

INTRABIOTICS PHARMACEUTICALS INC /DE

Form 10-Q

May 12, 2004

**Table of Contents**

**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 incorporation or organization)	(I.R.S. Employer Identification 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.

---

**TABLE OF CONTENTS**

**INTRABIOTICS PHARMACEUTICALS, INC.**

**FORM 10-Q**

**QUARTER ENDED March 31, 2004**

**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements (unaudited)</u></b>	
<u>Condensed Balance Sheets as of March 31, 2004 and December 31, 2003</u>	3
<u>Condensed Statements of Operations for the Three-Month Periods Ended March 31, 2004 and 2003</u>	4
<u>Condensed Statements of Cash Flows for the Three-Month Periods Ended March 31, 2004 and 2003</u>	5
<u>Notes to Condensed Financial Statements</u>	6
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	9
<b><u>Item 3. Quantitative and Qualitative Disclosure About Market Risk</u></b>	29
<b><u>Item 4. Controls and Procedures</u></b>	29
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	30
<b><u>Item 2. Changes in Securities and Use of Proceeds</u></b>	30
<b><u>Item 3. Defaults Upon Senior Securities</u></b>	30
<b><u>Item 4. Submission of Matters to a Vote of Security Holders</u></b>	30
<b><u>Item 5. Other Information</u></b>	30
<b><u>Item 6. Exhibits and Reports on Form 8-K</u></b>	30
<b><u>SIGNATURES</u></b>	31
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

## INTRABIOTICS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS  
(IN THOUSANDS)

	<b>MARCH 31, 2004 (Unaudited)</b>	<b>DECEMBER 31, 2003 (Note 1)</b>
<b>ASSETS</b>		
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	<b>\$ 23,128</b>	<b>\$ 27,326</b>
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
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
<b>Stockholders equity:</b>		
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	<b>20,214</b>	<b>25,628</b>
	<hr/>	<hr/>

Total liabilities and stockholders' equity	\$ 23,128	\$ 27,326
--	-----------	-----------

See accompanying notes

3

---

**Table of Contents**

## INTRABIOTICS PHARMACEUTICALS, INC.

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

	<b>THREE MONTHS ENDED MARCH 31,</b>	
	<b>2004</b>	<b>2003</b>
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

**Table of Contents**

## INTRABIOTICS PHARMACEUTICALS, INC.

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

	<b>THREE MONTHS ENDED MARCH 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Operating activities</b>		
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)
<b>Investing activities</b>		
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)	
<b>Financing activities</b>		
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



**Table of Contents**

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.

**Table of Contents**

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):

	<b>THREE MONTHS ENDED MARCH 31,</b>	
	<b>2004</b>	<b>2003</b>
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>

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

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:

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

**Table of Contents**

## Note 3. Comprehensive Loss

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

	<b>THREE MONTHS ENDED MARCH 31,</b>	
	<b>2004</b>	<b>2003</b>
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.

**Table of Contents**

**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.

**Table of Contents**

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

**Table of Contents**

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



## **Table of Contents**

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.

**Table of Contents**

*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.

**Table of Contents****Contractual Obligations**

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:

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

- (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.

## **Table of Contents**

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

**Table of Contents**

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.

**Table of Contents**

***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;

**Table of Contents**

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;



**Table of Contents**

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, Inc., among others, to provide clinical research services. The investigators and contract research organizations are not our employees, and we cannot control, other than by contract, the amount of resources, including time, that they devote to our product candidates. However, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols that have been approved by regulatory agencies for such trials. We have previously experienced a drug dispensing error by one of our contract research organizations, which adversely affected the results of one of our clinical trials for iseganan in oral mucositis.

The FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights and confidentiality of trial participants are protected. The FDA may inspect some of our clinical investigational sites, our contract research organizations' records and our facility and files to determine if clinical trials are conducted according to good clinical practices. If the FDA determines that a trial is not in compliance with good clinical practices, we may be required to repeat the clinical trial. If our contract research organizations fail to perform in accordance with our agreements with them, we may not complete our clinical programs on time or at all.

In connection with our reliance on our independent clinical investigators and contract research organizations, our clinical trials may be extended, delayed, suspended or terminated for a variety of reasons, including:

the failure of investigators and research organizations to comply with good clinical practice or to meet their contractual duties;

the failure of our independent investigators to devote sufficient resources to the development of our product candidates or to perform their responsibilities with sufficient expertise and care;

**Table of Contents**

our need to replace these third parties for any reason, including for performance reasons or if these third parties go out of business; or

problems in the quality or accuracy of the data they obtain due to the failure to collect, compile or analyze data appropriately, adhere to clinical protocols or regulatory requirements or for other reasons.

Extensions, delays, suspensions or terminations of our clinical trials as a result of the performance of our independent clinical investigators and contract research organizations will delay, and make more costly, regulatory approval for any product candidates that we may develop. Any change in a contract research organization during an ongoing clinical trial could seriously delay that trial and potentially compromise the results of the trial.

***We will be dependent on third-party contract manufacturers for the future production of iseganan and for producing information required to register iseganan with the FDA, if our trials are successful.***

We have relied on a single contract manufacturer to manufacture the iseganan bulk drug substance for our pivotal clinical trials. We currently maintain a sufficient inventory of iseganan to complete planned clinical trials. In addition, if no alternate sources of supply are developed, we will depend on this manufacturer to produce iseganan for FDA registration and to produce iseganan for future commercial use if our pivotal trials are successful. In 2003, we received a manufactured lot from this contract manufacturer that we have not yet been satisfied was manufactured in accordance with a validation plan or that related documentation is adequate. Although this lot is not expected to be required for our pivotal clinical trials, it is expected to be used to validate the manufacturing process. If the manufacturer is unable to validate the manufacturing process, produce iseganan and the required information for FDA registration, or produce iseganan for future commercial use on a timely basis and in accordance with set specifications, or we experience similar issues to those experienced on this order, we may not have sufficient quantities of iseganan and sufficient information to meet registration requirements or sufficient quantities of iseganan for future commercial use. We do not currently have any supply agreement with this or any other contract manufacturer to provide iseganan bulk drug substance.

We also rely on a single third-party supplier to produce iseganan formulated drug product for use in our clinical trials. We do not currently have any supply agreement with this third-party supplier. If this supplier is unable or fails to produce the required quantities of iseganan formulated drug product for clinical use or commercial sale on a timely basis, at commercially reasonable prices, and with sufficient purity, we will not have sufficient quantities to complete all of our planned clinical trials, or to meet commercial demand.

***The Fast Track designation for development of iseganan may not actually lead to a faster development or regulatory review or approval process and our Special Protocol Assessment approved by the FDA is subject to change.***

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. Marketing applications filed by sponsors of products in Fast Track development may qualify for expedited review under policies or procedures offered by the FDA, but the Fast Track designation does not assure such qualification. We have been granted Fast Track designation from the FDA for iseganan for the prevention of VAP. Iseganan's Fast Track designation may be withdrawn by the FDA if the FDA believes that it is no longer supported by data from our clinical development program. In addition,

**Table of Contents**

iseganan's Fast Track designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that the FDA will ultimately approve iseganan.

In September 2003, we formalized an agreed-upon pivotal clinical trial design for iseganan for the prevention of VAP with the FDA through a Special Protocol Assessment, or SPA. The SPA requires us to conduct a second identical pivotal trial. The SPA is subject to change based upon data produced from our pivotal trials, data produced from clinical trials conducted by third parties and other events outside of our control. The SPA does not guarantee that the requirements for approval of our product will not change and does not necessarily increase the likelihood that the FDA will ultimately approve our product for the prevention of VAP.

***Development and commercialization of competitive products or new technologies could reduce or prevent sales of any future products that we develop, acquire or license, which could materially harm our business.***

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 drug candidates that we develop, acquire or license. If we are unable to compete successfully with any future drug candidate, physicians may not prescribe and patients may not buy our drug.

We are aware of a clinical trial in Europe testing the utility of chlorhexidine, an antiseptic approved for gingivitis, also known as Peridex, for use in the prevention of VAP. We are also aware of one medical device product on the market and other medical device products in development for the prevention of VAP. In addition, it is possible that antimicrobial or antiseptic products already approved by the FDA for other indications may be used off-label by physicians for the prevention of VAP. Pharmaceutical companies, biotechnology companies and medical device companies may also develop products in the future that compete with iseganan for the prevention of VAP.

There are two approved pharmaceutical products used for the treatment of CF. TOBI is sold by Chiron Corporation and generated approximately \$170 million in sales in 2003. Colistin is sold by several manufacturers, in greater volume in Europe than in the United States. We are aware of two products that are in clinical development for the treatment of CF. Aztreonam is a product already approved for intravenous use in other bacterial infections and is in Phase II testing for the treatment of CF by Corus Pharma, Inc. Doripenem is an experimental agent in Phase I studies sponsored by Peninsula Pharmaceuticals, Inc. Both of these products are active against pseudomonas aeruginosa, the major pathogen in CF.

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

***We currently have no sales and marketing organization and, therefore, must develop a sales and marketing organization or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates.***

**Table of Contents**

Developing the sales force to market and sell products is a difficult, expensive and time-consuming process. We have no experience developing a sales organization and may be unsuccessful if we attempt to do so. If we are unable to develop an internal sales and marketing operation, we may not be able to increase market awareness and sell our product. We may also rely on third-party distributors to distribute our products or enter into marketing alliances to sell our products. We may not be successful in entering into distribution arrangements and marketing alliances with third parties. Our failure to successfully develop a sales organization or to enter into these arrangements on favorable terms could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Dependence on distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including:

we may be required to relinquish important rights to our products or product candidates;

we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;

our distributors or collaborators may experience financial difficulties; and

business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

***If physicians, patients, health care payors and the medical community do not accept our products, we may be unable to generate significant revenues, if any, and we may have to cease operations.***

Any drug candidate that we develop, acquire or license may not gain market acceptance among physicians, patients, health care payors and the medical community. If any drug candidate fails to achieve market acceptance, we may be unable to successfully market and sell the product, which would limit our ability to generate revenue. The degree of market acceptance of any drug candidate depends on a number of factors, including:

the belief of the medical community that VAP is a health issue that needs to be addressed;

demonstration of clinical efficacy and safety;

cost-effectiveness, in particular with iseganan's anticipated application for the prevention of VAP;

convenience and ease of administration;

potential advantage over alternative treatment methods;

sales, marketing and distribution support; and

the inability to administer our product in hospitals due to such third parties' internal policies and procedures that may deter the use and application of our product to their patients due to concerns of resistance or otherwise.

**Table of Contents**

Physicians will not prescribe our products until such time as clinical data or other factors demonstrate the safety and efficacy of our drugs as compared to other treatments. In practice, competitors may be more effective in marketing their drugs. Even if the clinical safety and efficacy of our product is established, physicians may elect not to prescribe its use. For example, physicians may be reluctant to use our product widely because of concern about developing microbial strains that are resistant to our drugs, or because of the cost of our drug.

***The failure to recruit and retain our chief executive officer and other employees may delay our ability to execute our business plan and our results of operations could suffer.***

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 or technical staff, we may be unable to successfully complete our planned clinical trials. In particular, the loss of the services of Henry J. Fuchs, our President and Chief Executive Officer, could significantly impede our research and development efforts, our relations with potential collaborators and completion of our planned clinical trials. We do not maintain key person life insurance and do not have an employment agreement with Dr. Fuchs or our other members of our management and technical staff. In October 2002, we completed a restructuring that included a reduction in force of approximately 70% of our workforce. As of April 12, 2004, we had 12 full-time employees. In order to pursue any future product development, marketing and commercialization, we will need to hire additional qualified scientific personnel to perform research and development and personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

We rely on consultants to assist us in formulating our research and clinical development strategy. These consultants 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.

***The departure of Henry J. Fuchs, our President and Chief Executive Officer, could require us to refund money to holders of our Series A preferred stock.***

If we fail to use our reasonable best efforts to retain the services of Henry J. Fuchs, our President and Chief Executive Officer, until the earlier to occur of the unblinding and public announcement of the results of our first pivotal clinical trial for VAP or May 1, 2005, then we must pay to each holder of our Series A preferred stock a one-time payment equal to 15.0% of the applicable holder's aggregate Series A preferred stock purchase price. Based on the number of shares of Series A preferred stock outstanding as of March 31, 2004, our potential exposure for this provision is \$487,500. This penalty will not apply if Dr. Fuchs' departure is the result of his death, disability or family emergency or if we retain services of an executive officer to replace Dr. Fuchs within 60 days of Dr. Fuchs' departure, for reasons other than his death, disability or family emergency, and such replacement is approved by the Board, including the member(s) of our Board designated by Tang Capital Partners.

***We will need to increase the size of our organization, and we may experience difficulties in managing growth.***

We are a small company with 12 employees as of April 12, 2004. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational,

**Table of Contents**

financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

manage our development efforts effectively;

manage our clinical trials effectively;

integrate additional management, administrative, manufacturing and sales and marketing personnel;

maintain sufficient administrative, accounting and management information systems and controls; and

hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

***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 expect 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 two issued U.S. patents and one pending patent application in the United States and several foreign jurisdictions that contain claims covering iseganan. 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. In addition, some of our patents have only been filed in a limited number of jurisdictions which may limit our ability to protect our rights in other jurisdictions. We currently do not have any issued patents in

**Table of Contents**

Europe or Japan covering iseganan, and we do not know whether any of our pending patent applications will result in the issuance of patents in these jurisdictions. 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 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 and would affect our results of operations and financial condition.***

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 because of litigation or interference proceedings initiated or threatened against us.

***Because there is a risk of product liability associated with our products, we face potential difficulties in obtaining insurance.***

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering product use in our clinical trials, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will provide adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

inability to conduct our clinical trials;

**Table of Contents**

withdrawal of clinical trial participants;  
costs of related litigation;  
substantial monetary awards to patients;  
loss of revenues;  
product recalls;  
injury to our reputation;  
decreased demand for our product candidates; and  
the inability to commercialize our product candidates.

***Directors, executive officers, principal stockholders and affiliated entities beneficially own approximately 52% of our capital stock and may be able to exert control over our activities, and the results of our operations and financial condition may suffer.***

As of March 31, 2004, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 52% of our outstanding common stock and Series A preferred stock on an as-converted basis. These stockholders, if acting together, will be able to control the outcome of any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions.

***The holders of our Series A preferred stock have voting and other rights that they could exercise against your best interests.***

The holders of our Series A preferred stock have rights to designate two members of our Board and to vote as a separate class on certain significant corporate transactions. The holders of Series A preferred stock are entitled to receive cumulative annual dividends of 8% of the original purchase price of \$10,000 per share, payable in common stock. In addition, upon our liquidation or dissolution (including a merger or acquisition), the holders of our Series A preferred stock are entitled to receive a liquidation preference in an amount equal to the greater of (i) \$10,000 per share of Series A preferred stock, or approximately \$3.25 million based on the 325 shares of Series A preferred stock currently outstanding, plus any declared but unpaid dividends or (ii) the amount that would have been paid had each such share of Series A preferred stock been converted to common stock. The holders of Series A preferred stock also have the right of first refusal to purchase their pro rata portion of any equity securities we propose to offer to any person. Such right of first refusal is subject to certain customary exclusions, including for shares issued pursuant to any options or other stock awards granted to employees, directors or consultants of IntraBiotics, equipment leasing arrangements, debt financings, strategic financings and public offerings that have been approved by the Board. The holders of Series A preferred stock may exercise these rights to the detriment of our common stockholders.

The holders of our Series A preferred stock also have the right at any time to request that we register for resale the shares of our common stock that they acquire upon conversion of their Series A preferred stock or upon exercise of their warrants to purchase our common stock, subject to certain limitations. A registration statement has been filed with the Securities and Exchange Commission and is currently effective for the resale



**Table of Contents**

of the shares of common stock issuable upon conversion of our Series A preferred stock and upon the exercise of those warrants. In addition, the holders of our Series A preferred stock may convert their Series A preferred stock into common stock and sell those shares of the common stock acquired upon such conversion in the public market in reliance upon Rule 144, subject in some cases to volume and other limitations. Future sales in the public market of such common stock, or the perception that such sales might occur, could adversely affect the prevailing market price of our common stock and could make it more difficult for us to raise funds through a public offering or private placement of our equity securities.

***Anti-takeover 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;

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 or for proposals that can be acted on at stockholder meetings;

require the approval from the holders of Series A preferred stock, prior to May 1, 2005, for any merger into or consolidation with any other corporation (other than a wholly-owned subsidiary corporation or for the purposes of changing our domicile) or the completion of any transaction or series of related transactions in which fifty percent or more of our voting power is transferred or the sale, lease or other disposition of all or substantially all of our assets;

authorize our Board to issue blank check preferred stock to increase the amount of outstanding shares; 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.

***The change in our stock price over time may significantly impact our results of operations through certain stock compensation charges that depend upon our closing stock price at the end of each quarter.***

Market prices for securities of biotechnology companies are general highly volatile and our stock may be subject to such volatility. Our non-cash variable stock compensation expense in relation to 308,835 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 is dependent upon the

**Table of Contents**

price of our common stock at each quarter end. 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, in relation to these options. Non-cash stock compensation expense will be incurred through the five-year term of the options, unless previously forfeited or exercised. Future changes in our stock price may therefore have a significant impact on our future results of operations as a result of this dependency.

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

During the three-month period ended March 31, 2004, our closing stock prices ranged from a low of \$13.46 to a high of \$18.00, and in 2003 ranged from a low of \$1.71 to a high of \$16.95. 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 regarding strategic alternatives, including a merger or sale of the company or acquisition or license of products or product candidates;

publicity regarding actual or perceived adverse events in our clinical trial or relating to products under development by us or our competitors;

the regulatory status of our product candidates;

failure of any of our product candidates, if approved, to achieve commercial success;

our ability to manufacture any products to commercial standards;

announcements of technological innovations or new commercial products by our competitors or us;

developments concerning proprietary rights;

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.

**Table of Contents**

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital until it is required to fund operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of March 31, 2004, we own financial instruments that are sensitive to market risk as part of our investment portfolio. To minimize this risk, in accordance with our investment policy guidelines, we place investments with high credit quality issuers and limit the amount of credit exposure to any one issuer. The average duration of our investment portfolio in the three-month period ended March 31, 2004 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, 2004. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk.

**ITEM 4. CONTROLS AND PROCEDURES**

**(a) Evaluation of disclosure controls and procedures**

Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of the end of the period covered by this report, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the Exchange Act)) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

**(b) Changes in internal controls**

There was no change in our internal control over financial reporting during our first fiscal quarter ended March 31, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

(a) We are not a party to any material legal proceedings.

(b) No legal proceedings were terminated in the first quarter.

**Item 2. Changes in Securities and Use of Proceeds and Issuer Purchases of Equity Securities**

None

**Item 3. Defaults Upon Senior Securities**

None

**Item 4. Submission of Matters to a Vote of Security Holders**

None

**Item 5. Other Information**

None

**Item 6. Exhibits and Reports on Form 8-K**

(a) *Exhibits*

The exhibits listed on the Exhibit Index (following the signature section of this Quarterly Report) are included, or incorporated by reference, in this Quarterly Report.

(b) *Reports on Form 8-K*

We filed a report on Form 8-K on March 5, 2004 concerning the issuance of a press release relating to our financial results for our fiscal fourth quarter and year ended December 31, 2003.

**Table of Contents**

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IntraBiotics Pharmaceuticals, Inc.

/s/ Henry J. Fuchs

---

May 12, 2004

Henry J. Fuchs, M.D.  
President and Chief Executive Officer

/s/ David J. Tucker

---

May 12, 2004

David J. Tucker  
Principal Financial Officer

**Table of Contents**

**EXHIBIT INDEX**

3.1	Certificate of Amendment of Amended and Restated Certificate of Incorporation; and Amended and Restated Certificate of Incorporation.(12)
3.2	Amended and Restated Bylaws (16)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation.(15)
3.4	Certificate of Designation filed with the Delaware Secretary of State on May 1, 2003.(15)
4.1	Amended and Restated Investor Rights Agreement dated October 15, 1999.(1)
4.2	Form of Stock Purchase Agreement by and between the Company and each selling stockholder, dated January 29, 2002.(4)
4.3	Form of Preferred Stock and Warrant Purchase Agreement, dated February 5, 2003, as amended on February 11, 2003.(11)
4.4	Form of Second Amendment to Preferred Stock and Warrant Purchase Agreement of February 5, 2003, dated April 10, 2003.(13)
4.5	Form of Warrant issued by the Company pursuant to Preferred Stock and Warrant Purchase Agreement of February 5, 2003, as amended of February 11, 2003 and April 10, 2003.(13)
4.6	Form of Common Stock and Warrant Purchase Agreement, dated October 6, 2003.(14)
4.7	Form of Warrant issued by the Company pursuant to the Common Stock and Warrant Purchase Agreement of October 6, 2003.(14)
10.1	Form of Indemnity Agreement.(1)
10.2	Amended and Restated 1995 Stock Option Plan, as amended on November 16, 2002.(10)(12)
10.2.2	Amended and Restated Form of Stock Option Agreement and Notice of Grant of Stock Options and Option Agreement.(1)(10)
10.3	2000 Equity Incentive Plan, as amended on February 11, 2003.(10)(12)
10.4	Purchase Supply Agreement by and between the Company and PolyPeptide Laboratories A/S dated January 3, 1997.(1)
10.5	Development Supply Agreement by and between the Company, PolyPeptide Laboratories A/S and Ferring Peptide Production AB dated January 3, 1997 and Amendment dated July 1, 1997.(1)
10.6	Second Amendment to the License Agreement by and between the Company and The Regents of the University of California dated June 12, 1996.(1)



**Table of Contents**

- 10.7 Third Amendment to the License Agreement by and between the Company and The Regents of the University of California dated September 16, 1997.(1)
- 10.8 License and Supply Agreement by and between the Company and Biosearch Italia S.p.A. dated May 8, 1998.(1)
- 10.9 2000 Employee Stock Purchase Plan and related documents.(1)(10)
- 10.10 Loan and Security Agreement by and between the Company and Silicon Valley Bank, dated August 25, 1999.(1)
- 10.11 Research and Technology Agreement by and between the Company and New Chemical Entities dated January 24, 2001.(2)
- 10.12 Letter Agreement by and between the Company and Biosearch Italia dated May 18, 2001.(3)
- 10.13 First Amendment to Research and Technology Agreement by and between the Company and Albany Molecular Research Inc. (successor to New Chemical Entities Inc.) dated April 13, 2001.(3)
- 10.14 Letter Agreement by and between the Company and Albany Molecular Research Inc. (successor to New Chemical Entities Inc.) dated June 21, 2001.(3)
- 10.15 Senior Executive Severance Benefit Plan, as amended and restated on August 1, 2002.(8)(10)
- 10.16 Executive Severance Benefit Plan, as amended and restated on August 1, 2002.(8)(10)
- 10.17 Summary of Officer Incentive Bonus Plan.(3)(10)
- 10.18 Release Agreement by and between the Company and Diversa Corporation dated July 27, 2001, including Warrant to Purchase Common Stock of the Company and Registration Rights Agreement.(6)
- 10.19 Letter Agreement dated November 28, 2001 by and between the Company and Ken Kelley.(5)(10)
- 10.20 Loan Modification Agreement by and between the Company and Silicon Valley Bank, dated April 29, 2002.(7)
- 10.21 Loan Modification Agreement by and between the Company and Silicon Valley Bank, dated June 10, 2002.(7)
- 10.22 2002 Non-Officer Equity Incentive Plan and related documents, as amended on February 3, 2003.(12)
- 10.23 Master Services Agreement by and among the Company, PPD Development, LP and PPD Global Ltd., dated July 29, 2002.(8)
- 10.24 Lease Termination Agreement by and between the Company and EOP-Shoreline Technology Park, L.L.C., dated November 22, 2002, including Common Stock Purchase Agreement.(9)
- 10.25



Lease Termination Agreement by and between the Company and Bruce H. Carter and Keith M. Carter,  
dated October 31, 2002.(12)

**Table of Contents**

- 10.26 Sublease Termination Agreement and Sublease by and between the Company and ReShape, Inc., dated October 31, 2002.(12)
- 10.27 Amendment and Assignment of Lease, Release and Assumption Agreement by and among the Company, PolyFuel, Inc. and 1245 Terra Bella Partners, LLC, dated December 20, 2002, including Warrant to Purchase Common Stock of the Company dated December 31, 2002.(12)
- 10.28 Termination of Development Supply Agreement and Purchase/Supply Agreement by and among the Company, PolyPeptide Laboratories A/S and PolyPeptide Laboratories AB, dated December 6, 2002.(12)
- 10.29 Lease Agreement by and between the Company and Embarcadero Corporate Center, dated February 10, 2003.(12)
- 10.30 Common Stock and Warrant Purchase Agreement, dated October 6, 2003 (the Purchase Agreement ) by and among the Company and each Investor as defined therein.(14)
- 10.31 Form of warrant issued by the Company in favor of each Investor, as defined in the Purchase Agreement.(14) 2004 Stock Incentive Plan. (16)
- 10.32 2004 Stock Incentive Plan. (16)
- 10.33 First Amendment to Office Lease, dated March 11, 2004, between the Company and Embarcadero Corporate Center. (16)
- 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.\*
- 31.2 Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.\*
- 32.1 Certifications of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

---

\* Filed hereto.

Confidential treatment request has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to exhibit to our Registration Statement on Form S-1 (File No. 333-95461) initially filed with the Securities and Exchange Commission on January 27, 2000 as subsequently amended.

(2) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on May 16, 2001.

(3) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on August 14, 2001.



**Table of Contents**

- (4) Incorporated by reference to exhibit to our Registration Statement on Form S-3 (File No. 333-82934) filed with the Securities and Exchange Commission on February 15, 2002.
- (5) Incorporated by reference to exhibit to our Form 10-K (File No. 000-29993) filed with the Securities and Exchange Commission on February 15, 2002.
- (6) Incorporated by reference to exhibit to our Registration Statement on Form S-3 (File No. 333-89840) filed with the Securities and Exchange Commission on June 5, 2002.
- (7) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on August 14, 2002.
- (8) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on November 14, 2002.
- (9) Incorporated by reference to exhibit to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on November 27, 2002.
- (10) Management contract or compensatory plan, contract or arrangement.
- (11) Incorporated by reference to Appendix B to the Definitive Proxy Statement for the Special Meeting of Stockholders (File No. 000-29993) filed with the Securities and Exchange Commission on March 3, 2003.
- (12) Incorporated by reference to exhibit to our Form 10-K (File No. 000-29993) filed with the Securities and Exchange Commission on March 31, 2003.
- (13) Incorporated by reference to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on May 14, 2003.
- (14) Incorporated by reference to exhibit to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on October 9, 2003.
- (15) Incorporated by reference to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on November 12, 2003.
- (16) Incorporated by reference to exhibit to our Registration Statement on Form S-1 (File No. 333-114451) initially filed with the Securities and Exchange Commission on April 14, 2004 as subsequently amended.