

INTRABIOTICS PHARMACEUTICALS INC /DE
Form 10-Q
May 15, 2002

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 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 0-29993

INTRABIOTICS PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of incorporation or organization)

94-3200380

(I.R.S. Employer Identification Number)

1245 TERRA BELLA AVENUE
MOUNTAIN VIEW, CA 94043
(Address of principal executive offices)

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

(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 37,539,029 shares of the Company's Common Stock, par value \$.001, outstanding as of May 10, 2002.

INTRABIOTICS PHARMACEUTICALS, INC.

FORM 10-Q

QUARTER ENDED MARCH 31, 2002

TABLE OF CONTENTS

PART I.	FINANCIAL INFORMATION
<u>Item 1.</u>	<u>Financial Statements</u> (unaudited) <u>Condensed Balance Sheets as of March 31, 2002 and December 31, 2001</u> <u>Condensed Statements of Operations for the Three -Month Periods Ended March 31, 2002 and March 31, 2001</u> <u>Statements of Cash Flows for the Three -Months Periods Ended March 31, 2002 and March 31, 2001</u> <u>Notes to Condensed Financial Statements</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosure About Market Risk</u>
PART II	<u>OTHER INFORMATION</u>
<u>Item 2.</u>	<u>Changes in Securities and Use of Proceeds</u>
<u>Item 6.</u>	<u>Exhibits and Reports on Form 8-K</u>
<u>SIGNATURES</u>	

Part I. Financial Information

Item I. Financial Statements

INTRABIOTICS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	MARCH 31, 2002 (Unaudited)	DECEMBER 31, 2001 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,226	\$ 27,982
Restricted cash deposits	7,488	7,488
Other current assets, primarily prepayments and deposits	4,502	5,412
Total current assets	50,216	40,882
Property and equipment, net	1,347	1,540
Other assets	43	43
Total assets	\$ 51,606	\$ 42,465
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 68	\$ 339
Accrued clinical costs	2,525	1,663
Accrued employee liabilities	260	579
Accrued restructuring charges	2,273	2,861
Deferred rent	697	618
Other accrued liabilities	571	818
Current financing obligations	4,375	4,375
Total current liabilities	10,769	11,253
Long-term financing obligations	4,531	5,000
Stockholders' equity:		
Common stock	36	30
Additional paid-in capital	211,032	196,575
Deferred stock compensation	(4,066)	(4,577)
Accumulated deficit	(170,696)	(165,816)
Total stockholders' equity	36,306	26,212
Total liabilities and stockholders' equity	\$ 51,606	\$ 42,465

See accompanying notes.

INTRABIOTICS PHARMACEUTICALS, INC
 CONDENSED STATEMENTS OF OPERATIONS
 (IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,		
	2002		2001
Operating expenses:			
Research and development	\$ 7,041	\$	15,524
Arbitration settlement	(3,600)		
General and administrative	1,460		4,108
Restructuring and other charges	91		
Total operating expenses	4,992		19,632
Operating loss	(4,992)		(19,632)
Interest income	265		1,227
Interest expense	(153)		(308)
Net loss	\$ (4,880)	\$	(18,713)
Basic and diluted net loss per share	\$ (0.14)	\$	(0.64)
Shares used to compute basic and diluted net loss per share	33,782		29,260

See accompanying notes.

INTRABIOTICS PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2002	2001
Operating activities		
Net loss	\$ (4,880)	\$ (18,713)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred stock compensation	488	649
Depreciation and amortization	193	462
Stock compensation expense	140	
Change in assets and liabilities		
Other current assets	910	(292)
Accounts payable	(271)	390
Accrued clinical costs	862	820
Accrued employee liabilities	(319)	366
Accrued restructuring charges	(588)	
Deferred rent	79	
Other accrued liabilities	(247)	167
Net cash used in operating activities	(3,633)	(16,151)
Investing activities		
Capital expenditures		(3,370)
Maturities of short-term investments		22,130
Net cash provided by investing activities		18,760
Financing activities		
Proceeds from issuance of common stock, net of issuance cost	14,346	30
Proceeds from financing obligations		1,209
Payments on financing obligations	(469)	(909)
Net cash provided by financing activities	13,877	330
Net increase in cash and cash equivalents	10,244	2,939
Cash and cash equivalents at beginning of period	27,982	38,983

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

Cash and cash equivalents at end of period	\$	38,226	\$	41,922
Supplemental disclosure of cash flow information				
Interest paid	\$	153	\$	308
Supplemental disclosure of non-cash information				
Deferred compensation (termination)	\$	(23)	\$	(183)

See accompanying notes.

INTRABIOTICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED 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 March 31, 2002 and December 31, 2001, and the results of its operations and cash flows for the three -month periods ended March 31, 2002 and 2001.

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, 2001, which are contained in the Company's Annual Report on Form 10-K, and filed with the Securities and Exchange Commission. The accompanying condensed Balance Sheet as of December 31, 2001 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 March 31, 2002 and December 31, 2001, the Company has restricted cash of \$2.0 million in connection with these leases.

Note 3 Net Loss Per Common Share

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

Net loss per share has been computed according to Financial Accounting Standards Board Statement No. 128, Earnings Per Share, 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 (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.

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 MARCH 31,		2001
	2002	(UNAUDITED)	
Basic and diluted:			
Net loss	\$	(4,880)	\$ (18,713)
Weighted-average shares used in computing basic and diluted net loss per share			
		33,782	29,260
Basic and diluted net loss per share	\$	(0.14)	\$ (0.64)

Note 4. 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 reduction in incidence and severity of oral mucositis in cancer patients. The Company recorded restructuring charges of approximately \$10.1 million and asset write down charges of approximately \$11.8 million, for a total of approximately \$21.9 million in charges associated with its restructuring plan in the second quarter of 2001. The \$10.1 million restructuring charge was for costs incurred in work force reduction, the termination of collaboration agreements and facilities consolidation.

The strategic restructuring included a reduction in force of approximately 90 positions in research and administration, or 71% of the Company's previous workforce of 127 employees. All of the terminated employees have left the Company as of December 31, 2001. During the quarter ended March 31, 2002, the Company received a refund of approximately \$75,000 for workman's compensation related to the terminated employees. No remaining severance amounts are payable as of March 31, 2002.

The restructuring also includes the terminations of certain research and development collaborations and the consolidation of operations into one existing facility in Mountain View, California. The estimated costs associated with terminated collaboration agreements were increased by \$166,000 in the quarter ended March 31, 2002. There is \$150,000 remaining payable for such agreements and costs.

The Company vacated three facilities in Mountain View, California comprising 142,000 square feet and continues to occupy one facility with 16,000 square feet. One of the vacated facilities has been sub-leased during 2001, and another was taken back by the landlord, with no continuing obligation to the Company. At March 31, 2002, \$2,123,000 remains in accrued restructuring charges related to this facility, representing nine months of rent and expenses associated with the lease on the facility, based on the Company's best estimate of the period for which the facility will remain vacant prior to sub-lease. The Company expects to incur the remaining restructuring obligation over the next nine months.

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

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

	Costs for Terminated Employees	Facilities Consolidations	Terminated collaboration agreements and other	Total
Accrued restructuring charges at December 31, 2001	\$	\$ 2,861	\$	\$ 2,861
Activity for the quarter ended March 31, 2002:				
Cash refunds (payments)	75	(738)	(16)	(679)
Adjustment to reflect revised estimates	(75)		166	91
Accrued restructuring charges at March 31, 2002	\$	\$ 2,123	\$ 150	\$ 2,273

Note 5. Stockholders Equity

On February 1, 2002, the Company sold 5,900,000 shares of common stock in a private placement resulting in net proceeds of approximately \$13.9 million.

Note 6. Arbitration Settlement

The arbitration between IntraBiotics and the contract vendor relating to a drug dispensing error in iseganan HCl oral solution phase III clinical trials was resolved amicably in January 2002. The Company received \$3.6 million in the settlement.

Note 7. Subsequent Events

In April 2002, the Company acquired Apothogen, Inc. for 450,000 shares of its common stock. Concurrently with the closing of the merger, Ernest Mario, Ph.D. joined the Company as Chairman and Chief Executive Officer and purchased \$5,000,000 of newly issued shares of our common stock in a private placement at a purchase price per share equal to the closing bid price as reported on the Nasdaq National Market on April 23, 2002.

In April 2002, the Company modified its loan agreement with Silicon Valley Bank (SVB). Modifications to the original agreement dated August 2001 included changes to the covenants.

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, uncertainties and assumptions. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those set forth under RISK RELATED TO OUR BUSINESS below. The following discussion should be read in conjunction with the financial statements and notes included elsewhere herein and the Company's 2001 audited financial statements and notes thereto included in its 2001 Annual Report on Form 10-K. All forward looking statements included in this document are based on information available to us on the date of this document, and except as required by law, IntraBiotics assume no obligation to update any of the forward-looking statements contained in this report to reflect any future events or developments.

Overview

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

IntraBiotics Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing and commercializing high-value anti-infectives and oncology therapeutics. We have initiated expanded human clinical trials to test for efficacy and safety, known as phase III trials, for iseganan HCl oral solution, for the reduction in the incidence and severity of ulcerative oral mucositis, a side effect of anti-cancer therapies.

The top-line results of our 545-patient Phase III clinical trial of iseganan HCl oral solution, to treat patients undergoing radiotherapy to prevent or reduce ulcerative oral mucositis showed no significant difference between iseganan and placebo in the primary or secondary end-points. The group of patients who received iseganan and the group of patients who received placebo did significantly better than the group of patients who received only the standard of care on both the primary and secondary endpoints. We are still in the process of fully analyzing and evaluating these data and full results will be presented at the Annual Meeting of the American Society for Clinical Oncology. We are also currently enrolling patients in a phase III trial for patients undergoing aggressive chemotherapy, and assuming that enrollment in the trial progresses according to plan, we expect to announce results of that trial no later than the fourth quarter of 2002.

We have also completed two earlier stage trials for other indications of iseganan HCl to prevent pneumonia in patients requiring breathing assistance from a mechanical ventilator and to treat respiratory infections in patients with cystic fibrosis. The data from each of these trials support the advancement to the next stage of human clinical testing for each of these two products.

Since commencing operations in 1994, we have not generated any revenue from product sales, and we have funded 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. During the quarter ended March 31, 2002, we completed a private placement of 5.9 million shares of common stock resulting in net proceeds of \$13.9 million and in April, 2002, Ernest Mario, Ph.D. purchased approximately 1.25 million shares of common stock resulting in net proceeds of \$5 million. We have incurred a loss in each year since inception, and we expect to incur substantial losses for at least the next several years. We expect that losses may fluctuate, and that such fluctuations may be substantial. As of March 31, 2002, the Company's accumulated deficit was approximately \$170.7 million. We will need to raise additional funds in the future to continue our operations.

In April 2002, the Company acquired Apothogen, Inc. for 450,000 shares of its common stock. Concurrently with the closing of the merger, Ernest Mario, Ph.D. joined the Company as Chairman and Chief Executive Officer.

RESULTS OF OPERATIONS

Three -month periods ended March 31, 2002 and 2001

IntraBiotics had no product sales or contract revenue for the three-month periods ended March 31, 2002 and 2001. We do not anticipate any product revenue in the near future.

Research and development expenses consist of costs related to our current phase III clinical trials for iseganan HCl oral solution. Research and development expenses decreased to \$7.0 million in the three-month period ended March 31, 2002 from \$15.5 million for the same period in 2001. The decrease is as a result of our May 2001 restructuring. Research and development costs for the quarter ended March 31, 2002 were related to the iseganan HCl for the prevention of oral mucositis program, and include costs for salaries for research and development personnel, contractor and clinical trial site fees, building and equipment costs, supplies, administrative expenses and allocations of corporate costs. During the quarter, approximately 70% of research and development expenses were for various contractor, consultant and clinical trial site fees. Included in research and development are non-cash stock compensation charges of \$281,000 and \$376,000 for the period ended March 31, 2002, and 2001 respectively.

The arbitration between us and the contract vendor relating to a drug dispensing error in iseganan HCl oral solution phase III clinical trials was resolved amicably in January 2002. We received \$3.6 million in the settlement.

General and administrative expenses decreased to \$1.5 million in the three-month period ended March 31, 2002 from \$4.1 million for the same period in 2001, primarily as a result of our restructuring in 2001. These costs include salaries for administrative personnel, outside contractors, legal fees, accounting fees, building and equipment costs, supplies and general administrative expenses.

We expensed \$488,000 of deferred compensation during the three-month period ended March 31, 2002, compared to \$649,000 for the same period in 2001. 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 expense in the three-month period ended March 31, 2002 decreased to \$281,000 from \$376,000 for the same period in 2001. The general and administrative deferred compensation expense in the three-month period ended March 31, 2002 decreased to \$207,000 from \$273,000 for the same period in 2001. 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.

On May 31, 2001, we 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 reduction in incidence and severity of oral mucositis in cancer patients. We recorded restructuring charges of approximately \$10.1 million and asset write down charges of approximately \$11.8 million, for a total of approximately \$21.9 million in charges associated with our restructuring plan in the second quarter of 2001. The \$10.1 million restructuring charge was for costs incurred in work force reduction, the termination of collaboration agreements and facilities consolidation.

The strategic restructuring included a reduction in force of approximately 90 positions in research and administration, or 71% of our previous workforce of 127 employees. All of the terminated employees have left the Company as of December 31, 2001. During the quarter ended March 31, 2002, we received a refund of approximately \$75,000 for workman's compensation related to the terminated employees. No remaining severance amounts are payable as of March 31, 2002.

The restructuring also includes the terminations of certain research and development collaborations and the consolidation of operations into one existing facility in Mountain View, California. The estimated costs associated with terminated collaboration agreements were increased by \$166,000 in quarter ended March 31, 2002. There is \$150,000 remaining payable for such agreements and costs.

We vacated three facilities in Mountain View, California comprising 142,000 square feet and continue to occupy one facility with 16,000 square feet. One of the vacated facilities has been sub-leased during 2001, and another was taken back by the landlord, with no continuing obligation to us. At March 31, 2002, \$2,123,000 remains in accrued restructuring charges related to this facility, representing nine months of rent and expenses associated with the lease on the facility, based on our best estimate of the period for which the facility will remain vacant prior to sub-lease. We expect to incur the remaining restructuring obligation over the next nine months.

Interest income decreased to \$265,000 in the three-month period ended March 31, 2002 from \$1.2 million for the same period in 2001. The decrease in interest income resulted from the decrease in average cash and investment balances primarily due to our phase III trials and lower interest rates. Interest expense decreased to \$153,000 for the three-month period ended March 31, 2002, from \$308,000 for the same period in 2001. The decrease was primarily attributed to a reduction of outstanding loan balances and a lower interest rate on our remaining debt.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2002, we had cash and cash equivalents of \$45.7 million, including restricted cash deposits of approximately \$2.0 million in connection with standby letters of credit for leased facilities, \$3.0 million for guarantees of product supplies and \$2.5 million supporting our line of credit as well as approximately \$8.9 million of debt to Silicon Valley Bank. We regularly invest excess funds in short-term money market funds.

On February 1, 2002, we sold 5.9 million shares of common stock in a private placement resulting in net cash proceeds of approximately \$13.9 million. In January 2002, we also received \$3.6 million in settlement of our arbitration with a contract vendor relating to a drug dispensing error.

in our phase III clinical trials.

Net cash used in operating activities for the three-month periods ended March 31, 2002 and 2001 was \$3.6 million and \$16.2 million, respectively. Cash used in operating activities in the three-month periods ended March 31, 2002 and 2001 were primarily the result of net losses.

Net cash provided by investing activities for the three-month periods ended March 31, 2002 and 2001 was zero and \$18.8 million, respectively. There were no investing activities for the period ended March 31, 2002. Cash provided by investing activities in the three-month period ended March 31, 2001

was due to the maturities of short-term investments of \$22.1 million partially offset by capital expenditures of \$3.4 million for equipment.

Net cash provided by financing activities for the three-month periods ended March 31, 2002 and 2001 was \$13.9 million and \$330,000, respectively. Cash provided by financing activities for the three-month period ended March 31, 2002 was from net proceeds of \$14.3 million in a private placement of 5.9 million shares of common stock and from the issuance of common stock through the exercise of stock options, partially offset by \$469,000 in payments on financing obligations. Cash provided by financing activities for the three-month period ended March 31, 2001, was from \$1.2 million in proceeds from financing obligation and \$30,000 from the issuance of common stock, partially offset by \$909,000 of payments on financing obligations.

In August 2001, we entered into a line of credit of \$2.5 million and a term loan agreement of \$7.5 million with Silicon Valley Bank. In April 2002, the term loan agreement was modified, which included changes to the financial covenants. At March 31, 2001, the balance drawn on the line of credit was \$2.5 million and the term loan agreement was utilized and had a balance due of approximately \$6.4 million.

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;

the costs of establishing sales, marketing and distribution capabilities;

the progress of our 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.

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, \$67.4 million in 2001 and \$4.9 million in the quarter ended March 31, 2002. As of March 31, 2002, our accumulated deficit was approximately \$170.7 million. We expect to continue to incur substantial additional losses for the foreseeable future primarily as a result of increases in clinical trial costs, and we may never become profitable. In addition, we expect to incur further 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, our initial

public offering of common stock in March 2000 and private placements of common stock during the quarter ended March 31, 2002 and in April 2002. 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 cash balances and cash equivalents net of restricted cash of approximately \$38.2 million, at March 31, 2002, in addition to approximately \$5.0 million received in April 2002, will be 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 years ended December 31, 1999, 2000 and 2001, net cash used for operating activities was \$25.1 million, \$50.4 million, and \$53.6 million, respectively. In May 2001, we implemented a restructuring plan in order to conserve our cash reserves. Our future liquidity and capital requirements will depend on many factors, including the timing, delay, cost, extent and results of clinical trials, payments associated with manufacturing scale-up, the costs and timing of regulatory approvals, the costs of establishing sales, marketing and distribution capabilities and costs associated with researching drug candidates, securing in-licensing opportunities and conducting preclinical research.

We believe that additional financing will 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. 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 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. If we are unable to demonstrate the safety and efficacy of iseganan HCl oral solution in phase III clinical trials, we may 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 for that indication. Clinical trials are expensive and time-consuming to conduct, and the timing and 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 May 2002, we announced that our clinical trial of iseganan HCl oral solution to treat patients undergoing radiotherapy to prevent or reduce oral mucositis had failed to demonstrate any difference between iseganan and placebo in the primary or secondary end-points. While we are still analyzing the data, we believe that iseganan does not provide clinical benefit for these patients. As a result, we intend to pursue the development of iseganan HCl oral solution only for patients undergoing chemotherapy and other formulations of iseganan in ventilator-assisted pneumonia and cystic fibrosis.

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. For example, in January 2001, we discovered that a contract vendor dispensed placebo and active drug in error to approximately one-third of the patients in our phase III clinical trial for iseganan HCl oral solution. As a result, we are conducting an additional phase III clinical trial, which has delayed our FDA approval process.

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 the delays are substantial, the increase in product development expenses could cause our losses to increase and diminish the commercial potential for our drug candidates.

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 rely on 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 with good clinical practices, 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.

In January 2001, an error on the part of one of our subcontractors that was managing the drug dispensing led to a dispensing error in both of our phase III clinical trials of iseganan HCl oral solution. We believe that as a result of this error, the clinical trial failed to demonstrate the efficacy of iseganan HCl oral solution for the reduction in incidence and severity of oral mucositis in patients receiving chemotherapy at the levels of statistical significance typically required by the FDA. As a result, we are conducting an additional phase III clinical trial and our timing for the FDA approval process has been delayed.

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

We rely on a single source of contract manufacturers, PolyPeptide Laboratories A/S and Patheon, Inc., to manufacture the bulk drug substance and formulated drug product on a commercial scale, respectively. While we maintain a limited inventory of our drug, we depend on contract manufacturers to produce our products for use in our clinical trials. Our contract manufacturers have limited experience in manufacturing iseganan HCl in quantities sufficient for commercialization and may have difficulty in scaling up production. If our contract manufacturers are unable or fail 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 to complete current and future clinical trials, or to meet commercial demand.

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

Our third-party manufacturers 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 manufacturers fail to comply with the FDA's current good manufacturing practices or if our contract manufacturers terminate 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 are extremely complex and proprietary. If we are unable to continue having iseganan manufactured by our current contract manufacturers, 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 U.S. or any foreign market. We must obtain approval from the FDA in order to sell our drug candidate in the U.S. and from foreign regulatory authorities in order to sell our drug candidate in other countries. We must successfully complete our phase III clinical trial 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. Delays in obtaining or failure to obtain regulatory approvals may:

delay or prevent the successful commercialization 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 candidate 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 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 candidate. If we are unable to compete successfully with our drug candidate, physicians may not recommend and patients may not buy our drug, 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. There is one approved device, Radiacare®, and several drugs in early stage clinical trials for prevention or treatment of oral mucositis. These include one antimicrobial agent, triclosan, and two growth factors, keratinocyte growth factor and keratinocyte growth factor-2. GM-CSF is also under development in radiotherapy-induced oral mucositis. The companies sponsoring these trials have successfully commercialized products in the past. In addition, there may be products under development of which we are unaware for the prevention or the treatment of oral mucositis.

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

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 nine patents and five 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 manufacturers perform the manufacturing processes covered by these trade secrets. Accordingly, our contract manufacturers and we must maintain confidentiality. We have confidentiality and proprietary information agreements with our contract manufacturers 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 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 U.S 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

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

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 candidate may not gain market acceptance among physicians, patients and the medical community. If our drug candidate fails 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.

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 product is established, physicians may elect not to recommend its use. 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, or because of the cost of our drug.

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 products.

We do not currently have marketing, sales or distribution capabilities. Initially we intend to establish a direct marketing and sales force in the U.S. and Canada. We intend to enter into arrangements with third parties to market and sell most of our products outside of the U.S. and Canada. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, we would be unable to commercialize these drug products. We must develop a marketing and sales force with technical expertise and distribution capabilities to market any of our products directly. 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 will need to hire additional qualified scientific personnel to perform research and development. 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 portion of our capital stock and may be able to exert control over our activities.

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 38% of our outstanding common stock. These stockholders, if acting together, may be able to significantly influence any 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.

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 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 ABOUT 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 currently have all of our funds in money market fund, which is sensitive to minimal market risk. Due to the short-term nature of this investment, a 50 basis point movement in market interest rates would not have a material impact on the fair value of our investment as of March 31, 2002 and the fiscal years December 31, 2001 and 2000. 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 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

On February 1, 2002, we sold 5.9 million shares of newly issued shares of our common stock in a private placement at a purchase price of \$2.50 per share to selected institutional and private investors, which resulted in net cash proceeds of approximately \$13.9 million to be used for working capital and other general corporate purposes. We issued the shares of common stock in reliance upon an exemption from the registration requirements of the Securities Act by virtue of Section 4(2) thereof and Regulation D promulgated thereunder. We filed a registration statement on Form S-3 (No. 333-82934) pursuant to the Securities Act of 1933, as amended, with the Securities and Exchange Commission related to the resale of the securities.

The Company's registration statement on Form S-1 (No. 333-95461) filed pursuant to the Securities Act of 1933, as amended, was declared effective on March 27, 2000. The Company incurred related offering costs of approximately \$9.2 million during the year ended December 31, 2000, of which \$7.9 million represented underwriting discounts and commissions. All initial public offering costs were direct or indirect payments to others. The net offering proceeds to the Company after all expenses were approximately \$103.3 million, and the balance of these proceeds is being used to fund clinical trials, the development and scale up of manufacturing processes by our contract manufacturers, research and development activities and other working capital and other general corporate purposes.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) List of Exhibits

Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation, incorporated by reference from the indicated exhibit to the Company's Registration Statement on Form S-1 (No. 333-95461) initially filed with the Securities and Exchange Commission on January 27, 2000, as amended.
3.2	Bylaws, incorporated by reference from the indicated exhibit to the Company's Registration Statement on Form S-1 (No. 333-95461) initially filed with the Securities and Exchange Commission on January 27, 2000, as amended.
4.3	Form of Stock Purchase Agreement by and between the Company and each selling stockholder, dated January 29, 2002, incorporated by reference from the indicated exhibit to the Company's Registration Statement on Form S-3 (No. 333-82934) filed with the Securities and Exchange Commission on February 15, 2002.
4.4	Letter Agreement by and among the Company and signatories thereto, dated April 23, 2002.

(b) Reports on Form 8-K

Edgar Filing: INTRABIOTICS PHARMACEUTICALS INC /DE - Form 10-Q

The Company filed a Current Report on Form 8-K on January 22, 2002 reporting under Item 5 that arbitration proceedings relating to a contractor error, which affected two clinical trials of iseganan HCl for the prevention of oral mucositis, had been amicably resolved and, in connection with that resolution, the Company received a payment of \$3.6 million.

The Company filed a Current Report on Form 8-K on January 30, 2002 announcing under Item 5 it had entered into definitive purchase agreements to sell approximately 5.9 million shares of newly issued common stock in a private placement to selected institutional and private investors, and that the private

placement is expected to raise net proceeds of approximately \$13.9 million, subject to customary closing conditions.

The Company filed a Current Report on Form 8-K on March 20, 2002 announcing under Item 5 that the results of its second phase III clinical trial of iseganan HCl oral solution, for the reduction of incidence of ulcerative oral mucositis in patients receiving radiation therapy for treatment of head and neck cancer, has been accepted for an oral presentation at the upcoming American Society of Clinical Oncology meeting in Orlando, Florida on Tuesday, May 21, 2002. The Company also announced that it has finalized its plans for statistical analysis of the two clinical trials based on input from the FDA.

The Company filed a Current Report on March 29, 2002 reporting under Item 5 that it was refiling its Management's Discussion & Analysis of Financial Condition and Results of Operations contained in its Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 15, 2002, in order to provide additional disclosure in the MD&A section, as suggested by the Commission pursuant to SEC Releases No. 33-8056 and No. 33-8040.

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.

IntraBiotics Pharmaceuticals, Inc.

May 15, 2002

/s/ Henry J. Fuchs M.D.
Henry J. Fuchs M.D.
President and Chief Operating Officer

May 15, 2002

/s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer