

INTRABIOTICS PHARMACEUTICALS INC /DE  
Form 10-Q  
November 08, 2001

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

***Form 10--Q***

ý Quarterly report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2001

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 0-29993

**INTRABIOTICS PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its charter)

DELAWARE

94-3200380

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(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

**1245 TERRA BELLA AVE., MT. VIEW, CA**

**94043**

(Address of principal executive offices)

(zip code)

**(650) 526-6800**

(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

No

There were 29,628,691 shares of the Company's Common Stock, par value \$.001, outstanding on October 31, 2001.

INTRABIOTICS PHARMACEUTICALS, INC.

FORM 10-Q

QUARTER ENDED SEPTEMBER 30, 2001

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## INTRABIOTICS PHARMACEUTICALS, INC.

## BALANCE SHEETS

(IN THOUSANDS)

	SEPTEMBER 30, 2001 (Unaudited)	DECEMBER 31, 2000 (Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 26,208	\$ 38,983
Restricted cash deposits	7,471	1,371
Short-term investments	7,500	45,711
Other current assets, primarily prepayments and deposits	5,830	10,101
Total current assets	47,009	96,166
Property and equipment, net	2,387	12,056
Other assets	43	66
Total assets	\$ 49,439	\$ 108,288
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 498	\$ 1,680
Accrued clinical costs	1,013	3,236
Accrued employee liabilities	552	625
Accrued restructuring charges	2,637	-
Deposits on sale of assets	951	-
Other accrued liabilities	1,493	854
Current financing obligations	4,375	3,629
Total current liabilities	11,519	10,024
Long-term financing obligations	5,469	8,309

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<b>Stockholders' equity:</b>			
Common stock		29	29
Additional paid-in capital		197,050	198,388
Deferred stock compensation		(6,249 )	(10,198 )
Accumulated other comprehensive income		(1 )	186
Accumulated deficit		(158,378 )	(98,450 )
<b>Total stockholders' equity</b>			
		32,451	89,955
<b>Total liabilities and stockholders' equity</b>			
	\$	49,439	\$ 108,288

See accompanying notes.

## INTRABIOTICS PHARMACEUTICALS, INC

## STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

(UNAUDITED)

	THREE MONTHS ENDED		THREE MONTHS ENDED	
	SEPTEMBER 30,		SEPTEMBER 30,	
	2001	2000	2001	2000
Operating expenses:				
Research and development	\$ 6,501	\$ 10,357	\$ 32,382	\$ 26,389
General and administrative	580	3,153	7,164	7,937
Restructuring and other charges	-	-	21,956	-
Total operating expenses	7,081	13,510	61,502	34,326
Operating loss	(7,081 )	(13,510 )	(61,502 )	(34,326 )
Interest income	531	1,805	2,528	4,139
Interest expense	(351 )	(120 )	(954 )	(358 )
Net loss	\$ (6,901 )	\$ (11,825 )	\$ (59,928 )	\$ (30,545 )
Basic and diluted net loss per share	\$ (0.23 )	\$ (0.41 )	\$ (2.04 )	\$ (1.50 )
Shares used to compute basic and diluted net loss per share	29,431	29,051	29,345	20,301
Pro forma basic and diluted net loss per share			\$	(1.15 )
Shares used to compute pro forma basic and diluted net loss per share				26,582

See accompanying notes.

## INTRABIOTICS PHARMACEUTICALS, INC.

## STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(UNAUDITED)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2001	2000
<b>Operating activities</b>		
Net loss	\$ (59,928 )	\$ (30,545 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,446	1,120
Amortization of deferred stock compensation	1,857	2,381
Write down of fixed assets	11,835	-
Fair value of warrants issued	560	-
Change in assets and liabilities		
Other assets	4,294	(8,198 )
Accounts payable	(1,182 )	188
Accrued clinical liabilities	(2,223 )	1,332
Accrued employee liabilities	(73 )	-
Accrued restructuring charges	2,637	-
Deposits on sale of assets	951	-
Other accrued liabilities	639	1,033
Amount payable to contract partner	-	(1,677 )
Net cash (used in) operating activities	(39,187 )	(34,366 )
<b>Investing activities</b>		
Capital expenditures	(3,612 )	(4,055 )
Purchase of short-term investments	(6,296 )	(51,098 )
Maturities of short-term investments	38,220	9,065
Net cash provided by / (used in) investing activities	28,312	(46,088 )
<b>Financing activities</b>		



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Proceeds from issuance of common stock	194		103,685
Proceeds from financing obligations	11,209		6,083
Payments on financing obligations	(13,303 )		(754 )
Net cash (used in) / provided by financing activities	(1,900 )		109,014
Net (decrease) / increase in cash and cash equivalents	(12,775 )		28,560
Cash and cash equivalents at beginning of period	38,983		18,862
Cash and cash equivalents at end of period	\$ 26,208	\$	47,422
Supplemental disclosure of cash flow information			
Interest paid	\$ 954	\$	302
Supplemental disclosure of non-cash information			
Conversion of preferred stock to common stock	\$ -	\$	79,609
Deferred compensation (termination)	\$ (2,092 )	\$	2,644

See accompanying notes.

INTRABIOTICS PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

Note 1. Basis of Presentation

The accompanying condensed financial statements are unaudited and have been prepared by the Company in accordance with the rules and regulations of the Securities and Exchange Commission for interim financial information, and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X.

Certain information and footnote disclosures normally included in the Company's annual audited financial statements (as required by generally accepted accounting principles) have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the Company's financial position as of September 30, 2001 and December 31, 2000, and the results of its operations and cash flows for the three and nine month periods ended September 30, 2001 and 2000.

The results of operations of the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2000, which are contained in the Company's Annual Report on Form 10-K, as amended, and filed with the Securities and Exchange Commission. The accompanying condensed Balance Sheet as of December 31, 2000 is derived from such audited financial statements.

Comprehensive loss is primarily comprised of net loss and net unrealized gains or losses on available-for-sale securities. There is no material difference between the reported net loss and the comprehensive loss for all periods presented.

Note 2. Lease Commitments and Equipment Financing Arrangements

The Company leases its facilities under operating lease agreements, which expire in July 2004 and April 2011. At September 30, 2001 and December 31, 2000, the Company had restricted cash of \$1,971,000 and \$1,371,000, respectively, in connection with these leases.

In December 2000, the Company entered into an equipment financing agreement to finance up to \$7.6 million of equipment. The interest rate varies according to U.S. Treasury rates. In December 2000, the Company completed two draws against this arrangement. The first draw was for \$3.8 million with a loan term of 36 months and an average annual interest rate of 9.98%. The second draw was for \$945,000 with a term of 48 months and an average annual interest rate of 9.64%. In March 2001, the Company completed a third draw for \$1.2 million with a loan term of 48 months and an average annual interest rate of 9.64%. The remaining balance available under this agreement of \$1.7 million expired on July 31, 2001.

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On August 20, 2001, the Company refinanced all of the existing financing obligations by entering into a new line of credit of \$2.5 million and term loan agreement of \$7.5 million. At September 30, 2001, the balance drawn on the line of credit was \$2.5 million, fully secured by a certificate of deposit. The term loan agreement was utilized and has a balance due of \$7.3 million as of September 30, 2001, secured by the assets of the Company. These financial obligations include various financial covenants, a performance covenant and various negative covenants.

Note 3. Cash, Cash Equivalents and Short-term Investments

The Company invests its excess cash in short-term money market funds and commercial paper. The following is a summary of the Company's cash, cash equivalents, restricted cash deposits and investments by major security type at their fair market value, which approximates carrying value based on quoted market values:

	<b>SEPTEMBER 30,</b>		<b>DECEMBER 31,</b>
	<b>2001</b>		<b>2000</b>
	<b>(IN THOUSANDS)</b>		
	<b>(UNAUDITED)</b>		
Operating cash	\$	3,204	\$ 723
Money market		23,004	38,260
Certificates of deposit - restricted cash		7,471	1,371
Commercial paper		7,500	45,711
	\$	41,179	\$ 86,065
Amounts included in cash and cash equivalents and restricted cash deposits	\$	33,679	\$ 40,354
Amounts included in short-term investments		7,500	45,711
	\$	41,179	\$ 86,065

The Company classifies all securities as either cash and cash equivalents or available for sale. The restricted cash of \$7.5 million consists of \$3.0 million pledged to PolyPeptide Laboratories, A/S for drug supply, \$2.5 million pledged as security on the line of credit and \$2.0 million pledged as security deposits on our leased facilities.

Note 4. Net Loss Per Common Share

Net loss per share has been computed according to Financial Accounting Standards Board Statement No. 128, Earnings Per Share ( SFAS 128 ), which requires disclosure of basic and diluted earnings per share. Basic and diluted earnings per share is calculated using the weighted-average number of shares of common stock outstanding during the period, less shares subject to repurchase. Diluted earnings per share include the impact of potentially dilutive securities. As the Company's potentially dilutive securities (convertible preferred stock, stock options, and warrants) were antidilutive for all periods, they were not included in the computation of weighted-average shares used in computing diluted net loss per share.

Pro forma net loss per share has been computed as described above and also gives effect to the conversion of convertible preferred shares not included above that automatically converted into common stock upon completion of the Company's initial public offering of common stock from the original date of issuance.

The following is a reconciliation of the numerator and denominator of basic and diluted net loss per share (in thousands, except per share amounts):

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30,		SEPTEMBER 30,	
	2001	2000	2001	2000
<b>(UNAUDITED)</b>				
Basic and diluted:				
Net loss	\$ (6,901 )	\$ (11,825 )	\$ (59,928 )	\$ (30,545 )
Weighted-average shares used in computing basic and diluted net loss per share				
	29,431	29,051	29,345	20,301
Basic and diluted net loss per share	\$ (0.23 )	\$ (0.41 )	\$ (2.04 )	\$ (1.50 )
Pro forma basic and diluted:				
Shares used above				20,301
Pro forma adjustment to reflect weighted-average effect of conversion of preferred stock from the date of issuance				6,281
Total weighted-average shares of common stock outstanding				26,582

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Pro forma basic and diluted net loss per share \$ (1.15 )

Note 5. Agreements

**On May 29, 2001, the Company amended its licensing and development agreement for its late stage ramoplanin program with Biosearch Italia, S.p.A. Under the terms of the agreement, IntraBiotics was reimbursed for ongoing clinical trial expenses during a three-month transition period ending August 31, 2001. At the end of this period, Biosearch assumed responsibility for the clinical development of ramoplanin oral powder at its own expense and retained worldwide rights to the product. In exchange for its clinical development expenses and efforts, IntraBiotics will receive a royalty on future net sales of ramoplanin oral in North America, if it is successfully developed.**

Furthermore, the agreement specifies that IntraBiotics retains its license to topical uses of ramoplanin unless certain clinical development milestones are not met. The agreement also allows for IntraBiotics to regain North American rights to the ramoplanin oral powder program under certain conditions and by paying certain fees to Biosearch Italia.

On May 29, 2001, the Company amended its licensing and development agreement for its late stage ramoplanin pr

On June 7, 2001, the Company terminated its research collaboration agreement with Cetek Corporation (Cetek). There were no charges associated with this termination agreement.

On June 21, 2001, the Company terminated its collaborative research and technology agreement with New Chemical Entities, Inc. (now Albany Molecular Research, Inc.) (AMRI). Under the terms of this termination agreement, IntraBiotics paid AMRI \$300,000.

On June 27, 2001, the Company entered into a binding term sheet related to termination of the discovery, development and license agreement with Diversa Corporation and on July 27, 2001, the Company entered into the final termination agreements. Under the terms of this termination agreement, IntraBiotics paid Diversa Corporation \$1,450,000 and will pay \$1,000,000 in the fourth quarter of 2001. In addition, the Company has issued warrants to purchase 700,000 shares of its common stock at an exercise price of \$2.00 per share, exercisable immediately for a period of four years.

On August 31, 2001, the Company's research collaboration agreement with BioSource Pharma Inc. (BioSource) was concluded. There were no charges to the Company associated with the expiration of this agreement.

#### **Note 6. Restructuring and other charges**

On May 31, 2001, the Company implemented a restructuring plan intended to conserve capital and help direct financial and human resources to the development of its lead product, iseganan HCl oral solution for the prevention of oral mucositis in cancer patients. IntraBiotics incurred restructuring charges of \$10.1 million and asset write down charges of \$11.8 million for a total of \$21.9 million in charges associated with its restructuring plan in the second quarter of 2001. As of September 30, 2001, the Company paid \$6.9 million of the restructuring costs, primarily in severance costs to approximately 90 employees, facilities consolidation costs and terminated collaboration agreements and expensed \$560,000 for warrants issued as part of a collaboration agreement termination. At September 30, 2001, approximately \$2.6 million remains in accrued restructuring charges.

The strategic restructuring included an immediate reduction in force of approximately 90 positions in research and administration, or 71% of our workforce on May 31, 2001, of 127 employees. All of those terminated employees left the Company by September 30, 2001. Following the restructuring, the Company retained approximately 33 full-time employees and several part-time employees or consultants largely focusing on drug development of iseganan HCl.

The restructuring also includes the termination of certain research and development collaborations and the consolidation of operations into one existing facility in Mountain View, California. The Company vacated three facilities in Mountain View, California with 142,000 square feet and continues to occupy one facility with 16,000 square feet.

On May 29, 2001, the Company amended its licensing and development agreement for its late stage ramoplanin pro

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The 2001 restructuring charges consist of the following (in thousands):

	<b>Costs for terminated employees</b>	<b>Facilities consolidation</b>	<b>Terminated collaboration agreements and other</b>	<b>Total</b>
Restructuring charges	\$ 2,911	\$ 3,150	\$ 4,060	\$ 10,121
Cash payments	(2,614 )	(1,821 )	(2,489 )	(6,924 )
Non-cash expenses	-	-	(560 )	(560 )
Accrued restructuring charges at September 30, 2001	\$ 297	\$ 1,329	\$ 1,011	\$ 2,637

Additionally, the Company wrote down to fair value, leasehold improvements, laboratory equipment, computers and other assets of \$11.8 million that are no longer being used as part of the restructuring plan.

**Note 7. Legal Proceedings**

On April 5, 2001, we commenced arbitration proceedings against Interactive Clinical Technologies, Inc. (ICTI) and Galen Holdings regarding the previously disclosed error in the drug dispensing for two of our Phase III clinical trials. We are seeking damages, including the full costs of one of the previous Phase III trials and partial costs of the second. On July 2, 2001, Galen Holdings sued IntraBiotics in the State of New Jersey Federal Court seeking an injunction barring the arbitration as to Galen. Galen is not seeking damages from IntraBiotics and the only issue raised by Galen's complaint is arbitrability. On September 25, 2001, ICTI filed a counter claim against IntraBiotics in the arbitration proceedings claiming unspecified damages due to breach of a confidentiality provision in the master agreement between ICTI and IntraBiotics based on the disclosure of ICTI's name in connection with the error. We expect both the arbitration and the associated litigation to be resolved in or before the first quarter of 2002.

On May 29, 2001, the Company amended its licensing and development agreement for its late stage ramoplanin pr



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

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements, which involve risks and uncertainties. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under RISKS RELATED TO OUR BUSINESS below. The following discussion should be read in conjunction with the financial statements and notes included elsewhere herein. Except as required by law, IntraBiotics disclaims any obligation to update any of the forward-looking statements contained in this report to reflect any future events or developments.*

**OVERVIEW**

IntraBiotics Pharmaceuticals, Inc. is developing new antibiotics, which address important unmet medical needs. We have focused our efforts and use of resources on our lead product, iseganan HCl oral solution for oral mucositis, which is in the third and final stage of human clinical testing prior to registration. A contractor's error damaged the first of two planned phase III trials, causing us to conduct a third phase III trial. As a consequence, IntraBiotics restructured its business to maximize the likelihood of success in registering this potential product. During the past quarter, we completed the majority of the restructuring effort and focused on iseganan HCl phase III trials for oral mucositis. We continue to delay our three phase II trials, iseganan HCl oral solution for prevention of ventilator-associated pneumonia, iseganan solution for inhalation for treatment of lung infections in patients with Cystic Fibrosis, and ramoplanin nasal for prevention of post-surgical staphylococcal infections, until additional capital resources become available.

On January 17, 2001, we announced our discovery of damage to the first phase III trial of iseganan HCl for prevention of oral mucositis in patients receiving chemotherapy. Oral mucositis is a potentially debilitating side effect of certain anti-cancer therapies resulting in infected ulcers in the mouth. The results were announced on May 14, 2001, after the trial was concluded, the final data analyzed, and the extent of damage assessed. The primary endpoint of ulceration did not achieve the statistical strength of evidence typically required for product registration ( $p=0.067$  compared to  $p<0.05$  for statistical significance). On May 31, 2001, IntraBiotics announced its plans to restructure its business as a result of the damage by a third party contractor's error.

Several other clinically meaningful endpoints did succeed with statistical significance (all with  $p<0.05$ ) in spite of the contractor's error in this trial. These endpoints include mouth pain, throat pain, difficulty swallowing and pain with swallowing, and the severity of stomatitis, or reduction in inflammation of the mouth. We then completed additional analyses of the results that indicate that the error caused the trial to underestimate the true benefit of iseganan HCl oral solution on each of these measures of oral pain, oral function and ulceration. Taken together, IntraBiotics believes that a repeat of the clinical trial has a high likelihood of demonstrating statistically significant results.

Based on our analysis of all of the end-points and the nature of the error, we chose to restructure our business to enable us to use our current capital resources and key personnel to conduct and complete another phase III trial in this chemotherapy patient population. This new trial is in addition to our ongoing and nearly fully enrolled trial in radiotherapy patients, in order to attempt to prove the efficacy and safety of the product. The next phase III trial in chemotherapy patients is expected to start in the fourth quarter of 2001 and conclude in the fourth quarter of 2002. The ongoing phase III trial in radiotherapy patients is expected to finish on schedule in the second quarter of 2002.

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We have also completed two earlier stage trials for other indications of the antibiotic iseganan HCl: the first to prevent pneumonia in patients using breathing assistance from a mechanical ventilator, a condition called ventilator-associated pneumonia (VAP) and the second, to treat respiratory infections in patients with Cystic Fibrosis (CF). We obtained data from a human clinical trial that tested for preliminary efficacy and safety, known as a phase IIa trial, for iseganan HCl oral solution in patients on ventilators. The results of this trial were presented in October 2001 at the European Society of Intensive Care Medicine and demonstrate the safety of iseganan HCl oral solution for this patient population. These data fully support the advancement of this program to the next stage of clinical testing.

We also obtained data from a human clinical trial that tested for preliminary safety, known as a phase I trial, for iseganan HCl solution for inhalation, (previously referred to as Protegrin IB-367 Aerosol), in patients with Cystic Fibrosis. The data from this trial was publicly presented at the North American meeting of the Cystic Foundation Society in October 2001 and support the advancement to the next stage of human clinical testing, phase II trial, for this product. We currently plan to obtain additional capital and human resources before proceeding to these next trials for either the VAP or the CF programs.

We amended our licensing and development agreement for our ramoplanin oral and ramoplanin topical programs with BioSearch Italia, S.p.A., (BioSearch) on May 29, 2001. The transfer of the clinical trials of ramoplanin oral powder for prevention of Vancomycin resistant enterococci (VRE) infections to BioSearch is complete. Under the terms of the new agreement, IntraBiotics will receive a royalty on future net sales on ramoplanin in North America, if it is successfully developed. In addition, the agreement specifies that IntraBiotics retain the rights to develop and commercialize ramoplanin for topical uses, including ramoplanin nasal, unless certain clinical development milestones are not met.

Since commencing operations in 1994, we have not generated any revenue from product sales, and we have funded our operations primarily from the proceeds of public and private placements of securities. We have incurred a loss in each year since inception, and we expect to incur substantial losses for at least the next several years. At September 30, 2001, our accumulated deficit was approximately \$158.4 million and our cash equivalents and short term investments balance was approximately \$41.2 million including restricted cash deposits of approximately \$7.5 million in connection with drug supply agreements, line of credit and standby letters of credit for leased facilities.

## RESULTS OF OPERATIONS

### *Three and nine month periods ended September 30, 2001 and 2000*

IntraBiotics had no product sales or contract revenue for the nine-month periods ended September 30, 2001 and September 30, 2000. The Company does not anticipate any product revenue in the near future.

On May 31, 2001, IntraBiotics announced that it would implement a restructuring plan intended to conserve capital and help direct financial and human resources to the development of its lead product, iseganan HCl oral solution for the prevention of oral mucositis in cancer patients. As a result, we incurred restructuring charges of \$10.1 million and asset write down charges of \$11.8 million for a total of \$21.9 million in the second quarter of 2001.

This \$10.1 million restructuring charge is for costs to be incurred in reducing our workforce, terminating collaboration agreements and downsizing facilities. In the nine months ended September 30, 2001, we paid \$6.9 million of the restructuring costs, primarily in severance costs, facilities consolidation costs and terminated collaboration agreements and expensed \$560,000 for warrants issued as part of a collaboration agreement termination. At September 30, 2001, approximately \$2.6 million remains in accrued restructuring charges.

The strategic restructuring included a reduction in force of approximately 90 positions in research and administration, or 71% of our workforce on May 31, 2001 of 127 employees. All of the terminated employees left the Company by September 30, 2001. Following the restructuring, we have retained approximately 33 full-time employees largely focusing on drug development of iseganan HCl.

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The restructuring also includes the termination of certain research and development collaborations and the consolidation of operations into one existing facility in Mountain View, California. We have vacated three facilities in Mountain View, California with 142,000 square feet and we continue to occupy one facility with 16,000 square feet.

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Additionally, we wrote down to fair value, \$11.8 million of leasehold improvements, laboratory equipment, computers and other assets that are no longer being used by us as part of the restructuring plan.

As a result of implementing our restructuring plan, we anticipate significantly lower total operating expenses in the range of \$6.0 million to \$10.0 million for the remaining quarter of 2001 as compared to \$13.5 million in the three months ended September 30, 2000.

Research and development expenses decreased to \$6.5 million in the three-month period ended September 30, 2001 from \$10.4 million for the same period in 2000, primarily as a result of our deliberate delay in commencing certain additional clinical trial work. Research and development expenses increased to \$32.4 million in the nine-month period ended September 30, 2001 from \$26.4 million for the same period in 2000. The increase for the nine-month period was attributable to higher personnel and payroll expenses, technology access fees, clinical trial activity, facilities and consulting expenses prior to the implementation of the restructuring plan.

General and administrative expenses decreased to \$600,000 and \$7.2 million in the three and nine-month periods ended September 30, 2001 from \$3.2 million and \$7.9 million for the same periods in 2000. The decrease was primarily attributed to decreased personnel and payroll expenses, consulting, legal, travel and other expenses associated with decreased business development activities.

In connection with the grant of certain stock options to employees, we recorded no deferred compensation in the three and nine-month period ended September 30, 2001 compared to none in the three-month period ended September 30, 2000 and \$2.6 million in the nine-month period ended September 30, 2000. Deferred compensation represents the difference between the deemed fair value of the common stock for financial reporting purposes and the exercise price of these options at the date of grant. Deferred compensation is presented as a reduction of stockholders equity and is amortized over the vesting period of the applicable options. In the three and nine-month periods ended September 30, 2001, there was a reduction in deferred compensation of \$1.7 million and \$2.1 million due to employee terminations.

We expensed \$537,000 and \$1.9 million of deferred compensation during the three and nine-month periods ended September 30, 2001, compared to \$794,000 and \$2.4 million of deferred compensation for the same periods in 2000. The decrease in deferred compensation expense was due to the cancellation of options for terminated employees. These amounts were expensed to research and development and to general and administrative expense based on the deferred compensation liability attributed to each department. The research and development deferred compensation amortization expense in the three and nine-month periods ended September 30, 2001 was \$311,000 and \$1.1 million, down from \$460,000 and \$1.4 million for the same periods in 2000. The general and administrative deferred compensation amortization expense in the three and nine-month periods ended September 30, 2001 was \$226,000 and \$782,000, down from \$334,000 and \$1.0 million for the same periods in 2000. We expect that deferred compensation expense will decrease in the future as a result of our reduction in workforce.

Interest income decreased to \$531,000 and \$2.5 million in the three and nine-month periods ended September 30, 2001 from \$1.8 million and \$4.1 million for the same periods in 2000. The decrease in interest income resulted from the decrease in average cash and investment balances. Interest expense increased to \$351,000 and \$954,000 for the three and nine-month periods ended September 30, 2001 from \$120,000 and \$358,000 for the same periods in 2000. The increase was primarily attributed to additional equipment financing obligations, lines of credit and the term loan.

### **LIQUIDITY AND CAPITAL RESOURCES**

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At September 30, 2001, we had cash, cash equivalents and short-term investments of \$41.2 million including restricted cash deposits of approximately \$7.5 million in connection with standby letters of credit for leased facilities, security deposit on the line of credit and drug supply agreements. The Company regularly invests excess funds in short-term money market funds and commercial paper.

Net cash used in operating activities for the nine-month periods ended September 30, 2001 and 2000 was \$39.2 million and \$34.4 million, respectively. Cash used in operating activities in the nine-month period ended September 30, 2001 was primarily the result of net losses decreases in accounts payables and decreases in accrued clinical liabilities offset by the write-off of assets and accrued liabilities associated with the Company's restructuring plan, decreases to other assets primarily prepaid expenses for clinical trials and decreases to interest receivable, an increase to deposits received for the sale of assets, and increases to other liabilities, primarily deferred rent in connection with our facilities leases. Cash used in operating activities in the nine-month period ended September 30, 2000 was primarily the result of net losses after adjustments to reconcile net losses to net cash, increased prepaid expenses primarily for clinical trials, and decreases in amounts payable to our contract partner offset by increases in accrued liabilities, increases in accrued clinical liabilities.

Net cash provided by investing activities for the nine-month period ended September 30, 2001 was \$28.3 million. Net cash used in investing activities for the nine-month period ended September 30, 2000 was \$46.1 million. Cash provided by investing activities in the nine-month period ended September 30, 2001 was due to the maturities of short-term investments of \$38.2 million partially offset by the purchase of short term investments of \$6.3 million and capital expenditures of \$3.6 million. Cash used in investing activities in the nine-month period ended September 30, 2000 was due to the purchase of short term investments of \$51.1 million and capital expenditures of \$4.1 million, offset by maturities of short-term investments of \$9.1 million.

Net cash used in financing activities for the nine-month period ended September 30, 2001 was \$1.9 million. Net cash provided by financing activities for the nine-month period ended September 30, 2000 was \$109.0 million. Cash used in financing activities for the nine-month period ended September 30, 2001 was due to payments on financing obligations of \$13.3 million partially offset by \$11.2 million in additional financing obligations and \$194,000 from the issuance of common stock. Cash provided by financing activities for the nine-month period ended September 30, 2000, was due to net proceeds from the issuance of common stock of \$103.7 million primarily from the initial public offering, and proceeds of \$6.1 million from financing obligations partially offset by payments of \$754,000 on financing obligations.

We expect to continue to incur substantial operating losses. We believe that existing capital resources and interest income will be sufficient to fund our operations for at least the next 12 months.

Our future capital requirements will depend on many factors, including:

- the timing, cost, extent and results of clinical trials;
- payments to third parties for manufacturing scale up;
- the costs and timing of regulatory approvals;
- the costs of acquiring technologies or assets that compliment our business;

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- the costs of establishing sales, marketing and distribution capabilities;
- the progress of our research and development activities;
- availability of technology in-licensing opportunities; and
- future opportunities for raising capital.

Until we can generate sufficient cash from our operations, which we do not anticipate in the foreseeable future, we will need to finance future cash needs through private and public financings, including equity financings. We cannot be certain that additional funding will be available when needed or on favorable terms. If funding is not available, we may need to delay or curtail our development and commercialization activities to a significant extent.



## **RISKS RELATED TO OUR BUSINESS**

*Our business faces significant risks and the risks described below may not be the only risks we face. Additional risks that we do not know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition, or results of operations could be materially adversely affected and the trading price of our common stock could decline.*

### **If we are unable to successfully complete our phase III trials for iseganan HCl, we may be unable to continue operations.**

We are focusing our human and capital resources on one product candidate, iseganan HCl, in late stages of development. If we are unable to successfully complete our current and planned phase III clinical trials for this product on time or at all, we may be unable to register the product with the FDA, commercialize the product, or continue operations. If we are unable to retain our key employees we may have to delay our clinical trials. Also, our current cash resources may not be adequate to complete all of the clinical trials necessary for product registration with the FDA.

### **We expect to continue to incur future operating losses and may never achieve profitability.**

We have never generated revenue from product sales and have incurred significant net losses in each year since inception. We incurred net losses of \$23.1 million in 1999, \$45.6 million in 2000 and \$59.9 million in the nine-months ended September 30, 2001. Our accumulated deficit was approximately \$158.4 million as of September 30, 2001. We expect to continue to incur substantial additional losses for the foreseeable future primarily as a result of our clinical trial expense costs, and we may never become profitable. In addition, we will continue to have expenses for development costs to commercialize iseganan HCl oral solution. To date, we have financed our operations primarily through the private sale of equity securities, funds received from a terminated collaboration agreement, the proceeds of equipment financing arrangements and our initial public offering of common stock in March 2000. We will receive product revenues only if we complete clinical trials with respect to one or more products, receive regulatory approvals and successfully commercialize such products.

### **We may be forced to raise capital sooner than currently anticipated and if we fail to obtain the capital necessary to fund our operations, we will be unable to develop our drug candidates and may have to cease operations.**

We believe that our current cash, cash equivalents and restricted cash deposits of approximately \$33.7 million, short-term investments of approximately \$7.5 million and interest income are sufficient to meet our operating and capital requirements for at least the next 12 months. However, we have based this estimate on assumptions that may prove to be wrong. For the nine months ended September 30, 2001 and the years ended December 31, 2000, 1999 and 1998, net cash used for operating activities was \$39.2 million, \$50.4 million, \$25.1 million and \$9.3 million, respectively. Our future liquidity and capital requirements will depend on many factors, including the timing, cost, extent and results of clinical trials, payments associated with manufacturing scale-up, the costs and timing of regulatory approvals, costs associated with researching drug candidates, securing in-licensing opportunities and conducting pre-clinical research.

Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Collaborative arrangements may require us to relinquish our rights to certain of our technologies, drug candidates or marketing territories. We believe that additional financing may be required in the future to fund our operations. We do not know whether additional financing will be

available when needed or on acceptable terms, if at all. If we are unable to raise additional financing when necessary, we may have to delay some or all of our product development efforts or be forced to cease operations.

**We depend on the outcome of our clinical trials and if they are unsuccessful, we may not be able to commercialize our products and generate product revenue.**

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through preclinical research and clinical trials that our drug candidates are safe and effective for use in humans. We currently have one drug candidate in phase III clinical trials, iseganan HCl oral solution. If this drug candidate fails to establish safety and efficacy in phase III clinical trials, we would be unable to obtain regulatory approval from the FDA or to commercialize the drug candidate, and we will be unable to generate product revenue from that candidate. Clinical trials are expensive and time-consuming to conduct, and the outcome of these trials is uncertain. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. A number of companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

In addition, if we have delays in clinical trials or the FDA approval process or if we need to perform more or larger clinical trials, our product development costs will increase and our ability to generate product revenue will be delayed.

Our commencement and completion of clinical trials may be delayed by many factors, including:

- slower than expected rate of patient recruitment;
- inability to adequately obtain data about patients after their treatment;
- additional regulatory requests;
- inability to manufacture sufficient quantities of materials used for clinical trials; or
- unforeseen safety issues.

**If our collaborative partners assisting in our clinical trials fail to appropriately manage our clinical trials, the trials could be delayed or could fail.**

We have limited experience in conducting and managing clinical trials. We rely on several contract research organizations, including PharmaNet, Inc., to assist us in managing and monitoring our clinical trials. The FDA may inspect some of our clinical investigational sites, our collaborative partner's records and our facility and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that the trials were not in compliance, we may be required to repeat the clinical trials. If our contract research organizations fail to perform under our agreements with them, we may face delays in completing our clinical trials or failure of our clinical program.

**If our single-source third party manufacturers fail to produce clinical or commercial quantities of our drug candidate, we may not have sufficient quantities of our drug candidate to meet demand.**

We rely on PolyPeptide to manufacture iseganan HCl on a commercial scale. While we maintain a limited inventory of iseganan HCl, we depend on this single-source contract manufacturer to produce our product for use in our clinical trials. Our contract manufacturer has limited experience in manufacturing iseganan HCl in quantities sufficient for commercialization and may have difficulty in scaling up production. If our contract manufacturer is unable or fails to produce the required quantities of iseganan HCl for clinical use or commercial sale on a timely basis, at commercially reasonable prices and with sufficient purity, we will not have sufficient quantities of iseganan HCl to complete current and future clinical trials, or to meet commercial demand. In addition, we intend to contract with third parties for the manufacture of the final formulation. We cannot guarantee that we will be able to contract with a reliable manufacturer on commercially reasonable terms.

Our third-party manufacturer and we are required to register manufacturing facilities with the FDA and foreign regulatory authorities. If these facilities become unavailable for any reason or if our contract manufacturer fail to comply with the FDA's current good manufacturing practices or if our contract manufacturer terminates their agreements with us, we would have to find an alternative source for manufacturing our drug candidates. There are, on a worldwide basis, a limited number of contract facilities in which our drug candidates can be produced according to current good manufacturing practice regulations. In addition, the manufacturing processes for iseganan HCl is extremely complex and proprietary. If we are unable to continue having iseganan HCl manufactured by our current contract manufacturer, we do not know if we could engage another contract manufacturer when needed or on acceptable terms, if at all.

**If we fail to obtain FDA approvals for our products, we will be unable to commercialize our drug candidates.**

We do not have a drug candidate approved for sale in the United States or any foreign market. We must obtain approval from the FDA in order to sell our drug candidates in the United States and from foreign regulatory authorities in order to sell our drug candidates in other countries. We must successfully complete our phase III clinical trials and demonstrate manufacturing capability before we can file with the FDA for approval to sell our products. The FDA could require us to repeat clinical trials as part of the regulatory review process. In addition, the FDA may require a review of our new drug application by an advisory panel, which may request additional information. Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of our drug candidate;

- diminish our competitive advantage; and

- defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive preclinical and clinical data and supporting information must be submitted to the FDA for each indication to establish safety and effectiveness in order to secure FDA approval. We have limited experience in obtaining such approvals, and cannot be certain when, if ever, we will receive these regulatory approvals.

In addition to initial regulatory approval, our drug candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation. Any approvals, once obtained, may be withdrawn if compliance with regulatory requirements is not maintained or safety problems are identified. Failure to comply with these requirements may subject us to stringent penalties.

**Development and commercialization of competitive products could reduce or prevent sales of our products and reduce revenue.**

We may be unable to compete successfully in the marketplace if other companies develop and commercialize competitive products that are less expensive, more effective, have fewer side effects or are easier to administer than our drug candidates. If we are unable to compete successfully with our drug candidates, physicians may not recommend and patients may not buy our drugs, which would cause our product revenue to decline.

There are several drugs commercially available or under development that might compete with iseganan HCl oral solution. For oral mucositis, there is one approved device, Radiacare®, and several drugs in early stage clinical trials. These include growth factors such as keratinocyte growth factors I and II, G-CSF and interleukin-11, as well as several small molecular entities including Ethyol®, amlexanox and glutamine. The companies sponsoring these trials have successfully commercialized products in the past. In addition, there may be products under development, which we are unaware for the treatment of oral mucositis.

Many of our competitors and related private and public research and academic institutions have substantially greater experience, financial resources and larger research and development staffs than we do. In addition, many of these competitors, either alone or together with their collaborative partners, have significantly greater experience than we do in developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We also compete with these organizations and other companies for in-licensing opportunities for future drug candidates, and for attracting scientific and management personnel.

**If we are unable to adequately protect our intellectual property, we may be unable to sell our products or to compete effectively.**

We rely on a combination of patents, trade secrets and contractual provisions to protect our intellectual property. If we fail to adequately protect our intellectual property, other companies or individuals may prevent us from selling our products or may develop competing products based on our technology. Our success depends in 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.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We try to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. For example, we own or have rights to seven patents and two pending patent applications in the U.S. However, the patent position of biopharmaceutical companies involves complex legal and factual questions. We cannot predict the enforceability or scope of any issued patents or those that may issue in the future. Patents, if issued, may be challenged, invalidated or circumvented. Consequently, if any patents that we own or license from third parties do not provide sufficient protection, our competitive position would be weakened. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. In addition, we may not be issued patents for our pending patent applications, those we may file in the future, or those we may license from third parties.

In addition to patents, we rely on trade secrets and proprietary know-how. Our contract manufacturer performs the manufacturing processes covered by these trade secrets. Accordingly, our contract manufacturer and we must maintain confidentiality. We have confidentiality and proprietary information agreements with our contract manufacturer and with our employees. These agreements may not provide meaningful protection or adequate remedies for our technology in the event of unauthorized use or disclosure of confidential and proprietary information.

**We may be subject to intellectual property litigation that could be costly and time-consuming.**

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. Although we are not currently a party to any intellectual property lawsuits, third parties may assert infringement or other intellectual property claims against us. We may have to pay substantial damages, including treble damages, for past infringement if it is ultimately determined that our products infringe a third party's proprietary rights. The defense and prosecution of intellectual property suits, U.S. Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the United States and internationally are costly and time-consuming to pursue and their outcome is uncertain. If we become involved in any of these proceedings, we will incur substantial expense and the efforts of our technical and management personnel will be significantly diverted. An adverse determination may result in the invalidation of our patents, subject us to significant liabilities or require us to seek licenses that may not be available from third parties on satisfactory terms, or at all. Our stock price could decline based on any public announcements related to litigation or interference proceedings initiated or threatened against us.



**If physicians and patients do not accept our products, we may be unable to generate significant revenue, if any.**

Our drug candidates may not gain market acceptance among physicians, patients and the medical community. If any of our drug candidates fail to achieve market acceptance, we may be unable to successfully market and sell the product, which would limit our ability to generate revenue. The degree of market acceptance of any drug candidate depends on a number of factors, including:

- demonstration of clinical efficacy and safety;
- cost-effectiveness;
- convenience and ease of administration;
- potential advantage over alternative treatment methods; and
- marketing and distribution support.

Currently, we have one drug candidate in phase III clinical trials and do not have any drug candidate approved by the FDA. Physicians will not recommend our products until such time as clinical data or other factors demonstrate the safety and efficacy of our drugs as compared to other treatments. In practice, competitors may be more effective in marketing their drugs. Even if the clinical safety and efficacy of our antibiotic products is established, physicians may elect not to recommend products. For example, physicians may be reluctant to prescribe widespread use of our products because of concern about developing bacterial strains that are resistant to our drugs.

**If we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to perform these services, we will be unable to commercialize our drug product.**

We do not currently have marketing, sales or distribution capabilities. Initially we intend to establish a direct marketing and sales force in the United States and Canada. If we fail to establish successful marketing and sales capabilities or fail to enter successful marketing arrangements with third parties, we would be unable to commercialize our drug product. We must develop a marketing and sales force with technical expertise and distribution capabilities to market our product directly. We intend to enter into arrangements with third parties to market and sell most of our products outside of the United States and Canada. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will be lower than if we marketed the products directly.

**The failure to recruit and retain key personnel may delay our ability to complete, develop and commercialize iseganan HCl oral solution.**

We are highly dependent on our management and technical staff. Competition for personnel is intense. If we lose the services of any of our senior management, we may be delayed in our product development and commercialization efforts. We do not maintain key person life insurance and do not have employment agreements with our management and technical staff. In order to pursue product development, marketing and commercialization plans, we may need to hire additional qualified scientific personnel. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

In addition, we rely on consultants to assist us in formulating our research and clinical development strategy. All of our consultants are employed by other entities. They may have commitments to, or relationships with, other entities that may limit their availability to us. The loss of the services of these personnel may delay our research and development efforts.

**Directors, executive officers, principal stockholders and affiliated entities own a significant portion of our capital stock and will have substantial control over our activities.**

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 51% of our outstanding common stock. These stockholders, if acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions.

**Antitakeover provisions in our charter documents and under Delaware law may make an acquisition of us more difficult.**

Provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders.

These provisions:

- provide for a classified board of directors of which approximately one third of the directors will be elected each year;
- allow the authorized number of directors to be changed only by resolution of the board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for nominations to the board of directors or for proposals that can be acted on at stockholder meetings; and
- limit who may call stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit large stockholders from consummating a merger with, or acquisition of us. These provisions may prevent a merger or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

**Our stock price may be volatile, and the value of your investment may decline.**

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The market prices for securities of biotechnology companies in general have been highly volatile and our stock may be subject to volatility. The following factors, in addition to the other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights;
- publicity regarding actual or perceived changes in program timelines or results obtained in our clinical trials;
- publicity regarding actual or perceived adverse events in our clinical trials or relating to products under development by our competitors;
- regulatory developments in the United States or foreign countries;
- litigation;
- significant short selling in our common stock;
- economic and other external factors; and
- period-to-period fluctuations in our financial results and changes in analysts' recommendations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE REGARDING MARKET RISK

The primary objective of our investment activities is to preserve our capital until it is required to fund operations at the same time maximizing the income we receive from our investments without significantly increasing risk. We own financial instruments that are sensitive to market risks as part of our investment portfolio. To minimize this risk, we maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including money market funds and commercial paper. The average maturity of all our investments in the nine months ended September 30, 2001 was less than one year. Due to the short-term nature of these investments, a 50 basis point movement in market interest rates would not have a material impact on the fair value of our portfolio as of September 30, 2001 and the fiscal years December 31, 2000 and 1999. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On April 5, 2001, we commenced arbitration proceedings against Interactive Clinical Technologies, Inc. (ICTI) and Galen Holdings regarding the previously disclosed error in the drug dispensing for two of our Phase III clinical trials. We are seeking damages, including the full costs of one of the previous Phase III trials and partial costs of the second. On July 2, 2001, Galen Holdings sued IntraBiotics in the State of New Jersey Federal Court seeking an injunction barring the arbitration as to Galen. Galen is not seeking damages from IntraBiotics and the only issue raised by Galen's complaint is arbitrability. On September 25, 2001, ICTI filed a counter claim against IntraBiotics in the arbitration proceedings claiming unspecified damages due to breach of a confidentiality provision in the master agreement between ICTI and IntraBiotics based on the disclosure of ICTI's name in connection with the error. We expect both the arbitration and the associated litigation to be resolved in or before the first quarter of 2002.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Our Registration Statement on Form S-1 filed pursuant to the Securities Act of 1933 (No. 333-95461) was declared effective on March 27, 2000. The net offering proceeds to us after all expenses was approximately \$103.3 million. From the effective date of the registration statement through September 30, 2001, \$33.1 million of the net proceeds have been used for our clinical trials, \$6.3 million for the development and scale up of manufacturing processes by our contract manufacturers, \$26.3 million for research and development, \$22.0 million for restructuring charges and \$16.5 million for working capital and other general purposes.

On July 27, 2001, we issued to Diversa Corporation a warrant to purchase up to 700,000 shares of our common stock at an exercise price of \$2.00 per share in connection with the termination of the Discovery, Development and License Agreement with Diversa. The sale and issuance of the warrant was made in reliance on Section 4(2) of the Securities Act of 1933 as a transaction not involving a public offering.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) List of Exhibits

None

(b) Reports on Form 8-K

The Company did not file a report on Form 8-K during the quarter ended September 30, 2001.

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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.

IntraBiotics Pharmaceuticals, Inc.

November 8, 2001 /S/ Kenneth J. Kelley  
Kenneth J. Kelley  
Chairman of the Board,  
President and Chief Executive Officer

November 8, 2001 /S/ Gary S. Titus  
Gary S. Titus  
Senior Director, Finance  
(Chief Accounting Officer)