negative industry or economic trends. If these estimates or their related assumptions change in the future, we may be required to record additional impairment charges for these assets. We adopted the provisions of Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets* and SFAS, No. 144, *Accounting for the Impairment of Long Lived Assets* as of January 1, 2002, and are required to test our intangible assets for impairment on a periodic basis. We had previously performed a review of the realizability of our intangible assets as of December 31, 2001 and determined that no impairment existed.

At the end of the second quarter of 2002, management concluded that certain conditions and events were such that impairment testing was required to be performed with respect to the goodwill and intangible assets acquired in the Eligix acquisition. These conditions and events included continued unfavorable economic conditions, sales of our HDM Cell Separation Systems that were significantly below expectations, including quarter-to-quarter declines in sales, and two reductions in force related to these activities. These indicators of impairment adversely affected the cash flow projections used to determine the fair value of the Eligix reporting unit and related intangible assets.

Fair value measurements of the Eligix reporting unit and related intangible assets were estimated with the assistance of a third-party specialist utilizing an income approach, which was finalized during

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the third quarter of 2002. Based on this analysis, we recorded a loss from impairment of \$18.0 million during the second quarter of fiscal 2002, in the accompanying statement of operations for the three and nine months ended September 30, 2002.

However, future events such as those described above, could cause us to conclude that additional impairment indicators exist and that goodwill or other intangible assets are impaired. Additionally, we will be required to perform our annual impairment test later in the fourth quarter of fiscal 2002. If future estimates of cash flows are less than currently projected, an additional impairment loss may be required. Any resulting impairment loss could have a material adverse impact on our financial position and results of operations.

*Revenue recognition.* Our revenue recognition policy is significant because our revenue is a key component of our results of operations. In addition, our revenue recognition determines the timing of certain expenses. We follow specific and detailed guidelines in measuring revenue; however, certain judgments affect the application of our revenue policy. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause our operating results to vary significantly from quarter to quarter and could result in future operating losses. For a description of our revenue recognition policy, see note 4 to our condensed consolidated financial statements.

*Inventories.* Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based on historical experience and forecasted product demand. We have only recently begun the commercialization of our products and have limited experience in assessing obsolescence. We evaluate the adequacy of these reserves periodically.

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**RISK FACTORS THAT MAY AFFECT RESULTS**

This Quarterly Report on Form 10-Q and certain other communications made by us contain forward-looking statements, including statements about our growth and future operating results, discovery, development and commercialization of products, potential acquisitions, strategic alliances and intellectual property. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We often use the words "believes", "anticipates", "plans", "expects", "intends" and similar expressions to help identify forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this Form 10-Q. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

**We will need to further reduce or offset our expenses in order to fund our operating and capital requirements in the near term.**

As announced on November 15, 2002, we have implemented a restructuring plan to preserve our rights to MEDI-507 while partnering, licensing, divesting or closing all other programs and assets in an effort to reduce our cash burn rate. In conjunction with the restructuring, we have given all of our employees a tentative notice of termination at a future date. We anticipate that our existing cash, cash equivalents and short-term investments, in conjunction with this restructuring plan, will be sufficient to fund our operating and capital requirements as currently planned into the second quarter of 2003.

Assuming the termination of our employees, our primary remaining expenses are our facility leases and related expenses. We will seek to renegotiate the facility leases in order to further reduce our cash burn rate. In addition, we anticipate that if we are able to successfully enter into partnering, licensing divestiture or similar arrangements for any or all of our programs other than MEDI-507 we may raise additional funds through the receipt of milestone payments, license fees or the support of the expenses related to all or a portion of our employees. If we are able to successfully renegotiate our facility leases and/or enter into partnering, licensing or divestiture arrangements, we may be able to extend the date through which our existing cash will be sufficient to fund our operating requirements. However, we can not assure you that we can successfully renegotiate our facility leases and/or enter into these arrangements on terms that are acceptable to us, if at all.

**Our common stock may be delisted from The Nasdaq National Market, which could cause the price to fall further and decrease its liquidity.**

Our common stock trades on The Nasdaq National Market. In order to continue trading on Nasdaq, we must comply with The Nasdaq National Market's continued listing requirements, which require that we either maintain a minimum stockholders' equity of \$10.0 million and a minimum closing bid price of \$1.00 per share or, if we fall below the minimum stockholder's equity requirement, maintain a minimum closing bid price of \$3.00 per share. At September 30, 2002, we had stockholder's equity of \$19.5 million. However, unless we are able to raise funds in the near term through sales of equity, or otherwise, our stockholder's equity will substantially decline. If our stockholder's equity falls below \$10.0 million, we will need to maintain a minimum closing bid price of \$3.00 rather than \$1.00. Since mid-October 2002, the closing bid price for our common stock has been below \$1.00.

If we do not satisfy Nasdaq's continued listing requirements, our common stock may be delisted from The Nasdaq National Market. The delisting of our common stock may result in the trading of the stock on the Nasdaq Small Cap Market, the over-the-counter markets in the so-called "pink sheets" or the NASD's electronic bulletin board. Consequently, a delisting of our common stock from The Nasdaq National Market would materially reduce the liquidity of our common stock, not only in the number of

shares that could be bought and sold, but also through delays in the timing of the transaction and reductions in securities analysts and media coverage. This may reduce the demand for our stock and significantly destabilize the price our stock. In addition, a delisting would materially adversely affect our ability to raise additional necessary capital.

**We have a history of operating losses and our future profitability is uncertain.**

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We were incorporated in 1990 and have experienced significant operating losses in each year since that date. As of September 30, 2002, our accumulated deficit was \$147.3 million. Our net loss for the nine months ended September 30, 2002 and for the fiscal years ended December 31, 2001, 2000 and 1999 was \$35.8 million, \$42.6 million, \$11.7 million and \$8.7 million, respectively. We expect to continue to incur significant losses for the foreseeable future. To date, our revenue has been generated principally from license fee and milestone payments from our collaborative partners. We may never achieve profitable operations.

**If the estimates we make, and the assumptions on which we rely, in preparing our financial statements prove inaccurate, our actual results may vary significantly.**

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There can be no assurance, however, that our estimates, or the assumptions underlying them, will be correct. Our actual financial results may vary significantly from the estimates contained in our financial statements.

**We depend on our BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems for all of our near-term product revenue, and if these products are not successfully commercialized, then we will not achieve profitability from the sale of these products.**

We expect to derive our near-term product revenues, if any, from sales of our BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems. We began distributing two of these products through a distribution agreement with Gambro in late 2001 and, to date, we have sold relatively few systems. On November 15, 2002, we notified Gambro that we believe it is in material breach of the distribution agreement. If Gambro does not cure its breach within the periods specified in the agreement, the agreement will terminate. Because we currently depend on our BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems to generate all of our near-term product revenue, if Gambro fails to achieve widespread market acceptance of these products or if Gambro fails to cure its breach and effectively market these products, we will not be able to grow our near-term product revenue or generate adequate funds to meet the expenses relating to the development and manufacture of these products.

**We are dependent on collaborative relationships to develop, manufacture and sell some products and products under development, and if these parties are not successful, then we will not achieve significant revenues.**

We have several strategic relationships for the development, manufacture and distribution of our products and products based upon our technologies. We have a collaborative agreement with MedImmune under which we have provided MedImmune with the exclusive worldwide right to develop and commercialize products derived from the BTI-322 and MEDI-507 antibodies. We also entered into a multi-year exclusive distribution agreement with Gambro for the distribution of our Eligix HDM Cell Separation Systems, and other cell separation systems we may in the future develop. In addition, our joint venture with Novartis, Immerge BioTherapeutics, has exclusively licensed to Novartis the right to

develop and commercialize any products derived from Immerge's research program in xenotransplantation, which refers to the transplantation of cells, tissues and organs from one species to another.

Under each of these collaborative agreements, we have the right to receive royalties or a share of revenue on product sales, if any. Our arrangements with our collaborative partners allow them significant discretion in determining the timing, efforts and resources that they will apply to the development, commercialization and sale of products based upon our technologies. For example, Novartis' commitment to fund Immerge BioTherapeutics ends in December 2003. Novartis is not obligated to provide additional funding after December 2003 or to otherwise continue the research and development of xenotransplantation products based upon our technologies. In October 2002, our partner MedImmune announced that it expects to initiate Phase III pivotal trials of our humanized monoclonal antibody MEDI-507 for the treatment of psoriasis in late 2003, later than it had previously projected. Moreover, in November 2002, we provided Gambro with notice that we believe it is in material breach of the distribution agreement and, if it does not timely cure its breach, the agreement will terminate. If any of these collaborative partners do not begin or complete clinical trials on an acceptable schedule, or otherwise perform successfully, such failure may delay or prevent regulatory approval and/or product launch, impair our competitive position or otherwise reduce or eliminate any royalties or profit sharing that we may otherwise be entitled to receive.

**If we or our partners do not develop and market new products, our ability to achieve profitability will be harmed.**

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Our ability to achieve profitability depends on our and our collaborative partners' ability to develop, obtain regulatory approval for, manufacture, introduce and successfully market new products and product candidates. These product candidates will require extensive development and testing, as well as regulatory approval, before they can be successfully marketed and sold to the public. The MEDI-507 antibody product under development, the Eligix HDM Cell Separation Systems technology and the prototype AlloMune Systems have been tested in relatively few patients and we and our partners may not be able to demonstrate the clinical benefits of these products in a larger patient population. Furthermore, the technology that we have exclusively licensed to our joint venture with Novartis Pharma AG is based upon the transplantation of organs from swine into humans. To our knowledge, transplantation of swine organs has never been tested in humans. In addition, any products under development may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use. If our and our partners' technological approaches are not successful or the medical community and/or third-party payors do not accept these products as clinically useful, cost-effective and safe, then our ability to achieve profitability will be substantially impaired.

**If clinical trials of our products under development are not successful or are not completed on a timely basis, we and our collaborative partners may not achieve profitability.**

To obtain regulatory approvals for the commercial sale of products under development by us and/or our collaborative partners, we and our collaborative partners will need to complete extensive clinical trials in humans to demonstrate the safety and efficacy of these products. We have had limited experience in conducting clinical trials. Even if we receive authorization from the FDA to commence clinical trials, we or our collaborative partners may not be able to successfully complete these trials within our anticipated timeframes, if at all. For example, in October 2002, our partner MedImmune announced that it expects to initiate Phase III pivotal trials of MEDI-507 for the treatment of psoriasis in late 2003, later than it had previously projected. Furthermore, we, our collaborative partners or the FDA may suspend our clinical trials at any time on various grounds, including a finding that the patients in the trials are being exposed to unacceptable health risks. Finally, our clinical trials, if

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completed, may not show the potential product to be safe or effective, thereby preventing regulatory approval.

**The product approval process is costly and lengthy and we and/or our collaborative partners may not obtain and maintain the regulatory approvals required to successfully market and sell our products under development.**

We and our collaborative partners must obtain regulatory approval for research and development activities and for our products before marketing or selling any products. We and our collaborative partners may not receive these required regulatory approvals. In addition, regulatory agencies may not grant such approvals on a timely basis or may revoke previously granted approvals or impose fines, suspensions, product recalls and other sanctions if we or our collaborative partners fail to comply with applicable regulatory requirements. If our products under development do not receive regulatory approvals, or if we or our collaborative partners do not otherwise comply with government regulations, our business would be harmed.

The process of obtaining FDA and other required regulatory approvals is expensive and typically takes a number of years, depending on the complexity and novelty of the product. Moreover, for any products that are approved, the marketing, distribution and manufacture of these products will remain subject to extensive regulatory requirements. For example, any regulatory approval for a product may limit the indications or markets in which the product can be used or require additional post-approval studies. Any regulatory body can have a product removed from the market if a previously unknown problem with the product is discovered. Any delay in obtaining or failure to obtain or maintain required clearance or approval of a product by the appropriate regulatory authorities, would materially adversely affect our ability to generate revenues from the affected product. We have limited experience in filing and prosecuting the applications required to gain and maintain regulatory approval.

There is limited regulatory precedent for the approval of products based upon the technologies that we and our collaborative partners are employing to develop products. MEDI-507, our AlloMune Systems and our Eligix HDM Cell Separation Systems are based on new technologies and/or new therapeutic approaches that have not been extensively tested in humans. Accordingly, the regulatory requirements governing these products under development may be more rigorous than for conventional products. In addition, the FDA has not yet established final or comprehensive guidelines for xenotransplantation. As a result, we may experience a longer regulatory process in connection with any products that we or our collaborators seek to develop based on these new technologies and/or new therapeutic approaches.

We and our collaborative partners also are subject to numerous foreign regulatory requirements governing the design and conduct of the clinical trials and the manufacturing and marketing of our future products. The approval procedure varies among countries. The time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, even if we receive FDA approval, we may not receive necessary approvals by regulatory authorities in other countries.

All of these regulatory risks also are applicable to development, manufacturing and marketing undertaken by our key collaborators and any other future collaborators who may seek to develop, market and sell products based upon our technologies.

**We have only limited sales and marketing experience and depend significantly on third parties who may not successfully commercialize our products.**

We rely significantly on sales, marketing and distribution arrangements with our collaborative partners. For example, we have granted Gambro exclusive worldwide distribution rights, exclusive of the United States, Canada and Japan, for our Eligix HDM Cell Separation Systems, and other cell separation products which we may in the future develop. On November 15, 2002, we notified Gambro

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that we believe it is in material breach of the distribution agreement between the parties. Under the terms of the agreement, unless Gambro cures its breach within the cure period specified in the agreement, the agreement will terminate. If the distribution agreement is terminated by us because Gambro can not cure its breach, we currently do not have, nor do we expect to be able to build, the sales and marketing operations to commence selling these products independently. We have also granted MedImmune exclusive worldwide marketing rights to the MEDI-507 product under development, and our joint venture with Novartis, Immerge BioTherapeutics, has granted to Novartis the exclusive worldwide right, but not the obligation, to develop and market products based upon our xenotransplantation technologies. We may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

**If we experience delays or interruptions in manufacturing of our Eligix HDM Cell Separation Systems, we may experience customer dissatisfaction and our reputation could suffer.**

If we fail to produce enough products at our own manufacturing facility or at a third-party manufacturing facility, we may be unable to deliver products to our customers on a timely basis, which could lead to customer dissatisfaction and could harm our reputation and ability to compete. We currently produce key components of our BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems in one manufacturing facility. We would likely experience significant delays or cessation in producing our BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems at this facility if a labor strike, natural disaster or other supply disruption were to occur. If we are unable to manufacture our Eligix HDM Cell Separation Systems at our own facility, we may be required to enter into arrangements with one or more contract manufacturing companies. We could encounter delays or difficulties establishing relationships with contract manufacturers or in establishing agreements on terms that are favorable to us. In addition, if we are required to depend on third-party manufacturers, our profit margins may be lower, which will make it more difficult for us to achieve profitability.

**Because we rely on a limited number of suppliers, we may experience difficulty in meeting our customers' demands for our Eligix HDM Cell Separation Systems in a timely manner or within budget.**

We currently purchase key components of our Eligix HDM Cell Separation Systems from a variety of outside sources. Some of these components may only be available to us through a few sources. We generally do not have long-term agreements with any of our suppliers.

Our reliance on our suppliers exposes us to risks, including:

the possibility that one or more of our suppliers could terminate their services at any time without penalty;

the potential inability of our suppliers to obtain required components;

the potential delays and expenses of seeking alternative sources of supply;

reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternative suppliers; and

the possibility that one or more of our suppliers could fail to satisfy any of the FDA's required current good manufacturing practices regulations.

Consequently, in the event that our suppliers delay or interrupt the supply of components for any reason, our ability to produce and supply our products to our distributor could be impaired, which could lead to customer dissatisfaction.

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**If we are not able to obtain patent protection for our discoveries or we infringe patent rights of third parties, then our ability to market our products will be substantially harmed.**

Our success depends in significant part on our ability to:

obtain patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

The validity and permissible scope of claims covered in patents relating to our technology involve important unresolved legal principles. Furthermore, there is substantial uncertainty as to whether human clinical data will be required for issuance of patents for human therapeutics. If human clinical data are required, our ability to obtain patent protection could be delayed or otherwise adversely affected.

Patents may not issue from any patent applications that we own or license. If patents do issue, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States are maintained in secrecy until patents issue, third parties may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

A patent recently issued to a major pharmaceutical company directed towards recombinant production of monoclonal antibodies. We may require a license under this patent with respect to MEDI-507. There can be no assurance that such a license will be granted to us or that we can obtain a license on terms favorable to us. If a required license is not available, our ability to generate revenue would be adversely affected.

We may not hold proprietary rights to all of the patents related to our proposed products or services. These patents may be owned or controlled by third parties. As a result, we or our collaborative partners may be required to obtain licenses under third-party patents to market our proposed products or services. If licenses are not available on acceptable terms, we or our collaborative partners will not be able to market these products or services.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements with our employees and consultants. We cannot guarantee these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known or independently developed by competitors.

**If we lose important license rights, we may be unable to successfully develop and commercialize our products and achieve profitability.**

We are a party to technology in-licenses with the Catholic University of Louvain, the Alberta Research Council and the Coulter Corporation. We expect to enter into additional licenses in the future. These in-licenses relate to important technologies that are necessary for the development and commercialization of our products. These licenses impose various commercialization, indemnification, royalty, insurance and other obligations on us. If we fail to comply with these requirements, the licensors will have the right to terminate these licenses or make the licenses non-exclusive, which could affect our ability to exploit important technologies that are required for successful development of our products.

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**We face substantial competition, which could adversely affect our profitability.**

We and our collaborative partners will compete with existing and new products being created by pharmaceutical, biopharmaceutical, biotechnology and medical device companies and universities. Many of these entities have significantly greater research and development capabilities, as well as substantial marketing, manufacturing, financial and managerial resources and represent significant competition. With respect to our currently marketed BCell-SC, CD8-DLI and CD8-SC Cell Separation Systems, we and our distribution partner are competing against large companies that have significantly greater financial resources and established marketing and distribution channels for competing products.

The pharmaceutical industry is intensely price competitive and we expect we and our collaborative partners will face this and other forms of competition. Development by others may render our products, products under development and technologies obsolete or noncompetitive, and we and our collaborative partners may not be able to keep pace with technological developments to maintain a competitive position in the market. Many of our competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for products that compete with our own. Some of these products may have an entirely different approach or means of accomplishing the desired therapeutic effect than our products and may be more effective and less costly. In addition, many of these competitors have significantly greater experience than we do in undertaking preclinical testing and human clinical trials and obtaining regulatory approvals of such products. Accordingly, our competitors may succeed in commercializing products more rapidly than we and our collaborative partners can.

**If we are unable to meet the operational, legal and financial challenges that we will encounter in our international operations, we may not be able to grow our business.**

We are subject to a number of challenges which specifically relate to our international business activities. Our international operations may not be successful if we are unable to meet and overcome these challenges, which would limit the growth of our business. These challenges include:

failure of local laws to provide the same degree of protection against infringement of our intellectual property;

protectionist laws and business practices that favor local competitors, which could slow our growth in international markets; and

potentially longer sales cycles to sell products, which could slow product orders and, accordingly, our revenue growth from international sales.

**Our stock price is highly volatile, and the market price of our common stock may rapidly and substantially decline.**

The market price of our common stock is highly volatile. For example, during the past three years, our stock price fluctuated from a low sale price of \$0.28 in the month of October 2002 from a high sale price of \$23.00 in the quarter ended March 31, 2000. Prices for our common stock will be determined in the market place and may be influenced by many factors, including fluctuations in our financial results and investors' perceptions of us, as well as their perceptions of general economic, industry and market conditions, and the daily trading volumes of our common stock. Market fluctuations may adversely affect the market price of our common stock and may cause a rapid and substantial decline in the value of your investment in our common stock. In particular, factors that may cause such volatility include our ability to complete clinical trials of our product candidates, the results of such trials, our ability to expand sales of our products and our ability to meet the expectations of investors and securities analysts.

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In the past, companies that have experienced volatility in the market price of their stock have been subject to class action litigation. If we were to become involved in this type of litigation, even if it was found that the claim had no merit, we could incur substantial costs and diversion of management's attention, which could harm our business, financial condition and operating results.

**The general business climate is uncertain and we do not know how this will impact our business or our stock price.**

Over the past two years, there have been dramatic changes in economic conditions, and the general business climate has been negatively impacted. Indices of the U.S. stock markets have fallen significantly and consumer confidence has waned. Compounding the general unease about the current business climate are the still unknown economic and political impacts of the September 11, 2001 terrorist attacks and hostilities abroad. We are unable to predict how any of these factors may affect our business or stock price.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS**

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The primary objective of the investment portfolio is to preserve our capital until we are required to fund operations, including our research and development activities. All of these market-risk sensitive instruments are classified as held-to-maturity and are not held for trading purposes. We do not own derivative financial instruments in our investment portfolio. Our investment portfolio includes investment-grade debt instruments. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. We do not anticipate any near-term changes in the nature of our market risk exposure or management's objectives and strategies with respect to managing such exposures.

**ITEM 4. CONTROLS AND PROCEDURES**

- a.) *Evaluation of disclosure controls and procedures.* Based on their evaluation of the Company's disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934) as of a date within 90 days of the filing date of this Quarterly Report on Form 10-Q, the Company's chief executive officer and chief financial officer has concluded that the Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and are operating in an effective manner.
  
- b.) *Changes in internal controls.* There were no significant changes in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

**PART II. OTHER INFORMATION**

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS:**

BioTransplant's Annual Meeting of Stockholders was held on July 31, 2002. The following represents the results of the voting on proposals submitted to a vote of stockholders at such meeting:

- 1. The following persons were elected to serve as directors of BioTransplant for the ensuing year:

	<b>For</b>	<b>Withheld Authority</b>
Elliot Lebowitz, Ph.D.	16,044,210	141,124
James C. Foster, J.D.	16,044,210	141,124
Daniel O. Hauser, Ph.D.	16,046,419	138,915
Arnold L. Oronsky, Ph.D.	16,046,419	138,915
Michael S. Perry, D.V.M., Ph.D.	16,046,419	138,915
Susan M. Racher	16,046,419	138,915



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2.

To ratify the selection of Ernst & Young LLP as BioTransplant's independent auditors for the fiscal year ending December 31, 2002.

<u>FOR</u>	<u>AGAINST</u>	<u>ABSTAINING</u>
16,048,928	131,806	4,600

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

- a) The Exhibit Index following the signature page is incorporated herein by reference.
- b) The following reports on Form 8-K were filed by the Company during the quarter ended September 30, 2002:
  - (1) The Company filed a Current Report on Form 8-K dated July 22, 2002 on August 2, 2002 to report pursuant to Item 5 (Other Events) that it had issued (i) a press release announcing that Donald B. Hawthorne had been elected to the positions of President and Chief Executive Officer of the Company and (ii) a press release announcing a restructuring plan.

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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 thereunto duly authorized.

November 19, 2002

BIOTRANSPLANT INCORPORATED  
(Registrant)

By: /s/ DONALD B. HAWTHORNE

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Name: Donald B. Hawthorne  
Title: President, Chief Executive Officer  
and Chief Financial Officer

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**CERTIFICATION**

I, Donald B. Hawthorne, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of BioTransplant Incorporated;
- 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3.

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Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4.

The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a)

Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b)

Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c)

Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5.

The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a)

All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b)

Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6.

The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: November 19, 2002

/s/ DONALD B. HAWTHORNE

Donald B. Hawthorne

*Chief Executive Officer and Chief Financial Officer*

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### Exhibit Index

<b>Exhibit No.</b>	<b>Description</b>
10.1	Severance Agreement, dated as of August 19, 2002, between the Registrant and Elliot Lebowitz
99.1	Certificate of the Chief Executive Officer and Chief Financial Officer of BioTransplant Incorporated pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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[BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS \(Unaudited\)](#)

[BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS \(Unaudited\)](#)

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