

INTRABIOTICS PHARMACEUTICALS INC /DE

Form 10-Q

May 12, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
Form 10-Q

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

For the quarterly period ended March 31, 2004

or

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

For the transition period from to

Commission File Number 0-29993

INTRABIOTICS PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

DELAWARE	94-3200380
(State or other jurisdiction of	(I.R.S. Employer Identification
incorporation or organization)	Number)

2483 East Bayshore Road, Suite 100

Palo Alto, CA 94303

(Address of principal executive offices)

(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

Indicate by checkmark whether registrant is an accelerated filer (as defined in Rule 12b-2 of Securities Exchange Act of 1934). Yes No

There were 5,364,383 shares of the Registrant's common stock, par value \$0.001, outstanding as of March 31, 2004.

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FORM 10-Q

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INTRABIOTICS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	MARCH 31, 2004 (Unaudited)	DECEMBER 31, 2003 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,910	\$ 14,286
Restricted cash	250	250
Short-term investments	18,410	12,108
Prepaid expenses	351	478
	<hr/>	<hr/>
Total current assets	22,921	27,122
Property and equipment, net	16	20
Other assets	191	184
	<hr/>	<hr/>
Total assets	\$ 23,128	\$ 27,326
	<hr/>	<hr/>
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 16	\$ 141
Accrued clinical liabilities	2,435	1,046
Accrued employee liabilities	150	101
Other accrued liabilities	313	410
	<hr/>	<hr/>
Total current liabilities	2,914	1,698
Stockholders equity:		
Convertible preferred stock	1,771	1,771
Common stock	5	5
Additional paid-in capital	240,111	239,237
Deferred stock compensation	(172)	(188)
Accumulated other comprehensive income		2
Accumulated deficit	(221,501)	(215,199)
	<hr/>	<hr/>
Total stockholders equity	20,214	25,628
	<hr/>	<hr/>

Total liabilities and stockholders' equity	\$ 23,128	\$ 27,326
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See accompanying notes

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INTRABIOTICS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2004	2003
Operating expenses:		
Research and development	\$ 4,459	\$ 268
General and administrative	1,851	1,665
	<u> </u>	<u> </u>
Total operating expenses	6,310	1,933
	<u> </u>	<u> </u>
Operating loss	(6,310)	(1,933)
Interest Income	73	26
	<u> </u>	<u> </u>
Net Loss	(6,237)	(1,907)
Non-cash dividends on Series A preferred stock	(65)	
	<u> </u>	<u> </u>
Net loss applicable to common stockholders	\$(6,302)	\$(1,907)
	<u> </u>	<u> </u>
Basic and diluted net loss per share applicable to common stockholders	\$ (1.19)	\$ (0.58)
	<u> </u>	<u> </u>
Shares used to compute basic and diluted net loss per share applicable to common stockholders	5,316	3,269
	<u> </u>	<u> </u>

See accompanying notes

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INTRABIOTICS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2004	2003
Operating activities		
Net loss	\$ (6,237)	\$ (1,907)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred stock compensation	16	62
Stock compensation expense	588	3
Depreciation and amortization	7	26
Change in assets and liabilities:		
Prepaid expenses	127	(399)
Other assets	(7)	(9)
Accounts payable	(125)	260
Accrued clinical liabilities	1,389	
Accrued employee liabilities	49	206
Accrued restructuring charges		(64)
Other accrued liabilities	(32)	(89)
	<u> </u>	<u> </u>
Net cash used in operating activities	(4,225)	(1,911)
Investing activities		
Capital expenditures	(3)	
Purchases of short term investments	(10,229)	
Proceeds from sale or maturity of short-term investments	3,925	
	<u> </u>	<u> </u>
Net cash used in investing activities	(6,307)	
Financing activities		
Proceeds from issuance of common stock upon exercise of options	156	1
	<u> </u>	<u> </u>
Net cash provided by financing activities	156	1
	<u> </u>	<u> </u>
Net decrease in cash and cash equivalents	(10,376)	(1,910)
Cash and cash equivalents at beginning of period	14,286	10,170
	<u> </u>	<u> </u>
Cash and cash equivalents at end of period	<u>\$ 3,910</u>	<u>\$ 8,260</u>

Supplemental disclosure of non-cash information:

Net deferred stock compensation (cancellations due to employee terminations)	\$		\$	(272)
		<u> </u>		<u> </u>
Issuance of common stock dividend on Series A preferred stock	\$	65	\$	
		<u> </u>		<u> </u>

See accompanying notes

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INTRABIOTICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

Note 1. Basis of Presentation and Summary of Significant Accounting Policies

The accompanying condensed financial statements are unaudited and have been prepared by IntraBiotics Pharmaceuticals, Inc. (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 accounting principles generally accepted in the United States) have been condensed or omitted. The interim condensed financial statements, in the opinion of management, reflect all adjustments (consisting entirely of normal recurring adjustments) necessary for a fair presentation of the Company's financial position as of March 31, 2004, and the results of its operations and cash flows for the three-month periods ended March 31, 2004 and 2003.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the entire fiscal year. These interim condensed financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2003, which are contained in the Company's Annual Report on Form 10-K, and filed with the Securities and Exchange Commission on March 19, 2004. The condensed balance sheet as of December 31, 2003 is derived from such audited financial statements.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes, including amounts accrued for clinical trial costs and stock-based compensation.

The Company's estimate of accrued costs is based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

Note 2. Stock-Based Compensation

In February 2003, the Board approved a cancellation and re-grant of 308,835 unexercised stock options held by existing employees and directors of the Company in a one-for-one exchange and 12,500 options that were re-granted in connection with the cancellation of 54,166 unexercised stock options held by a director of the Company. The newly-granted options have an exercise price equal to the closing price of the Company's common stock on the Nasdaq National Market on February 5, 2003, or \$2.76 per share. These options generally vest over a four-year period and will expire in February 2008 if not previously exercised. Variable accounting is being applied to the newly-granted options throughout their term.

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As permitted by Statement of Financial Accounting Standards No. 123 (SFAS 123), Accounting for Stock-Based Compensation, as amended by Statement of Financial Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, the Company has elected to follow APB 25 and related interpretations in accounting for stock-based employee compensation. Under APB 25, if the exercise price of an employee or director stock option is set equal or in excess of the fair market value of the underlying stock on the date of grant, no compensation expense is recognized. In February 2003, certain stock options for which the exercise prices had originally been set at less than the fair market value of the underlying stock on the grant date, were cancelled and re-granted in a one-for-one exchange. The Company had recorded deferred compensation for the difference between the original exercise price and the fair market value of the underlying stock on the grant date as a component of stockholders' equity, and the total was being amortized on a straight-line basis over the vesting period of the original awards, ranging from four to six years. The related re-granted options all vest over a four-year period, and the remaining unamortized deferred compensation as of the re-grant date is now being amortized over the new four-year vesting schedule, commencing at the date of re-grant.

Options or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS 123 and the FASB's Emerging Issues Task Force issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, and are recognized over the related service period and are periodically re-measured as the underlying options vest.

The following table illustrates the effect on net loss applicable to common stockholders and net loss per share applicable to common stockholders if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in thousands, except per share amounts):

	THREE MONTHS ENDED MARCH 31,	
	2004	2003
Net loss applicable to common stockholders, as reported	\$(6,302)	\$(1,907)
Add: Stock-based employee compensation expense included in reported net loss applicable to common stockholders	291	62
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(614)	(423)
Net loss applicable to common stockholders, pro forma	<u>\$(6,625)</u>	<u>\$(2,268)</u>
Net loss per share applicable to stockholders:		
Basic and diluted as reported	<u>\$ (1.19)</u>	<u>\$ (0.58)</u>
Basic and diluted pro forma	<u>\$ (1.25)</u>	<u>\$ (0.69)</u>

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The fair value for the Company's options was estimated at the date of grant using the Black-Scholes option pricing model for the three-month periods ended March 31, 2004 and 2003 with the following weighted-average assumptions:

	THREE MONTHS ENDED MARCH 31,	
	2004	2003
Risk-free interest rate	3.09%	2.91%
Volatility	1.00	1.00
Dividend yield		
Expected life of option	5 years	5 years

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Note 3. Comprehensive Loss

The components of comprehensive loss in each year presented are as follows:

	THREE MONTHS ENDED MARCH 31,	
	2004	2003
Net loss	\$(6,237)	\$(1,907)
Unrealized loss on available-for-sale securities	(2)	
Comprehensive loss	<u>\$(6,239)</u>	<u>\$(1,907)</u>

Note 4. Net Loss Per Share

Basic and diluted net loss per share applicable to common stockholders is presented in accordance with Financial Accounting Standards Board Statement No. 128, Earnings Per Share, and is calculated using the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share applicable to common stockholders includes the impact of potentially dilutive securities (stock options, warrants and convertible preferred stock). As the Company's potentially dilutive securities were anti-dilutive for all periods presented, they are not included in the calculations of diluted net loss per share applicable to common stockholders. The total number of shares underlying the stock options, warrants and convertible preferred stock excluded from the calculations of net loss per share applicable to common stockholders was 3,342,316 and 984,598 for the three-month periods ended March 31, 2004 and 2003, respectively.

Note 5. Commitments

At March 31, 2004, the Company has a total of \$437,500 in commitments to its contract manufacturer for drug substance, representing \$250,000 due upon acceptance of a drug order, when and if such acceptance occurs, and \$187,500 in fees for storage of iseganan until December 2007.

In March 2004 we agreed to extend the existing lease for our facility in Palo Alto, California through June 30, 2005, and also leased an additional facility in the same building for the period April 1, 2004 to June 30, 2005. The new lease for both premises includes an option to extend until December 31, 2005 at the then market rate for the building. Under the terms of the lease, the Company is committed to pay rent of approximately \$146,000 in 2004 and \$96,000 in 2005.

Note 6. Subsequent Events

On May 10, 2004, the Company issued and sold 3,000,000 shares of common stock, \$0.001 par value, in an underwritten public offering. The underwriters have a 30-day over-allotment option to purchase an additional 450,000 shares of common stock. The offering resulted in net proceeds of approximately \$36.1 million, based on a public

offering price of \$13.00 per share, and after deducting the underwriting discount and commissions and other estimated offering expenses. The primary purpose of the offering is to provide additional funding for conducting clinical trials, research and development, as well as for other general corporate purposes.

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ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes included in our quarterly report on this Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2003. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may 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 "Factors That Could Affect Future Results". All forward-looking statements included in this document are based on information available to us on the date of this document and we assume no obligation to update any forward-looking statements contained in this Form 10-Q.

Overview

We are developing novel antimicrobial drugs derived from protegrins, a class of mammalian peptides that is part of the body's natural defense against invading microbes, including bacteria, fungi and viruses. Our product candidate, iseganan, is a synthetic protegrin analog that has been selected for its broad spectrum microbe-killing activity and its low propensity to engender resistance. Iseganan is currently in clinical development for two indications: the prevention of ventilator-associated pneumonia, or VAP, and the treatment of lung infections associated with cystic fibrosis, or CF. Additionally, we are evaluating the use of iseganan in other types of infection where we believe that its properties may render it more effective than current therapies.

Our research and development expenses are expected to at least double in 2004 as compared to 2003, primarily as a result of the costs associated with our first pivotal trial for the prevention of VAP. If this trial is successful, a second pivotal trial will be required to support registration of iseganan.

A trial's completion date and completion costs are difficult to predict, and delays may be caused by many factors, including: slower than expected rate of patient enrollment; inability to adequately obtain data about patients after their treatment in our clinical trials; additional regulatory requests; inability to manufacture sufficient quantities of materials for clinical trials or validation; the failure by contract research organizations to appropriately manage clinical trials; or unforeseen safety issues. As a result, our research and development expenses may fluctuate significantly, and past trends are not indicative of future spending.

Our cash, cash equivalents, restricted cash and short-term investments totaled \$22.6 million as of March 31, 2004, including the proceeds of two private placements during 2003. In May 2003, we completed a preferred stock placement resulting in net cash proceeds of \$3.2 million, and in October 2003 we completed a common stock placement resulting in net cash proceeds of \$18.5 million. The primary purpose of the financings was to provide additional funding for the two pivotal trials of iseganan for the prevention of VAP, as well as for other general corporate purposes and working capital.

On May 10, 2004, we issued and sold 3,000,000 shares of common stock, \$0.001 par value, in an underwritten public offering. The underwriters have a 30-day over-allotment option to purchase an additional 450,000 shares of common stock. The offering resulted in net proceeds of approximately \$36.1 million, based on a public offering price of \$13.00 per share, and after deducting the underwriting discount and commissions and other estimated offering expenses. The primary purpose of the offering is to provide us with additional funding for conducting clinical trials, research and development, as well as for other general corporate purposes.

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We will need to raise additional funds in the future to continue our operations, complete the FDA approval process of iseganan for the prevention of VAP if our trials are successful, commence commercialization if FDA approval is received, and pursue other indications. We cannot be certain that the results of either of the two pivotal trials for the prevention of VAP or trials for other indications will be successful, and product revenues may only be generated if we receive the required regulatory approvals and can successfully commercialize a product.

As of March 31, 2004, we had received and accepted over eight kilograms of finished iseganan drug substance, which was booked to research and development expense in 2002 in accordance with our standard accounting practices. The quantity is sufficient to complete our planned clinical trials, but further quantities will be required to validate the manufacturing process, and for commercial use if we successfully obtain FDA approval for any indication.

In 2003, we wrote off \$2.4 million of prepaid iseganan drug substance to research and development expense, relating to an order of seven kilograms of drug substance that was expected to be delivered in 2003, but that we have not yet been satisfied was manufactured in accordance with a validation plan or with adequate documentation. We are currently discussing this matter with our contract manufacturer, and the write-off was recorded due to significant uncertainty over the timing and outcome of these discussions.

In 2003 and the three-month period ended March 31, 2004, we recorded non-cash stock compensation expense of approximately \$1.0 million and \$275,000, respectively, for 308,835 unexercised stock options that were cancelled and re-granted in a one-for-one exchange and 12,500 options that were re-granted in connection with the cancellation of 54,166 unexercised stock options in February 2003. The re-granted options have an exercise price equal to the closing price of our common stock on the Nasdaq National Market on February 5, 2003, or \$2.76 per share. The options generally vest over a four-year period and will expire in February 2008 if not previously exercised. Variable accounting is being applied to the re-granted options throughout their term. The related compensation expense depends on both the cumulative vesting of outstanding options and the price of our common stock at each quarter end, and therefore may have a significant impact on our future results of operations.

We intend that the following discussion of our financial condition and results of operations will provide information to assist in the understanding of our financial statements, the changes in certain key items in those financial statements from year to year, and the primary factors that accounted for those changes, as well as how certain accounting principles, policies and estimates affect our financial statements.

Critical Accounting Policies

General

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an ongoing basis, we evaluate these estimates, including those related to clinical trial accruals and stock-based compensation. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent

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from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. Management believes the following critical accounting policies reflect its more significant estimates and assumptions used in the preparation of the financial statements.

Clinical Trial Accruals

The Company's accrued costs for clinical trial activities are based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CROs), investigators, drug processors, laboratories, consultants, or other clinical trial service providers that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the service provider, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, and pre-approval of any changes in scope of the services to be performed. Each CRO provides an estimate of costs incurred but not invoiced at the end of each period for each individual trial. The estimates are reviewed and discussed with the CRO as necessary, and included in research and development expenses for the related period. For investigator study grants, which are paid quarterly on a per-patient basis to the institutions performing the clinical study, the Company accrues an estimated amount based on patient enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced. No adjustments for material changes in estimates have been recognized in any period presented.

Stock-Based Compensation

In February 2003, the Board of Directors approved a cancellation and re-grant of 308,835 unexercised stock options held by existing employees and directors of the Company in a one-for-one exchange and 12,500 options that were re-granted in connection with the cancellation of 54,166 unexercised stock options held by a director of the Company. The options generally vest over a four-year period and will expire in February 2008 if not previously exercised. Variable accounting is being applied to the re-granted options throughout their term. The related compensation expense depends on both the cumulative vesting of outstanding options and the price of the Company's common stock at each quarter end, and therefore may have a significant impact on the Company's future results of operations. No adjustments for material changes in estimates have been recognized in any period presented.

As permitted by Statement of Financial Accounting Standards No. 123 (SFAS 123), Accounting for Stock-Based Compensation , as amended by Statement of Financial Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, the Company has elected to follow APB 25 and related interpretations in accounting for stock-based employee compensation. Under APB 25, if the exercise price of an employee or director stock option is set equal or in excess of the fair market value of the underlying stock on the date of grant, no compensation expense is recognized. In February 2003, certain employee and director stock options for which the exercise prices had originally been set at less than the fair market value of the underlying stock on the grant date, were cancelled and re-granted in a one-for-one exchange. The Company had

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recorded deferred compensation for the difference between the original exercise price and the fair market value of the underlying stock on the grant date as a component of stockholders' equity, and the total was being amortized on a straight-line basis over the vesting period of the original awards, ranging from four to six years. The related re-granted options all vest over a four-year period, and the remaining unamortized deferred compensation as of the re-grant date is now being amortized over the new four-year vesting schedule, commencing at the date of re-grant. The amount of deferred stock compensation expense to be recorded in future periods could decrease if options, for which accrued but unvested compensation has been recognized, are forfeited prior to vesting. No adjustments for material changes in estimates have been recognized in any period presented.

Options or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS 123 and the FASB's Emerging Issues Task Force issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and are recognized over the related service period and are periodically re-measured as the underlying options vest. The fair values are estimated using the Black-Scholes option pricing model, and are periodically re-measured as the underlying options vest. The option pricing model is dependent on a number of inputs, which may change over time. Other option pricing models may produce fair values that are substantially different from the Black-Scholes model. No adjustments for material changes in estimates have been recognized in any period presented.

Results of Operations

Three-Month Periods Ended March 31, 2004 and 2003

Research and Development

Research and development expenses primarily include clinical trial expenses, research and development payroll expense, drug substance expense, allocated facilities costs and non-cash stock compensation charges. Research and development expenses increased to \$4.5 million in the three-month period ended March 31, 2004 from \$268,000 in the three-month period ended March 31, 2003. The increase is primarily due to \$4.1 million of clinical trial expenses relating to the first pivotal trial of iseganan for the prevention of VAP, which commenced in September 2003 and was the only clinical trial in progress during the three-month period ended March 31, 2004. There were no clinical trials in progress in the three-month period ended March 31, 2003.

We expect research and development expenses to at least double in 2004 compared to 2003, primarily as a result of the costs associated with our first pivotal trial of iseganan for the prevention of VAP.

General and Administrative

General and administrative costs primarily include administrative payroll expense, outside contractors, legal and accounting fees, insurance, non-cash stock compensation charges, facilities and other general administrative expenses. General and administrative expenses increased to \$1.9 million in the three-month period ended March 31, 2004 from \$1.7 million in the three-month period ended March 31, 2003. The increase is primarily due to increased non-cash stock compensation charges of \$546,000 in the three-month period ended March 31, 2004 as compared to \$65,000 in the comparable period of 2003, partially offset by \$380,000 of severance costs recorded in the three-month period ended March 31, 2003 related to the reduction of sales, marketing and business development staff.

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Interest Income

Interest income was \$73,000 and \$26,000 in the three-month periods ended March 31, 2004 and 2003, respectively. The increase in interest income resulted from an increase in average interest earning investment balances in the 2004 period as compared to the 2003 period.

Net Loss and Net Loss Applicable to Common Stockholders

Net loss applicable to common stockholders was \$6.3 million and \$1.9 million for the three-month periods ended March 31, 2004 and 2003, respectively, and included the impact of non-cash Series A preferred stock dividends of \$65,000 and \$0 in the three-month periods ended March 31, 2004 and 2003, respectively. Preferred stock dividends represent the 8% annual dividends payable quarterly in common stock to the holders of our Series A preferred stock.

Liquidity and Capital Resources

At March 31, 2004, we had cash and cash equivalents of \$3.9 million, representing a decrease of \$10.4 million from the balance of \$14.3 million as of December 31, 2003. Short-term investments were \$18.4 million at March 31, 2004 as compared to \$12.1 million at March 31, 2003, and restricted cash remained at \$250,000. We had no debt outstanding as of March 31, 2004. We invest excess funds in short-term money market funds and securities pursuant to our investment policy guidelines.

Net cash used in operating activities for the three-month periods ended March 31, 2004 and 2003 was \$4.2 million and \$1.9 million, respectively. The cash used consisted primarily of the net loss for each period, adjustments for non-cash stock compensation expense and changes in prepaid expenses and accrued clinical liabilities.

Net cash used in investing activities for the three-month periods ended March 31, 2004 and 2003 was \$6.3 million and \$0, respectively. The cash used in the 2004 period related to the purchase of \$10.2 million of short-term investments, partially offset by proceeds from the sale or maturity of short-term investments of \$3.9 million.

Net cash provided by financing activities for the three-month periods ended March 31, 2004 and 2003 was \$156,000 and \$1,000, respectively. The cash provided in both periods related to the exercise of stock options.

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The impact that our contractual obligations as of March 31, 2004 are expected to have on our liquidity and cash flow in future periods is as follows:

	Payments Due by Period				
	Total	Less than 1 Year	Between 1-3 Years	Between 3-5 Years	More than 5 Years
			(In thousands)		
Drug substance(1)	\$438	\$ 300	\$ 100	\$ 38	\$ 0
Operating leases(2)	242	194	48		
Total contractual commitments	\$680	\$ 494	\$ 148	\$ 38	\$ 0

- (1) Drug substance commitments are to the contract manufacturer of iseganan bulk drug substance. In 2004, the commitment represents the potential payment of \$250,000 upon acceptance of an order, when and if acceptance occurs, and \$50,000 in fees for storage of iseganan. The remaining \$137,500 represents storage fees for iseganan through 2007.
- (2) Operating leases relate to the lease for our facilities in Palo Alto, California. In March 2004, we agreed to extend the existing lease through June 30, 2005, and also leased an additional facility in the same building for the period April 1, 2004 to June 30, 2005. The new lease for both premises includes an option to extend until December 31, 2005 at the then market rate for the building. Under the terms of the lease, the Company is committed to pay rent of approximately \$146,000 in 2004 and \$96,000 in 2005.

There were no purchase obligations as of March 31, 2004 that included material penalties for cancellation and were enforceable and legally binding.

Indemnifications

In the ordinary course of business, we enter into contractual arrangements under which we may agree to indemnify the third party to such arrangement from any losses incurred relating to the services they perform on behalf of IntraBiotics or for losses arising from certain events as defined within the particular contract, which may include, for example, litigation or claims relating to past performance. Such indemnification obligations may not be subject to maximum loss clauses. Historically, payments made related to these indemnifications have been immaterial. In addition, we have entered into indemnity agreements with each of our directors and executive officers. Such indemnity agreements contain provisions which are in some respects broader than the specific indemnification provisions contained in Delaware law. We also maintain an insurance policy for our directors and executive officers insuring against certain liabilities arising in their capacities as such.

Future Capital Requirements

We expect to continue to incur substantial operating losses and will not receive any product revenues until a product candidate has been approved by the FDA and successfully commercialized. We currently anticipate our cash, cash equivalents and investments to be sufficient to fund operations for at least the next 12 months. We expect, however, that we will need to raise significant additional funds to continue our operations, complete the FDA approval process of iseganan for VAP if our trials are successful, commence commercialization if FDA approval is received, and pursue other indications.

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This forecast is a forward-looking statement that involves risks and uncertainties, and actual results could vary. Our future capital requirements will depend on many factors, including:

uncertainty of the timing, delay, cost, extent and results of clinical trials;

future opportunities for raising capital when needed or on favorable terms;

payments to third parties for manufacturing scale up and validation;

the costs and timing of regulatory approvals;

the costs of establishing sales, marketing and distribution capabilities;

the progress of our development activities;

risk of delays in conducting clinical trials due to factors such as slower than expected rate of patient enrollment;

inability to acquire sufficient quantities of materials used for clinical trials;

our ability to establish partnership collaborations and agreements;

difficulties with clinical supplies or unforeseen safety issues; and

regulatory risks, risks related to proprietary rights, market acceptance and competition.

Until we can generate sufficient cash from our operations, which we do not expect for the foreseeable future, we expect to finance future cash needs through private and public financings, including equity financings. We may also generate cash through collaboration or licensing arrangements, although no such transactions are currently under negotiation. We cannot be certain, however, that additional funding will be available when needed or on favorable terms. If additional funding is not available, we may need to delay or curtail our development and clinical trial activities to a significant extent, or we may be forced to cease operations.

Factors That Could Affect Future Results

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.

If either of our two pivotal clinical trials of iseganan for the prevention of ventilator-associated pneumonia, or VAP, or any future clinical trials of iseganan for other indications are unsuccessful, we could have to cease operations.

We currently have only one product candidate in late stage clinical trials. We previously completed three Phase III clinical trials of iseganan for the prevention of ulcerative oral mucositis, a complication that develops in certain cancer patients receiving chemotherapy or radiation therapy that results in painful ulcer-like sores in the mouth and throat. All three of these clinical trials failed to meet their primary end points, and we are no

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longer pursuing iseganan for the prevention of ulcerative oral mucositis. We are currently pursuing iseganan for the prevention of VAP. Enrollment in the first of two pivotal trials commenced in September 2003, and we expect to announce results of this first trial by the end of 2004. The failure of either of these two pivotal trials in meeting their primary end points, or of any other future clinical trials of iseganan for alternative indications, will negatively impact our future operating results and may force us to cease operations. In addition, even if the trials meet their primary end points, iseganan may not be approved, if, for instance, there are significantly more deaths in the treatment group than in the placebo group.

If we fail to complete any clinical trial, or fail to obtain U.S. Food and Drug Administration, or FDA, approval for any product candidate that we develop, acquire or license, we may never achieve profitability and may have to cease operations.

We do not have a drug approved for sale in the United States or any foreign market. We do not know whether we will be successful in developing iseganan for the prevention of VAP or other indications, or in developing, acquiring or licensing any other products and successfully obtaining FDA or foreign approvals for them. We must successfully complete clinical trials and demonstrate manufacturing capability before we can file with the FDA for approval to sell any product in the United States or with foreign regulatory authorities in order to sell in other countries. The FDA could require us to repeat or perform additional clinical trials as a result of its regulatory review. There is no guarantee that foreign regulatory authorities will approve our products on the same data required by the FDA, and, as a result, we may be required to perform additional clinical trials before being approved to sell in foreign markets. Delays in obtaining or failure to obtain regulatory approvals may:

delay or prevent the successful commercialization of our drug candidate;

diminish any competitive advantage we may have; 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. A number of new drugs for certain indications, iseganan for the prevention of oral mucositis included, have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. A number of companies have also suffered significant setbacks in advanced clinical trials, including issues related to the design or conduct of those trials. We have had to re-perform a Phase III clinical trial in the past, following a drug dispensing error by a contract vendor. We have limited experience in obtaining drug approvals. We cannot be certain when, if ever, we will receive these regulatory approvals. If we are unable to demonstrate the safety and efficacy of any drug candidate, we will be unable to obtain the required regulatory approvals, and we will be unable to commercialize a drug candidate and generate product revenue.

In addition to initial regulatory approval, any drug 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.

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Difficulties and risks associated with conducting our clinical trials could cause delays in, or prevent us from, receiving approval or successfully commercializing our product, which would materially harm our business.

Planned clinical trials may not begin on time or may need to be restructured after they have begun. Clinical trials can be delayed for a variety of reasons, including:

competition in recruiting clinical investigators;

negotiating acceptable clinical trial agreement terms with prospective trial sites;

obtaining institutional review board approval to conduct a clinical trial at a prospective site;

recruiting patients to participate in a clinical trial;

management of data related to our clinical programs;

the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;

the placement of a clinical hold on a study;

the failure of third parties conducting and overseeing the operations of clinical trials to perform their contractual or regulatory obligations in a timely fashion;

exposure of clinical trial patients to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial; and

inability to obtain prompt regulatory review and agreement on key design features of clinical studies.

In addition, there are a number of difficulties and risks associated with clinical trials. These difficulties and risks may result in the failure to receive regulatory approval to sell our product candidates or the inability to commercialize any of our product candidates. The possibility exists that:

we may discover that a product candidate does not exhibit the expected therapeutic results in humans, causes harmful side effects or has other unexpected characteristics that delay or preclude regulatory approval or limit commercial use if approved;

the results from early clinical trials may not be predictive of results that will be obtained in expanded, advanced clinical trials;

patients may drop out of our clinical trials;

our clinical trials may not yield a sufficient number of infected patients in the placebo group to provide statistically significant results;

the clinical procedures outlined in our clinical trial protocols may not be properly followed, which could produce inconclusive results or prematurely end such clinical trial;

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our clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials; and

the cost of our clinical trials may be greater than we currently anticipate.

We expect to continue to incur operating losses for the foreseeable future and may never achieve profitability.

We have never generated revenues from product sales and have incurred significant net losses in each year since inception. We incurred net losses of \$13.3 million in 2003 and \$6.2 million in the three-month period ended March 31, 2004. As of March 31, 2004, our accumulated deficit was approximately \$221.5 million. We expect to continue to incur substantial additional losses for the foreseeable future, and we may never become profitable. 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 are currently conducting a pivotal trial of iseganan for the prevention of VAP. We are also developing iseganan for cystic fibrosis, or CF, and may develop iseganan for other indications in the future or acquire or license other products.

We will receive revenues from product sales or royalties only if we complete clinical trials with respect to one or more products, receive regulatory approvals and successfully commercialize such products. We do not know whether we will be successful in developing iseganan for our currently planned prevention of VAP indication or other indications, or in acquiring or licensing other products.

We must raise capital to continue our operations, 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 will need to raise additional funds to continue our operations, complete the FDA approval process of iseganan for the prevention of VAP if our trials are successful, commence commercialization if FDA approval is received, and pursue other indications. 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 our product development efforts or any product acquisitions or be forced to cease operations. Our future liquidity and capital requirements will also depend on many other factors, including:

the timing, cost and progress of our prevention of VAP trials and any other clinical trials we may conduct;

the timing of, and the costs involved in, obtaining regulatory approvals for any product in the United States and other countries;

decisions with respect to strategic alternatives;

the success of our development and commercialization of our product candidates;

the scope and results of our clinical trials;

advancement of other product candidates into clinical development;

potential acquisition or in-licensing of other products or technologies;

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the costs of manufacturing activities;

the costs of commercialization activities, including product marketing, sales and distribution;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property-related costs, including any possible litigation costs;

the effect of competing technological and market developments; and

our ability to establish and maintain collaborative and other strategic arrangements.

Adequate financing may not be available on terms acceptable to us, if at all. We may continue to seek additional capital through public or private equity offerings, debt financings or collaborative arrangements and licensing agreements.

If the contract research organizations assisting in our clinical trials fail to appropriately manage our clinical trials, the trials could be delayed or could fail, and our results of operations and financial condition would suffer.

We rely on contract research organizations to assist us in managing and monitoring our clinical trials. We have entered into agreements with Amarex, LLC, Orion Clinical Services, Ltd, Advanced Clinical Trials, Inc. and Icon Laboratories, In