

INTRABIOTICS PHARMACEUTICALS INC /DE

Form 10-Q

August 13, 2003

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**Form 10-Q**

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

**For the quarterly period ended June 30, 2003**

**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**

(State or other jurisdiction of incorporation or  
organization)

**94-3200380**

(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 3,282,768 shares of the Company's Common Stock, par value \$.001, outstanding as of July 31, 2003.

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QUARTER ENDED June 30, 2003

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## PART I. FINANCIAL INFORMATION

## ITEM I. CONDENSED FINANCIAL STATEMENTS

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

	JUNE 30, 2003	DECEMBER 31, 2002
	(Unaudited)	(Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,495	\$ 10,170
Restricted cash	250	250
Short-term investments	196	2,895
Prepaid drug substance	2,375	2,375
Prepaid expenses	630	247
	<u>14,946</u>	<u>15,937</u>
Total current assets	14,946	15,937
Property and equipment, net	60	112
Other assets	184	177
	<u>184</u>	<u>177</u>
Total assets	<u>\$ 15,190</u>	<u>\$ 16,226</u>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 238	\$ 345
Accrued clinical liabilities	57	
Accrued employee liabilities	155	135
Accrued restructuring charges		64
Other accrued liabilities	212	202
	<u>662</u>	<u>746</u>
Total current liabilities	662	746
<b>Stockholders equity</b>		
Preferred stock	1,886	
Common stock	3	3
Additional paid-in capital	218,825	216,466
Deferred stock compensation	(195)	(720)
Accumulated deficit	(205,991)	(200,269)
	<u>14,528</u>	<u>15,480</u>
Total stockholders equity	14,528	15,480
Total liabilities and stockholders equity	<u>\$ 15,190</u>	<u>\$ 16,226</u>

See accompanying notes.



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

(UNAUDITED)

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2003	2002	2003	2002
Operating expenses:				
Research and development	\$ 1,352	\$ 6,411	\$ 1,620	\$ 13,452
General and administrative	1,043	2,447	2,708	3,907
Arbitration settlement				(3,600)
Restructuring and other charges				91
Total operating expenses	2,395	8,858	4,328	13,850
Operating loss	(2,395)	(8,858)	(4,328)	(13,850)
Interest income	45	215	71	480
Interest expense		(113)		(266)
Other income		784		784
Net loss	(2,350)	(7,972)	(4,257)	(12,852)
Non-cash deemed dividend related to beneficial conversion feature of Series A preferred stock	(1,418)		(1,418)	
Dividends on Series A preferred stock	(47)		(47)	
Net loss applicable to common stockholders	\$(3,815)	\$(7,972)	\$(5,722)	\$(12,852)
Basic and diluted net loss per share applicable to common stockholders	\$ (1.17)	\$ (2.58)	\$ (1.75)	\$ (4.31)
Shares used to compute basic and diluted net loss per share applicable to common stockholders	3,270	3,095	3,269	2,955

See accompanying notes.

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

	<b>SIX MONTHS ENDED JUNE 30,</b>	
	<b>2003</b>	<b>2002</b>
<b>Operating activities</b>		
Net loss	\$ (4,257)	\$ (12,852)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred stock compensation	95	687
Depreciation and amortization	52	390
Acquired workforce amortization		93
Stock compensation expense	44	604
Gain on sale of pre-clinical programs		(775)
Change in assets and liabilities:		
Prepaid expenses	(383)	993
Other assets	(7)	(1)
Accounts payable	(107)	(299)
Accrued clinical liabilities	57	1,811
Accrued employee liabilities	20	(335)
Accrued restructuring charges	(64)	(1,507)
Deferred rent		144
Other accrued liabilities	(37)	(329)
Net cash used in operating activities	(4,587)	(11,376)
<b>Investing activities</b>		
Proceeds from sale of pre-clinical programs		400
Maturities of short-term investments	2,699	
Cash received in acquisition of subsidiary		58
Net cash provided by investing activities	2,699	458
<b>Financing activities</b>		
Proceeds from issuance of common stock, net	1	19,438
Proceeds from issuance of Series A preferred stock and warrants, net	3,212	
Payments on financing obligations		(937)
Net cash provided by financing activities	3,213	18,501
Net increase in cash and cash equivalents	1,325	7,583
Cash and cash equivalents at beginning of period	10,170	27,982
Cash and cash equivalents at end of period	\$ 11,495	\$ 35,565
Supplemental disclosure of cash flow information:		
Interest paid	\$	\$ 266
Supplemental disclosure of non-cash information:		
Net deferred stock compensation (cancelations due to employee termination)	\$ (430)	\$ (518)
Other assets received from sale of pre-clinical programs	\$	\$ 375



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	_____	_____
Beneficial conversion feature on Series A preferred stock	\$ (1,418)	\$
	_____	_____
Accrual for issuance of common stock dividend on Series A preferred stock	\$ (47)	\$
	_____	_____
Cash flow for acquisition of subsidiary:		
Acquired workforce	\$	\$ 1,676
Other current assets acquired		297
Property and equipment acquired		56
Liabilities assumed		(75)
Acquisition costs incurred		(88)
Common stock issued		(1,924)
	_____	_____
Cash received in acquisition	\$	\$ (58)
	_____	_____

See accompanying notes.

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INTRABIOTICS PHARMACEUTICALS, INC.  
NOTES TO CONDENSED FINANCIAL STATEMENTS  
(Unaudited)

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

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

Certain information and footnote disclosures normally included in the Company's annual audited financial statements (as required by accounting principles generally accepted in the United States) have been condensed or omitted. The interim condensed financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of the Company's financial position as of June 30, 2003, the results of its operations for the three- and six-month periods ended June 30, 2003 and 2002 and cash flows for the six-month periods ended June 30, 2003 and 2002.

The results of operations of the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These interim condensed financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2002, which are contained in the Company's Annual Report on Form 10-K, as amended, and filed with the Securities and Exchange Commission. The condensed balance sheet as of December 31, 2002 is derived from such audited financial statements.

*Use of estimates*

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Recent Accounting Pronouncements*

In August 2002, the Financial Accounting Standards Board issued Statement No. 146 (SFAS No. 146), *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 supersedes Emerging Issues Task Force Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs To Exit an Activity (Including Certain Costs Associated with a Restructuring)* and requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, as opposed to when management is committed to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. This Statement is effective for exit or disposal activities initiated after December 31, 2002. The provisions of SFAS No. 146 are required to be applied prospectively after the adoption date to newly initiated exit activities, and may affect the timing of recognizing future restructuring costs, as well as the amounts recognized. The adoption of the statement on January 1, 2003 did not have a material impact on the Company's financial position, results of operations or disclosure.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued. FIN 45 is effective on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements for interim and annual periods ending after December 31, 2002. The adoption of FIN 45 did not have any impact on the Company's financial position, results of operations or disclosure.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 became effective in the Company's fiscal year 2002. The Company has elected to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees* to account for employee and director stock options. See Stock-Based Compensation (Note 2) for disclosures required by SFAS No. 148.



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In January 2003, the FASB issued FASB Interpretation No. 46 ( FIN 46 ), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of FIN 46 did not have any effect on the Company's financial position, results of operations or disclosure.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include stock with mandatory redemption, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and must be applied to the Company's existing financial instruments effective July 1, 2003, the beginning of the first fiscal period after June 15, 2003. The Company does not expect the adoption of SFAS No. 150 to have a material effect on its financial position, results of operations or disclosure.

**Note 2. Stock-Based Compensation**

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 the Company's employee and director stock options equals or exceeds the fair market value of the underlying stock on the date of grant, no compensation expense is recognized. When the exercise price of the employee or director stock options is less than the fair market value of the underlying stock on the grant date, the Company records deferred compensation for the difference. Deferred compensation is being amortized on a straight-line basis over the vesting period of the original award, ranging from four to six years.

Options or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS 123, 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 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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>
Net loss applicable to common stockholders, as reported	\$(3,815)	\$(7,972)	\$(5,722)	\$(12,852)
Add: Stock-based employee compensation expense included in reported net loss	57	199	119	687
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(387)	(620)	(810)	(1,079)
Pro forma net loss applicable to common stockholders	<u>\$(4,145)</u>	<u>\$(8,393)</u>	<u>\$(6,413)</u>	<u>\$(13,244)</u>
Net loss per share applicable to common stockholders:				
Basic and diluted as reported	<u>\$ (1.17)</u>	<u>\$ (2.58)</u>	<u>\$ (1.75)</u>	<u>\$ (4.31)</u>
Basic and diluted pro forma	<u>\$ (1.27)</u>	<u>\$ (2.71)</u>	<u>\$ (1.96)</u>	<u>\$ (4.43)</u>

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The fair value for the Company's options was estimated at the date of the grant using the Black-Scholes option pricing model for the three- and six-month periods ended June 30, 2003 and 2002 with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Risk-free interest rates	2.32%	4.44%	2.62%	4.45%
Volatility	1.00	1.00	1.00	1.00
Dividend yield				
Expected life of option	5 years	5 years	5 years	5 years

**Note 3. Comprehensive Loss**

Comprehensive loss is solely comprised of the net loss in each period presented.

**Note 4. Contractual Commitments**

In February 2003, the Company entered into an operating lease agreement for a facility in Palo Alto, California, which expires in June 2004. Under the terms of the lease, the Company is committed to pay an aggregate of approximately \$84,000 in 2003 and \$43,000 in 2004.

**Note 5. Stock Options Cancellation and Regrant**

In February 2003, the Board of Directors approved a cancellation and re-grant of 321,335 unexercised stock options held by the existing employees and directors of the Company. Upon election by the participants, the unexercised stock options were all cancelled and new stock options were granted in a one-for-one exchange. The re-granted options have an exercise price equal to the closing price of the Company's common stock on the Nasdaq National Market as of February 5, 2003, or \$2.76 per share, post-split (see Note 8). The options vest over a four-year period and will expire in February 2008 if not exercised. Variable accounting is being applied to the re-granted options, starting from the date of re-grant, and the related compensation expense may have a significant impact on the Company's future results of operations. Compensation expense recorded for these options during both the three- and six-month periods ended June 30, 2003 was \$24,000.

**Note 6. 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, less shares subject to repurchase. 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, they are not included in the calculations of diluted net loss per share applicable to common stockholders. The total number of shares excluded from the calculations for stock options, warrants and convertible preferred stock were 2,724,878 and 402,414 for the three-month periods ended June 30, 2003 and 2002, respectively, and 2,668,892 and 330,680 for the six-month periods ended June 30, 2003 and 2002, respectively.

**Note 7. Restructuring and Other Charges**

In October 2002, the Company announced a restructuring plan as a result of the failure of its then recently completed phase III clinical trial for the prevention of oral mucositis in cancer patients. This restructuring plan reduced headcount by 26 employees in research and development and general and administrative, or 70% of the Company's workforce. In accordance with provisions of EITF 94-3 and related interpretations, the Company recorded restructuring charges of \$848,000 for severance costs of which \$784,000 were paid as of December 31, 2002. No other charges were expensed as a result of the restructuring plan. The remaining severance accrual as of December 31, 2002 of \$64,000 was paid in January 2003 to employees who left the company in December 2002. No other charges were expensed in 2003 as a result of the restructuring plan.

**Note 8. Reverse Stock Split**

On April 3, 2003, the Company's stockholders authorized a 1-for-12 reverse stock split of all outstanding shares of the Company's



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common stock. The Company effected the split on April 10, 2003. All share and per share amounts have been retroactively adjusted to reflect the stock split for all periods presented.

Note 9. Stockholders' Equity

On May 1, 2003, in a private placement transaction, the Company sold 350 shares of a newly created Series A convertible preferred stock (the Preferred Stock) of \$0.001 par value, and issued warrants to purchase 920,699 shares of common stock, resulting in net cash proceeds of \$3.2 million. The primary purpose of completing the private placement was to provide funds for the clinical trial of iseganan HCl for the prevention of ventilator-associated pneumonia (VAP), as well as for other general corporate purposes and working capital.

The Preferred Stock is convertible into 1,841,404 shares of common stock at any time, at a conversion price of \$1.90 per share, subject to anti-dilution adjustments upon the occurrence of certain events, such as stock splits, payment of dividends to common stockholders, reorganizations, mergers or consolidations. Each share of Preferred Stock automatically converts into shares of common stock on the tenth day after the day that the closing sale price of the Company's common stock on the Nasdaq National Market has reached at least \$8.28 and has remained at such level for 20 consecutive trading days, but only after the earlier to occur of (1) the unblinding and the public announcement of the results of the Company's phase II/III clinical trial of iseganan HCl for the prevention of VAP, or (2) the second anniversary of the date the Preferred Stock was first issued. The holders of Preferred Stock are also entitled to receive, but only out of funds legally available for dividends, cumulative dividends payable quarterly, at the annual rate of eight percent of the original issue price of \$10,000 on each outstanding share of Preferred Stock. The dividend shall be paid in common stock based on the average of the closing sales prices of the common stock on the Nasdaq National Market for the five trading days immediately preceding and ending on the last trading day prior to the date the dividends are payable. The dividends are paid in preference to any other declared dividends. Upon any liquidation, dissolution or winding up (as such terms are defined in the Company's Certificate of Designation) of the Company, before any distribution or payment can be made to the holders of the Company's common stock, each holder of Preferred Stock is entitled to receive an amount equal to \$10,000 plus all accrued or declared and unpaid dividends. Each share of Preferred Stock is entitled to a number of votes equal to the number of shares of common stock issuable based upon a conversion price equal to the closing bid price of the common stock on the Nasdaq National Market on the date the Preferred Stock and Warrant Purchase Agreement was signed. The number of votes is not adjustable except upon a stock split, a reverse stock split, or other similar event affecting the rights of the Preferred Stock. Holders of Preferred Stock are also entitled to elect two members of the Board of Directors, and a majority of the holders of the Preferred Stock must consent to certain actions prior to the Company taking them.

In connection with the sale of the Preferred Stock, the Company issued immediately exercisable warrants to purchase 920,699 shares of the Company's common stock to the purchasers of the Preferred Stock, at an exercise price of \$2.07 per share, subject to anti-dilution adjustments upon the occurrence of certain events, such as stock splits, payment of dividends to common stockholders, reorganizations, mergers or consolidations. Additionally, the exercise price of the warrants is reduced by 50% if the Company's common stock is delisted from the Nasdaq National Market. The warrants will expire in five years, if not exercised. The warrants issued to the holders of Preferred Stock were assigned a value of \$1,326,000, which decreased the carrying value of the Preferred Stock. The warrants were valued using the Black-Scholes method with the following assumptions: a risk-free interest rate of 2.52%; an expiration date of April 30, 2008; volatility of 100% and a dividend yield of 0%. In connection with the issuance of the Preferred Stock and warrants, the Company recorded \$1,418,000 related to the beneficial conversion feature on the Preferred Stock as a deemed dividend, which increased the loss applicable to common stockholders in the calculation of basic and diluted net loss per common share. A beneficial conversion feature is present because the effective conversion price of the Preferred Stock was less than the fair value of the common stock on the commitment date. Pursuant to the terms of the Preferred Stock and Warrant Purchase Agreement, the Company is subject to certain negative and restrictive covenants, such as limitations on indebtedness and the issuance of additional equity securities without specific Board approvals. The Company is currently in compliance with each of the covenants.

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

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements, which involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth below under RISKS RELATED TO OUR BUSINESS. The following discussion should be read in conjunction with the financial statements and notes included elsewhere herein and in our 2002 audited financial statements and notes thereto included in our 2002 Annual Report on Form 10-K, as amended. All forward-looking statements included in this document are based on information available to us on the date of this document, and except as required by law, we assume no obligation to update any of the forward-looking statements contained in this report to reflect any future events or developments.*

**Overview**

IntraBiotics Pharmaceuticals, Inc. is a biopharmaceutical company currently focused on developing an oral solution of iseganan hydrochloride, or iseganan HCl, for the prevention of ventilator-associated pneumonia, or VAP. Iseganan HCl is an antimicrobial drug, or a drug capable of destroying microorganisms, including bacteria and fungi, that cause disease, and is effective against many drug-resistant, disease-causing bacteria and fungi. VAP is a bacterial pneumonia that can develop in patients receiving mechanical (artificial) ventilation and is the most common infection occurring in mechanically-ventilated patients.

In 2002, we were primarily developing iseganan HCl for the prevention of ulcerative oral mucositis, a complication that develops in cancer patients receiving chemotherapy or radiation that results in painful ulcer-like sores in the mouth and throat. We were evaluating whether an infectious component of oral mucositis could be prevented or reduced by this drug candidate. We concluded two large studies, one in patients receiving radiation therapy to the head and neck, and a second in patients undergoing aggressive chemotherapy. In the radiation therapy study, there was no difference between iseganan HCl and placebo, and in the chemotherapy study, differences in favor of iseganan HCl were insufficient to achieve statistical significance. Iseganan HCl appears to be safe when applied to the oral cavity. We are not pursuing further development of iseganan HCl to prevent oral mucositis, and instead we are now developing iseganan HCl to prevent VAP.

An original Investigational New Drug Application, or IND, was submitted in December 1999 to support a phase I/IIa trial of iseganan HCl to evaluate safety and antimicrobial activity in mechanically-ventilated patients who are at risk of developing VAP. This study was completed in February 2001. A phase I/IIIa trial attempts to obtain preliminary indicators of safety and efficacy of a drug candidate in a smaller patient population. The phase I/IIIa study demonstrated that single doses of iseganan HCl reduced the level of bacteria in the oral cavity by more than 100-fold compared to pre-treatment baseline levels in patients who required mechanical ventilation, and that administration of iseganan HCl every four hours progressively reduced the level of bacteria in the oral cavity.

We have met with members of our Steering Committee and Data Monitoring Committee, which are comprised of doctors and statisticians who are experienced in the care of mechanically-ventilated patients and/or the design of clinical trials. Together, we designed a phase II/III study to test the effectiveness of iseganan HCl in preventing VAP. A phase II/III study attempts to establish the safety and efficacy of a drug candidate in an expanded patient population. In April 2003, we amended our IND to formally submit the phase II/III clinical study protocol for FDA review and comment, and the requirements for registration are currently being discussed with the FDA. The aggregate costs incurred for the development of iseganan HCl for the prevention of VAP during 2000, 2001, 2002 and the first six months of 2003, were approximately \$4.0 million. We cannot be certain that iseganan HCl oral solution will prove to be safe or effective in the prevention of VAP, or will receive regulatory approvals.

The Company has in the past ordered and received, and may in the future receive, significant quantities of iseganan HCl drug substance. The Company's policy is to record any prepayments of such orders as Prepaid drug substance. When title to the drug substance is accepted by the Company, the purchase price, including prepaid amounts, is accounted for as a research and development expense. As a result, the Company may at times hold a significant amount of iseganan HCl inventory, with the value of this drug substance not reflected on the Company's balance sheet.



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At June 30, 2003, the Company held over seven kg of finished iseganan HCl and a significant amount of partially completed iseganan HCl drug product. Also at June 30, 2003, the Company has prepaid drug substance of \$2.4 million relating to a previously placed order of an additional seven kg of iseganan HCl expected to be delivered in the second half of 2003. When title to this seven kg order is accepted, the Company will record a research and development expense for this \$2.4 million, plus \$250,000 for an additional amount payable upon transfer of title. The Company is currently discussing the release and acceptance of this order with its manufacturing partner, as one manufacturing step in the production of the related lot, Lot I, was performed outside of set specifications.

Since commencing operations in 1994, we have not generated any revenue from product sales, and we have funded our operations primarily through the private sale of equity securities, funds received from a terminated collaboration agreement, the proceeds of equipment financing arrangements and our initial public offering of common stock in March 2000. On May 1, 2003, in a private placement transaction, we sold shares of a newly created Series A convertible preferred stock and warrants to purchase common stock resulting in aggregate net cash proceeds of \$3.2 million. The primary purpose of completing the private placement was to provide funds for our Phase II/III clinical trial of iseganan HCl for the prevention of VAP as well as for other general corporate purposes and working capital. We will need to raise additional funds in the future to continue our operations.

In February 2003, the Board of Directors approved a cancellation and re-grant of 321,335 unexercised stock options held by the existing employees and directors of the Company. Upon election by the participants, the unexercised stock options were all cancelled and new stock options were granted in a one-for-one exchange. The re-granted options have an exercise price equal to the closing price of the Company's common stock on the Nasdaq National Market as of February 5, 2003, or \$2.76 per share, post-split (see Note 8). The options vest over a four-year period and will expire in February 2008 if not exercised. Variable accounting is being applied to the re-granted options, starting from the date of re-grant, and the related compensation expense may have a significant impact on the Company's future results of operations. Compensation expense recorded for these options during both the three- and six-month periods ended June 30, 2003 was \$24,000.

On April 3, 2003, the Company's stockholders authorized a 1-for-12 reverse stock split of all outstanding shares of the Company's common stock. The split became effective on April 10, 2003. All share and per share amounts have been retroactively adjusted to reflect the stock split for all periods presented.

## **Critical Accounting Policies**

There have been no material changes to the Company's critical accounting policies, which are included and described in our Form 10-K, as amended, for the year ended December 31, 2002 filed with the Securities and Exchange Commission.

## **Results of Operations**

### ***Three- and six-month Periods Ended June 30, 2003 and 2002***

#### ***Research and Development***

Research and development expenses in 2003 primarily consist of costs related to the preparation for a new phase II/III clinical trial of iseganan HCl for the prevention of VAP, and in 2002 consisted primarily of costs related to phase III clinical trials of iseganan HCl for the prevention of oral mucositis. Research and development expenses decreased to \$1.4 million in the three-month period ended June 30, 2003, from \$6.4 million for the same period in 2002, and decreased to \$1.6 million in the six-month period ended June 30, 2003, from \$13.5 million for the same period in 2002. The decrease reflects the higher cost of enrolling patients for the phase III oral mucositis trial in 2002, as compared to the cost of preparations for the new phase II/III VAP trial in 2003. We expect research and development expenses to increase significantly as patients are enrolled for the new phase II/III VAP trial. Our research and development headcount has decreased to four at June 30, 2003, from 23 at June 30, 2002, primarily as a result of a reduction in workforce in October 2002 due to negative results from the oral mucositis trial. We believe our current staff is sufficient to conduct the planned phase II/III trial for the prevention of VAP. Research and development costs primarily include salaries for research and development personnel, clinical trial expenses from clinical trial service providers, drug substance, consulting expenses, supplies, administrative and patent-related expenses and allocated facilities costs. Approximately 83% and 74%, of research and development expenses for the three-month periods ended June 30, 2003 and 2002, respectively, and 73% and 77% for the six-month periods ended June 30, 2003 and 2002, respectively, were related to clinical trial activities performed by the clinical trial service providers. Included in research and development expenses are non-cash stock compensation charges of \$3,000 and \$314,000 for the three-month periods

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ended June 30, 2003 and 2002, respectively, and \$3,000 and \$595,000 for the six-month periods ended June 30, 2003 and 2002, respectively. The decrease between periods is primarily due to the cancellation of options for terminated employees.

*General and Administrative*

General and administrative expenses decreased to \$1.0 million in the three-month period ended June 30, 2003, from \$2.4 million for the same period in 2002, and decreased to \$2.7 million in the six-month period ended June 30, 2003, from \$3.9 million for the same period in 2002. The decreases in general and administrative expense in both periods are a result of reduced headcount, decreased outside service costs, decreased facility-related costs such as depreciation and rent, and an overall decrease in other general operating expenses. General and administrative costs primarily include salaries for administrative personnel, outside contractors, legal and accounting fees, insurance, deferred compensation, facilities, supplies and general administrative expenses. Included in general and administrative expenses are non-cash stock compensation charges of \$71,000 and \$349,000 for the three-month periods ended June 30, 2003 and 2002, respectively, and \$136,000 and \$696,000 for the six-month periods ended June 30, 2003 and 2002, respectively. The decrease between periods is primarily due to the cancellation of options for terminated employees.

*Arbitration Settlement*

During the six-month period ended June 30, 2002, we received \$3.6 million from a contract vendor as a result of an arbitration settlement relating to a drug dispensing error in iseganan HCl oral solution phase III clinical trials. We had no comparable item for the three- and six-month periods ended June 30, 2003.

*Restructuring and Other Charges*

There were no expenses recorded for restructuring during the three- and six-month periods ended June 30, 2003, compared to \$0 and \$91,000 for the same periods in 2002, respectively. The decrease in restructuring and other charges was due to the fact that no new restructuring actions occurred during the first six-months of 2003 as compared to the same period in 2002.

*Interest Income and Expense*

Interest income decreased to \$45,000 and \$71,000 in the three- and six-month periods ended June 30, 2003, respectively, from \$215,000 and \$480,000 for the same periods in 2002, respectively. The decrease in interest income resulted from the decrease in average interest earning investment balances as well as lower interest rates in 2003 relative to the comparable prior year periods. Interest expense decreased to zero for the three- and six-month periods ended June 30, 2003, from \$113,000 and \$266,000 for the same periods in 2002, respectively. The decrease in interest expense is attributed to the repayment of our line of credit and bank loan in October 2002.

*Other Income*

In May 2002, we completed the sale of two pre-clinical anti-infective programs to Micrologix Biotech Inc., a Canadian company, for cash and 750,000 shares of Series A preferred stock of Micrologix, and recognized other income of \$775,000 in the three-month period ended June 30, 2002. We had no comparable item for the three- and six-month periods ended June 30, 2003. The Micrologix Series A preferred shares are redeemable at \$1 per share or convertible into common stock at the election of Micrologix upon the occurrence of certain time and achievement milestones as follows: (1) shares converted into common stock with a value of \$400,000 upon the four month anniversary of the effective date of the agreement; (2) shares will convert into common stock with a value of \$100,000 upon commencement of certain toxicology studies; and (3) shares will convert into common stock with a value of \$250,000 upon filing for marketing approval for certain drugs in certain countries. During the quarter ended September 30, 2002, \$200,000 of other income was recognized in connection with the redemption of 400,000 shares of Series A preferred stock of Micrologix at \$1 per share, which was triggered by the first milestone set forth above.

*Net Loss and Net Loss Applicable to Common Stockholders*

For the three- and six-month periods ended June 30, 2003, we incurred net losses of \$2.4 million and \$4.3 million, respectively, as compared to net losses of \$8.0 million and \$12.9 million for the same periods in 2002, a decrease of \$5.6 million and \$8.6 million, respectively. Net losses applicable to common stockholders were \$3.8 million and \$5.7 million for the three- and six-month periods ended June 30, 2003, respectively, and included the impact of a non-cash deemed dividend related to a beneficial conversion feature on our Series A preferred stock of \$1.4 million and Series A preferred stock dividends of \$47,000. A beneficial conversion feature is

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present because the effective conversion price of the preferred stock was less than the fair value of the common stock on the commitment date. Preferred stock dividends represent the accrual of the 8% annual dividends payable quarterly to the holders of our Series A preferred stock in the form of our common stock. Net losses applicable to common stockholders were the same as net losses for the three- and six-month periods ended June 30, 2002.

### **Liquidity and Capital Resources**

Cash, cash equivalents, short-term investments and restricted cash were \$11.9 million as of June 30, 2003, compared to \$13.3 million as of December 31, 2002. At June 30, 2003, we had restricted cash deposits of \$250,000 in connection with a standby letter of credit issued to PolyPeptide Laboratories A/S for a drug substance. We had no debt outstanding as of June 30, 2003. We invest excess funds in short-term money market funds.

Net cash used in operating activities for the six-month periods ended June 30, 2003 and 2002 was \$4.6 million and \$11.4 million, respectively. Our cash used for operating activities in each period consisted primarily of the net loss for each period, excluding non-cash items consisting primarily of stock-related compensation expenses, and in 2002, non-cash income of \$775,000 related to the gain on the sale of the two pre-clinical programs to Micrologix.

Net cash provided by investing activities for the six-month periods ended June 30, 2003 and 2002 was \$2.7 million and \$458,000, respectively. The cash provided in 2003 related to the maturity of short-term investments, and in 2002 primarily related to the proceeds from the sale of the two pre-clinical programs to Micrologix.

Net cash provided by financing activities for the six-month periods ended June 30, 2003 and 2002 was \$3.2 million and \$18.5 million, respectively. The cash provided in 2003 related to the private placement transaction in May 2003, in which the Company sold 350 shares of a newly created Series A convertible preferred stock and issued warrants to purchase 920,699 shares of common stock, resulting in net cash proceeds of \$3.2 million.

The Preferred Stock is convertible into 1,841,404 shares of common stock at any time, at a conversion price of \$1.90 per share, subject to anti-dilution adjustments upon the occurrence of certain events, such as stock splits, payment of dividends to common stockholders, reorganizations, mergers or consolidations. The shares of Preferred Stock carry with them certain rights and privileges as set forth in the Company's Certificate of Designation and the Preferred Stock and Warrant Purchase Agreements governing the sale of the Preferred Stock and the issuance of the warrants. Each share of Preferred Stock automatically converts into shares of common stock on the tenth day after the day that the closing sale price of the Company's common stock on the Nasdaq National Market has reached at least \$8.28 and has remained at such level for 20 consecutive trading days, but only after the earlier to occur of (1) the unblinding and the public announcement of the results of the Company's phase II/III clinical trial of iseganan HCl for the prevention of VAP, or (2) the second anniversary of the date the Preferred Stock was first issued. The holders of Preferred Stock are also entitled to receive, but only out of funds legally available for dividends, cumulative dividends payable quarterly, at the annual rate of eight percent of the original issue price of \$10,000 on each outstanding share of Preferred Stock. The dividend shall be paid in common stock based on the average of the closing sales prices of the common stock on the Nasdaq National Market for the five trading days immediately preceding and ending on the last trading day prior to the date the dividends are payable. The dividends are paid in preference to any other declared dividends. Upon any liquidation, dissolution or winding up (as such terms are defined in the Company's Certificate of Designation) of the Company, before any distribution or payment can be made to the holders of the Company's common stock, each holder of Preferred Stock is entitled to receive an amount equal to \$10,000 plus all accrued or declared and unpaid dividends. Each share of Preferred Stock is entitled to a number of votes equal to the number of shares of common stock issuable based upon a conversion price equal to the closing bid price of the common stock on the Nasdaq National Market on the date the Preferred Stock and Warrant Purchase Agreement was signed. The number of votes is not adjustable except upon a stock split, a reverse stock split, or other similar event affecting the rights of the Preferred Stock. Holders of Preferred Stock are also entitled to elect two members of the Board of Directors, and a majority of the holders of the Preferred Stock must consent to certain actions prior to the Company taking them.

In connection with the sale of the Preferred Stock, the Company issued immediately exercisable warrants to purchase 920,699 shares of the Company's common stock to the purchasers of the Preferred Stock, at an exercise price of \$2.07 per share, subject to anti-dilution adjustments upon the occurrence of certain events, such as stock splits, payment of dividends to common stockholders, reorganizations, mergers or consolidations. Additionally, the exercise price of the warrants is reduced by 50% if the Company's common stock is delisted from the Nasdaq National Market. The warrants will expire in five years, if not exercised. Pursuant to the terms of the Preferred Stock and Warrant Purchase Agreement, the Company is subject to certain negative and restrictive covenants, such as limitations on indebtedness and the

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issuance of additional equity securities without specific Board approvals. The Company is currently in compliance with each of the covenants.

Cash provided by financing activities for the six-month period ended June 30, 2002 was primarily from net proceeds of \$13.9 million and \$5.0 million from two private placements of common stock, partially offset by \$937,000 in payments on financing obligations to a bank.

The following are future contractual commitments at June 30, 2003, (in thousands):

Contractual Commitments	Payments Due by Period				
	Total	2003	2004	2005	Thereafter
Drug substance	\$475	\$275	\$50	\$50	\$100
Operating leases	93	50	43		
Severance payments	40	40			
Consulting payments	83	83			
<b>Total contractual commitments</b>	<b>\$691</b>	<b>\$448</b>	<b>\$93</b>	<b>\$50</b>	<b>\$100</b>

The \$475,000 drug substance commitment represents a commitment to PolyPeptide Laboratories A/S. In 2003 the commitment represents the payment of \$250,000 upon acceptance of a drug substance and a \$25,000 fee for storage of drug substance. The remaining \$200,000 represents storage fees for our drug substance in future periods.

Operating leases relate to the lease for our facility in Palo Alto, California, which expires in June 2004. Under the terms of the lease we have committed to pay a total of \$84,000 and \$43,000 in 2003 and 2004, respectively.

Severance payments relate to the reduction of general and administrative staff during the six-month period ended June 30, 2003.

Consulting payments relate to an obligation to pay ongoing consulting payments to Mr. Ken Kelley, a former officer, through September 30, 2003. The aggregate payments for the duration of the agreement will total \$550,000.

We expect to continue to incur substantial operating losses. We currently anticipate our capital will be sufficient to fund operations for the next 12 months, although this is dependent upon the rate of enrollment and other factors impacting the timing and cost of the Phase II/III trial of iseganan HCl oral solution for the prevention of VAP. We will need to raise additional funds in the future to continue our operations.

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:

- the timing, delay, cost, extent and results of clinical trials;
- future opportunities for raising capital;
- payments to third parties for manufacturing scale up;
- the costs and timing of regulatory approvals;
- the costs of establishing sales, marketing and distribution capabilities; and
- the progress of our development activities.

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 cannot be certain 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.



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### **Risks Related to Our Business**

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

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

We have never generated revenue from product sales, and we have incurred significant net losses in each year since inception. We incurred net losses applicable to common stockholders of \$34.5 million in 2002 and \$5.7 million in the six-month period ended June 30, 2003. As of June 30, 2003, our accumulated deficit was approximately \$206.0 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.

In the first quarter of 2003, we commenced preparations for a new phase II/III trial of iseganan HCl oral solution for the prevention of VAP. We may also develop iseganan HCl for other indications in the future or acquire or license other products. We will receive product revenues only if we complete clinical trials with respect to one or more products, receive regulatory approvals and successfully commercialize such products. We do not know whether we will be successful in developing iseganan HCl for our currently planned VAP indication or other indications, or in acquiring or licensing other products.

#### **We depend on the outcome of our clinical trial for the prevention of VAP and any future clinical trials for other indications for iseganan HCl or for products that we may license or acquire, and if they are unsuccessful, we will not be able to commercialize any products and may be forced to cease operations.**

We had only one late stage lead product, iseganan HCl for the treatment of ulcerative oral mucositis, which failed in the phase III trial conducted on patients with head and neck cancer receiving radiotherapy and the phase III trial conducted on patients with cancer receiving aggressive chemotherapy. Our other indications for iseganan HCl are in earlier stages of clinical development. In the first quarter of 2003, we commenced preparations for a new phase II/III trial of iseganan HCl oral solution for the prevention of VAP, and we are focusing our resources on this trial. The requirements for registration are currently being discussed with the FDA. It is possible that the final design will call for an enrollment of significantly greater than the 500 patients indicated in the originally submitted study protocol, followed by a confirmatory Phase III trial of a similar size. An increase in planned enrollment would increase the cost of the Phase II/III trial and the time it takes to complete, and we would need to raise additional funds to complete this trial. If this phase II/III trial fails to meet its primary endpoint, and we do not acquire or license any additional product candidates, we may not be able to commercialize any products and we may be forced to cease operations. In addition, as a result of our focus on the VAP trial and the delay in clinical development of any other drug candidates, our ability to generate product revenue will be delayed, and we do not expect to generate product revenue in the near term.

#### **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.**

For the year ended December 31, 2002 and the six-month period ended June 30, 2003, net cash used for operating activities was \$26.3 million and \$4.6 million, respectively. At June 30, 2003, our cash and cash equivalents, including short-term investments, were \$11.9 million, which included restricted cash of \$250,000. We currently anticipate this capital will be sufficient to fund operations for the next 12 months, although this is dependent upon the rate of enrollment and other factors impacting the timing and cost of the Phase II/III trial of iseganan HCl oral solution for the prevention of VAP. We will need to raise additional funds in the future to continue our operations.

Our future liquidity and capital requirements will depend on many factors, including the final design, timing, cost, and progress of our current VAP trial, our evaluation of, and decisions with respect to, our strategic alternatives, costs associated with the regulatory approvals, securing in-licensing opportunities, purchasing additional products or drug candidates and conducting pre-clinical research and clinical development of those drug candidates.

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We believe that additional financing will be required in the future to fund our operations, conduct any other possible trials of iseganan HCl, or commercialize our current and any future product candidates. 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.

**If we raise additional capital by issuing securities or through collaboration and licensing arrangements, our existing stockholders may experience dilution or we may be required to relinquish rights to our technologies or product candidates.**

We may raise additional financing through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. To the extent we raise additional capital by issuing equity securities, our stockholders may experience dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

**If our contract research organizations assisting in our clinical trials fail to appropriately manage our clinical trial, the trial could be delayed or could fail.**

We rely on contract research organizations to assist us in managing and monitoring our clinical trial. We have entered into agreements with Amarex, LLC, Orion Clinical Services, Ltd., Icon Laboratories, Inc., Patheon Inc., Fisher Scientific International Inc. and Advanced Clinical Trials, Inc. to provide clinical research services. The FDA may inspect some of our clinical investigational sites, our contract research organizations' records and our facility and files to determine if the clinical trial is conducted according to good clinical practices. If the FDA determines that the 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 under our agreements with them, we may face delays in completing our clinical trial or failure of our clinical program.

**If we fail to obtain FDA approvals for any future products that we develop, acquire or license, we will be unable to commercialize our drug candidates.**

We do not have a drug approved for sale in the U.S. or any foreign market. We must obtain approval from the FDA in order to sell our drug candidate in the U.S. and from foreign regulatory authorities in order to sell our drug candidate in other countries. We must successfully complete pivotal clinical trials and demonstrate manufacturing capability before we can file with the FDA for approval to sell our products. The FDA could require us to repeat clinical trials as part of the regulatory review process. Delays in obtaining or failure to obtain regulatory approvals may:

delay or prevent the successful commercialization of our drug candidate;

diminish our competitive advantage; and

defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical 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 HCl 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 suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. We have limited experience in obtaining such approvals, and cannot be certain when, if ever, we will receive these regulatory approvals. If we are unable to demonstrate the safety and efficacy of our drug candidate, we will be unable to obtain the required regulatory approvals and we will be unable to commercialize the drug candidate and generate product revenue.

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

**Development and commercialization of competitive products could reduce or prevent sales of any future products that we develop, acquire or license.**

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

We are not aware of any products that compete with iseganan HCl for the prevention of VAP. However, pharmaceutical companies and biotechnology companies may develop products in the future that compete with iseganan HCl for the prevention of VAP. 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 drugs, obtaining regulatory approvals and manufacturing and marketing products. We also compete with these organizations and other companies for in-licensing opportunities for future drug candidates, and for attracting scientific and management personnel.

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

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

obtain patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

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

We 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 or have rights to nine patents and six pending patent applications in the U.S. However, the patent position of biopharmaceutical companies involves complex legal and factual questions. We cannot predict the enforceability or scope of any issued patents or those that may issue in the future. Patents, if issued, may be challenged, invalidated or circumvented. Consequently, if any patents that we own or license from third parties do not provide sufficient protection, our competitive position would be weakened. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. In addition, we may not be issued patents for our pending patent applications, those we may file in the future or those we may license from third parties.

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

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

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. Although we are not currently a party to any lawsuits, third parties may assert infringement or other intellectual property claims against us. We may have to pay substantial damages, including treble damages for past infringement if it is ultimately determined that our products infringe a third party's proprietary rights. The defense and prosecution of intellectual property suits, U.S. Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the U.S and internationally are costly and time-consuming to pursue and their outcome is uncertain. If we become involved in any of these proceedings, we will incur substantial expense, and the efforts of our 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



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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.

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

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

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

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

### **The failure to recruit and retain key personnel may delay our ability to execute our business plan.**

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 trial for VAP. In particular, the loss of the services of Henry J. Fuchs, our President and Chief Executive Officer, or Steven Ketchum, our Vice President, Regulatory Affairs, could significantly impede our research and development efforts, our relations with potential collaborators and completion of our planned clinical trial for VAP. We do not have employment agreements with Mr. Fuchs or Mr. Ketchum. We do not maintain key person life insurance and do not have employment agreements with our other members of management and technical staff. In October 2002, we completed a restructuring that included a reduction in force of approximately 70% of our workforce. Since then we have further reduced our staff, and as of June 30, 2003, we had nine 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.

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

### **Directors, executive officers, principal stockholders and affiliated entities beneficially own approximately 58% of our capital stock and may be able to exert control over our activities.**

As of June 30, 2003, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 58% of our outstanding common stock. 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.

### **Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more difficult.**

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

These provisions:

provide for a classified board of directors of which approximately one third of the directors will be elected each year;

allow the authorized number of directors to be changed only by resolution of the board of directors;

require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;

establish advance notice requirements for nominations to the board of directors or for proposals that can be acted on at stockholder meetings; and

limit who may call stockholder meetings.

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

**If we are unable to maintain our Nasdaq National Market listing, the liquidity of our common stock would be seriously impaired and we would become subject to various statutory requirements and contractual provisions, which would likely harm our business.**

On November 12, 2002, we received a letter from Nasdaq advising us that our common stock had not met Nasdaq's minimum bid price requirement for 30 consecutive trading days and that, if we were unable to demonstrate compliance with this requirement during the 90 calendar days ending on February 10, 2003, our common stock may be subject to delisting from the Nasdaq National Market. On March 19, 2003, we received an additional letter from Nasdaq advising us that our grace period for regaining compliance had been extended in accordance with Nasdaq's new rules, until May 12, 2003. On April 10, 2003, we effected a 1-for-12 reverse stock split to regain compliance with this listing requirement and, on May 16, 2003 we received a letter from Nasdaq stating that we had regained compliance and the matter was closed. However, we cannot assure that the stock split will be sufficient to maintain our stock price on a sustainable basis.

The Nasdaq National Market further requires maintenance of a minimum market value of publicly held shares of \$5 million. Publicly held shares are defined as total shares outstanding less any shares held by officers, directors or beneficial owners of 10% or more of our outstanding shares of common stock. We cannot assure that we will be able to comply with these requirements.

The Nasdaq National Market also requires maintenance of minimum stockholders' equity of \$10 million. On May 1, 2003, we raised an additional \$3.5 million in equity financing before issuance costs. However, as we expend capital resources on our clinical trial, it is likely that our stockholders' equity will fall below the \$10 million minimum during 2003 if we do not raise additional funding.

If we are unable to meet the Nasdaq National Market requirements, at the discretion of Nasdaq, our common stock may be transferred to the Nasdaq SmallCap Market. Transferring to the Nasdaq SmallCap Market would provide us with an additional grace period to satisfy the minimum bid price requirement provided that we meet the Nasdaq SmallCap Market's other listing requirements, including the maintenance of stockholders' equity of at least \$5 million. In such event we would still be required to satisfy various listing maintenance standards for our common stock to be quoted on the Nasdaq SmallCap Market, including the minimum bid price requirement after expiration of any grace periods. If we fail to meet such standards, our common stock would likely be delisted from the Nasdaq SmallCap Market and it would trade on the over-the-counter bulletin board, commonly referred to as the "pink sheets". Such alternatives are generally considered as less efficient markets and would seriously impair the liquidity of our common stock and limit our potential to raise future capital through the sale of our common stock, which could materially harm our business.

If we are delisted from the Nasdaq National Market, we will face a variety of legal and other consequences that will likely negatively affect our business including, without limitation, the following:

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we may lose our exemption from the provisions of Section 2115 of the California Corporations Code, which imposes aspects of California corporate law on certain non-California corporations operating within California. As a result, (i) our board of directors would no longer be classified and our stockholders would elect all of our directors at each annual meeting, (ii) our stockholders would be entitled to cumulative voting, and (iii) we would be subject to more stringent stockholder approval requirements and more stockholder-favorable dissenters' rights in connection with certain strategic transactions;

the state securities law exemptions available to us would be more limited and, as a result, future issuances of our securities may require time-consuming and costly registration statements and qualifications;

due to the application of different securities law exemptions and provisions, we may be required to amend our stock option and stock purchase plans and comply with time-consuming and costly administrative procedures;

the exercise price on the warrants issued in conjunction with the issuance of Series A Preferred Stock would be reduced by 50%, and

we may lose current or potential investors.

**We may become subject to the SEC's penny stock rules, which may decrease the liquidity of our common stock and negatively impact the ability of purchasers of our common stock to sell our common stock in the secondary market.**

SEC rules place restrictions on the ability of brokers or dealers to sell securities that are defined as penny stocks, which include securities priced under five dollars, unless an exception to the penny stock rules applies. We are not currently subject to the penny stock rules because our common stock currently qualifies for two separate exceptions to the SEC's penny stock rules. The first exception for which we qualify renders the penny stock rules inapplicable if our securities are traded on Nasdaq. As discussed in the immediately preceding risk factor, our common stock is currently traded on the Nasdaq, but we may be delisted from the Nasdaq if we do not continue to meet the Nasdaq's listing requirements. In addition, the penny stock rules do not apply to securities of companies that have been in continuous operation for at least three years and have net tangible assets (total assets less intangible assets minus liabilities, based on audited financial statements) in excess of \$2.0 million. We have been in continuous operation for more than three years, and, based on audited financial statements as of December 31, 2002, we had net tangible assets of approximately \$15.5 million. Therefore, our common stock also qualifies for this exception to the penny stock rules. However, as we expend capital resources on our clinical trial, our net tangible assets will continue to decrease and we may not be able to continue to qualify for this exemption, unless we raise additional funding.

If we were to become subject to the SEC's penny stock rules, brokers or dealers would generally be required to provide a purchaser of our common stock with a disclosure document stating, among other things:

that penny stocks are risky and informing the customer of his or her right to pricing information relating to our common stock and to information regarding the compensation to be received by the salesperson and the brokerage firm for effecting a trade in our common stock;

that the broker must send its customer a written statement for the customer to sign that accurately describes the customer's financial situation, investment experience, and investment goals, and that contains a statement as to why the brokerage firm decided penny stocks are a suitable investment for its customer; and

the purchaser's possible legal remedies in the event our common stock is sold to the purchaser in violation of the penny stock rules. If we were to become subject to the SEC's penny stock rules, the restrictions noted above may make it less likely that brokers or dealers would effect transactions in our common stock and therefore may decrease the liquidity of our common stock and the ability of purchasers of our common stock to sell our common stock in the secondary market.

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

The market prices for securities of biotechnology companies in general have been highly volatile and our stock may be subject to volatility. After accounting for the effect of our 1-for-12 reverse stock split on April 10, 2003, during 2002 our closing stock prices

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ranged from a low of \$3.24 to a high of \$57.60, and ranged from a low of \$1.71 to a high of \$5.73 during the six-month period ended June 30, 2003. 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;

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.

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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. We currently have all of our funds in bank accounts and a money market fund, which are sensitive to minimal market risk. Due to the short-term nature of this investment, a 50 basis point movement in market interest rates would not have a material impact on the fair value of our investment as of June 30, 2003. 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 their evaluation as of the end of the period covered by this report, our principal executive officer and principal financial officer have concluded that IntraBiotics' disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, were sufficiently effective to ensure that the information required to be disclosed by IntraBiotics in this quarterly report on Form 10-Q was adequately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-Q.

(b) Changes in internal controls

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2003 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

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## PART II. OTHER INFORMATION

## ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

On May 1, 2003, in a private placement transaction, the Company sold 350 shares of a newly created Series A convertible preferred stock and issued warrants to purchase 920,699 shares of common stock for \$3.5 million, resulting in net cash proceeds after expenses of \$3.2 million. The primary purpose of completing the private placement was to provide funds for the clinical trial of iseganan HCl for the prevention of VAP. For information relating to the terms of conversion of the Series A preferred stock, the terms of exercise of the warrants and the effect of the issuance of these securities on the holders of our common stock, see Note 9 to the Condensed Financial Statements included herein.

The securities were issued and sold pursuant to Section 4(2) of the Securities Act of 1933, as amended. Specifically, we relied on Rule 506 of Regulation D. All of the purchasers of the securities executed investor questionnaires that represented that each investor was an accredited investor as that term is defined in Rule 501 of Regulation D of the Securities Act of 1933, as amended. In addition, the requirements in Rule 502 of Regulation D were also met. On May 15, 2003, we filed a registration statement on Form S-3 (No. 333-105288) with the Securities and Exchange Commission relating to the resale of securities sold in the private placement transaction and on June 25, 2003 we amended that registration statement.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On April 3, 2003, the Company held a special stockholder meeting to (i) approve amendments to the Company's amended and restated certificate of incorporation to effect a reverse split of the Company's common stock in a range of 1:8 to 1:12 (Proposal 1), (ii) approve and ratify the sale and issuance, in a private placement, of up to 350 shares of Series A Convertible Preferred Stock, and warrants with proceeds of up to \$3,500,000 (Proposal 2), (iii) approve an amendment to the Company's 2000 Equity Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under this plan by 1,900,000 shares (Proposal 3), and (iv) approve an amendment to the Company's certificate of incorporation to increase authorized shares of common stock from 70,000,000 to 100,000,000 in the event the reverse stock split in Proposal 1 was not approved by the stockholders (Proposal 4). With respect to proposal 2, the Company adjourned the special meeting until April 23, 2003 and then adjourned special meeting again until April 30, 2003. The voting results were as follows:

	<u>Votes for</u>	<u>Votes against</u>	<u>Abstentions</u>	<u>Broker Non-Votes</u>
Proposal 1	26,632,443	2,038,861	23,346	
Proposal 2	16,304,028	5,941,036	1,300,830	15,685,457
Proposal 3	22,708,232	5,912,171	74,247	
Proposal 4	25,781,250	2,865,567	21,347	26,486

The Company's Annual Meeting of Stockholders was held on June 5, 2003. Of the 3,269,168 shares outstanding and eligible to vote as of the record date, 2,198,243 were present or represented by proxy at the meeting. The results of the voting on the matters submitted to the stockholders are as follows: (1) to elect the following two directors to hold office until the 2006 Annual Meeting of Stockholders:

<u>Name</u>	<u>Votes for</u>	<u>Withheld</u>
Ernest Mario	2,057,460	140,783
Henry J. Fuchs	2,057,460	140,783

(2) To ratify the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as independent auditors of the Company for its fiscal year ending December 31, 2003. The voting results were as follows:

<u>Votes For</u>	<u>Votes Against</u>	<u>Abstentions</u>
2,196,956	1,144	143



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ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) List of Exhibits

Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation.(1)
3.2	Bylaws.(2)
4.1	Amended and Restated Investor Rights Agreement dated October 15, 1999.(2)
4.2	Form of Stock Purchase Agreement by and between the Company and each selling stockholder, dated January 29, 2002.(3)
4.3	Form of Preferred Stock and Warrant Purchase Agreement, dated February 5, 2003, as amended on February 11, 2003.(4)
4.4	Form of Second Amendment to Preferred Stock and Warrant Purchase Agreement of February 5, 2003, dated April 10, 2003.(5)
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.(5)
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certification by the Chief Executive Officer and the Chief Financial Officer of the Company, as required by Rule 13a-14(b) Or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States. Code (18 U.S.C. 1350).

- (1) 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.
- (2) 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.
- (3) 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.
- (4) 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.
- (5) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on May 14, 2003.

(b) *Reports on Form 8-K*

We furnished a report on Form 8-K, dated April 29, 2003, announcing the dissemination of a press release announcing certain financial results for the quarter ended March 31, 2003.



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**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

August 13, 2003

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

/s/ Eric H. Bjerkholt

August 13, 2003

Eric H. Bjerkholt  
Chief Financial Officer

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