BIOTRANSPLANT INC
Form 10-Q
May 15, 2002

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

ý **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Quarterly Period Ended March 31, 2002

or

o **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 0-28324

BIOTRANSPLANT INCORPORATED

(Exact name of registrant as specified in its Charter)

Delaware	**04-3119555**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification Number)

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)

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 ý NO o

The number of shares outstanding of the Registrant's Common Stock as of May 6, 2002: 21,325,382 shares.

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES
FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2002

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,226,611	$ 5,698,609

	March 31, 2002	December 31, 2001
Restricted cash	308,330	411,470
Short-term investments	5,559,794	8,546,726
Accounts receivable, trade, net	257,950	242,045
Accounts receivable from Immerge	383,302	662,783
Inventory, net	374,824	646,713
Prepaid expenses and other current assets	893,416	983,588
Total current assets	12,004,227	17,191,934
Property and equipment, net	4,326,751	4,341,007
Other long-term assets	128,000	128,000
Intangible assets, net	9,625,000	10,017,856
Goodwill, net	18,060,188	18,060,188
TOTAL ASSETS	$ 44,144,166	$ 49,738,985
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 1,131,350	$ 1,257,256
Current obligation under capital lease	45,215	45,215
Accounts payable	1,920,881	1,270,787
Accrued expenses	1,967,802	2,326,520
Current portion of deferred revenue	858,864	858,864
Total current liabilities	5,924,112	5,758,642
Long-term debt, net of current portion	36,689	261,640
Long-term obligation under capital leases, net of current portion	18,205	32,746
Deferred revenue, net of current portion	4,592,657	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 at March 31, 2002 and December 31, 2001; issued and outstanding 21,325,382 shares at March 31, 2002 and 21,272,672 shares at December 31, 2001	213,254	212,728
Additional paid-in capital	152,244,877	152,088,879
Deferred compensation	(796,348)	(1,951,838)
Accumulated deficit	(118,089,280)	(111,471,185)
Total stockholders' equity	33,572,503	38,878,584
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 44,144,166	$ 49,738,985

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,	
	2002	**2001**
Revenues:		
License fees	$ 214,716	$
Product revenue	261,900	
Total revenues	476,616	
Expenses:		
Cost of product revenues	157,591	
Research and development	4,199,344	1,985,167
General and administrative	1,171,460	481,726
Amortization of intangible assets	392,856	
Stock-based compensation (1)	1,155,490	
Total expenses	7,076,741	2,466,893
Operating loss	(6,600,125)	(2,466,893)
Interest income	34,224	169,811
Interest expense	(52,194)	(14,461)
Net loss	$ (6,618,095)	$ (2,311,543)
Net loss per common share, basic and diluted	$ (0.31)	$ (0.20)
Weighted average common shares outstanding, basic and diluted	21,292,502	11,796,358

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

Research and development	$ 1,149,715	$
General and administrative	5,775	
Total stock-based compensation	$ 1,155,490	$

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

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2002	**2001**
Cash flows from operating activities:		
Net loss	$ (6,618,095)	$ (2,311,543)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	272,310	85,087
Amortization of intangible assets	392,856	
Stock-based compensation	1,155,490	
Decrease in investment in Stem Cell Sciences		15,000
Changes in current assets and liabilities:		
Accounts receivable, trade	(15,905)	
Accounts receivable from Immerge	279,481	(131,229)
Accounts receivable from Eligix		(2,000,000)
Prepaid expenses and other current assets	90,172	(27,674)
Inventories	271,889	
Accounts payable	650,093	210,745
Accrued expenses	(358,717)	(366,471)
Deferred revenue	(214,716)	
Net cash used in operating activities	(4,095,142)	(4,526,085)
Cash flows from investing activities:		
Purchases of property and equipment	(258,054)	(8,253)
Purchases of short-term investments		(3,428)
Proceeds from maturities of short-term investments	2,986,932	3,395,000
Net cash provided by investing activities	2,728,878	3,383,319
Cash flows from financing activities:		
Payments of long-term debt	(350,857)	(58,333)
Release of restricted funds	103,140	
Payments of obligations under capital leases	(14,541)	(13,058)
Proceeds from sale of common stock	156,524	6,090
Net cash used in financing activities	(105,734)	(65,301)
Net decrease in cash and cash equivalents	(1,471,998)	(1,208,067)
Cash and cash equivalents, beginning of period	5,698,609	11,481,297
Cash and cash equivalents, end of period	$ 4,226,611	$ 10,273,230
Supplemental disclosures and noncash transactions:		
Interest paid during the period	$ 54,558	$ 14,402

	Three Months Ended March 31,	

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: its dependence on key individuals and 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 products.

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 generally accepted accounting principles 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 $6.6 million and $42.6 million for the quarter ended March 31, 2002 and year ended December 31, 2001, respectively, and had an accumulated deficit of approximately $118.1 million and $111.5 million as of March 31, 2002 and December 31, 2001, respectively. The Company has funded these losses principally through equity financings. At March 31, 2002, the Company has approximately $10.1 million in cash, cash equivalents and short-term investments. Management believes that these resources will be adequate to fund operations into the first quarter of 2003.

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.

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

3. IMMERGE BIOTHERAPEUTICS, INC.

In September 2000, the Company and Novartis 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 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 March 31, 2002 and 2001, BioTransplant has recorded offsets to its expenses of approximately $1.4 million and $1.5 million for research and development services, respectively, and approximately $243,000 and $244,000 for general and administrative services and support, respectively, provided under the agreement. Of these amounts, approximately $383,000 is included as accounts receivable from Immerge on March 31, 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 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. The Company also received license fees and milestone payments in connection with the Gambro BCT distribution agreement (see Note 9). 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 fees and milestone payments over the life of the related alliance when such fees are received in conjunction with alliances which have multiple elements.

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

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 March 31, 2002) during the drawdown period with an option to convert during the repayment period to an annual fixed rate at the three-month London Interbank Offered Rate ("LIBOR") (1.96% at March 31, 2002) plus 2.25%. Borrowings under the term note are secured by equipment and fixtures purchased using the proceeds of the note. There were $194,000 in borrowings outstanding under this term note at March 31, 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 of March 31, 2002, $308,000 of this amount is still restricted.

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 $183,000 in borrowings outstanding under this term note at March 31, 2002. The second loan and security agreement was entered into by Eligix in June 1999 and allows the Company to borrow up to $2,700,000. The minimum funding amount is $35,000. Each note will have 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 $789,000 in borrowings outstanding under this term note at March 31, 2002. The weighted average interest rate on these Eligix loan and security agreements outstanding was 13.62% at March 31, 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.

7. ELIGIX ACQUISITION

On May 15, 2001, the Company completed its acquisition of Eligix, Inc. The transaction was accounted for as a purchase and, accordingly, the purchase price of $48.0 million for the acquisition of Eligix has been 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. For the three months ended March 31, 2002, the Company recorded $393,000 in amortization expense related to intangible assets acquired in the purchase.

Of the 5,610,000 shares 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. Any indemnification escrow shares that, 15 months following the completion of the merger, have not been used to satisfy indemnification claims made by BioTransplant and that are not subject to any unresolved claims for indemnification by BioTransplant, will be distributed to the Eligix stockholders.

Additionally, for the three months ended March 31, 2002, the Company recorded $37,000 in stock based compensation related to the vesting of stock options held by employees and consultants of Eligix.

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 vest 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 are being expensed over the vesting period of the shares. During the three months ended March 31, 2002, the Company amortized approximately $1,119,000 of deferred compensation allocated to research and development related to the vesting of these shares.

8. GOODWILL AND OTHER INTANGIBLE ASSETS ADOPTION OF SFAS NOS. 141 AND 142

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 minimum annual impairment tests in accordance with the Statements. Other intangible assets will continue to be amortized over their useful lives.

For the Eligix acquisition, which was completed prior to June 30, 2001, the Company has applied the new rules on accounting for business combinations and goodwill and other intangible assets beginning in the first quarter of 2002. The Company will perform the first of the required impairment tests of goodwill as of January 1, 2002 prior to June 30, 2002, and has not yet determined what the effect, if any, of these tests will be on earnings and financial position of the Company. Goodwill subject to such impairment testing was $18,060,188 at March 31, 2002.

The adoption of the new standards does not impact the financial results for the three months ended March 31, 2001 as no goodwill amortization was recorded during that period.

Acquired intangible assets subject to amortization consist of capitalized acquired technology of $11,000,000 related to the Eligix acquisition (see Note 7). As of March 31, 2002, accumulated amortization on acquired technology is equal to $1.4 million. For the three months ended March 31, 2002, amortization expense for intangible assets was $393,000. The estimated annual amortization expense for intangible assets for the current and next five fiscal years is $1.6 million.

BIOTRANSPLANT INCORPORATED AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Unaudited)

9. GAMBRO BCT DISTRIBUTION AGREEMENT

In August 2001, BioTransplant entered into an exclusive distribution agreement with Gambro BCT, 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 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 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. The first two of these products, the Eligix BCell-SC and CD8-DLI Cell Separation Systems, have received CE mark approval, permitting their sale in the European Union. Gambro will be responsible for continued clinical market development and all other aspects of marketing, sales and distribution. 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 is recognizing these amounts as revenue over the seven-year term of the distribution agreement. During the year ended December 31, 2001, the Company recognized $334,000 as license fee revenues, all of which were shipped to Gambro's location in the United States, and of March 31, 2002, $5.5 million is included as deferred revenue in the accompanying consolidated balance sheets. BioTransplant may receive future milestone payment for other new products, if any, receiving CE mark approval.

10. ACCOUNTING FOR THE IMPAIRMENT OF LONG LIVED ASSETS

In accordance with SFAS No. 144, "Accounting for the Impairment of Long Lived Assets," which the Company adopted on January 1, 2002, the Company assesses the realizability of certain intangible assets. Under SFAS 144, the Company is required to assess the valuation of its long-lived assets including intangible assets based on the estimated cash flow to be generated by such assets. Based on its most recent analysis, the Company believes that no indications of impairment exist as of March 31, 2002.

11. SUBSEQUENT EVENT

On May 8, 2002, the Company announced 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. The Company expects to record a charge of approximately $280,000 in the second quarter of 2002 for employee termination costs.

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 will be required to conduct significant additional research, development, testing and regulatory compliance activities that, together with general and administrative expenses, are expected to result in significant and increasing operating losses for at least the next several years.

In addition to conducting research, development and manufacturing on our own, 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 refer to as MEDI-507, a humanized monoclonal antibody we exclusively licensed to MedImmune for stand-alone indications. MedImmune is currently conducting 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, two versions of which are now being marketed in Europe. 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.

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 which could total up to an additional $11.0 million. All milestone payments which are received are repayable from royalties on the BTI-322 monoclonal antibody and other related products.

Eligix Acquisition

On May 15, 2001, we completed our acquisition of Eligix, Inc. 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 shares issued to Eligix employees are subject to a repurchase option which lapses over a one-year period.

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. Synergies, such as the value expected to be derived from the planned use of our Eligix HDM Cell Separation Systems technology in our AlloMune Systems, are excluded from the valuation pursuant to applicable accounting standards and SEC guidelines. 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 exists. The reallocation had no impact on our statement of operations for the year ended December 31, 2001.

Gambro Distribution Eligix HDM Cell Separation Systems

In August 2001, we entered into an exclusive distribution agreement with Gambro BCT, a wholly-owned subsidiary of Gambro AB, for the distribution of our Eligix HDM Cell Separation Systems. Under this agreement, as amended, we have 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. Gambro also has the option to negotiate the terms of an exclusive arrangement for Canada. If we are unable to negotiate an exclusive arrangement in Canada and subsequently reach 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 us. 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 we may seek to engage in with respect to distribution in Japan.

We and Gambro will share revenues under the distribution agreement based upon a specific formula. Under the terms of the agreement, we will be responsible for developing, manufacturing and seeking to obtain CE Mark approval for our Eligix HDM Cell Separation Systems. The first two of these products, the BCell-SC and CD8-DLI Cell Separation Systems, have received CE Mark approval, permitting their sale in the European Union. Gambro will be responsible for continued 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, plus milestone payments of $2.0 million for obtaining CE Mark approval for our BCell-SC and CD8-DLI Cell Separation Systems. We are recognizing these amounts as revenue over the seven-year term of the distribution agreement. We are entitled to receive future milestone payments for other new products, if any, receiving CE Mark approval. We expect to receive CE Mark approval for our CD8-SC Cell Separation System in late 2002.

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 quarters ending March 31, 2002 and 2001, we recorded approximately $2,039,000 and $1,890,000 in research and development services and support, respectively, and approximately $242,000 and $250,000 in general and administrative services and support reimbursement.

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 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 March 31, 2002, and 2001

Revenues for the three months ended March 31, 2002 were $477,000. There were no revenues for the three months ended March 31, 2001. Revenues for the three months ended March 31, 2002 was due to product sales of $262,000 and $215,000 in Gambro milestone payments and upfront license fees, which are being recognized ratably over the remaining life of the Gambro BCT distribution agreement, as described in Note 9 of the notes to condensed consolidated financial statements.

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 increased to $4.2 million for the three months ended March 31, 2002 from $2.0 million for the three months ended March 31, 2001. This increase was primarily due to the inclusion of Eligix expenses for the three months ended March 31, 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 $1.2 million for the three months ended March 31, 2002, compared to $481,000 for the three months ended March 31, 2001. This increase was due to the inclusion of Eligix expenses for the three months ended March 31, 2002.

Interest income decreased to $34,000 for the three months ended March 31, 2002 from $170,000 for the three months ended March 31, 2001. The decrease was due primarily to lower cash balances available for investment purposes and lower interest rates in the three months ended March 31, 2002.

As a result of the above factors and approximately $1.5 million of non-cash Eligix merger-related expenses (see Note 7 to the notes to condensed consolidated financial statements) recognized in the first quarter of 2002, the Company generated a net loss for the three months ended March 31, 2002 of $6.6 million, or $0.31 per share, compared to a net loss of $2.3 million, or $0.20 per share for the three months ended March 31, 2001.

LIQUIDITY AND CAPITAL RESOURCES

Background

Since our inception, our operations have been funded principally through the net proceeds of an aggregate of $99.8 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 $118.1 million and the investment of approximately $9.6 million in equipment and leasehold improvements through March 31, 2002.

During the quarter ended March 31, 2002 and year ended December 31, 2001, we used cash in operating activities of $4.1 million and $13.1 million, respectively. The cash used in operations resulted primarily from our operating loss adjusted for non-cash expenses and changes in our working capital.

During 2001, we used $9.8 million of cash in investing activities, consisting primarily of $1.1 million of property and equipment additions, a net increase in short-term investments of $5.2 million and $3.5 million of cash paid for transaction costs in connection with the acquisition of Eligix. During the quarter ended March 31, 2002, we generated cash from investing activities of $2.7 million. The net proceeds from investing activities consisted of maturities of short-term investments offset by the purchase of property and equipment.

During the year ended December 31, 2001, we generated cash of $17.5 million from financing activities. During the quarter ended March 31, 2002, we used $106,000 in financing activities. Our financing activities consisted principally of issuances of our common stock and long-term debt offset by payments on long-term debt.

During 1999, we extended the term of, and increased our borrowings under, our term note with a bank from $500,000 to $1.0 million for certain equipment and fixtures borrowing. As of March 31, 2002, there was approximately $175,000 in borrowings outstanding. We are required to maintain certain financial covenants under the agreement. As of March 31, 2002, we were in compliance with these covenants. 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 March 31, 2002, the aggregate amount outstanding under these two loans was approximately $1.0 million.

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, each of which allows us to cancel without penalty, given sufficient notice, total approximately $5.4 million, which includes approximately $2.9 million payable in 2002. We lease our facilities under operating leases that expire between 2003 and 2009.

On May 8, 2002, we announced 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 expect to record a charge of approximately $280,000 in the second quarter of 2002 for employee termination costs.

Current Resources

We had cash, cash equivalents and short-term investments of $10.1 million as of March 31, 2002, as compared to $14.7 million as of December 31, 2001.

We anticipate that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating and capital requirements as currently planned into the first quarter of 2003. We will need to raise additional funds, and may seek to raise these funds through additional financings, including public or private equity offerings, collaborative arrangements with corporate partners or a combination of any of the foregoing. There can be no assurance that funds will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to delay, scale back or eliminate some or all of our product development programs or to license to others the right to commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves, any of which would have a material and adverse effect on us.

Even if we are able to raise the substantial additional funds required to finance our operations, our cash requirements may vary materially from those now planned. Factors that may affect this variability include, without limitation:

the progress of our research and development programs;

the scope and results of preclinical and clinical testing;

changes in existing and potential relationships with corporate collaborators;

the time and cost in obtaining regulatory approvals;

the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses;

our ability to establish development and commercialization capacities or relationships; and

the costs of manufacturing.

CRITICAL ACCOUNTING POLICIES

While our significant accounting policies are summarized in Note 2 to our 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 most application of 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 March 31, 2002, we had $27.7 million of intangible assets and goodwill, net, which accounted for approximately 63.7% 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 impairment charges for these assets. We adopted the provisions of Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*, as of January 1, 2002, and will be required to test our intangible assets for impairment during the first six months of fiscal 2002, and then on a periodic basis thereafter. We performed a review of the realizability of our intangible assets as of December 31, 2001 and determined that no impairment exists. However, future events could cause us to conclude that impairment indicators exist and that goodwill or other intangible assets are impaired. Any resulting impairment loss could have a material adverse impact on our financial position and results of operations.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), which supersedes SFAS No. 121 and the accounting and reporting provisions of APB Opinion No. 30. SFAS 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets and is effective for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years. Accordingly, we adopted this standard effective January 1, 2002. The adoption of SFAS 144 did not have a material impact on our financial statements.

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 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.

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

We were incorporated in 1990 and have experienced significant operating losses in each year since that date. As of March 31, 2002, our accumulated deficit was $118.1 million. Our net loss for the quarter ended March 31, 2002 and for the fiscal years ended December 31, 2001, 2000 and 1999 was $6.6 million, $42.6 million, $11.7 million and $8.7 million, respectively. We expect to continue to incur significant losses for the foreseeable future. We only began selling our BCell-SC and CD8-DLI Cell Separation Systems in Europe in late 2001. To date, our revenue has been generated principally from license fee and milestone payments from our collaborative partners. We may never achieve significant revenues from product sales, and we may not achieve profitable operations.

We will require substantial additional financing, which may be difficult to obtain and may dilute your ownership interest in us.

We anticipate that our existing funds will be sufficient to fund our operating and capital requirements as currently planned into the first quarter of 2003. We expect to use rather than generate funds from operations for the foreseeable future. The actual amount of funds we will

require will be determined by a number of factors, many of which are beyond our control. In particular, we will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our AlloMune Systems and Eligix HDM Cell Separation Systems and to manufacture products that are approved for commercial sale, such as our BCell-SC and CD8-DLI Cell Separation Systems, which we began selling through a distributor in Europe in late 2001. If we cannot raise more funds, we could be required to reduce our capital expenditures, scale back or abandon our research and product development activities, reduce our workforce and license to others products or technologies we would otherwise seek to commercialize ourselves.

We will seek additional funding through collaborative arrangements, by borrowing money or by selling additional equity securities. Any sales of additional equity securities are likely to result in further dilution to our then existing stockholders. Further, if we issue additional equity securities, the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock. We may also borrow money from conventional lenders, possibly at high interest rates and on other terms that are unfavorable to us, which will increase the risk of your holdings. Despite our efforts, additional funding may not be available to us at all or only on terms that are unacceptable to us. We also could be required to seek funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products which we would otherwise pursue on our own.

We will depend on our BCell-SC and CD8-DLI Cell Separation Systems for substantially all of our near-term product revenue, and if these products do not gain widespread market acceptance, then our near-term product revenue will not grow.

Our future growth depends upon our ability to successfully commercialize and sell our products. We expect to derive most of our near-term product revenues from sales of our BCell-SC and CD8-DLI Cell Separation Systems. We began distributing these products through a distribution agreement with Gambro in late 2001 and, to date, we have sold relatively few devices. Because we currently depend on our BCell-SC and CD8-DLI Cell Separation Systems to generate substantially all of our near-term product revenue, if we fail to achieve widespread market acceptance of these products or if Gambro BCT fails to effectively market these products, we will not be able to grow our near-term product revenue.

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

Our ability to achieve profitability depends on our ability to develop, obtain regulatory approval for, manufacture, introduce and successfully market new products and product candidates, either directly or with our partners. Our 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 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. As a consequence, we are not sure whether any of our products under development or the products under development by our collaborators will be effective in treating any of the disorders we have targeted. 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 technological approach is not successful or the medical community and/or third-party payors do not accept our products as clinically useful, cost-effective and safe, then neither we nor our collaborators will be able to develop or commercialize these products, which will substantially impair our ability to achieve profitable operations.

If clinical trials of our products under development are not successful or are not completed on a timely basis, we will not be able to develop and commercialize these products and, therefore, we may not achieve profitability.

To obtain regulatory approvals for the commercial sale of our products under development, 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.

Prior to commencing new clinical trials, we must submit investigational new drug and/or investigational device exemption applications to the Food and Drug Administration. 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 an acceptable timeframe, if at all. How quickly we and our collaborative partners complete clinical trials is dependent in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. In particular, the patient population for a number of our potential products is small. If we experience delays in patient enrollment, we may incur additional costs and delay our research and development programs.

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

We are dependent on our collaborative partners to conduct clinical trials on our MEDI-507 and xenotransplantation products and, therefore, we are not in control of the timing of these clinical trials.

We are dependent upon MedImmune to conduct clinical trials with respect to MEDI-507 and will be dependent upon Novartis to conduct clinical trials for the development of xenotransplantation products, if any, that arise out of our joint venture's research program. We may become dependent upon other third parties to conduct future clinical trials of our AlloMune Systems and Eligix HDM Cell Separation Systems. As a result, we will have less control over these clinical trials than if we were conducting the trials directly. Consequently, these trials may not begin or be completed on a schedule that is acceptable to us, which could lead to delays or uncertainties in the regulatory approval process or in the commercial introduction of these products, either of which could substantially harm our business and ability to achieve profitability.

The approval process is costly and lengthy and we may not obtain and maintain the regulatory approvals required to successfully market and sell our products.

We must obtain regulatory approval for our ongoing research and development activities and before marketing or selling any of our products. For example, although our BCell-SC and CD8-DLI Cell Separation Systems have received CE Mark approval in Europe, we will need to conduct extensive clinical trials and receive FDA approval before we can market these products in the U.S. We may not receive regulatory approvals to conduct clinical trials of our products or to manufacture or market our products. 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 fail to comply with applicable regulatory requirements. If our products do not receive regulatory approvals, or if we 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 our approved products, the marketing, distribution and manufacture of these products 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 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 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 are dependent on collaborative relationships to develop, manufacture and sell some products, 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 have 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. Gambro has been granted the exclusive right to distribute these products worldwide, with the exception of the United States, Canada and Japan. 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 ability to achieve revenue under these arrangements will be heavily dependent on a number of factors, including the efforts and activities of our collaborative partners. Our arrangements with our collaborative partners allow them significant discretion in determining the efforts and resources that they will apply to the development, commercialization and sale of products based upon our technologies. If any of these collaborative partners do not perform successfully, such failure may delay or prevent regulatory approval, product launch, impair our ability to deliver products on a timely basis, impair our competitive position or otherwise reduce or eliminate any sales revenues that we may receive.

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

We have only limited sales, marketing and product distribution experience, and our current sales and marketing operations, which we only recently began to develop, is not sufficient to achieve the market presence and sales we need to expand our business. We plan to rely significantly on sales, marketing and distribution arrangements with third parties, including 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. Either we or Gambro may terminate the agreement if the other party breaches a material covenant, agreement or obligation under the agreement. If Gambro terminates the distribution agreement, we currently do not have 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 rights to develop and market products based upon our xenotransplantation technologies. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms which are favorable to us, if at all. In addition, 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.

We may seek to independently market products that are not already subject to marketing agreements with other parties. If we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- we may not be able to attract and build a significant and skilled marketing staff or sales force;
- the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

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 and CD8-DLI Cell Separation Systems in one manufacturing facility. We would likely experience significant delays or cessation in producing our BCell-SC and CD8-DLI 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.

We will depend on third-party manufacturers to produce some of our products under development, and if these third parties do not successfully manufacture our products our business will be harmed.

We currently rely upon MedImmune to produce material for preclinical and clinical testing of MEDI-507 and expect to continue to do so in the future. In addition, if we receive the necessary regulatory approvals for other products under development, we also expect to rely upon third parties, including our collaborative partners, to produce materials required for commercial production. We may not be able to enter into commercial-scale manufacturing contracts on a timely or commercially reasonable basis, if at all. To the extent that we enter into manufacturing arrangements with third parties, we will be dependent upon these third parties to perform their obligations in a timely and effective manner. If third-party manufacturers with whom we contract fail to perform their obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including:

- we may not be able to initiate or continue clinical trials of products that are under development;
- we may be delayed in submitting applications for regulatory approvals for our products; and
- we may not be able to meet commercial demands for any approved products.

If we or our third-party manufacturers fail to comply with regulatory requirements, we could experience disruptions in the manufacture and sale of our products.

Manufacturers, including us, must adhere to the FDA's current good manufacturing practices regulations, which are enforced by the FDA through its facilities inspection program. We and any of our third-party manufacturers may not be able to comply or maintain compliance with good

manufacturing practices regulations. If we or our manufacturers fail to comply with these regulations, our receipt of premarket approval and/or our ability to continue manufacturing our products could be significantly delayed, or we or the third-party manufacturer could be subject to FDA enforcement action. For a premarket approval device, if we change our manufacturing facility or switch to a third-party manufacturer we will be required to submit a premarket approval application supplement before the change is implemented. If we experience any regulatory-related manufacturing delays or difficulties, our ability to deliver products to our distributors or customers would be impaired, which could reduce our revenues and harm our business.

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.

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 may be necessary for the development and commercialization of our products. These licenses impose various commercialization, indemnification, royalty, insurance and other obligations on us. Although we currently meet the requirements imposed by the licenses, if we fail to comply with these requirements in the future, 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.

We face substantial competition, which could adversely affect our revenues and results of operations.

The products we develop and market 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 and CD8-DLI Cell Separation Systems, we 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 will face this and other forms of competition. Development by others may render our products or technologies obsolete or noncompetitive, and we 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 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 currently expect to derive substantially all of our near-term product revenue from the sale through a third-party distributor of our BCell-SC and CD8-DLI Cell Separation Systems in the European Union. 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 business exposes us to the risk of product liability claims for which we may not be adequately insured.

We face an inherent business risk of exposure to product liability claims in the event that the use of our products results in adverse effects during research, clinical development or commercial use. We cannot guarantee we will avoid significant product liability exposure. Our product liability insurance coverage is currently limited to $10.0 million, which may not be adequate to cover potential liability exposures. Moreover,

adequate insurance coverage may not be available at an acceptable cost, if at all. Any product liability claim would distract management's attention, impair market acceptance of our products and our reputation and harm our ability to achieve revenue from sales of the product.

Our inability to attract or retain key personnel could harm our business.

Our ability to develop our business depends in part upon our attracting and retaining qualified management and scientific personnel. The number of qualified personnel is limited and competition for such personnel is intense. We may not be able to continue to attract or retain qualified people. The loss of our key personnel or the failure to recruit additional key personnel could significantly impede attainment of our objectives and harm our financial condition and results of operations.

The uncertainty of pharmaceutical pricing and reimbursement may negatively impact our results of operations.

Our ability to successfully commercialize our products may depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. The pricing, availability of distribution channels and reimbursement status of newly approved healthcare products is highly uncertain and we cannot assure you that adequate third-party coverage will be available for us to maintain price levels sufficient for realization of an appropriate return on our investment in product development. In certain foreign markets, pricing or profitability of healthcare products is subject to government control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, an increasing emphasis on managed care in the U.S. has and will continue to increase the pressure on

pharmaceutical pricing. While we cannot predict whether any such legislative or regulatory proposals will be adopted or the effect such proposals or managed care efforts may have on our business, the announcement of such proposals or efforts could harm our ability to raise capital, and the adoption of such proposals or efforts could harm our results of operations. Further, to the extent that such proposals or efforts harm other pharmaceutical companies that are prospective corporate partners, our ability to establish corporate collaborations may be adversely affected. In addition, third-party payors are increasingly challenging the prices charged for medical products and services. We do not know whether our products and product candidates, if approved, will be considered cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive basis.

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 $1.87 in the quarter ended March 31, 1999 to 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.

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 18 months, 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. Accordingly, it is generally accepted that the United States is in a recession. 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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings: None

Item 2. Changes in Securities: None

Item 3. Defaults upon Senior Securities: None

Item 4. Submission of Matters to a Vote of Security Holders: None

Item 5. Other Information: None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a)

None

b)

The Company filed a Current Report on Form 8-K on April 18, 2002 to report, pursuant to Item 4, that on April 12, 2002 its Board of Directors took action to dismiss Arthur Andersen LLP as its independent auditors and to engage Ernst & Young LLP as its independent auditors for the fiscal year ended December 31, 2002.

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.

BIOTRANSPLANT INCORPORATED
(Registrant)

Date: May 15, 2002

By: /s/ RICHARD V. CAPASSO

Richard V. Capasso
Vice President, Finance and Treasurer
(Principal Financial and Accounting Officer)

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PART I. FINANCIAL INFORMATION