INTRABIOTICS PHARMACEUTICALS INC /DE
Form 10-Q
November 12, 2003

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2003
or

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

For the transition period from to

Commission File Number 0-29993

INTRABIOTICS PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

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

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 x No o

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

There were 5,253,983 shares of the Company s Common Stock, par value $.001, outstanding as of October 31, 2003.

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PART I. FINANCIAL INFORMATION

ITEM I. FINANCIAL STATEMENTS

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

	SEPTEMBER 30, 2003	DECEMBER 31, 2002
	(Unaudited)	(Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 10,061	$ 10,170
Restricted cash	250	250
Short-term investments		2,895
Prepaid drug substance		2,375
Prepaid expenses	467	247
Total current assets	10,778	15,937
Property and equipment, net	31	112
Other assets	184	177
Total assets	$ 10,993	$ 16,226
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 376	$ 345
Accrued clinical liabilities	128	
Accrued employee liabilities	91	135
Accrued restructuring charges		64
Other accrued liabilities	244	202
Total current liabilities	839	746
Stockholders equity:		
Preferred stock	1,886	
Common stock	3	3
Additional paid-in capital	219,244	216,466
Deferred stock compensation	(180)	(720)
Accumulated deficit	(210,799)	(200,269)
Total stockholders equity	10,154	15,480
Total liabilities and stockholders equity	$ 10,993	$ 16,226

See accompanying notes.

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

(UNAUDITED)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2003	2002	2003	2002
Operating expenses:				
Research and development	$ 3,641	$ 3,955	$ 5,261	$ 17,407
General and administrative	1,125	2,388	3,833	6,295
Arbitration settlement				(3,600)
Restructuring and other charges		5,140		5,231
Total operating expenses	4,766	11,483	9,094	25,333
Operating loss	(4,766)	(11,483)	(9,094)	(25,333)
Interest income	28	143	99	623
Interest expense		(131)		(397)
Other income		200		984
Net loss	(4,738)	(11,271)	(8,995)	(24,123)
Non-cash deemed dividend related to beneficial conversion feature of Series A preferred stock			(1,418)	
Dividends on Series A preferred stock	(70)		(117)	
Net loss applicable to common stockholders	$(4,808)	$(11,271)	$(10,530)	$(24,123)
Basic and diluted net loss per share applicable to common stockholders	$ (1.46)	$ (3.59)	$ (3.22)	$ (7.99)
Shares used to compute basic and diluted net loss per share applicable to common stockholders	3,283	3,143	3,274	3,018

See accompanying notes.

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

(UNAUDITED)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2003	2002
Operating activities		
Net loss	$ (8,995)	$ (24,123)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred stock compensation	110	848
Depreciation and amortization	81	575
Acquired workforce amortization		234
Stock compensation expense	411	619
Gain on sale of pre-clinical programs		(975)
Change in assets and liabilities:		
Prepaid expenses	2,155	2,025
Other assets	(7)	
Accounts payable	31	(33)
Accrued clinical liabilities	128	(222)
Accrued employee liabilities	(44)	(300)
Accrued restructuring charges	(64)	2,859
Deferred rent		203
Other accrued liabilities	(28)	(396)
Net cash used in operating activities	(6,222)	(18,686)
Investing activities		
Capital expenditures		(17)
Proceeds from sale of pre-clinical programs		400
Maturities of short-term investments	2,895	
Cash received in acquisition of subsidiary		58
Net cash provided by investing activities	2,895	441
Financing activities		
Proceeds from issuance of common stock, net	6	19,472
Proceeds from issuance of Series A preferred stock and warrants, net	3,212	
Payments on financing obligations		(1,406)
Net cash provided by financing activities	3,218	18,066
Net decrease in cash and cash equivalents	(109)	(179)
Cash and cash equivalents at beginning of period	10,170	27,982
Cash and cash equivalents at end of period	$ 10,061	$ 27,803
Supplemental disclosure of cash flow information:		
Interest paid	$	$ 397
Supplemental disclosure of non-cash information:		
Net deferred stock compensation (cancellations due to employee termination)	$ (430)	$ (1,076)

Other assets received from sale of pre-clinical programs	$	$ 575
Beneficial conversion feature on Series A preferred stock	$ (1,418)	$
Issuance of common stock dividend on Series A preferred stock	$ (117)	$
Cash flow for acquisition of subsidiary:		
Acquired workforce	$	$ 1,694
Other current assets acquired		297
Property and equipment acquired		56
Liabilities assumed		(75)
Acquisition costs incurred		(106)
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 entirely of normal recurring adjustments) necessary for a fair presentation of the Company s financial position as of September 30, 2003, the results of its operations for the three- and nine-month periods ended September 30, 2003 and 2002 and cash flows for the nine-month periods ended September 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 entire 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/A, and filed with the Securities and Exchange Commission on June 25, 2003. 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 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, as amended, must be applied for the first interim or annual period ending after December 15, 2003. The adoption of FIN 46 did not have any impact on the Company s financial position, results of operations or disclosure.

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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 adoption of SFAS No. 150 did not have a material impact on the Company s 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 an employee or director stock option is set equal or in excess of the fair value of the underlying stock on the date of grant, no compensation expense is recognized. If the exercise price of the employee or director stock option is set at less than the fair value of the underlying stock on the grant date, the Company records deferred compensation for the difference. Deferred compensation is 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss applicable to common stockholders, as reported	$(4,808)	$(11,271)	$(10,530)	$(24,123)
Add: Stock-based employee compensation expense included in reported net loss	300	161	419	848
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(384)	(720)	(1,194)	(1,799)
Pro forma net loss applicable to common stockholders	$(4,892)	$(11,830)	$(11,305)	$(25,074)
Net loss per share applicable to common stockholders:				
Basic and diluted as reported	$ (1.46)	$ (3.59)	$ (3.22)	$ (7.99)
Basic and diluted pro forma	$ (1.49)	$ (3.76)	$ (3.45)	$ (8.20)

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- and nine-month periods ended September 30, 2003 and 2002 with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Risk-free interest rate	3.20%	3.35%	2.81%	4.08%
Volatility	1.00	1.00	1.00	1.00

Dividend yield				
Expected life of option	5 years	5 years	5 years	5 years

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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 amount 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 existing employees and directors of the Company. Upon election by the participants, all of the unexercised stock options were 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 on 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 previously 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 of $285,000 and $309,000 was recorded for these options during the three- and nine-month periods ended September 30, 2003, respectively.

Note 6. Net Loss Per Common 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, 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 common share were 3,200,874 and 623,410 for the three-month periods ended September 30, 2003 and 2002, respectively, and 2,991,807 and 385,114 for the nine-month periods ended September 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 administration, 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. 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 common stock, which was effected 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), $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 a clinical trial of iseganan HCl for the prevention of ventilator-associated pneumonia (VAP), as well as for other general corporate purposes and working capital.

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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 adjustment 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 first pivotal 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 will 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 adjustment 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 will be reduced by 50% if the Company s common stock is delisted from the Nasdaq National Market. The warrants will expire on May 1, 2008, if not previously 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 May 1, 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 approvals by the Board of Directors. The Company is currently in compliance with each of the covenants.

Note 10. Subsequent Events

On October 9, 2003, a holder of 25 shares of Preferred Stock converted the shares into 131,529 shares of common stock. On the same date, the same investor exercised warrants to purchase 65,764 shares of common stock, using the net exercise method, resulting in the issuance of 55,344 shares of common stock. There were no cash proceeds to the Company resulting from these transactions.

On October 10, 2003, in a private placement transaction, the Company sold 1,774,000 shares of newly issued common stock, $0.001 par value, and issued warrants to purchase 354,800 shares of the Company s common stock, resulting in net cash proceeds of approximately $18.4 million. Of these shares and warrants, 120,000 shares and 24,000 warrants were sold to an affiliate of a member of the Company s Board of Directors. The primary purpose of completing the private placement was to provide additional funding for the two pivotal trials of iseganan HCl for the prevention of VAP, as well as for other general corporate purposes and working capital.

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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/A, filed with the SEC on June 25, 2003. 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 patients in intensive care units.

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 therapy 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.

A phase I/IIa trial of iseganan HCl oral solution evaluating safety and antimicrobial activity in mechanically-ventilated patients was completed in February 2001. A phase I/IIa trial attempts to obtain preliminary indicators of safety and efficacy of a drug candidate in a smaller patient population. The trial 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. In this study, we also selected the optimal formulation and dosage strength of iseganan HCl, and demonstrated that administration 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 pivotal study to test the effectiveness of iseganan HCl in preventing VAP. A pivotal study attempts to establish the safety and efficacy of a drug candidate in an expanded patient population.

In September 2003, we reached a Special Protocol Assessment, or SPA, agreement with the FDA on the requirements for registration of iseganan HCl for the prevention of VAP. Under our agreement with the FDA, we are required to conduct two identical pivotal, randomized, double-blind, placebo-controlled, multinational clinical trials. These pivotal trials are designed to assess the safety and efficacy of iseganan HCl and to demonstrate iseganan HCl s ability to reduce the incidence of pneumonia in patients who are receiving mechanical ventilation. In each trial, approximately 900 patients will be enrolled and will be randomized to receive either iseganan HCl or placebo six times per day for up to 14 days, while being mechanically ventilated. Enrollment in the first pivotal trial commenced in September 2003, and we expect to announce its results by the end of 2004. We cannot be certain that iseganan HCl will prove to be safe or effective in the prevention of VAP, or will receive regulatory approvals.

On October 10, 2003, we completed a private placement in which we sold shares of common stock and warrants to purchase common stock resulting in aggregate net cash proceeds of approximately $18.4 million. The primary purpose of the financing was to provide additional funding for the two pivotal trials of iseganan HCl for the prevention of VAP, as well as for other general corporate purposes and working capital. We expect that we will need to raise additional funds in the future to complete these trials and to continue our operations.

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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. The aggregate costs incurred for the development of iseganan HCl for the prevention of VAP during 2000, 2001, 2002 and the first nine months of 2003, were approximately $5.0 million.

The Company has in the past ordered and received, and may in the future receive, significant quantities of iseganan HCl. The Company s policy is to record any prepayments of such orders as Prepaid drug substance . Upon formal acceptance by the Company of each delivery, 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 for which there is no net carrying value on the Company s balance sheet. At September 30, 2003, the Company held over seven kilograms of finished iseganan HCl drug substance and a significant amount of partially completed iseganan HCl that has been charged to research and development expense in line with this policy.

During 2002, we prepaid $2.4 million for an order of seven kilograms of iseganan HCl bulk drug substance that was expected to be delivered in the second half of 2003. An additional $250,000 is payable when and if this order is accepted by us. Our general practice is that when we accept the delivery of the order, we expense the prepaid amount to research and development expense. Although the product is not expected to be needed for clinical trials, it was expected to be used by us to validate our manufacturing process. However, we have not yet been satisfied that the lot was manufactured in accordance with a validation plan or that related documentation will be adequate, and we are currently discussing this with our contract manufacturer. Due to significant uncertainty over the timing and outcome of these discussions, we have written off the entire $2.4 million prepaid amount as of September 30, 2003. The financial statements for the three- and nine-month periods ended September 30, 2003 reflect a corresponding research and development expense of $2.4 million.

In February 2003, the Board of Directors approved a cancellation and re-grant of 321,335 unexercised stock options held by existing employees and directors of the Company. Upon election by the participants, all of the unexercised stock options were 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 on February 5, 2003, or $2.76 per share, post-split. The options 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, 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 of $285,000 and $309,000 was recorded for these options during the three- and nine-month periods ended September 30, 2003, respectively.

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, which was effected 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/A, for the year ended December 31, 2002 filed with the Securities and Exchange Commission on June 25, 2003.

Results of Operations

Three- and Nine-Month Periods Ended September 30, 2003 and 2002

Research and Development

Research and development expenses were $3.6 million in the three-month period ended September 30, 2003, including a write-off of $2.4 million for prepaid iseganan HC1 drug substance, compared to $4.0 million in the prior year period, and $5.3 million and $17.4 million in the nine-month periods ended September 30, 2003 and 2002, respectively. The lower amounts in 2003 are primarily due to the lower cost of preparations for the first pivotal trial of iseganan HC1 for the prevention of VAP compared to the cost of enrolling patients for phase III oral mucositis trials in 2002.

Of the research and development expenses above, $1.0 million and $2.9 million for the three-month periods ended September 30, 2003 and 2002, respectively, and $2.1 million and $13.3 million for the nine-month periods ended September 30, 2003 and 2002,

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respectively, were related to clinical trial activities performed by clinical trial service providers. Other research and development expenses primarily include research and development payroll expense, drug substance expense, allocated facilities costs and non-cash stock compensation charges. Non-cash stock compensation charges were $20,000 and $56,000 for the three-month periods ended September 30, 2003 and 2002, respectively, and $23,000 and $651,000 for the nine-month periods ended September 30, 2003 and 2002, respectively. The decrease between periods is primarily due to the cancellation of options for terminated employees and consultants.

We expect research and development expense, excluding the write-off of the $2.4 million prepaid for iseganan HC1, to increase significantly as patients are enrolled in the first pivotal trial of iseganan HCl for the prevention of VAP.

General and Administrative

General and administrative expenses were $1.1 million and $2.4 million in the three-month periods ended September 30, 2003 and 2002, respectively, and $3.8 million and $6.3 million in the nine-month periods ended September 30, 2003 and 2002 respectively. 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 administrative payroll expense, outside contractors, legal and accounting fees, insurance, non-cash stock compensation charges, facilities, supplies and other general administrative expenses. Non-cash stock compensation charges were $362,000 and $120,000 for the three-month periods ended September 30, 2003 and 2002, respectively, and $498,000 and $816,000 for the nine-month periods ended September 30, 2003 and 2002, respectively. The increase between the three-month periods is primarily due to stock compensation charges for variable accounting of options that were cancelled and re-granted in February 2003. The decrease between the nine-month periods is primarily due to the cancellation of options for terminated employees and consultants.

Arbitration Settlement

During the nine-month period ended September 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 in the same period of 2003.

Restructuring and Other Charges

There were no expenses recorded for restructuring during the three- and nine-month periods ended September 30, 2003, compared to $5.1 million and $5.2 million for the same periods in 2002, respectively. The decrease in restructuring and other charges was due to the fact that there were no restructurings during the first nine-months of 2003.

Interest Income and Interest Expense

Interest income was $28,000 and $143,000 in the three-month periods ended September 30, 2003 and 2002, respectively, and $99,000 and $623,000 in the nine-month periods ended September 30, 2003 and 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 nine-month periods ended September 30, 2003, from $131,000 and $397,000 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 $200,000 and $975,000 in the three- and nine-month periods ended September 30, 2002, respectively. We had no comparable items for the same periods in 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,

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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

Net loss was $4.7 million in the three-month period ended September 30, 2003, compared to $11.3 million in the prior year period, and $9.0 million and $24.1 million in the nine-month periods ended September 30, 2003 and 2002, respectively. Net loss applicable to common stockholders was $4.8 million and $10.5 million for the three- and nine-month periods ended September 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 in the nine-month period ended September 30, 2003, and Series A preferred stock dividends of $70,000 and $117,000 in the three- and nine-month periods ended September 30, 2003, respectively. 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. 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 loss applicable to common stockholders was the same as net loss for the three- and nine-month periods ended September 30, 2002.

Liquidity and Capital Resources

Cash, cash equivalents, short-term investments and restricted cash were $10.3 million as of September 30, 2003, compared to $13.3 million as of December 31, 2002. At September 30, 2003, we had restricted cash deposits of $250,000 in connection with a standby letter of credit issued to a contract manufacturer in relation to an order of iseganan HC1. We had no debt outstanding as of September 30, 2003. We currently invest excess funds in short-term money market funds.

Net cash used in operating activities for the nine-month periods ended September 30, 2003 and 2002 was $6.2 million and $18.7 million, respectively. Our cash used for operating activities in each period consisted primarily of the net loss for each period, adjustments for non-cash items and changes in prepaid expenses and accrued liabilities. Non-cash items consisted primarily of stock-related compensation expenses, and in 2002, non-cash income of $975,000 related to the gain on the sale of the two pre-clinical programs to Micrologix.

Net cash provided by investing activities for the nine-month periods ended September 30, 2003 and 2002 was $2.9 million and $441,000, respectively. The cash provided in 2003 related to the maturity of short-term investments of $2.9 million, and in 2002 primarily related to the proceeds from the sale of the two pre-clinical programs to Micrologix of $400,000.

Net cash provided by financing activities for the nine-month periods ended September 30, 2003 and 2002 was $3.2 million and $18.1 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 adjustment 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 first pivotal 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 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 will 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

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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 adjustment 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 will be reduced by 50% if the Company s common stock is delisted from the Nasdaq National Market. The warrants will expire on May 1, 2008 if not previously 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 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 nine-month period ended September 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 $1.4 million in payments on financing obligations to a bank.

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

	Payments Due by Period					
Contractual Commitments	**Total**	**2003**	**2004**	**2005**	**2006**	**2007**
Drug substance	$463	$263	$50	$50	$50	$50
Operating leases	68	25	43			
Total contractual commitments	$531	$288	$93	$50	$50	$50

The $463,000 drug substance amount represents total commitments to the same contract manufacturer to which we prepaid $2.4 million for an order of seven kilograms of iseganan HCl bulk drug substance. In 2003, the commitment represents the potential payment of $250,000 upon acceptance of this order, when and if this occurs, and a $12,500 fee for storage of iseganan HC1. The remaining $200,000 represents storage fees for iseganan HC1 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 an aggregate amount of $84,000 and $43,000 in 2003 and 2004, respectively.

We expect to continue to incur substantial operating losses. We currently anticipate our cash, cash equivalents and investments, including approximately $18.4 million in net proceeds from the private placement completed on October 10, 2003, to be sufficient to fund operations for at least the next 12 months. We expect that we will need to raise additional funds in the future to complete our pivotal trials and to continue 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

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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 loss applicable to common stockholders of $34.5 million in 2002 and $10.5 million in the nine-month period ended September 30, 2003. As of September 30, 2003, our accumulated deficit was approximately $210.8 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 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 trials of iseganan HCl for the prevention of VAP and any future clinical trials of iseganan HCl for other indications, or for products that we may license or acquire. If these trials are unsuccessful, we will not be able to commercialize any products and may be forced to cease operations.

We currently have only one product candidate, iseganan HCl. In 2002, we completed two Phase III clinical trials of iseganan HCl 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. Both of these clinical trials failed to meet their primary endpoints and we are no longer pursuing iseganan HCl for the prevention of ulcerative oral mucositis. We are currently pursuing iseganan HCl for the prevention of VAP. In September 2003, we reached an SPA agreement with the FDA on the design of our pivotal trials to be conducted in support of registration of iseganan HCl for the prevention of VAP. However, the SPA agreement does not guarantee that we will receive approval from the FDA. Enrollment in the first pivotal trial commenced in September 2003, and we expect to announce its results by the end of 2004. If this pivotal 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.

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 nine-month period ended September 30, 2003, net cash used for operating activities was $26.3 million and $6.2 million, respectively. At September 30, 2003, our cash and cash equivalents, including short-term investments, were $10.3 million, which included restricted cash of $250,000. On October 10, 2003, we completed a private placement in which we sold shares of common stock and warrants to purchase common stock resulting in aggregate net cash proceeds of approximately $18.4 million.

Our future liquidity and capital requirements will depend on many factors, including the timing, cost, and progress of our current VAP trial, the rate of patient enrollment, 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.

We expect that we will need to raise additional funds in the future to complete the pivotal trials of iseganan HCl for the prevention of VAP, and we believe that additional financing will be required in the future to fund our operations, conduct any other possible trials of iseganan HC1, 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.

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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.

We are dependent on a third party contract manufacturer for the future production of iseganan HCl and for producing information required to register iseganan HCl with the FDA if our trials are successful. If our manufacturing partner fails to manufacture iseganan HCl in accordance with set specifications or fails to produce the necessary information, our operations could be adversely affected.

During 2002, we prepaid $2.4 million for an order of seven kilograms of iseganan HCl bulk drug substance that was expected to be delivered in the second half of 2003. An additional $250,000 is payable when and if this order is accepted by us. We currently have recorded restricted cash of $250,000 on our balance sheet in relation to the payable. Our general practice is that when we accept the delivery of the order, we expense the prepaid amount to research and development expense. Although the product is not expected to be needed for clinical trials, it is expected to be used by us to validate our manufacturing process. However, we have not yet been satisfied that the lot was manufactured in accordance with a validation plan or that related documentation will be adequate, and we are currently discussing this with our contract manufacturer. Due to significant uncertainty over the timing and outcome of these discussions, we have written off the entire $2.4 million prepaid amount as of September 30, 2003. The financial statements for the quarter ended September 30, 2003 reflect a corresponding research and development expense of $2.4 million.

We have relied on a single contract manufacturer to manufacture the iseganan HCl bulk drug substance for our pivotal clinical trials. We currently maintain a sufficient inventory of iseganan HCl to complete planned clinical trials. However, we currently depend on this manufacturer to produce iseganan HCl and information required for FDA registration. In addition, we will depend on this manufacturer in the future to produce iseganan HCl for future commercial use if our pivotal trials are successful. If this manufacturer is unable to validate the manufacturing process, both producing iseganan HCl and the required information for registration and commercial use on a timely basis in accordance with set specifications, and we experience similar issues to those experienced on the current order, we may not have sufficient quantities of iseganan HCl and sufficient information to meet registration requirements or for future commercial use.

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

We rely on contract research organizations to assist us in managing and monitoring our clinical trial. We have entered into agreements with Amarex, LLC, Orion Clinical Services, Ltd and Advanced Clinical Trials, Inc., among others, 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 United States or any foreign market. We must obtain approval from the FDA in order to sell iseganan HCl or any future drug candidate in the United States and from foreign regulatory authorities in order to sell iseganan HCl or any future 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 any competitive advantage we may have; and

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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.

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 five pending patent applications in the United States. 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

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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 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 drug candidate that we develop, acquire or license may not gain market acceptance among physicians, patients 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:

demonstration of clinical efficacy and safety;

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

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 trials 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 trials 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. As of September 30, 2003, we had nine full-time employees. In order to pursue any future product

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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 55% of our capital stock and may be able to exert control over our activities.

As of October 10, 2003, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 55% 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.

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

- provide for a classified board of directors of which approximately one third of the directors will be elected each year;
- allow the authorized number of directors to be changed only by resolution of the board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for nominations to the board of directors or for proposals that can be acted on at stockholder meetings; and
- limit who may call stockholder meetings.

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

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

The market prices for securities of biotechnology companies in general have been highly volatile and our stock may be subject to volatility. After accounting for the effect of our 1-for-12 reverse stock split on April 10, 2003, during 2002 our closing stock prices 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 $14.00 during the nine-month period ended September 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;

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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. As of September 30, 2003, all of our funds were held in bank accounts and a money market fund, which are minimally sensitive to 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 September 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 September 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 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) List of Exhibits

Number	
3.1	Amended and Restated Certificate of Incorporation.(1)
3.2	Bylaws.(2)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on April 10, 2003.
3.4	Certificate of Designation filed with the Delaware Secretary of State on May 1, 2003.
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)
4.6	Form of Common Stock and Warrant Purchase Agreement, dated October 6, 2003. (6)
4.7	Form of Warrant issued by the Company pursuant to the Common Stock and Warrant Purchase Agreement of October 6, 2003. (6)
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.

(6) Incorporated by reference to exhibit to our Form 8-K (File No. 000-29993) filed with SEC on October 9, 2003.

(b) *Reports on Form 8-K*

We furnished a report on Form 8-K, dated August 14, 2003, announcing the dissemination of a press release announcing certain financial results for the quarter ended June 30, 2003 and filed a report on Form 8-K, dated September 19, 2003, announcing the dissemination of a press release announcing our Special Protocol Assessment agreement with the FDA.

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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

November 12, 2003 — Henry J. Fuchs, M.D.
President and Chief Executive Officer

/s/ Eric H. Bjerkholt

November 12, 2003 — Eric H. Bjerkholt
Chief Financial Officer

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EXHIBIT INDEX

Number	
3.1	Amended and Restated Certificate of Incorporation.(1)
3.2	Bylaws.(2)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on April 10, 2003.
3.4	Certificate of Designation filed with the Delaware Secretary of State on May 1, 2003.
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)
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