INTRABIOTICS PHARMACEUTICALS INC /DE
Form 10-Q/A
June 25, 2003

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 10-Q/A

## (Amendment No. 1)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the quarterly period ended March 31, 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 þ 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 þ

There were 3,269,168 shares of the Company s Common Stock, par value $.001, outstanding as of April 30, 2003.

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**Explanatory Note**

This amendment does not reflect events occurring after the original filing of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2003 (the Form 10-Q ) or update those disclosures as presented in the Form 10-Q, except to reflect certain revisions and clarifications in Items 2 and 6 of this Amendment No. 1 to Form 10-Q.

**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. 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 focused on developing an antimicrobial drug, a drug capable of destroying microorganisms that cause disease. Our only drug in development is iseganan hydrochloride, or HCl, oral solution for the prevention of ventilator-associated pneumonia, or VAP. Iseganan HCl is an antimicrobial drug that kills a wide variety of microorganisms, including bacteria and fungi, and is effective against many drug-resistant, disease-causing bacteria and yeast. 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.

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. 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. The phase I/ IIa study demonstrated 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. We have also met with the FDA to obtain their feedback on the trial. In April 2003, we amended our Investigational New Drug application. The phase II/ III trial is designed to enroll 500 patients in a double blind, placebo controlled study. Enrollment in the trial is expected to begin in the middle of 2003, and preliminary data from this trial are expected in the second quarter of 2004. The aggregate costs incurred for the development of iseganan HCl for the prevention of VAP during 2000, 2001,

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2002 and the first quarter of 2003, were approximately $2.9 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.

At March 31, 2003, the Company held over seven kg of finished iseganan HCl and a significant amount of partially completed iseganan HCl drug product. Also at March 31, 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 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.

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 gross cash proceeds of $3.5 million. The primary purpose of completing the private placement was to provide funds to allow us to conduct and complete our 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 regrant of stock options held by the remaining employees, consultants and directors of the Company. The purpose of this program is to both provide a long-term incentive to the Company s employees, directors and consultants and to further align their interests with those of its stockholders. Participants in the program elected to exchange their current unexercised options in a one-for-one exchange for new options, except for Dr. Mario s 54,166 options granted in 2002 outside of the plan, which were exchanged for 12,500 new options. Upon election, all current stock options were cancelled and new stock options were granted. New options were issued with an exercise price equal to the closing price on February 5, 2003, or $2.76 per share (post-split). All new options vest monthly over a four-year period beginning in March 2003. The new options have a five-year life and will expire before March 2008 if not exercised. Variable accounting will be used, starting on the date of regrant, on the new stock option grants and may have a significant impact on the Company s future results of operations. During the three-month period ended March 31, 2003, the Company recorded zero compensation expense related to variable accounting for these options.

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 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.

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**Results of Operations**

***Three-month Periods Ended March 31, 2003 and 2002***

*Research and Development*

Research and development expenses for the three-month period ended March 31, 2003 consist of costs related to the preparation for a new phase II/III clinical trial for iseganan HCl oral solution for the prevention of VAP. For the three-month period ended March 31, 2002, the research and development expenses consisted of costs related to our phase III clinical trials for iseganan HCl oral solution for the prevention of oral mucositis. Research and development expenses decreased to $268,000 in the three-month period ended March 31, 2003 from $7.0 million for the same period of 2002. Expenses related to our then-enrolling phase III clinical trials for iseganan HCl oral solution for the prevention of oral mucositis during the 2002 period were significantly higher than expenses in the 2003 period related to the commencement of preparations for the new phase II/III clinical trial for the prevention of VAP. We expect research and development expenses to increase significantly as patients are enrolled in the second half of 2003 and the first half of 2004 for the new phase II/III clinical trial. In addition, in October 2002, as a result of negative results for the oral mucositis trial, we reduced our research and development headcount from 27 at March 31, 2002 down to three at March 31, 2003. 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 expenses and allocated facilities costs. For the three-month periods ended March 31, 2003 and 2002, approximately 24% and 70%, respectively, of research and development expenses were related to clinical trial activities performed by the clinical trial service providers. Included in research and development expenses are non-cash deferred compensation charges of $0 and $281,000 in the three-month period ended March 31, 2003 and 2002, respectively. The decrease between periods was due to the cancellation of options for terminated employees.

*General and Administrative*

General and administrative expenses increased to $1.7 million in the three-month period ended March 31, 2003, from $1.5 million for the same period in 2002. The increase in general and administrative expense is primarily a result of $380,000 of severance costs recorded in the three-month period ended March 31, 2003 for the reduction of sales, marketing and business development staff as well as reduced allocation of facilities and general administrative expenses to research and development activities. General and administrative costs 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 deferred compensation charges of $62,000 and $207,000 in the three-month period ended March 31, 2003 and 2002, respectively. The decrease between periods was due to the cancellation of options for terminated employees.

*Arbitration Settlement*

The arbitration between us and a contract vendor relating to a drug dispensing error in iseganan HCI oral solution phase III clinical trials was resolved amicably in January 2002. We received $3.6 million in the settlement during the quarter ended March 31, 2002 and we had no comparable item for the three-month period ended March 31, 2003.

*Restructuring and Other Charges*

There were no expenses recorded for restructuring during the three-month period ended March 31, 2003, compared to $91,000 for the same period in 2002. The decrease in restructuring and other charges was due to the fact that there were no new restructuring actions occurring in the first quarter of 2003 as compared to the same period of 2002.

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*Interest Income and Expense*

Interest income decreased to $26,000 in the three-month period ended March 31, 2003 from $265,000 for the same period in 2002. 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 period. Interest expense decreased to zero for the three-month period ended March 31, 2003 from $153,000 for the same period in 2002. The decrease in interest expense is attributed to the repayment of our line of credit and bank loan in October 2002.

**Liquidity and Capital Resources**

Cash, cash equivalents, short-term investments and restricted cash were $11.4 million as of March 31, 2003, compared to $13.3 million as of December 31, 2002. At March 31, 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 March 31, 2003. We invest excess funds in short-term money market funds.

Net cash used in operating activities for the three-month periods ended March 31, 2003 and 2002 was $1.9 million and $3.6 million, respectively. Our cash used for operating activities in each period consisted primarily of the net loss for each period, excluding non-cash expenses consisting primarily of amortization of deferred stock compensation expense, and a decrease in prepaid expenses in 2002.

Net cash provided by investing activities for the three-month periods ended March 31, 2003 and 2002 was zero.

Net cash provided by financing activities for the three-month periods ended March 31, 2003 and 2002 was $1,000 and $13.9 million, respectively. Cash provided by financing activities for the three-month period ended March 31, 2003 was from the issuance of common stock purchased under the Employee Stock Purchase Plan. Cash provided by financing activities for the three-month period ended March 31, 2002 was due to $14.3 million of gross proceeds from the issuance of 5.9 million shares of common stock in a private placement transaction, partially offset by $469,000 in payments on financing obligations to a bank.

The following are future contractual commitments at March 31, 2003, (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual Commitments** | **Total** | **2003** | **2004** | **2005** | **Thereafter** |
| Drug substance | $ 528 | $328 | $ 50 | $ 50 | $100 |
| Operating leases | 119 | 76 | 43 | | |
| Severance payments | 237 | 237 | | | |
| Consulting payments | 165 | 165 | | | |
| Total contractual commitments | $1,049 | $806 | $ 93 | $ 50 | $100 |

The $528,000 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, $40,000 for the completion of a development report, and a $38,000 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.

The severance payments relate to the reduction of staff during the three-month period ended March 31, 2003, primarily associated with sales, marketing and business development staff.

The 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 total $550,000, with the remaining $220,000 as of December 31,

2002 to be paid in 2003.

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We expect to continue to incur substantial operating losses. Including the completion of the $3.5 million financing on May 1, 2003, we believe that existing capital resources and interest income will be sufficient to fund our planned operations for at least the next 12 months, as we pursue the development of iseganan HCl for the prevention of VAP.

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.

**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 of $34.5 million in 2002 and $1.9 million in the three-month period ended March 31, 2003. As of March 31, 2003, our accumulated deficit was approximately $202.2 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 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.**

At March 31, 2003, our cash and cash equivalents, including short-term investments, were $11.4 million, which included restricted cash of $250,000. We believe these cash, cash equivalents and investments, in addition to the $3.5 million gross proceeds from the private placement completed on May 1, 2003, will be sufficient to meet our current operating and capital requirements for at least the next 12 months. However, we have based this estimate on assumptions that may prove to be wrong, and we cannot assure that estimates and

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assumptions will remain unchanged in the future. For example, we are currently assuming that we will have iseganan HCl in active clinical development over the next 12 months without any significant staff or other resources expansion. To the extent we pursue the development of iseganan HCl for other indications or acquire or license other products, we will need to raise additional capital to fund clinical development costs. For the year ended December 31, 2002 and the three-month period ended March 31, 2003, net cash used for operating activities was $26.3 million and $1.9 million, respectively. Our future liquidity and capital requirements will depend on many factors, including timing, cost and progress of our 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.

We believe that additional financing will be required in the future to fund our operations, conduct any other possible iseganan HCl trials 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.

**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, 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. If the FDA requests that we change important design aspects of this trial, then the trial may proceed more slowly than anticipated, making the trial more expensive to conduct and potentially less likely to succeed. 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.

**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.

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**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.**

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

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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 seven 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 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

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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. Through April 30, 2003, we have further reduced our sales, marketing and business development staff, and as of March 31, 2003, we had eight 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 our consultants are employed by other entities. They may have commitments to, or relationships with, other entities that may limit their availability to us. The loss of the services of these personnel may delay our research and development efforts.

**Directors, executive officers, principal stockholders and affiliated entities beneficially own approximately 57% of our capital stock and may be able to exert control over our activities.**

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 57% 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.

**Antitakeover provisions in our charter documents and under Delaware law may make an acquisition of us more difficult.**

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

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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, 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 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 has 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. 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. 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 stockholder s 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.

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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:

- 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, 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) in excess of $2.0 million. We have been in continuous operation for more than three years, and, 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.

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**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 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 during the three-month period ended March 31, 2003 the closing prices ranged from a low of $1.80 to a high of $3.96. 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;

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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## PART II. OTHER INFORMATION

**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) |
| 99.1 | Certification by the Chief Executive Officer and the Chief Financial Officer of the Company, as required by Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. § 1350, as adopted). |

(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 filed a report on Form 8-K, dated February 6, 2003, announcing (i) that we had entered into a agreement to sell a newly created Series A convertible preferred stock and warrants to purchase common stock of the company, (ii) the election of Henry J. Fuchs as Chief Executive Officer, and (iii) the approval by the Board of Directors and the completion of our option cancellation and regrant program.

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**SIGNATURES**

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

INTRABIOTICS PHARMACEUTICALS, INC.

/s/ HENRY J. FUCHS

June 24, 2003

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

/s/ ERIC H. BJERKHOLT

June 24, 2003

Eric H. Bjerkholt
*Chief Financial Officer*

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**CERTIFICATIONS**

I, Henry J. Fuchs, M.D. certify that:

1. I have reviewed this quarterly report on Form 10-Q/ A of IntraBiotics Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report, as amended, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, as amended, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

/s/ HENRY J. FUCHS

Henry J. Fuchs, M.D.
*Chief Executive Officer*

Date: June 24, 2003

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I, Eric H. Bjerkholt, certify that:

1. I have reviewed this quarterly report on Form 10-Q/ A of IntraBiotics Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report, as amended, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, as amended, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

/s/ ERIC H. BJERKHOLT

Eric H. Bjerkholt
*Chief Financial Officer*

Date: June 24, 2003

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