INTRABIOTICS PHARMACEUTICALS INC /DE
Form 10-Q/A
May 16, 2001

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Form 10-Q/A

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 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**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
2021 STIERLIN COURT, 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 x No o

There were 29,297,793 shares of the Company s Common Stock, par value $.001, outstanding on April 30, 2001.

INTRABIOTICS PHARMACEUTICALS, INC.

FORM 10-Q/A
QUARTER ENDED MARCH 31, 2000

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INTRABIOTICS PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
(IN THOUSANDS)

(UNAUDITED)

	MARCH 31, 2001	DECEMBER 31, 2000
Assets		(Note 1)
Current assets:		
Cash and cash equivalents	$41,922	$38,983
Restricted cash deposits	1,371	1,371
Short-term investments	23,601	45,711
Other current assets, primarily prepayments and deposits	10,393	10,101
Total current assets	77,287	96,166
Property and equipment, net	14,964	12,056
Other assets	66	66

Total assets	$92,317	$108,288
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$2,070	$1,680
Accrued clinical costs	4,056	3,236
Accrued employee liabilities	991	625
Other accrued liabilities	1,021	854
Current financing obligations	3,896	3,629
Total current liabilities	12,034	10,024
Long-term financing obligations	8,342	8,309
Stockholders equity:		
Common stock	29	29
Additional paid-in capital	198,235	198,388
Deferred stock compensation	(9,366)	(10,198)
Accumulated other comprehensive income	206	186
Accumulated deficit	(117,163)	(98,450)
Total stockholders' equity	71,941	89,955
Total liabilities and stockholders' equity	$92,317	$108,288

See accompanying notes.

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

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
Operating expenses:		
Research and development	$15,524	$5,438
General and administrative	4,108	2,137
Total operating expenses	19,632	7,575
Operating loss	(19,632)	(7,575)
Interest income	1,227	414

Interest expense	(308)	(137)
Net loss	$(18,713)	$(7,298)
Basic and diluted net loss per share	$(0.64)	$(2.62)
Shares used to compute basic and diluted net loss per share	29,260	2,785
Pro forma basic and diluted net loss per share		$(0.34)
Shares used to compute pro forma basic and diluted net loss per share		21,659

See accompanying notes.

INTRABIOTICS PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
Operating activities		
Net loss	$(18,713)	$(7,298)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	462	286
Amortization of deferred stock compensation	649	794
Change in assets and liabilities		
Other current assets	(292)	(423)
Accounts payable	390	(1,334)
Accrued clinical liabilities	820	(171)
Accrued employee liabilities	366	-
Other accrued liabilities	167	753
Amount payable to contract partner	-	(1,677)
Net cash used in operating activities	(16,151)	(9,070)
Investing activities		
Capital expenditures	(3,370)	(1,065)
Maturities of short-term investments	22,130	2,036
Net cash provided by investing activities	18,760	971
Financing activities		
Proceeds from issuance of common stock	30	103,789

Proceeds from financing obligations	1,209	1,166
Payments on financing obligations	(909)	(266)
Net cash provided by financing activities	330	104,689
Net increase in cash and cash equivalents	2,939	96,590
Cash and cash equivalents at beginning of period	38,983	18,862
Cash and cash equivalents at end of period	$41,922	$115,452
Supplemental disclosure of cash flow information		
Interest paid	$308	$137
Supplemental disclosure of non-cash information		
Conversion of preferred stock to common stock	$-	$79,609
Deferred compensation (termination)	$(183)	$2,645

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, 2001 and December 31, 2000, and the results of its operations and cash flows for the three month periods ended March 31, 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.

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivatives and Hedging Activities" (SFAS 133), which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as "derivatives") and for hedging activities. SFAS 133 (as deferred by SFAS 137) is effective for the Company s year ending December 31, 2001. As the Company does not currently hold derivatives or engage in hedging transactions, there was no current impact to the Company s results of operations, financial position, or cash flows upon the adoption of SFAS 133 in the quarter ended March 31, 2001.

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, 2001 and December 31, 2000, the Company has restricted cash of $1,371,000 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 can be drawn down on or before July 31, 2001.

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, based on quoted market values:

	MARCH 31, 2001	DECEMBER 31, 2000
	(IN THOUSANDS)	
	(UNAUDITED)	
Operating cash	$344	$723
Money market	41,578	38,260
Certificates of deposit	1,371	1,371
Commercial paper	23,601	45,711
	$66,894	$86,065
Amounts included in cash and cash equivalents and restricted cash deposits	$43,293	$40,354
Amounts included in short-term investments	23,601	45,711
	$66,894	$86,065

The Company classifies all securities as either cash and cash equivalents or available for sale.

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 MARCH 31,	
	2001	2000
	(UNAUDITED)	
Basic and diluted:		
Net loss	$(18,713)	$(7,298)
Weighted-average shares used in computing basic and diluted net loss per share	29,260	2,785
Basic and diluted net loss per share	$(0.64)	$(2.62)
Pro forma basic and diluted:		
Shares used above		2,785
Pro forma adjustment to reflect weighted-average effect of conversion of preferred stock from the date of issuance		18,874
Total weighted-average shares of common stock outstanding		21,659
Pro forma basic and diluted net loss per share		$(0.34)

Note 5. Agreements

In April 2001, the Company entered into a research collaboration with Cetek Corporation (Cetek). This research collaboration will allow IntraBiotics to utilize Cetek's proprietary capillary electrophoresis (CE) screening technology to identify compounds with antibacterial or antifungal properties. Cetek will receive an initiation fee and milestone payments for achievement of various goals under the agreement.

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. develops a portfolio of new antibacterial and antifungal drugs for the prevention or treatment of serious infectious diseases. We have initiated expanded human clinical trials to test for efficacy and safety, known as phase III trials, for two product candidates. The first product is iseganan HCl oral solution, previously referred to as Protegrin IB-367 Rinse, for the treatment of oral mucositis, a side effect of anti-cancer therapies. In April 2001, our preliminary results from the first phase III trial for patients undergoing chemotherapy indicated that the product candidate did not meet its primary endpoint of reducing ulceration, but did meet its secondary endpoint of reducing pain and was well tolerated. We believe that a reduction in the sample size of patients who were properly treated due to a dosing error by a third-party contractor resulted in a lesser value of statistical significance for the endpoints of the trial. We have done an additional subset analysis of the phase III data in which the primary endpoint was met. On that basis, we plan to undertake a new phase III trial of iseganan HCl oral solution for the prevention of oral mucositis in chemotherapy patients. We continue to enroll patients in a second phase III trial of iseganan HCl oral solution for patients undergoing radiotherapy. Our second product is ramoplanin oral powder, previously referred to as

Ramoplanin Oral, for the prevention of infections due to vancomycin-resistant enterococci, or VRE. In March 2001, the steering committee for the clinical trial determined that the rate of enrollment in the trial has not been sufficient and that completion of the study would be delayed by a year or more. We are currently enrolling patients in the phase III trial for ramoplanin oral powder.

We have also completed two earlier stage trials for other uses of the antibiotic iseganan HCl. These uses are to prevent infections of patients either with breathing assistance from a mechanical ventilator or with a specific disease, Cystic Fibrosis. 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. 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 each of these trials support the advancement to the next stage of human clinical testing for each of these two products, but we currently plan to obtain sufficient capital and human resources before proceeding to these next trials.

We plan to allocate our capital and human resources across our product portfolio of new antibiotics as appropriate given changing internal and external factors. We expect to incur significant additional clinical trial expenses in connection with the new phase III clinical trial for iseganan HCl oral solution in chemotherapy patients and plan to shift resources among our programs. We are also considering cost cutting measures, which if implemented, would cause us to be unable to pursue our product development programs at the levels currently conducted. See Risks Related to Our Business Based on our results from the phase III trial for iseganan HCl oral solution in chemotherapy patients, we are undertaking a new clinical trial and are considering significant cost cutting measures.

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. We expect that losses may fluctuate, and that such fluctuations may be substantial. At March 31, 2001, our accumulated deficit was approximately $117.2 million.

RESULTS OF OPERATIONS

Three month periods ended March 31, 2001 and 2000

IntraBiotics had no product sales or contract revenue for the three-month periods ended March 31, 2001 and 2000. The Company does not anticipate any product revenue in the near future.

Research and development expenses increased to $15.5 million in the three-month period ended March 31, 2001 from $5.4 million for the same period in 2000. The increase was attributable to higher personnel and payroll expenses, technology access fees, clinical trial activity, facilities and consulting expenses. We are evaluating our research and development spending in response to the phase III clinical trial results announced in April 2001 for iseganan HCl oral solution (previously referred to as Protegrin IB-367) in patients receiving chemotherapy and our cash position. These results indicated that the product candidate did not meet its primary endpoint of reducing ulceration, but did meet its secondary endpoint of reducing pain and was well tolerated.

General and administrative expenses increased to $4.1 million in the three-month period ended March 31, 2001 from $2.1 million for the same period in 2000. The increase was primarily attributed to increased personnel and payroll expenses, consulting, legal, professional, travel and other expenses associated with increased business development activities. We are evaluating our general and administrative spending in response to the phase III clinical trial results announced in April 2001 for iseganan HCl oral solution in patients receiving chemotherapy and our cash position.

In connection with the grant of certain stock options to employees, the Company recorded no deferred compensation in the three month period ended March 31, 2001 and deferred compensation of $2.6 million in the three-month period ended March 31, 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.

We expensed $649,000 of deferred compensation during the three-month period ended March 31, 2001, compared to $794,000 of deferred compensation for the same period in 2000. The decrease in deferred compensation expense was due to the cancellation of options from employment terminations. 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-month periods ended March 31, 2001 was $376,000, down from $460,000 for the same period in 2000. The general and administrative deferred compensation amortization expense in the three-month period ended March 31, 2001 was $273,000, down from $334,000 for the same period in 2000.

Interest income increased to $1.2 million in the three-month period ended March 31, 2001 from $414,000 for the same period in 2000. The increase in interest income resulted from the increase in average cash and investment balances primarily due to the Company s prior financing activities. Interest expense increased to $308,000 for the three-month period ended March 31, 2001, from $137,000 for the same period in 2000. The increase was primarily attributed to additional equipment financing obligations.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2001, we had cash, cash equivalents and short-term investments of $66.9 million including restricted cash deposits of approximately $1.4 million in connection with standby letters of credit for leased facilities and short-term investments of $23.6 million. The Company regularly invests excess funds in short-term money market funds and commercial paper.

Net cash used in operating activities for the three-month periods ended March 31, 2001 and 2000 was $16.2 million and $9.1 million, respectively. Cash used in operating activities in the three-month period ended March 31, 2001 was primarily the result of net losses and increased prepaid expenses primarily for clinical trials, offset by increases in accounts payable, accrued clinical liabilities, accrued employee liabilities, asset depreciation and amortization and deferred stock compensation amortization. Cash used in operating activities in the three-month period ended March 31, 2000 was primarily the result of net losses, increased prepaid expenses primarily for clinical trials and decreases in accounts payable, accrued clinical liabilities and amounts payable to contract partner, offset by increases in accrued liabilities, asset depreciation and amortization and deferred stock compensation amortization.

Net cash provided by investing activities for the three-month periods ended March 31, 2001 and 2000 was $18.8 million and $1.0 million, respectively. 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. During the three months ended March 31, 2000, the Company used cash to purchase equipment of $1.1 million.

Net cash provided by financing activities for the three-month periods ended March 31, 2001 and 2000 was $330,000 and $104.7 million, respectively. Cash provided by financing activities for the three-month period ended March 31, 2001 was from $1.2 million in additional financing obligations and $30,000 from the issuance of common stock, partially offset by $909,000 in payments on financing obligations. Cash provided by financing activities for the three-month period ended March 31, 2000, was due to net proceeds from the issuance of common stock, of $103.8 million from the initial public offering, and net proceeds of $900,000 from 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 into the first quarter of 2002 assuming our current rate of expenditures do not change. We are considering cost cutting measures and shifting resources among our programs which would extend that time frame and to fund our new phase III clinical trial for iseganan HCl but any such cost cutting measures would cause us to be unable to pursue our product development programs at the levels at which they are currently being conducted.

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 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 and if we do not have sufficient capital necessary to fund our operations, we may need to delay or curtail our development and commercialization activities to a significant extent and may have to cease operations. See

Risks Related to Our Business If we do not have the capital necessary to fund our operations, we will be unable to develop our drug candidates and may have to cease operations."

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.

Based on our results from the phase III trial for iseganan HCl oral solution in chemotherapy patients, we are undertaking a new clinical trial and are considering significant cost cutting measures.

In April 2001, we announced preliminary results from our first completed phase III clinical trial of iseganan HCl oral solution for the prevention of oral mucositis in patients undergoing high-dose chemotherapy for the treatment of cancer. The results indicated that the product candidate did not meet its primary endpoint of reducing ulceration, but did meet its secondary endpoint of reducing pain and was well tolerated. We believe that an error by a third-party contractor in assigning drug or placebo which reduced the sample size of patients who were properly treated resulted in a lesser value of statistical significance for the trial. In an effort to understand the impact of the contractor s error, we undertook an additional subset analysis of the phase III data in which the primary endpoint was met. On that basis, we plan to undertake a new phase III trial of iseganan HCl oral solution for the prevention of oral mucositis in chemotherapy patients which will result in significant additional clinical trial costs. The significant costs of the clinical trial will require us to reallocate our current resources among our programs, and we are considering cost cutting measures in order to fund the clinical trial. The need to run an additional clinical trial will delay submission of an NDA to the FDA, and we cannot guarantee that the outcome of the trial will be positive.

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 $18.7 million in the quarter ended March 31, 2001. Our accumulated deficit was approximately $117.2 million, as of March 31, 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 in pre-clinical research to identify new product candidates and manufacturing and development costs to commercialize ramoplanin and iseganan HCl oral solution, formerly referred to as Protegrin IB-367 Rinse. 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.

If we do not have 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 $43.3 million, short-term investments of approximately $23.6 million and interest income are sufficient to meet our operating and capital requirements into the first quarter of 2002 assuming our current rate of expenditures do not change. We are considering cost cutting measures and shifting resources among our programs which would extend that time frame and to fund our new phase III clinical trial for iseganan HCl but any such cost cutting measures would cause us to be unable to pursue our product development programs at the levels at which they are currently being conducted. For the quarter ended March 31, 2001 and the years ended December 31, 2000, 1999 and 1998, net cash used for operating activities was $16.2 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. We plan to undertake a new phase III trial of iseganan HCl oral solution for the prevention of oral mucositis which will result in significant additional clinical trial costs. The significant costs of the clinical trial will require us to reallocate our current resources among our programs.

We believe that additional financing is required in the future to fund our operations. We do not know whether additional financing will be available or on acceptable terms, if at all. If we are unable to raise additional financing, we would 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 two drug candidates in phase III clinical trials, iseganan HCl oral solution and ramoplanin oral powder. In April 2001, the results from our phase III clinical trial of iseganan HCl oral solution for the prevention of oral mucositis in chemotherapy patients indicated that the product candidate did not meet its primary endpoint of reducing ulceration, but did meet its secondary endpoint of reducing pain and was well tolerated. Based on an additional subset analysis of the data from the clinical trial in which the primary endpoint was met, we plan to undertake a new phase III clinical trial of iseganan HCl oral solution for the prevention of oral mucositis. If either 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.

For example, in March 2001, the steering committee for the clinical trial determined that the rate of enrollment in the phase III clinical program for ramoplanin oral powder has not been sufficiently accelerated and that completion of the study would be delayed a year or more. 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 products.

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. and Amarex Clinical Research, 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.

The results from our phase III clinical trial of iseganan HCl oral solution for the prevention of oral mucositis in chemotherapy patients indicated that the product candidate did not meet its primary endpoint of reducing ulceration, but did meet its secondary endpoint of reducing pain and was well tolerated. We believe that the dispensing error by the contractor resulted in a lesser value of statistical significance for the endpoints of the trial. As a result, we plan to undertake a new phase III clinical of iseganan HCl oral solution for the prevention of oral mucositis in chemotherapy patients which will result in additional clinical trial costs and will delay the filing of an NDA with the FDA and the timing of any regulatory approval.

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 PolyPeptide and Biosearch to manufacture our bulk drug substances on a commercial scale. While we maintain a limited inventory of our drug candidates, we depend on these single-source contract manufacturers to produce each of our products for use in our clinical trials. Our contract manufacturers have limited experience in manufacturing iseganan HCl or ramoplanin 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 our drug candidates 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 our drug candidates 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 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 and ramoplanin are extremely complex and proprietary. If we are unable to continue having iseganan HCl or ramoplanin 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 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. Delays in obtaining or failure to obtain regulatory approvals may:

delay or prevent the successful commercialization of any of our drug candidates;

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 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 ramoplanin oral powder and iseganan HCl oral solution. To the best of our knowledge, there are no direct competitors approved or under development for the prevention of VRE bloodstream infections. However, there are two approved products for the treatment of VRE infections, Synercid® and Zyvox®. For oral mucositis, there is one approved device, Radiacare®, and several drugs in early stage clinical trials. These include two growth factors, keratinocyte growth factor and interleukin-11, as well as a chemoprotective agent, Ethyol®. 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 of VRE bloodstream infections or 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 eight patents and eleven 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 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 two drug candidates 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 products.

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 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. 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, ramoplanin oral powder and our earlier stage products.

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. 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.

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 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 first quarter of 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 March 31, 2001 and 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 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

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 registration statement through March 31, 2001, $24.2 million of the net proceeds have been used for our clinical trials, $4.5 million for the development and scale up of manufacturing processes by our contract manufacturers, $20.5 million for research and development and $13.6 million for working capital and other general 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, as currently in effect.
3.2	Bylaws, as currently in effect.
10.21*	Drug Discovery, Development, and License Agreement by and between IntraBiotics and Diversa Corporation dated January 6, 2001.
10.22*	Research and Technology Agreement by and between IntraBiotics and New Chemical Entities dated January 24, 2001.

	Incorporated by reference from IntraBiotics Registration Statement on Form S-1 (No. 333-95461) initially filed with the SEC on January 27, 2000 and subsequently amended.
*	Confidential treatment requested with respect with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

(b) Reports on Form 8-K

The Company did not file a report on Form 8-K during the quarter ended March 31, 2001.

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.

/s/ Kenneth J. Kelley

May 14, 2001 — Kenneth J. Kelley
Chairman of the Board,
President and Chief Executive Officer

/s/ Sandra J. Wrobel

May 14, 2001 — Sandra J. Wrobel
Chief Financial Officer