

INTRABIOTICS PHARMACEUTICALS INC /DE

Form 10-K

March 19, 2004

Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

☐ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 0-29993

IntraBiotics Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

*(State or Other Jurisdiction of
Incorporation or Organization)*

94-3200380

*(IRS Employer
Identification No.)*

2483 East Bayshore Road, Suite 100, Palo Alto, CA

(Address of principal executive offices)

94303

(Zip code)

Registrant's telephone number, including area code:

(650) 526-6800

Securities registered under Section 12(b) of the Exchange Act:

None.

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, par value \$.001 per share

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in PART III of this Form 10-K or any amendment to this Form 10-K. ☐

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

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

The aggregate market value of the Common Stock, held by non-affiliates of the registrant, based on the closing price on June 30, 2003 as reported by the Nasdaq National Market was approximately \$10,632,000. The determination of affiliate status for the purposes of this calculation is not necessarily a conclusive determination for other purposes. The calculation excludes approximately 613,000 shares held by directors, officers and stockholders whose ownership exceeds five percent of the Registrant's outstanding common stock as of June 30, 2003. Exclusion of these shares should not be construed to indicate that such person controls, is controlled by or is under common control with the Registrant. The number of shares outstanding of the registrant's Common Stock, par value \$0.001 per share, as of February 27, 2004 was 5,310,661 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Part III Portions of the registrant's definitive proxy statement to be issued in conjunction with the registrant's annual stockholders meeting to be held on June 10, 2004 are incorporated by reference into Part III of this report. Except as expressly incorporated by reference, the Registrant's proxy statement shall not be deemed to be a part of this report.

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I</u>	
<u>Item 1.</u> Business	2
<u>Item 2.</u> Properties	8
<u>Item 3.</u> Legal Proceedings	8
<u>Item 4.</u> Submission of Matters to a Vote of Security Holders	8
<u>PART II</u>	
<u>Item 5.</u> Market for Registrant's Common Equity and Related Stockholder Matters	9
<u>Item 6.</u> Selected Financial Data	11
<u>Item 7.</u> Management's Discussion and Analysis of Financial Condition and Results of Operations	12
<u>Item 7A.</u> Quantitative and Qualitative Disclosure About Market Risk	26
<u>Item 8.</u> Financial Statements and Supplementary Data	27
<u>Item 9.</u> Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	49
<u>Item 9A.</u> Controls and Procedures	49
<u>PART III</u>	
<u>Item 10.</u> Directors and Executive Officers of the Registrant	49
<u>Item 11.</u> Executive Compensation	49
<u>Item 12.</u> Security Ownership of Certain Beneficial Owners and Management	49
<u>Item 13.</u> Certain Relationships and Related Transactions	49
<u>Item 14.</u> Principal Accountant Fees and Services	49
<u>PART IV</u>	
<u>Item 15.</u> Exhibits, Financial Statement Schedules and Reports on Form 8-K	50
<u>EXHIBIT 23.1</u>	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

Table of Contents

PART I

This report contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry, and include, but are not limited to, statements and concerns about plans to: continue development of our current product candidate; conduct clinical trials with respect to product candidates; seek regulatory approvals; address certain markets; engage third party manufacturers to supply our commercial requirements; market, sell and distribute our products; and evaluate additional product candidates for subsequent clinical and commercial development. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," or the negative of such terms and other comparable words. These statements involve known and unknown risks and uncertainties that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among others, those discussed under the captions "Business," "Factors That Could Affect Future Results" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Except as required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Item 1. Business

BUSINESS

Overview

Our strategy is to develop novel biopharmaceutical products for the management of serious infections, including those involving multi-drug-resistant organisms. We are currently developing an oral solution of iseganan hydrochloride (iseganan HCl), an antimicrobial drug, for the prevention of ventilator-associated pneumonia (VAP). VAP is a bacterial pneumonia that can develop in patients receiving mechanical (artificial) ventilation and is the most common infection occurring in patients in the intensive care unit. One potential benefit of preventing VAP would be to reduce the need for antibiotics and subsequent emergence of antibiotic resistance. There are no products approved by health authorities for the prevention of VAP. In addition, we intend to pursue additional indications for iseganan HCl, including treatment of infections in patients with cystic fibrosis. We own worldwide rights to iseganan HCl for all indications.

In September 2003 we launched the first of two pivotal trials of iseganan HCl oral solution for the prevention of VAP. The U.S. Food and Drug Administration (FDA) have granted Fast-Track designation status and a Special Protocol Assessment agreement (SPA) on the design of the two pivotal efficacy trials for this indication. In addition, the FDA accepted the program for inclusion in its Continuous Marketing Application (CMA) Pilot 2 Program. The Fast-Track designation is intended to facilitate the development and expedite the review of a new drug that is intended to treat a serious or life-threatening condition, and that demonstrates the potential to address an unmet medical need. The SPA agreement specifies in writing the pivotal clinical trial requirements for registration of iseganan HCl for the prevention of VAP. The objective of the CMA Pilot 2 program is to evaluate the costs and benefits of enhanced sponsor access to guidance and feedback from the FDA during the Investigational New Drug (IND) phase of new drug development of Fast-Track products.

Under our SPA agreement with the FDA, we are required to conduct two identical pivotal, randomized, double-blind, placebo-controlled, multinational clinical trials. The 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 VAP in patients who are undergoing mechanical ventilation and survive fourteen days. 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. We expect to announce results of the first pivotal trial by the end of 2004. If this trial is successful, we will then conduct the second pivotal trial to support registration of iseganan HCl. We cannot be certain that the first pivotal trial results will be available before the end of 2004, or whether this trial will be successful. In addition, prior to the submission of a New Drug

Table of Contents

Application (NDA) with the FDA, we must satisfy FDA requirements for all other scientific data elements, such as supportive toxicology studies, and validation of the process in which iseganan HCl is manufactured.

On December 31, 2003 we had cash, cash equivalents, restricted cash and short-term investments totaling \$26.6 million, which we currently anticipate to be sufficient to fund operations for at least the next 12 months. We will need to raise substantial additional funds to continue our operations, complete the second pivotal efficacy trial of iseganan HCl for VAP if the first trial is successful, complete the FDA approval process, and commence commercialization if FDA approval is received.

Our Strategy

Our goal is to build a biopharmaceutical company with a portfolio of products for the management of serious infections including those involving multi-drug-resistant organisms. The key elements of our strategy are to:

Complete the clinical development of iseganan HCl for the prevention of VAP;

Pursue additional indications for iseganan HCl, including treatment of infections in patients with cystic fibrosis;

Opportunistically evaluate and acquire additional products that are consistent with our strategy, and;

Leverage and expand our management, clinical and regulatory expertise in anti-infective therapeutics.

Clinical Pipeline

Isegaran HCl

Isegaran HCl belongs to a novel class of naturally-occurring antimicrobial peptides known as Protegrins. Protegrins were originally isolated from mammalian blood cells and are part of the body's first line of biological defense against invading bacteria and fungi. Isegaran HCl is the company's first product candidate. It is a synthetic version of naturally-occurring Protegrins and has shown potent and broad-spectrum antimicrobial properties, and is therefore believed to have great potential in fighting multi-drug-resistant bacteria and fungi that cannot be killed using conventional antibiotics.

We have been developing iseganan HCl in the clinical setting since 1997. In 2002, we completed two phase III trials of 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. Isegaran HCl appears to be safe when applied to the oral cavity. We ceased further development of iseganan HCl for oral mucositis in 2002, and are currently not performing any drug research activities. We are now focused on developing iseganan HCl to prevent VAP, as well as evaluating its potential use in other applications.

Isegaran HCl Oral Solution for Prevention of VAP

Isegaran HCl oral solution is currently in the first of two pivotal clinical trials for the prevention of VAP. VAP is the most common infection in the hospital intensive care unit (ICU). An important risk factor for the development of pneumonia in artificially-ventilated patients is the duration of mechanical ventilation. More than 1 million critically-ill patients in North America, Western Europe, and Japan receive life support via a mechanical ventilator for more than 48 hours. These patients are particularly vulnerable to developing VAP. Up to one in three patients ventilated for at least 48 hours will develop VAP. VAP arises following aspiration of the patient's bacteria-laden saliva around the ventilator tube, which acts like a wick in the otherwise sterile lower airway. Introduction of bacteria into the lungs then increases the propensity for infection and pneumonia. VAP is associated with a high rate of morbidity, leading to prolonged dependence on artificial ventilation and extended hospital stays. The current treatment for VAP is broad-spectrum antibiotic therapy,

Table of Contents

which may account for increased incidence of bacterial resistance to antibiotics and a resultant decreased ability to fight infections.

Prevention may be an effective means by which to reduce VAP and its associated morbidity. Effective prevention will reduce the morbidity in mechanically-ventilated patients, and may shorten the length of time patients require mechanical ventilation. Reduction of VAP may also decrease associated costs, as well as lessen the use of antibiotics to treat infections. It has been shown that other, conventional antibiotics can be used to prevent VAP and associated clinical complications, however, such antibiotics are known to cause overgrowth and resistance, thus reducing available treatment options. Currently no pharmaceutical product has been approved by health authorities for the prevention of 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 than a phase II or phase III trial. In the phase I/IIa trial, we administered iseganan HCl to patients for up to five days and demonstrated that the oral solution was well tolerated and provided a significant antimicrobial effect in mechanically-ventilated patients. 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 believe these results support further development of iseganan HCl oral solution for the prevention of VAP.

Iseganan HCl Oral Solution for Treatment of Respiratory Infections in Cystic Fibrosis Patients

We believe iseganan HCl may be effective in treating respiratory infections in cystic fibrosis (CF) patients. CF is the most common, lethal inherited abnormality in Caucasians. As a result of inheritance of an abnormal gene from each parent, CF patients produce a thick, sticky mucous from their lungs, and recurrent infection of the airway occurs. Patients require antibiotic therapy, delivered either by inhalation or intravenously, from early in life. Eventually, bacteria become resistant to the antibiotics used and alternative antibiotics must be used. In spite of the use of antibiotics, airway infection persists and progressive destruction of lung function ensues. Patients usually succumb to their progressive pulmonary infection, and the median survival is only 34 years of age.

We have shown that iseganan HCl is active in killing the predominant pathogens involved in infections experienced by patients suffering from CF, including those pathogens that are resistant to today's antibiotics. Because iseganan HCl is active against a wider range of pathogens and is unlikely to generate antibiotic resistance, we believe iseganan HCl may offer significant advantages over current therapy and other antibiotics in development. We have shown that iseganan HCl reduces lung infection in an animal model when delivered by aerosol, suggesting that iseganan HCl may offer patients a new alternative. Iseganan HCl has not been observed to cause resistance to other micro-organisms, or to itself.

Two phase I studies of iseganan HCl solution for inhalation, administered as a single dose or up to five doses, have enabled us to establish the dose tolerance and further develop the formulation for this product candidate. These studies also demonstrated that iseganan HCl solution for inhalation was well tolerated when administered to patients with CF. However, we cannot be certain that after further study iseganan HCl solution for inhalation will prove to be safe or effective in treating respiratory infections, or will receive regulatory approvals. In addition, we are currently focusing our resources on the VAP program and are not expending significant resources on the program for respiratory infections in CF patients.

Clinical Supplies and Manufacturing

We currently have sufficient quantities of iseganan HCl to complete the planned pivotal clinical trials for the prevention of VAP, but further quantities will be required to validate the manufacturing process and for commercial use if we successfully obtain FDA registration for this indication. We intend to use contract manufacturers for the supply of our clinical and commercial product needs. To date, we have relied on a single

Table of Contents

contract manufacturer, PolyPeptide Laboratories A/ S (PolyPeptide), to manufacture the iseganan HCl bulk drug substance for our pivotal clinical trials. Although we presently have no supply agreement with this supplier, we are in active discussions with PolyPeptide and other potential suppliers regarding future supply arrangements. We also rely on a single third party supplier, Patheon, Inc., to produce iseganan HCl formulated drug product for use in our pivotal clinical trials. A related discussion of the risks and uncertainties associated with the manufacture of drug substance and drug product is set forth in the *Factors that could affect future results*, under the heading *We will be dependent on third party contract manufacturers 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 partners fail to manufacture iseganan HCl in accordance with set specifications or fail to produce the necessary information, our operations and related results could be adversely affected.*

Commercialization Strategy

We own worldwide rights to iseganan HCl, and are currently evaluating our alternatives for commercialization of iseganan HCl. We may choose to form a partnership with an established pharmaceutical company for commercialization worldwide. Alternatively, we may pursue a hybrid strategy of establishing a partnership covering commercialization outside of the U.S., while retaining commercial rights for ourselves in the U.S. We cannot guarantee that we will successfully develop or commercialize our product candidate, establish a successful partnership, achieve significant market penetration, or generate any revenues from our product.

Competition

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 and other resources than we do. In addition, they may have greater experience in developing drugs, obtaining regulatory approvals and manufacturing and marketing products. We believe the principal bases for competition for our drug candidate are potential effectiveness, price and reimbursement status, ease of administration and side-effect profile. We cannot give any assurances that we can effectively compete with these other pharmaceutical and biotechnology companies.

Intellectual Property

In April 1994, we entered into a license agreement with The Regents of the University of California, under which we have exclusive rights to develop and commercialize Protegrin-based products, such as iseganan HCl. To date, we have paid a \$50,000 licensing fee, \$25,000 upon the filing of an Investigational New Drug application and \$50,000 upon the initiation of a phase III trial. We are obligated to bear all patent costs and submit semi-annual progress reports to the Regents until the first commercial sale. Subsequent to this sale, we are obligated to provide quarterly royalty reports and make quarterly royalty payments to the Regents. The Regents have the right to inspect our royalty records at any time.

We may terminate the agreement upon prior written notice, which shall be effective 90 days after the date of such notice. The Regents may provide a notice of default if any of the following occur: we fail to use diligent efforts to develop and commercialize Protegrin-based products, we are unable to meet certain targets for raising capital or expending resources for the development and commercialization of Protegrin-based products, or we cannot achieve the commercialization milestones stated in a development plan that we presented to the Regents. Upon receipt of the notice of default, we have 90 days to cure the default. If we do not cure the default, the agreement automatically terminates. The agreement is effective for the life of the Regents' patent rights, unless all patent applications are abandoned or no patents are issued, or for 17 years from the first commercial sale of the licensed product, whichever comes first.

We own one U.S. patent which contains claims covering, among other antimicrobial peptides, iseganan HCl, and methods of making and using these antimicrobial peptides. We also own another U.S. patent that contains claims covering pharmaceutical compositions of antimicrobial peptides, including iseganan HCl, and

Table of Contents

methods of using these antimicrobial peptides. These patents expire no earlier than 2016. In addition, we are either the owner or exclusive licensee from The Regents of the University of California of five other U.S. patents covering related antimicrobial peptides and/or their uses. We also own two U.S. patents and have two pending U.S. applications with claims covering related antimicrobial peptides. In addition, we have one pending U.S. application with claims directed to methods of using iseganan HCl or pharmaceutical compositions thereof to prevent VAP.

Applications covering iseganan HCl and the related antimicrobial peptides, as well as their uses, are either pending or have issued in major foreign jurisdictions. Australia has issued patents covering iseganan HCl and the related antimicrobial peptides, as well as their uses. Such patents expire no earlier than 2016. In addition, patent applications covering iseganan HCl and the related antimicrobial peptides, as well as their uses and/or pharmaceutical compositions, are pending in Japan, Canada, Hong Kong, and Israel, and are pending or granted in Europe. Currently the most important patents in the portfolio are the issued patents covering iseganan HCl and pharmaceutical compositions thereof and the pending patents covering the use of iseganan HCl to prevent VAP.

We cannot guarantee that patents will be issued as a result of any patent application or that patents that have issued will be sufficient to protect our technology or products. We cannot predict the enforceability or scope of any issued patent or those that may issue in the future. Moreover, others may independently develop similar technologies or duplicate the technology we have developed. We also rely on trade secrets and proprietary know-how for protection of certain of our intellectual property. We cannot guarantee that our confidentiality agreements provide adequate protection or remedies in the event of unauthorized use or disclosure of our intellectual property. Third parties may assert infringement or other claims against us. Even if these claims are without merit, defending a lawsuit takes significant time, may be expensive and may divert management attention from other business concerns and if unsuccessful, we may be forced to license the intellectual property.

Government Regulation

Governmental authorities in the U.S. and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, of our products. The FDA regulates drugs, including antibiotics, under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

The steps required before a drug may be marketed in the U.S. include:

submission to the FDA of an investigational new drug exemption for human clinical testing, which must become effective before human clinical trials may commence;

adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;

submission to the FDA of a new drug application; and

FDA review and approval of the new drug application.

An investigational new drug application automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the investigational new drug exemption. In such a case, the investigational new drug application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an investigational new drug application will result in the FDA allowing clinical trials to commence.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. A phase I or phase II trial attempts to obtain preliminary indicators of safety and efficacy of a drug candidate in a smaller patient population. Phase II/ III or phase III trials that are suitable for FDA

Table of Contents

registration, often referred to as pivotal trials, usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. We cannot assure you that any of these trials we undertake will be completed successfully within any specified period of time, or at all. Furthermore, we, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of a new drug application requesting approval to market the product for one or more indications. Before approving a new drug application, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless compliance with current good manufacturing practices is satisfactory. If the FDA determines the new drug application and the manufacturing facilities are acceptable, the FDA will issue an approval letter. If the FDA determines the new drug application submission or manufacturing facilities are not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the new drug application does not satisfy the regulatory criteria for approval. The testing and approval process requires substantial time, effort, and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

If regulatory approval is obtained, we will be required to comply with a number of post-approval requirements. For example, as a condition of approval of the new drug application, the FDA may require post marketing testing and surveillance to monitor the drug's safety or efficacy. In addition, holders of an approved new drug application are required to report certain adverse reactions, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to current good manufacturing practices after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with current good manufacturing practices. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with current good manufacturing practices.

We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and we cannot be sure that future FDA inspections will not identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product may result in restrictions on a product, manufacturer, or holder of an approved new drug application, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

The FDA provides periods of marketing exclusivity for new drugs that are the subject of an approved new drug application. Isegran HCl oral solution, if approved, may qualify for marketing exclusivity, which would prevent any competitors from seeking approval of a generic version until five years after approval of our product candidate. Even if a product is approved and granted exclusivity, it does not prevent the approval and marketing of competing products.

Outside the U.S., our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all the risks associated with FDA approval described above. The requirements governing conduct of clinical trials and marketing authorization vary widely from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

Table of Contents

We plan to choose the appropriate route of European regulatory filing in an attempt to accomplish the most rapid regulatory approvals. However, the chosen regulatory strategy may not secure regulatory approvals or approvals of the chosen product indications. In addition, these approvals, if obtained, may take longer than anticipated. We cannot assure you that any of our product candidates will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

Employees

As of February 27, 2004, we had ten full-time employees, five of whom are engaged in product development activities and five of whom are engaged in general and administrative activities. We also make extensive use of consultants and other third party clinical service providers in the execution of our strategy. Our employees are not represented by a collective bargaining agreement. We believe that we have good relations with our employees.

Available Information

Our website address is www.intrabiotics.com. We make available free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after filing.

Item 2. *Properties*

We are currently leasing one facility at 2483 East Bayshore Road, Suite 100, in Palo Alto, California. The facility provides approximately 3,600 square feet of office space. The lease expires on May 31, 2004 and includes an option to extend until November 30, 2004. We believe that we will need to add additional facilities to allow for growth in headcount within the next year.

Item 3. *Legal Proceedings*

- (a) We are not a party to any material legal proceedings.
- (b) No legal proceedings were terminated in the fourth quarter.

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

No matters were submitted to the vote of stockholders through the solicitation of proxies or otherwise during the three-month period ended December 31, 2003.

Table of Contents**PART II****Item 5. *Market for Registrant's Common Equity and Related Stockholder Matters***
Market for Common Equity

Our common stock began trading on the Nasdaq National Market on March 28, 2000, under the symbol IBPI. Prior to that time, there had been no public market for our common stock. We effected a 1:12 stock split on April 10, 2003. The table below sets forth the high and low bid prices for our common stock for the periods indicated:

	High	Low
1st Quarter ended March 31, 2002	*\$55.32	*\$27.84
2nd Quarter ended June 30, 2002	*\$59.52	*\$11.04
3rd Quarter ended September 30, 2002	*\$28.20	*\$3.96
4th Quarter ended December 31, 2002	*\$7.68	*\$3.00
1st Quarter ended March 31, 2003	*\$4.08	*\$1.56
2nd Quarter ended June 30, 2003	\$6.48	*\$2.28
3rd Quarter ended September 30, 2003	\$15.60	\$3.08
4th Quarter ended December 31, 2003	\$17.50	\$10.50

* Bid price is adjusted to reflect the 1:12 stock split effected on April 10, 2003.

As of February 27, 2004, there were 137 holders of record of common stock. We estimate that included within the holders of record are approximately 3,000 beneficial owners of common stock. As of February 27, 2004, the closing price for our common stock was \$18.00.

Recent Sales of Unregistered Securities

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 the Company's 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. The foregoing purchases and sales were exempt from registration under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof, on the basis that the transaction did not involve a public offering.

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 \$18.5 million. 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. The foregoing purchases and sales were exempt from registration under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof, on the basis that the transaction did not involve a public offering.

Dividend Policy

We have not paid and do not plan to pay any cash dividends on our common stock in the foreseeable future. We intend to retain any earnings for use in our business operations.

Table of Contents**Equity Compensation Plan Information**

The following table provides certain information with respect to all equity compensation plans in effect as of December 31, 2003.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders			
Amended and Restated 1995 Stock Option Plan(1)	14,375	\$ 5.97	
2000 Employee Stock Purchase Plan(2)			
2000 Equity Incentive Plan	628,065	\$ 3.65	229,608(3)
Equity compensation plans not approved by security holders			
2002 Non-Officer Equity Incentive Plan	180,541	\$ 3.82	10,424
Total	822,981	\$ 3.73	240,032

- (1) No new stock awards may be granted under the Amended and Restated 1995 Stock Option Plan.
- (2) Generally, on each December 31, the 2000 Employee Stock Purchase Plan share reserve will increase automatically by the lesser of (i) 1% of the outstanding Common Stock, (ii) 41,666 shares, or (iii) a lesser amount determined by the Board. However, this plan was suspended in March 2003, and consequently there are currently no securities reserved for issuance under this plan.
- (3) On each December 31, the 2000 Equity Incentive Plan share reserve will increase automatically by the lesser of (i) 5% of the outstanding shares of Common Stock on a fully diluted basis, (ii) 166,666 shares, or (iii) a lesser amount determined by the Board. An additional increase in the reserve of 158,333 shares was approved by the stockholders of IntraBiotics in a special meeting on April 3, 2003.

The following is a brief summary of material features of plans adopted without stockholder approval.

2002 Non-Officer Equity Incentive Plan

Our 2002 Non-Officer Equity Incentive Plan provides for stock awards (grants of non-statutory stock options, stock bonuses or rights to acquire restricted stock) to employees and consultants who are not our officers. Officers not previously employed by us may also be granted stock awards. An aggregate of 190,965 shares of common stock have been reserved for issuance under this plan. As of December 31, 2003, options to purchase 180,541 shares were outstanding and 10,424 shares remained available for grant. The exercise price of options granted under the plan may not be less than 85% of the fair market value of our common stock on the date of the grant. Options granted under the plan have a maximum term of ten years and typically vest over a four-year period. Options may be exercised prior to vesting, subject to repurchase rights in favor of IntraBiotics that expire over the vesting period. Shares issued under a stock bonus award may be issued in exchange for past services performed for us. Shares issued pursuant to restricted stock awards may not be purchased for less than 85% of the fair market value of our common stock on the date of grant. Shares issued pursuant to stock bonuses and restricted stock awards may be subject to vesting and a repurchase option in favor of IntraBiotics. The plan and stock awards issued thereunder may be amended by the Board at any time or from time to time. The plan is subject to certain adjustment and change of control provisions similar to those governing the terms of our equity incentive plans approved by stockholders.

Table of Contents**Item 6. Selected Financial Data**

The following selected financial data should be read in conjunction with our financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Items 7 and 8 of this report. The financial data for periods prior to the financial statements presented in Item 8 of this Form 10-K are derived from audited financial statements not included in this Form 10-K.

	Year Ended December 31,				
	2003	2002	2001	2000	1999
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Contract revenue	\$	\$	\$	\$	\$ 7,863
Operating expenses:					
Research and development	7,727	23,053	38,034	39,152	26,102
General and administrative	5,782	8,617	9,202	11,560	6,082
Restructuring and other charges		6,118	21,956		
Arbitration settlement		(3,600)			
Impairment of acquired workforce		1,365			
Total operating expenses	13,509	35,553	69,192	50,712	32,184
Operating loss	(13,509)	(35,553)	(69,192)	(50,712)	(24,321)
Interest income	166	703	2,843	5,699	1,372
Interest expense		(459)	(1,110)	(563)	(166)
Other income, net	31	856	93		
Net loss	(13,312)	(34,453)	(67,366)	(45,576)	(23,115)
Non-cash deemed dividend related to beneficial conversion feature of Series A preferred stock	(1,436)				
Non-cash dividends on Series A preferred stock	(182)				
Net loss applicable to common stockholders	\$ (14,930)	\$ (34,453)	\$ (67,366)	\$ (45,576)	\$ (23,115)
Basic and diluted net loss per share applicable to common stockholders	\$ (4.01)	\$ (11.25)	\$ (27.47)	\$ (24.29)	\$ (259.48)
Shares used to compute basic and diluted net loss per share applicable to common stockholders	3,720	3,064	2,453	1,876	89

	As of December 31,				
	2003	2002	2001	2000	1999

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

Cash, cash equivalents, restricted cash deposits and short-term investments	\$ 26,644	\$ 13,315	\$ 35,470	\$ 86,065	\$ 31,429
Working capital	25,424	15,191	29,629	86,142	25,743
Total assets	27,326	16,226	42,465	108,288	35,958
Long term obligations, less current portion			5,000	8,309	1,725
Accumulated deficit	(215,199)	(200,269)	(165,816)	(98,450)	(52,874)
Total stockholders equity	25,628	15,480	26,212	89,955	27,914

Table of Contents

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Form 10-K. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under Factors That Could Affect Future Results. All forward-looking statements included in this document are based on information available to us on the date of this document and we assume no obligation to update any forward-looking statements contained in this Form 10-K.

Overview

IntraBiotics Pharmaceuticals, Inc. is a biopharmaceutical company currently focused on the development of an oral solution of iseganan hydrochloride (iseganan HCl), an antimicrobial drug, for the prevention of ventilator-associated pneumonia (VAP). 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 September 2003, we launched the first of two pivotal trials of iseganan HCl oral solution for the prevention of VAP. The U.S. Food and Drug Administration (FDA) have granted Fast-Track designation status and a Special Protocol Assessment agreement (SPA) on the design of the two pivotal efficacy trials for this indication. The Fast-Track designation is intended to facilitate the development and expedite the review of a new drug that is intended to treat a serious or life-threatening condition, and that demonstrates the potential to address an unmet medical need. The SPA agreement specifies in writing the pivotal clinical trial requirements for registration of iseganan HCl for the prevention of VAP. Under our SPA, we are required to conduct two identical pivotal, randomized, double-blind, placebo-controlled, multinational clinical trials. We expect to announce the results of the first pivotal trial by the end of 2004. Our research and development expenses are expected to at least double in 2004 as compared to 2003, primarily as a result of the costs associated with the first pivotal trial. If this trial is successful, we will then conduct the second pivotal trial to support registration of iseganan HCl.

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

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

Our cash, cash equivalents, restricted cash and short-term investments totaled \$26.6 million as of December 31, 2003, including the proceeds of two private placements during 2003. In May 2003 we completed a preferred stock placement resulting in net cash proceeds of \$3.2 million, and in October 2003 we completed a common stock placement resulting in net cash proceeds of \$18.5 million. The primary purpose of the financings was to provide additional funding for the two pivotal trials of iseganan HCl for the prevention of VAP, as well as for other general corporate purposes and working capital.

As of December 31, 2003, the Company has received and accepted over eight kilograms of finished iseganan HCl drug substance, which was booked to research and development expense in 2002 in accordance with our standard accounting practices. The quantity is sufficient to complete the two pivotal clinical trials of

Table of Contents

iseganan HCl for the prevention of VAP, but further quantities will be required to validate the manufacturing process, and for commercial use if we successfully obtain FDA registration for this indication.

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

In 2003, we recorded non-cash stock compensation expense of approximately \$1.0 million for 308,835 unexercised stock options that were cancelled and re-granted in a one-for-one exchange and 12,500 options that were re-granted in connection with the cancellation of 54,166 unexercised stock options in February 2003, upon approval by the Board of Directors. 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. The options generally vest over a four-year period and will expire in February 2008 if not previously exercised. Variable accounting is being applied to the re-granted options throughout their term. The related compensation expense depends on both the cumulative vesting of outstanding options and the price of the Company's common stock at each quarter end, and therefore may have a significant impact on the Company's future results of operations.

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.

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

Critical Accounting Policies and Estimates

General

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

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

Clinical Trial Accruals

The Company's accrued costs for clinical trial activities are based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CROs), investigators, drug processors, laboratories, consultants, or other clinical trial service providers that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount

Table of Contents

based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the service provider, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, and pre-approval of any changes in scope of the services to be performed. Each CRO provides an estimate of costs incurred but not invoiced at the end of each period for each individual trial. The estimates are reviewed and discussed with the CRO as necessary, and included in research and development expenses for the related period. For investigator study grants, which are paid quarterly on a per-patient basis to the institutions performing the clinical study, the Company accrues an estimated amount based on patient enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced. No adjustments for material changes in estimates have been recognized in any period presented.

Stock-Based Compensation

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

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

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

Table of Contents**Results of Operations*****Comparison of Years Ended December 31, 2003, 2002 and 2001******Revenues***

IntraBiotics had no product sales or contract revenue for the years ended December 31, 2003, 2002 and 2001. We do not anticipate any product revenues until we obtain FDA approval for, and commence commercialization of, any product candidate.

Expenses***Research and Development***

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
			(In thousands)		
Research and development	\$ 7,727	(66.5)%	\$ 23,053	(39.4)%	\$ 38,034

Research and development expenses primarily include clinical trial expenses, research and development payroll expense, drug substance expense, allocated facilities costs and non-cash stock compensation charges. Research and development expenses decreased in 2003 by \$15.3 million from 2002, primarily due to a \$9.3 million reduction in clinical trial expenses and a \$3.2 million reduction in research and development payroll expense, allocated facilities costs and non-cash stock compensation charges as a result of restructuring activities in 2002. The clinical trial expenses of \$4.3 million in 2003 relate to the first pivotal trial of iseganan HCl for the prevention of VAP, which commenced in September 2003. In 2002 and 2001, clinical trial expenses of \$13.6 million and \$20.0 million, respectively, primarily related to studies of iseganan HCl for oral mucositis, an indication that we are no longer pursuing. Research and development expenses decreased in 2002 by \$15.0 million from 2001, primarily due to reductions of \$5.1 million in research and development payroll expense, \$6.7 million in outside services related to clinical trials and \$2.1 million in license fees.

In 2003, research and development expenses include a write-off of \$2.4 million for prepaid iseganan HCl drug substance, relating to an order of seven kilograms of iseganan HCl bulk drug substance that was expected to be delivered in 2003. We have not yet been satisfied that the lot was manufactured in accordance with a validation plan or that related documentation is adequate, and we are currently discussing this with our contract manufacturer. Due to significant uncertainty over the timing and outcome of these discussions, the entire \$2.4 million prepaid amount was written off in September 2003. In 2002, research and development expenses included a \$4.8 million charge in relation to the delivery of certain other lots of iseganan HCl bulk drug substance as a result of the termination of a supply agreement with the same contract manufacturer. A discussion of the risks and uncertainties associated with the manufacture of drug substance and drug product is set forth in the

Factors that could affect future results, under the heading *We will be dependent on third party contract manufacturers 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 partners fail to manufacture iseganan HCl in accordance with set specifications or fail to produce the necessary information, our operations and related results could be adversely affected*.

Non-cash stock compensation charges were \$59,000, \$656,000 and \$1.5 million for the years ended December 31, 2003, 2002 and 2001, respectively. The decreases between each period are primarily due to the cancellation of options for terminated employees and consultants.

We expect research and development expenses to at least double in 2004 compared to 2003 as patients continue to be enrolled in the first pivotal trial of iseganan HCl for the prevention of VAP, which is currently our primarily focus.

Drug development in the United States is a process that includes several steps defined by the FDA. The process begins with the filing of an Investigational New Drug (IND) application that, if successful, allows clinical study of the potential new drug. Clinical development typically involves three phases of study: phase I, II and III. Pivotal trials are trials that are suitable for submission to the FDA for regulatory approval, and generally comprise either phase II/ III or phase III trials. The most significant costs associated with

Table of Contents

clinical development are for phase III trials, as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a new drug application (NDA) may be filed with the FDA. In responding to an NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. The lengthy process of seeking regulatory approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could have a material adverse effect on our results of operations. A discussion of the related risks and uncertainties are set forth in the *Factors that could affect future results* under the heading *If we fail to complete any clinical trial, or fail to obtain FDA approval for any product candidate that we develop, acquire or license, we may never achieve profitability and we may have to cease operations.*

General and Administrative

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(In thousands)				
General and administrative	\$5,782	(32.9)%	\$8,617	(6.4)%	\$9,202

General and administrative expenses in 2003 decreased by \$2.8 million from 2002, primarily due to reduced headcount and facility-related costs as a result of a restructuring in October 2002. The decrease in 2002 of \$585,000 from 2001 was primarily attributed to the reduction in headcount as a result of a restructuring implemented in May 2001, partially offset by the acquisition of Apothogen in April 2002, which increased general and administrative headcount, and a \$344,000 charge in conjunction with the termination of two property leases in the fourth quarter of 2002. We expect total general and administrative expenses to be similar in 2004 compared to 2003, although a number of factors may significantly impact the total expense in 2004, including the impact of changes in our stock price on non-cash stock compensation charges. A discussion of the related risks and uncertainties are set forth in the *Factors that could affect future results* under the heading *The change in our stock price over time may significantly impact our results of operations through certain stock compensation charges that depend upon our closing stock price at the end of each quarter.*

General and administrative costs primarily include administrative payroll expense, outside contractors, legal and accounting fees, insurance, non-cash stock compensation charges, facilities, travel and other general administrative expenses. Non-cash stock compensation charges were \$1.3 million, \$1.7 million and \$1.4 million for the years ended December 31, 2003, 2002 and 2001, respectively.

Restructuring and Other Charges

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(In thousands)				
Restructuring and other charges	\$	(100.0)%	\$6,118	(72.1)%	\$21,956

There were no restructurings during 2003. In 2002, restructuring expenses were primarily comprised of \$5.2 million as a result of a facilities lease termination agreement and \$848,000 of severance costs as a result of a restructuring in October 2002 due to the failure of two phase III clinical trials. The restructuring reduced our headcount to 11 as of December 31, 2002 from 37 as of December 31, 2001. The \$5.2 million lease termination expense included cash payments, the issuance of common stock and the write-off of a deferred rent balance. Of the \$848,000 severance costs, \$784,000 was paid in 2002 and the remaining \$64,000 was paid in January 2003.

Restructuring charges of \$22.0 million were recorded in 2001 resulting from a restructuring plan implemented in May 2001 in order to conserve capital and focus resources on the development of iseganan HCl. The restructuring charges included asset write down charges of \$11.8 million, costs related to work force reduction of \$2.9 million, termination costs for collaboration agreements of \$4.1 million and facilities consolidation costs of \$3.2 million.

Table of Contents

The workforce reduction comprised 90 employees, who were all terminated in 2001, representing a 71% reduction in force. The estimated cost of terminating the collaboration agreements was increased by \$483,000 in the fourth quarter of 2001 and \$166,000 in 2002.

The facilities consolidation costs related to the vacating of three facilities in Mountain View, California, totaling 142,000 square feet. One of the vacated facilities was subleased during 2001, the second was terminated in October 2001 and the third in January 2003. In 2001, an adjustment was made to increase restructuring charges associated with facilities consolidation by \$1.9 million for additional costs related to the third vacated facility. In November 2002, we reached agreements with the landlords of this building and the facility, which we had subleased, to terminate the leases. The additional expense recorded during 2002 was \$5.2 million and included cash payments, the issuance of common stock and the write-off of a deferred rent balance.

Additionally as a part of the May 2001 restructuring plan, we wrote down to estimated fair value \$11.8 million of leasehold improvements, laboratory equipment, computers and other assets that were no longer being used. In the fourth quarter of 2001 we received proceeds from the disposition of certain leasehold improvements and other assets previously written down in excess of the amounts originally estimated. As a result, we recognized a gain of \$2.2 million that offset restructuring and other charges in the statement of operations for 2001.

Arbitration Settlement

During the year ended December 31, 2002, we received \$3.6 million from a contract vendor as a result of an arbitration settlement relating to a drug dispensing error in a phase III trial of iseganan HCl for oral mucositis. We had no comparable item in 2003 or 2001.

Interest Income and Expense

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(In thousands)				
Interest income	\$ 166	(76.4)%	\$ 703	(75.3)%	\$ 2,843
Interest expense	\$	(100.0)	(459)	(58.7)	(1,110)

Interest income decreased in both 2003 and 2002, primarily resulting from decreases in average interest earning investment balances and lower interest rates in each year.

Interest expense decreased to zero in 2003 due to the repayment of our line of credit and bank loan in October 2002. The decrease in 2002 from 2001 was primarily attributed to a reduction in the average balance of our line of credit and a reduction in applicable interest rates.

Other Income, net

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(In thousands)				
Other income, net	\$ 31	(96.4)%	\$ 856	820.4%	\$ 93

Other income, net in 2002 includes \$975,000 from the sale of two pre-clinical anti-infective programs to Micrologix Biotech Inc., a Canadian company, in May 2002, for \$400,000 in cash and 750,000 shares of Series A preferred stock of Micrologix. The 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. Other income of \$775,000 was recognized in the second quarter of 2002 upon receipt of the \$400,000 in cash and the 750,000 shares, and other income of \$200,000 was recognized in the third quarter of 2002 upon redemption of 400,000 of the

Table of Contents

shares at \$1 per share, which was triggered by the first milestone set forth above. No other income was recorded in either 2003 or 2001 as a result of this transaction.

Income Taxes

Since inception, we have incurred operating losses and accordingly have not recorded a provision for income taxes for any of the periods presented. As of December 31, 2003, we had net operating loss carryforwards for federal and state income tax purposes of approximately \$192.0 million and \$44.0 million, respectively. We also had federal and state research and development tax credits each of approximately \$3.3 million. If not utilized, the net operating losses and credits will expire in the years 2004 through 2023. Utilization of net operating losses and credits may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended. The annual limitation may result in the expiration of our net operating losses and credit carryforwards before they can be used. Please read Note 11 of the Notes to the Financial Statements included in Item 8 of this Form 10-K for further information.

Liquidity and Capital Resources

	2003	Change	2002	Change	2001
	(In thousands)				
Cash, cash equivalents, restricted cash and short-term investments	\$26,644	100.1%	\$13,315	(62.5)%	\$35,470

At December 31, 2003, we had cash and cash equivalents of \$14.3 million, representing an increase of \$4.1 million from December 31, 2002. Short-term investments were \$12.1 million in 2003 as compared to \$2.9 million in 2002, and restricted cash remained at \$250,000. We had no debt outstanding as of December 31, 2003. We invest excess funds in short-term money market funds and securities pursuant to our investment policy guidelines. The following is an analysis of changes in our cash and cash equivalents in each respective year.

	2003	2002	2001
	(In thousands)		
Net cash used in operating activities	\$ (8,823)	\$ (26,347)	\$ (53,602)
Net cash provided by (used in) investing activities	(9,211)	(1,552)	44,693
Net cash provided by (used in) financing activities	22,150	10,087	(2,092)
Net increase (decrease) in cash and cash equivalents	\$ 4,116	\$ (17,812)	\$ (11,001)

The net cash used in operating activities decreased in 2003 from 2002, primarily due to a reduction in the net loss from \$34.5 million to \$13.3 million, which primarily resulted from lower clinical trial expenses between the respective years and restructuring actions taken in 2002. The decrease from 2001 to 2002 was primarily due to a reduction in net loss from \$67.4 million to \$34.5 million, which primarily resulted from \$22.0 million of restructuring expenses in 2001, and related reductions in operating cash outflows as a result of lower clinical trial activity and internal operating costs in 2002.

The net cash used in investing activities in 2003 relates to the purchase of \$12.1 million of short-term investments, partially offset by the maturity of short-term investments of \$2.9 million. In 2002, the cash used primarily relates to the purchase of \$2.9 million of short-term investments, partially offset by the proceeds from the sale of two pre-clinical programs to Micrologix for \$800,000. The change from 2001 to 2002 was primarily due to the maturities of short-term investments totaling \$51.8 million in 2001.

The cash provided by financing activities in 2003 primarily related to two private placement transactions. In May 2003, 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, and in October 2003, the Company sold 1,774,000 shares of newly issued common stock and issued warrants to purchase 354,800 shares of common stock, resulting in net cash proceeds of \$18.5 million. Cash provided by

Table of Contents

financing activities in 2002 was primarily due to net proceeds of approximately \$14.0 million and \$5.0 million from two private placements of common stock, partially offset by \$9.4 million in payments on financing obligations to a bank. The cash used in financing activities in 2001 was primarily due to payments on financing obligations of \$13.8 million, partially offset by proceeds from financing obligations of \$11.2 million.

Contractual Obligations

The impact that our contractual obligations as of December 31, 2003 are expected to have on our liquidity and cash flow in future periods is as follows, (in thousands):

	Payments Due by Period				
	Total	Less Than 1 Year	Between 1-3 Years	Between 3-5 Years	More Than 5 Years
Drug substance(1)	\$450	\$300	\$100	\$ 50	\$ 0
Operating leases(2)	43	43	—	—	—
Total contractual commitments	\$493	\$343	\$100	\$ 50	\$ 0

- (1) Drug substance commitments are 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 2004, the commitment represents the potential payment of \$250,000 upon acceptance of this order, when and if this occurs, and \$50,000 in fees for storage of iseganan HCl. The remaining \$150,000 represents storage fees for iseganan HCl through 2007.
- (2) Operating leases relate to the lease for our facility in Palo Alto, California, which expires on May 31, 2004, and includes an option to extend until November 30, 2004. Under the terms of the lease we have committed to pay \$43,000 in 2004.

There were no purchase obligations as of December 31, 2003 that included material penalties for cancellation and were enforceable and legally binding.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as that term is defined in Rule 303 of Regulation S-K) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Indemnifications

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

Future Capital Requirements

We expect to continue to incur substantial operating losses and will not receive any product revenues until a product candidate has been approved by the FDA and successfully commercialized. We currently anticipate our cash, cash equivalents and investments to be sufficient to fund operations for at least the next 12 months. We expect, however, that we will need to raise significant additional funds to continue our operations,

Table of Contents

complete the second pivotal efficacy trial of iseganan HCl for VAP if the first trial is successful, and for the FDA approval process and commercialization if FDA approval is received.

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 may also generate cash through collaboration or licensing arrangements, although no such transactions are currently under negotiation. We intend to raise additional capital in 2004 in one or more transactions. We cannot be certain, however, that additional funding will be available when needed or on favorable terms. If additional funding is not available, we may need to delay or curtail our development and clinical trial activities to a significant extent, or we may be forced to cease operations.

Recent Accounting Pronouncements

See Note 2 of the financial statements for a full description of recent accounting pronouncements including the respective effects on the Company's financial condition, results of operations and disclosure.

Factors That Could Affect Future Results

Our future financial condition results of operations and disclosures could be materially affected by the risks and uncertainties discussed below, or otherwise, and historic trends should not be used to anticipate results or trends in future periods.

If either of our two pivotal clinical trials of iseganan HCl for the prevention of VAP or any future clinical trials of iseganan HCl for other indications are unsuccessful, we 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. Enrollment in the first of two pivotal trials commenced in September 2003, and we expect to announce its results by the end of 2004. The failure of either of the two pivotal trials in meeting their primary endpoint, or of any other future clinical trials of iseganan HCl for alternative indications, will negatively impact our future operating results and may force us to cease operations.

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

We do not have a drug approved for sale in the United States or any foreign market and we do not know whether we will be successful in developing iseganan HCl for the prevention of VAP or other indications, or in developing, acquiring or licensing any other products and successfully obtaining FDA or foreign approvals for them. We must successfully complete clinical trials and demonstrate manufacturing capability before we can file with the FDA for approval to sell any product in the United States or with foreign regulatory authorities in

Table of Contents

order to sell to other countries. The FDA could require us to repeat or perform amended clinical trials as a result of their regulatory review, and there is no guarantee that foreign regulatory authorities will acknowledge approvals by the FDA, and we may be required to perform additional clinical trials before being approved to sell in foreign markets. Delays in obtaining or failure to obtain regulatory approvals may:

delay or prevent the successful commercialization of our drug candidate;

diminish any competitive advantage we may have; and

defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive 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 also suffered significant setbacks in advanced clinical trials, including issues related to the design or conduct of those trials. We have had to re-perform a phase III clinical trial in the past, following a drug dispensing error by a contract vendor. We have limited experience in obtaining drug approvals, and cannot be certain when, if ever, we will receive these regulatory approvals. If we are unable to demonstrate the safety and efficacy of any drug candidate, we will be unable to obtain the required regulatory approvals and we will be unable to commercialize a drug candidate and generate product revenue.

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

We must raise capital to continue our operations, and if we fail to obtain the capital necessary to fund our operations, we will be unable to develop our drug candidates and may have to cease operations.

We expect, that we will need to raise significant additional funds to complete the second pivotal efficacy trial of iseganan HCl for VAP if the first trial is successful, and for the FDA approval process and commercialization if FDA approval is received. We also believe that additional financing will be required in the future to fund our operations, to conduct any trials of iseganan HCl for other indications, to acquire or license any other products, or to commercialize any other 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. Our future liquidity and capital requirements will also depend on many other factors, including the timing, cost, and progress of our current VAP trial, the cost to obtain regulatory approval for any product in the United States and other countries, and decisions with respect to strategic alternatives.

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.

Additional financing may be raised through public or private equity offerings, debt financings or additional collaboration and licensing arrangements. To the extent that 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.

Table of Contents

We will be dependent on third party contract manufacturers 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 partners fail to manufacture iseganan HCl in accordance with set specifications or fail to produce the necessary information, our operations and related results could be adversely affected.

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

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

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 and our results of operations and financial condition would suffer.

We rely on contract research organizations to assist us in managing and monitoring our clinical 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.

Development and commercialization of competitive products or new technologies could reduce or prevent sales of any future products that we develop, acquire or license, and our results of operations would suffer.

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.

Table of Contents

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 ten patents and four 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 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 and would affect our results of operations and financial condition.

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

Table of Contents

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

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 and our results of operations could suffer.

We are highly dependent on our management and technical staff. Competition for personnel is intense. If we lose the services of any of our senior management or technical staff, we may be unable to successfully complete our planned clinical trials 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 December 31, 2003, we had nine full-time employees. In order to pursue any future product development, marketing and commercialization, we will need to hire additional qualified scientific personnel to perform research and development and personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

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

Directors, executive officers, principal stockholders and affiliated entities beneficially own approximately 53% of our capital stock and may be able to exert control over our activities, and our results of operations and financial condition may suffer.

As of December 31, 2003, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 53% 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.

Table of Contents

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.

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

Market prices for securities of biotechnology companies are general highly volatile and our stock may be subject to such volatility. Our non-cash variable stock compensation expense in relation to 308,835 stock options that were cancelled and re-granted in a one-for-one exchange and 12,500 options that were re-granted in connection with the cancellation of 54,166 unexercised stock options in February 2003 is dependent upon the price of our common stock at each quarter end. In 2003, we recorded non-cash variable stock compensation expense of approximately \$1.0 million in relation to these options. These expenses will be incurred through the five year term of the options, unless previously forfeited or exercised. Future changes in the Company's stock price may therefore have a significant impact on the Company's future results of operations as a result of this dependency.

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

After accounting for the effect of our 1-for-12 reverse stock split in April 2003, during 2002 our closing stock prices ranged from a low of \$3.24 to a high of \$57.60, and in 2003 ranged from a low of \$1.71 to a high of \$16.95. The following factors, in addition to the other risk factors described in this section, may have a significant impact on the market price of our common stock:

announcements regarding strategic alternatives, including a merger or sale of the company or acquisition or license of products or product candidates;

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

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

developments concerning proprietary rights;

regulatory developments in the United States or foreign countries;

litigation;

significant short selling in our common stock;

Table of Contents

economic and other external factors; and

period-to-period fluctuations in our financial results and changes in analysts' recommendations.

Item 7A. 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 December 31, 2003, we own financial instruments that are sensitive to market risk as part of our investment portfolio. To minimize this risk, in accordance with our investment policy guidelines, we place investments with high credit quality issuers and limit the amount of credit exposure to any one issuer. The average duration of our investment portfolio in 2003 and 2002 was less than one year. Due to the short-term nature of these investments, a 50 basis point movement in market interest rates would not have a material impact on the fair value of our portfolio as of December 31, 2003 and 2002. We have no investments denominated in foreign country currencies and therefore our investments are not subject to foreign currency exchange risk.

The following table summarizes the average interest rate and fair market value of the short-term investments held by us as of December 31, 2003, 2002 and 2001 (in thousands).

Short-term investments:	Total Cost	Fair Market Value	Average Interest Rate
December 31, 2003	\$ 12,106	\$ 12,108	1.36%
December 31, 2002	\$ 2,895	\$ 2,895	1.83%
December 31, 2001	\$	\$	

Table of Contents

Item 8. *Financial Statements and Supplementary Data*

INTRABIOTICS PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Ernst & Young LLP, Independent Auditors	28
Balance Sheets	29
Statements of Operations	30
Statement of Stockholders' Equity	31
Statements of Cash Flows	33
Notes to Financial Statements	34

Table of Contents

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders of

IntraBiotics Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of IntraBiotics Pharmaceuticals, Inc. as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of IntraBiotics Pharmaceuticals, Inc. as of December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 6, 2004

Table of Contents

INTRABIOTICS PHARMACEUTICALS, INC.

BALANCE SHEETS

	December 31,	
	2003	2002
	(In thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,286	\$ 10,170
Restricted cash	250	250
Short-term investments	12,108	2,895
Prepaid drug substance		2,375
Prepaid expenses	478	247
Total current assets	27,122	15,937
Property and equipment, net	20	112
Other assets	184	177
Total assets	\$ 27,326	\$ 16,226
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 141	\$ 345
Accrued clinical liabilities	1,046	
Accrued employee liabilities	101	135
Accrued restructuring charges		64
Other accrued liabilities	410	202
Total current liabilities	1,698	746
Commitments		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value:		
5,000,000 shares authorized at December 31, 2003 and 2002; 325 and 0 shares outstanding at December 31, 2003 and 2002, respectively; \$3,250 and \$0 aggregate liquidation preference at December 31, 2003 and 2002, respectively	1,771	
Common stock, \$0.001 par value:		
70,000,000 and 50,000,000 shares authorized at December 31, 2003 and 2002, respectively; 5,298,206 and 3,268,819 shares outstanding at December 31, 2003 and 2002, respectively	5	3
Additional paid-in capital	239,237	216,466
Deferred stock compensation	(188)	(720)
Accumulated other comprehensive income	2	
Accumulated deficit	(215,199)	(200,269)
Total stockholders' equity	25,628	15,480
Total liabilities and stockholders' equity	\$ 27,326	\$ 16,226

See accompanying notes.

Table of Contents**INTRABIOTICS PHARMACEUTICALS, INC.****STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2003	2002	2001
	(In thousands, except per share amounts)		
Operating expenses:			
Research and development	\$ 7,727	\$ 23,053	\$ 38,034
General and administrative	5,782	8,617	9,202
Restructuring and other charges		6,118	21,956
Arbitration settlement		(3,600)	
Impairment of acquired workforce		1,365	
	<u> </u>	<u> </u>	<u> </u>
Total operating expenses	13,509	35,553	69,192
	<u> </u>	<u> </u>	<u> </u>
Operating loss	(13,509)	(35,553)	(69,192)
Interest income	166	703	2,843
Interest expense		(459)	(1,110)
Other income, net	31	856	93
	<u> </u>	<u> </u>	<u> </u>
Net loss	(13,312)	(34,453)	(67,366)
Non-cash deemed dividend related to beneficial conversion feature of Series A preferred stock	(1,436)		
Non-cash dividends on Series A preferred stock	(182)		
	<u> </u>	<u> </u>	<u> </u>
Net loss applicable to common stockholders	<u>\$ (14,930)</u>	<u>\$ (34,453)</u>	<u>\$ (67,366)</u>
	<u> </u>	<u> </u>	<u> </u>
Basic and diluted net loss per share applicable to common stockholders	<u>\$ (4.01)</u>	<u>\$ (11.25)</u>	<u>\$ (27.47)</u>
	<u> </u>	<u> </u>	<u> </u>
Shares used to compute basic and diluted net loss per share applicable to common stockholders	<u>3,720</u>	<u>3,064</u>	<u>2,453</u>
	<u> </u>	<u> </u>	<u> </u>

See accompanying notes.

Table of Contents**INTRABIOTICS PHARMACEUTICALS, INC.****STATEMENT OF STOCKHOLDERS EQUITY**

	Convertible Preferred Stock		Common Stock		Additional	Deferred	Accumulated		Total
					Paid-In	Stock	Other	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Compensation	Comprehensive Income (Loss)		
(In thousands)									
Balances at December 31, 2000		\$	2,433	\$ 2	\$ 198,415	\$ (10,198)	\$ 186	\$ (98,450)	\$ 89,955
Issuance of common stock upon exercise of options for cash			45		435				435
Stock compensation for consultant services					5				5
Issuance of common stock for the employee stock purchase plan for cash			3		36				36
Issuance of warrants to purchase 58 shares of common stock					560				560
Issuance of common stock for employee services			2		39				39
Amortization of deferred stock compensation						2,734			2,734
Cancellation of stock options related to employee terminations					(2,887)	2,887			
Comprehensive loss:									
Net loss								(67,366)	(67,366)
Unrealized gain (loss) on securities							(186)		(186)
Comprehensive loss									(67,552)
Balances at December 31, 2001			2,483	2	196,603	(4,577)		(165,816)	26,212
Issuance of common stock upon exercise of options for cash			29		471				471
Issuance of common stock on private placement for cash			596	1	18,980				18,981
Issuance of common stock on acquisition of Apothogen Inc.			37		1,924				1,924
Stock compensation for consultant services					512				512
Issuance of common stock for the employee stock purchase plan for cash			1		10				10
Issuance of warrants to purchase 4 shares of common stock					7				7
Issuance of common stock for employee services			123		545				545
Amortization of deferred stock compensation						1,271			1,271
					(2,586)	2,586			

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

Cancellation of stock
options related to employee
terminations
Net loss and comprehensive
loss

(34,453)

(34,453)

Table of Contents**INTRABIOTICS PHARMACEUTICALS, INC.****STATEMENT OF STOCKHOLDERS EQUITY (Continued)**

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Deferred Stock	Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Compensation	Income (Loss)	Deficit	Equity
(In thousands)									
Balances at December 31, 2002			3,269	3	216,466	(720)		(200,269)	15,480
Issuance of common stock upon exercise of options for cash			50		380				380
Issuance of common stock and warrants on private placement, net of \$710 issuance costs			1,774	2	18,536				18,538
Issuance of Series A preferred stock and common stock warrants on private placement, net of \$268 issuance costs		1,906			1,326				3,232
Beneficial conversion feature on Series A preferred stock					1,436			(1,436)	
Issuance of common stock upon conversion of Series A preferred stock		(135)	132		135				
Issuance of common stock as dividend on series A preferred stock			18		117			(182)	(65)
Issuance of common stock upon exercise of warrants			55						
Amortization of deferred stock compensation						126			126
Stock compensation for variable option awards					993				993
Stock compensation for consultant services					254				254
Cancellation of stock options related to employee terminations					(406)	406			
Comprehensive loss:									
Net loss								(13,312)	(13,312)
Unrealized gain on securities							2		2
Comprehensive loss									(13,310)
Balances at December 31, 2003		\$ 1,771	5,298	\$ 5	\$ 239,237	\$ (188)	\$ 2	\$ (215,199)	\$ 25,628

See accompanying notes

Table of Contents

INTRABIOTICS PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2003	2002	2001
	(In thousands)		
Operating activities			
Net loss	\$(13,312)	\$(34,453)	\$(67,366)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred stock compensation	126	1,271	2,734
Stock compensation expense	1,247	1,057	44
Depreciation and amortization	92	725	1,690
Write down of property and equipment		274	9,658
Acquired workforce write down and amortization		1,694	
Gain on sale of pre-clinical programs		(975)	
Fair value of warrants issued		7	560
Change in assets and liabilities:			
Restricted cash		7,238	(6,117)
Prepaid expenses	2,144	3,087	4,689
Other assets	(7)	41	23
Accounts payable	(204)	(245)	(1,341)
Accrued clinical liabilities	1,046	(1,663)	(1,573)
Accrued employee liabilities	(34)	(475)	(46)
Accrued restructuring charges	(64)	(2,797)	2,861
Deferred rent		(618)	384
Other accrued liabilities	143	(515)	198
Net cash used in operating activities	(8,823)	(26,347)	(53,602)
Investing activities			
Capital expenditures		(41)	(3,665)
Proceeds from sale of property and equipment		526	2,833
Proceeds from sale of pre-clinical programs		800	
Purchase of short term investments	(12,106)	(2,895)	(6,296)
Proceeds from sale or maturity of short-term investments	2,895		51,821
Cash received in acquisition of subsidiary		58	
Net cash provided by (used in) investing activities	(9,211)	(1,552)	44,693
Financing activities			
Proceeds from issuance of Series A preferred stock in private placement, net	3,232		
Proceeds from issuance of common stock in private placements, net	18,538	18,981	
Proceeds from issuance of common stock upon exercise of options	380	481	471
Proceeds from financing obligations			11,209
Payments on financing obligations		(9,375)	(13,772)
Net cash provided by (used in) financing activities	22,150	10,087	(2,092)
Net increase (decrease) in cash and cash equivalents	4,116	(17,812)	(11,001)
Cash and cash equivalents at beginning of period	10,170	27,982	38,983

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

Cash and cash equivalents at end of period	\$ 14,286	\$ 10,170	\$ 27,982
	<u> </u>	<u> </u>	<u> </u>
Supplemental disclosure of cash flow information:			
Interest paid	\$	\$ 459	\$ 1,110
	<u> </u>	<u> </u>	<u> </u>
Supplemental disclosure of non-cash information:			
Net deferred stock compensation (cancellations due to employee termination)	\$ (406)	\$ (2,586)	\$ (2,887)
	<u> </u>	<u> </u>	<u> </u>
Beneficial conversion feature on Series A preferred stock	\$ (1,436)	\$	\$
	<u> </u>	<u> </u>	<u> </u>
Issuance of common stock dividend on Series A preferred stock	\$ (182)	\$	\$
	<u> </u>	<u> </u>	<u> </u>
Issuance of common stock upon conversion of Series A preferred stock	\$ (135)	\$	\$
	<u> </u>	<u> </u>	<u> </u>
Other assets received from sale of pre-clinical programs	\$	\$ 375	\$
	<u> </u>	<u> </u>	<u> </u>
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)	
	<u> </u>	<u> </u>	<u> </u>
Cash received in acquisition	\$	\$ (58)	\$
	<u> </u>	<u> </u>	<u> </u>

See accompanying notes.

Table of Contents

NOTES TO FINANCIAL STATEMENTS

1. Description of Business

IntraBiotics Pharmaceuticals, Inc. (IntraBiotics or the Company), was incorporated in the state of Delaware on January 19, 1994. IntraBiotics is currently focused on developing iseganan HCl oral solution for the prevention of ventilator-associated pneumonia (VAP). The Company has devoted substantially all of its efforts and resources since incorporation to research and development related to its antimicrobial products.

The Company has funded its operations primarily through its initial public offering of common stock in March 2000, the private sale of equity securities, funds received from a terminated collaboration agreement, the proceeds of equipment financing arrangements and the sale of two pre-clinical anti-infective programs. The Company expects that its available cash, cash equivalents, restricted cash and short-term investments of \$26.6 million at December 31, 2003 will be adequate to fund operations through at least December 31, 2004.

We will need to raise substantial additional funds to continue our operations, complete the second pivotal efficacy trial of iseganan HCl for VAP, complete the FDA approval process, and commence commercialization. Management plans to continue to finance the Company's operations through private and public financings, including equity financings, or through collaboration or licensing arrangements. There can be no assurance that the Company will be able to enter into financing arrangements on acceptable terms in the future, if at all. Prior to product commercialization, if the financing arrangements contemplated by the Company are not consummated, the Company may have to seek other sources of capital or re-evaluate its operating plans.

2. Summary of Significant Accounting Policies

Use of Estimates

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

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

Cash Equivalents and Short-Term Investments

Cash equivalents are comprised of money market funds and debt securities with original maturities of less than 90 days. Short-term investments include securities with maturities of less than one year from the balance sheet date, or securities with maturities of greater than one year that are specifically identified to fund current operations. All cash equivalents and short-term investments are classified as available-for-sale. The Company's investment securities are recorded at their fair market value, based on quoted market prices. The cost of securities when sold is based upon the specific identification method. Any unrealized gains and losses are recorded as other comprehensive income and included as a separate component of stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale investments are included in other income, net in the statements of operations.

Fair Value of Financial Instruments

The fair value of financial instruments, including cash, cash equivalents, short-term investments, accounts payable and accrued liabilities approximate their carrying value.

Table of Contents

NOTES TO FINANCIAL STATEMENTS (Continued)

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation, which is calculated using the straight-line method over the estimated useful lives of the respective assets, generally being three to five years. Leasehold improvements are depreciated over the terms of the facilities leases.

Impairment of Long-Lived Assets

Long-lived assets and certain identifiable intangible assets to be held and used are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is generally based on an estimate of undiscounted cash flows resulting from the use of the assets and their eventual disposition. In the event that such cash flows are insufficient to recover the carrying amount of the assets, the assets are written down to the estimated fair value. Long-lived assets to be disposed of are reported at the lower of the carrying amount or the estimated fair value less costs to sell.

Research and Development and Concentrations of Risk

Research and development expenditures are charged to operations as incurred, and include fees paid to contract research organizations and other clinical service providers, payroll expense, drug substance expense, allocated facilities costs and non-cash stock compensation charges.

The Company has relied on a single contract manufacturer to manufacture bulk drug substance for the current pivotal clinical trials, although it currently maintains a sufficient inventory to complete these trials. If no alternate sources of supply are developed, the Company will depend on this manufacturer to produce bulk drug substance and information required for FDA registration of the related drug, and to produce the drug for future commercial use if the trials are successful. The Company also relies on a single third party supplier to produce the formulated drug product for use in the current clinical trials.

Clinical Trial Accruals

The Company's accrued costs for clinical trial activities are based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CROs), investigators, drug processors, laboratories, consultants, or other clinical trial service providers that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the service provider, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, and pre-approval of any changes in scope of the services to be performed. Each CRO provides an estimate of costs incurred but not invoiced at the end of each period for each individual trial. The estimates are reviewed and discussed with the CRO as necessary, and included in research and development expenses for the related quarter. For investigator study grants, which are paid quarterly on a per-patient basis to the institutions performing the clinical study, the Company accrues an estimated amount based on patient enrollment in each quarter.

Stock-Based Compensation

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

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

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

The following table illustrates the effect on net loss applicable to common stockholders and 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):

	Year Ended December 31,		
	2003	2002	2001
Net loss applicable to common stockholders, as reported	\$(14,930)	\$(34,453)	\$(67,366)
Add: Stock-based employee compensation expense included in reported net loss applicable to common stockholders	1,119	1,271	2,734
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,577)	(6,084)	(5,895)
Net loss applicable to common stockholders, pro forma	\$(15,388)	\$(39,266)	\$(70,527)
Net loss per share applicable to common stockholders:			
Basic and diluted as reported	\$ (4.01)	\$ (11.25)	\$ (27.47)
Basic and diluted pro forma	\$ (4.14)	\$ (12.82)	\$ (28.76)

The fair value for the Company's options was estimated at the date of the grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2003	2002	2001
Risk-free interest rate	2.92%	2.89%	3.75%
Volatility	1.00	1.00	0.75
Dividend yield			
Expected life of option	5 years	5 years	5 years

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

The fair value of the employees' purchase rights under the Company's Employee Stock Purchase Plan, which was suspended in March 2003 (see Note 9), was estimated using the Black-Scholes option pricing model with the above weighted average assumptions for volatility and dividend yield, expected lives of

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)**

6 months, and risk free interest rates of 1.26% in 2002 and 3.75% in 2001. The weighted-average fair value for rights issued under the Purchase Plan for 2002 and 2001 was \$5.40 and \$32.40, respectively.

Comprehensive Loss

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

	Year Ended December 31,		
	2003	2002	2001
Net loss	\$ (13,312)	\$ (34,453)	\$ (67,366)
Unrealized gain (loss) on available-for-sale securities	2		(186)
Comprehensive loss	\$ (13,310)	\$ (34,453)	\$ (67,552)

Net Loss Per Share

Basic and diluted net loss per share applicable to common stockholders is presented in accordance with Financial Accounting Standards Board Statement No. 128, *Earnings Per Share*, and is calculated using the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share applicable to common stockholders includes the impact of potentially dilutive securities (stock options, warrants and convertible preferred stock). As the Company's potentially dilutive securities were anti-dilutive for all periods presented, they are not included in the calculations of diluted net loss per share applicable to common stockholders. The total number of shares underlying the stock options, warrants and convertible preferred stock excluded from the calculations of net loss per share applicable to common stockholders was 3,297,363, 693,845 and 370,704 for the years ended December 31, 2003, 2002 and 2001, respectively.

Reclassifications

Certain reclassifications of prior year amounts have been made to conform to current year classifications. Reclassifications related to cash proceeds from option exercises in 2002 and 2001 have been made in the Statement of Cash Flows to conform to current year classifications.

Recent Accounting Pronouncements

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, as amended, 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 March 15, 2004. The adoption of FIN 46 is not expected to have any impact on the Company's financial position, results of operations or disclosure.

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

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,

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)**

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. The provisions of SFAS No. 150 are generally effective for all financial instruments entered into or modified after May 31, 2003, except for those provisions relating to non-controlling interests that have been deferred, 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. If the deferred provisions of SFAS No. 150 are finalized in their current form, management does not expect adoption to have a material effect on the Company's financial position, results of operations or disclosure.

3. Available-For-Sale Investments

The following is a summary of the Company's available-for-sale investments as of December 31, 2003 and 2002 (in thousands):

December 31, 2003			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
			Estimated Fair Value
Money market funds	\$ 13,845	\$	\$ 13,845
Auction rate securities	8,200		8,200
U.S. government agencies	3,906	2	3,908
	<u>\$ 25,951</u>	<u>\$ 2</u>	<u>\$ 25,953</u>
Reported as:			
Cash equivalents			\$ 13,845
Short-term investments			12,108
			<u>\$ 25,953</u>
December 31, 2002			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
			Estimated Fair Value
Money market funds	\$ 6,775	\$	\$ 6,775
Certificates of deposit	2,895		2,895
	<u>\$ 9,670</u>	<u>\$</u>	<u>\$ 9,670</u>
Reported as:			
Cash equivalents			\$ 6,775
Short-term investments			2,895
			<u>\$ 9,670</u>

For the years ended December 31, 2003, 2002 and 2001, there were no gross realized gains or losses on available-for-sale investments.

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)**

The following is a summary of amortized cost and estimated fair value of available-for-sale investments by contract maturity (in thousands):

	December 31, 2003		December 31, 2002	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Due in less than one year	\$ 24,201	\$ 24,202	\$ 9,670	\$ 9,670
Due in one year or more	1,750	1,751	—	—
	<u>\$ 25,951</u>	<u>\$ 25,953</u>	<u>\$ 9,670</u>	<u>\$ 9,670</u>

4. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2003	2002
Machinery and equipment	\$ 328	\$ 365
Leasehold improvements	—	16
	<u>328</u>	<u>381</u>
Less accumulated depreciation	(308)	(269)
Property and equipment, net	<u>\$ 20</u>	<u>\$ 112</u>

Depreciation and amortization expense for property and equipment totaled \$92,000, \$725,000 and \$1.7 million for the years ended December 31, 2003, 2002 and 2001, respectively.

5. Other Accrued Liabilities

Other accrued liabilities consist of the following (in thousands):

	December 31,	
	2003	2002
Accrued professional fees	\$ 300	\$ 202
Accrued dividends	65	—
Other accrued liabilities	45	—
Total other accrued liabilities	<u>\$ 410</u>	<u>\$ 202</u>

— —

6. Commitments

At December 31, 2003, the Company has a total of \$450,000 in commitments to its contract manufacturer for drug substance, representing \$250,000 upon acceptance of a drug order, when and if such acceptance occurs, and \$200,000 in fees for storage of iseganan HC1 until December 2007.

In February 2003, the Company entered into an operating lease agreement for a facility in Palo Alto, California. The lease expires in May 2004 and includes an option to extend until November 30, 2004. Under the terms of the lease, the Company is committed to pay rent of \$43,000 in 2004. Total rent expense for the years ended December 31, 2003, 2002, and 2001 was approximately \$93,000, \$3.0 million, and \$5.0 million, respectively. Of the \$3.0 million rent expense in 2002, \$2.5 million was included in restructuring charges. Of the \$5.0 million rent expense in 2001, \$3.2 million was included in restructuring charges.

Table of Contents

NOTES TO FINANCIAL STATEMENTS (Continued)

7. Restructuring and Other Charges

In May 2001, the Company implemented a restructuring plan intended to conserve capital and focus resources on the development of iseganan HCl. As a result of this plan, the Company recorded restructuring charges of \$10.1 million and asset write down charges of \$11.8 million in 2001. The \$10.1 million restructuring charge comprised costs related to work force reduction of \$2.9 million, costs for the termination of collaboration agreements of \$4.1 million and facilities consolidation costs of \$3.2 million.

For the years ended December 31, 2002 and 2001, respectively, \$8.6 million and \$8.9 million of the restructuring charges were paid in cash, primarily for severance costs to terminated employees, termination fees on collaboration agreements and termination payments for vacated buildings.

The workforce reduction comprised 90 employees, who were all terminated in 2001, representing a 71% reduction in force. The estimated cost of terminating the collaboration agreements was increased by \$483,000 in 2001 and \$166,000 in 2002. There were no remaining amounts payable under these agreements as of December 31, 2002.

The facilities consolidation costs related to the vacating of three facilities in Mountain View, California, totaling 142,000 square feet. One of the vacated facilities was subleased during 2001, the second was terminated in October 2001 and the third in January 2003. In 2001, an adjustment was made to increase restructuring charges associated with facilities consolidation by \$1.9 million for additional costs related the third vacated facility. In November 2002, the Company reached agreements with the landlords of this building and the facility, which the Company had subleased, to terminate the leases. The additional expense recorded during 2002 was \$5.2 million and included cash payments, the issuance of common stock and the write-off of a deferred rent balance. At December 31, 2002 there were no accrued restructuring charges related to these facilities.

Additionally as a part of the May 2001 restructuring plan, the Company wrote down to estimated fair value \$11.8 million of leasehold improvements, laboratory equipment, computers and other assets that were no longer being used. In 2001 we received proceeds from the disposition of certain leasehold improvements and other assets previously written down in excess of the amounts originally estimated. As a result, the Company recognized a gain of \$2.2 million that offset restructuring and other charges in the statement of operations for 2001.

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)**

The May 2001 restructuring consisted of the following activity (in thousands):

	Costs for Terminated Employees	Facilities Consolidation	Terminated Collaboration Agreements and Other	Total
2001 Activity				
Original restructuring charges	\$ 2,911	\$ 3,150	\$ 4,060	\$ 10,121
Cash refund (payments)	(2,675)	(2,219)	(3,983)	(8,877)
Non-cash expenses issuance of warrants			(560)	(560)
Adjustment to reflect revised estimates	(236)	1,930	483	2,177
Accrued restructuring charges at December 31, 2001		2,861		2,861
2002 Activity				
Cash refund (payments)	75	(8,464)	(166)	(8,555)
Non-cash expenses issuance of common stock		(437)		(437)
Reclass deferred rent liability		861		861
Adjustment to reflect revised estimates	(75)	5,179	166	5,270
Accrued restructuring charges at December 31, 2002	\$	\$	\$	\$

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 amounts were expensed in 2003 as a result of this restructuring plan.

8. Acquisition

In April 2002, the Company acquired Apothogen, Inc., a privately held pharmaceutical in-licensing company based in North Carolina. The Company issued 37,500 shares of its common stock in exchange for all of Apothogen's outstanding capital stock. The total purchase price of \$2.0 million was determined based on the average closing price of the Company's stock on the two days prior to the closing date, the closing date and two days after the closing date.

The Company allocated the purchase price based on the relative fair value of the net tangible and intangible assets acquired. Net tangible assets were valued at \$300,000 and consisted primarily of cash, other current assets and fixed assets. The amount of the purchase price in excess of the net tangible assets acquired of \$1.7 million was allocated to acquired workforce, which was to be amortized over three years. The acquired workforce, net of amortization, of \$1.4 million was deemed to be impaired after the failed results of the phase III trial of iseganan HCl for the prevention of oral mucositis in cancer patients receiving chemotherapy were announced. The acquired workforce was comprised of sales and marketing management, and given there would be no drug approval in the near future, the acquired workforce was deemed impaired, and therefore written down to zero in December 2002.

The Company acquired Apothogen in order to obtain its workforce, including the services of Dr. Ernest Mario, to obtain additional seasoned executives who could bring expertise in the commercialization of

Table of Contents

NOTES TO FINANCIAL STATEMENTS (Continued)

products, including product launch, and other strategic relationships. Concurrent with the closing of the acquisition, Ernest Mario, Ph.D. joined the Company as Chairman and Chief Executive Officer and purchased \$5.0 million of newly issued shares of the Company's common stock in a private placement at a purchase price of \$48.12 per share. Dr. Ernest Mario is currently Chairman of the Company's Board of Directors.

9. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock, of \$0.001 par value. 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 the Company's 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.

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 and such dividends shall be payable in cash. 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 sale price, or bid price if no sales were reported, 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, a volatility factor of 1.00 and a dividend yield of 0%. In connection with the issuance of the Preferred Stock and warrants, the Company recorded \$1,436,000 related to the beneficial conversion feature on the Preferred Stock as a deemed dividend,

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)**

which increased the loss applicable to common stockholders in the calculation of basic and diluted net loss per 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.

In October 2003, a holder of 25 shares of Preferred Stock converted the shares into 131,529 shares of common stock. The same investor concurrently 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.

The Company had 325 and zero shares of preferred stock outstanding as of December 31, 2003 and 2002, respectively. The Board of Directors may determine the rights, preferences and privileges of any preferred stock issued in the future.

Common Stock

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, at \$10.85 per share, and issued warrants to purchase 354,800 shares of the Company's common stock, resulting in net cash proceeds of \$18.5 million. The warrants have an exercise price of \$10.85 per share, subject to adjustment upon a subdivision or combination of the Company's outstanding common stock, and will expire on October 10, 2008, if not previously exercised.

Common Stock Reserved for Future Issuance

Shares of common stock reserved for future issuance at December 31, 2003 were as follows:

Equity incentive plans	1,063,013
Warrants	1,272,235
Series A convertible preferred stock	1,709,875
	<hr/>
Total shares reserved for future issuance	4,045,123
	<hr/>

Warrants

In July 2001, the Company issued warrants to purchase 58,333 shares of the Company's common stock at an exercise price of \$24.00 per share. These warrants were issued in connection with the termination of the discovery, development and license agreement with Diversa Corporation. The warrants will expire on July 27, 2005, if not previously exercised. The fair value of these warrants was estimated using the Black-Scholes option pricing model with the following weighted average assumptions: a risk-free interest rate of 6%, a contractual life of four years, a volatility factor of 0.75 and a dividend yield of 0%. The weighted-average fair value of these warrants was \$9.60. The value assigned to these warrants was \$560,000, which was included as part of the Company's May 2001 restructuring charges.

In December 2002, the Company issued warrants to purchase 4,167 shares of the Company's common stock at an exercise price of \$3.48 per share. These warrants were issued in connection with the termination of the lease agreement with the landlord of certain office facilities. The warrants will expire on December 31, 2007, if not previously exercised. The fair value of these warrants was estimated using the Black-Scholes option pricing model with the following weighted average assumptions: a risk-free interest rate of 1.5%, a contractual life of five years, a volatility factor of 0.50 and a dividend yield of 0%. The weighted-average fair value of these warrants was \$1.56. The value assigned to these warrants was \$6,500, which was included in General and administrative as part of the Company's 2002 operating expense.

Table of Contents

NOTES TO FINANCIAL STATEMENTS (Continued)

Stock Option Plans

The 1995 Incentive Stock Plan (1995 Plan) was terminated as of the effective date of the initial public offering in March 2000, and no new stock options may be granted thereunder. The termination of the 1995 Plan will have no effect on the options that have been granted thereunder. Stock options granted under the 1995 Plan may either be incentive stock options or nonstatutory stock options. Incentive stock options were granted with exercise prices of not less than the fair value of the common stock on the date of grant, as determined by the Board of Directors. Nonstatutory options were granted with exercise prices of not less than 85% of the fair value of the common stock on the date of the grant, as determined by the Board of Directors. All options granted have a term not greater than 10 years from the grant date. The options vest ratably over a period ranging from four to six years.

The 2000 Equity Incentive Plan (2000 Plan) was adopted in 2000 and originally allowed for the granting of options, stock bonuses and rights to acquire restricted stock of up to 416,666 shares of common stock to employees, consultants, and directors. Under the 2000 Plan, on December 31 of each year, starting with December 31, 2000 and continuing through December 31, 2008, the share reserve will automatically be increased by a number of shares equal to the lesser of:

5% of the then outstanding shares of common stock on a fully diluted basis;

166,666 shares; or

a lesser number of shares to be determined by the Board of Directors.

Under this provision, on December 31, 2003, the Board of Directors increased the number of shares in the reserve by 166,666 shares, and for the years ended December 31, 2002 and 2001, determined not to increase the number of shares in the reserve. The total number of common stock shares authorized for issuance under the 2000 Plan is 877,885, including an increase of 158,333 shares on April 3, 2003, as approved by the stockholders of the Company in a special meeting.

Stock options granted under the 2000 Plan may either be incentive stock options or nonstatutory stock options. Incentive stock options may be granted with exercise prices of not less than the common stock price on the date of the grant. Nonstatutory options may be granted with exercise prices of not less than 85% of the common stock price on the date of the grant. All options are to have a term not greater than 10 years from the grant date. The Board of Directors shall determine the time or times during the term when the options may be exercised and the number of shares for which an option may be granted. Options vest ratably over a period ranging from 18 months to six years.

The 2002 Non-Officer Equity Incentive Plan (2002 Plan) was adopted in August 2002 and allows the granting of stock awards through nonstatutory stock options, stock bonuses and rights to acquire restricted common stock of up to 208,333 shares of common stock to employees and consultants of the Company, following an increase to the reserve of 75,000 shares on February 3, 2003, as approved by the Board of Directors.

Stock options granted under the 2002 Plan, must be nonstatutory stock options. Nonstatutory options may be granted with exercise prices of not less than 85% of the common stock price on the date of the grant. All options are to have a term not greater than 10 years from the grant date. The Board of Directors shall determine the time or times during the term when the options may be exercised and the number of shares for which an option may be granted. Options vest ratably over a period ranging from 18 months to six years.

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)**

A summary of the Company's stock option activity and related information is as follows:

	Options Outstanding	
	Number of Shares	Weighted-Average Exercise Price
Balance at December 31, 2000	432,858	\$ 92.76
Granted	237,433	\$ 61.68
Exercised	(45,283)	\$ 10.44
Cancelled	(312,638)	\$ 119.52
Balance at December 31, 2001	312,370	\$ 52.08
Granted	477,083	\$ 34.68
Exercised	(28,924)	\$ 15.96
Cancelled	(129,194)	\$ 54.12
Balance at December 31, 2002	631,335	\$ 39.24
Granted	822,527	\$ 2.97
Exercised	(49,863)	\$ 7.68
Cancelled	(581,018)	\$ 40.93
Balance at December 31, 2003	822,981	\$ 3.73

At December 31, 2003, 2002, and 2001, options to purchase 165,187, 211,131 and 109,536 shares of common stock, respectively, were exercisable. The following table summarizes information about options outstanding and exercisable at December 31, 2003:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
\$ 1.80-\$ 2.40	62,048	7.95	\$ 2.04	12,134	\$ 2.35
\$ 2.76-\$ 2.76	692,337	6.97	\$ 2.76	132,292	\$ 2.76
\$ 4.80-\$ 10.80	27,460	9.34	\$ 5.58	460	\$ 9.33
\$ 13.53-\$ 19.80	36,823	8.48	\$ 16.25	17,488	\$ 18.62
\$ 35.88-\$ 48.60	3,417	8.20	\$ 43.61	2,396	\$ 41.61
\$144.00-\$187.50	896	1.68	\$ 147.06	417	\$ 150.57
	822,981	7.19	\$ 3.73	165,187	\$ 5.36

The weighted-average fair value of options granted during 2003, 2002, and 2001 was \$2.24, \$25.92 and \$37.80, respectively

2000 Employee Stock Purchase Plan

In January 2000, the Board of Directors adopted the 2000 Employee Stock Purchase Plan (the "Purchase Plan"), which was approved by stockholders in February 2000, authorizing the issuance of 41,666 shares of common stock pursuant to purchase rights granted to employees. In

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

2001 and 2002, the Board of Directors determined not to increase the number of shares in the reserve. In March 2003, the Purchase Plan was suspended, and the shares reserved for issuance under this plan were reduced to zero.

The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. Prior to its suspension, the Purchase Plan permitted eligible employees to purchase common stock at a discount, but only through payroll deductions, during defined offering periods. The price at which stock is purchased under the purchase plan is equal to 85%

Table of Contents

NOTES TO FINANCIAL STATEMENTS (Continued)

of the fair market value of the common stock on the first or last day of the offering period, whichever is lower. The initial offering period commenced on the effective date of the initial public offering.

Stock Compensation

In February 2003, the Board of Directors approved a cancellation and re-grant of 308,835 unexercised stock options held by existing employees and directors of the Company in a one-for-one exchange and 12,500 options that were re-granted in connection with the cancellation of 54,166 unexercised stock options held by a director of the Company. The newly-granted options have an exercise price equal to the closing price of the Company's common stock on the Nasdaq National Market on February 5, 2003, or \$2.76 per share. The options generally vest over a four-year period and will expire in February 2008 if not previously exercised. Variable accounting is being applied to the re-granted options throughout their term. Compensation expense of \$993,000 was recorded for these options during the year ended December 31, 2003.

Deferred compensation in connection with the grant of certain stock options to employees and officers on or prior to the Company's initial public offering on March 20, 2000 and in connection with an agreement to modify the vesting of one officer's unvested stock options is being amortized to expense on a straight-line basis over the vesting period of the options, ranging from four to six years. The vesting schedule of the unexercised portion of the granted options was changed following their cancellation and re-grant in February 2003, and consequently the amortization schedule was also changed to reflect the new four-year vesting schedule. During the years ended December 31, 2003, 2002, and 2001, the Company recorded amortization of deferred stock compensation expense of \$126,000, \$1.3 million and \$2.7 million, respectively. In connection with the termination of various employees and cancellation of unvested stock options, the Company recorded a reduction to deferred stock compensation of \$406,000, \$2.6 million and \$2.9 million in the years ended December 31, 2003, 2002 and 2001, respectively.

10. Licensing, Research, and Technology Contracts

In January 2001, the Company entered a strategic drug discovery, development and licensing agreement with Diversa Corporation (Diversa) to identify novel types of antimicrobial drugs. Under the terms of this agreement, the companies planned to collaborate to identify and develop novel drugs derived from Diversa's recombinant natural product libraries that demonstrate antibacterial or antifungal properties. Diversa was to receive technology access fees, research support, and success-based milestone payments for each drug developed as well as royalties on any products commercialized under the agreement. The technology access fee under this agreement was \$3.0 million, with the first fee payment of \$1.0 million paid in January 2001 and expensed to research and development, \$1.0 million fee which would have been payable on December 1, 2001 and the final \$1.0 million fee payable on December 1, 2002. In exchange, IntraBiotics was to have an exclusive, worldwide license to any products identified and developed during the collaboration. On July 27, 2001, the Company terminated the discovery, development and license agreement with Diversa Corporation. Under the terms of this termination agreement, IntraBiotics paid Diversa Corporation \$2.45 million and issued warrants to purchase 58,333 shares of its common stock at an exercise price of \$24.00 per share, exercisable immediately for a period of four years, which were included in the restructuring expense. No additional payments are due under this agreement.

In January 2001, the Company entered into a renewable, two-year research and technology licensing agreement for the discovery of new anti-infective therapies with Albany Molecular Research, Inc. (AMRI). The agreement provided that AMRI was to receive technology access fees, research funding, and success-based milestone payments for each drug discovered during the collaboration and developed by our sublicensees or us. AMRI was to be entitled to royalty payments on any third and subsequent products resulting from the collaboration. The Company paid an initial signing fee of \$200,000 under this agreement in January 2001, which was included in research and development expense. In addition, the technology access fee was \$400,000, payable in eight quarterly payments of \$50,000 beginning in January 2001 through November 2002. In exchange, the Company was to have an exclusive, worldwide license to develop and commercialize drugs

Table of Contents

NOTES TO FINANCIAL STATEMENTS (Continued)

that emerge from the collaboration. On June 21, 2001, the Company terminated its collaborative research and technology agreement with AMRI. Under the terms of this termination agreement, IntraBiotics paid AMRI \$300,000, which was included in the restructuring expense. No additional payments are due under this agreement.

During 1998, the Company recorded \$2.0 million in license fee expense in connection with the purchase of rights from Biosearch Italia S.p.A. to develop and commercialize ramoplanin, which was a phase I clinical-stage product candidate. The purchase price, which was expensed as in-process research and development as the rights had no alternative future use, consisted of the issuance of 20,833 shares of Series F preferred stock at \$48.00 per share and \$1.0 million in cash. In 1998, the Company paid and recorded a milestone of \$2.0 million for the commencement of the phase II clinical trial. In 2000, the Company paid and recorded a \$2.5 million milestone payment to Biosearch Italia for the commencement of Phase III clinical studies. In May 2001, the Company amended its licensing and development agreement for its late stage ramoplanin program with Biosearch Italia, S.p.A. Under the terms of the amended agreement, the Company was reimbursed for ongoing clinical trial expenses during a three-month transition period ended August 31, 2001. At the end of this period, Biosearch Italia S.p.A. assumed responsibility for the clinical development of ramoplanin oral powder at its own expense and retained worldwide rights to the product. In exchange for its clinical development expenses and efforts, the Company will receive a royalty on future net sales of ramoplanin oral in North America, if it is successfully developed.

In January 1997, the Company entered into an agreement with PolyPeptide Laboratories A/ S to develop a manufacturing process for its drug substance iseganan HCl, previously referred to as Protegrin IB-367, and was obligated to pay up to \$2.9 million based upon achievement of certain development milestones. The Company also entered into related purchase and supply agreements with PolyPeptide. In December 2002, the Company reached an agreement with PolyPeptide Laboratories A/ S to (i) take delivery of 14 kg of completed iseganan, (ii) take delivery of partially completed fragments, (iii) cancel the development, purchase and supply agreements between the companies, and (iv) for PolyPeptide Laboratories A/ S to store the finished product and the fragments for a period of up to five years at a cost of \$50,000 per year. Under this agreement, the Company paid PolyPeptide \$4.7 million upon execution of the termination agreement, assigned letters of credit totaling \$547,000 and was expected to pay an additional \$250,000 in 2003 upon delivery and acceptance of a seven kg lot of drug substance (lot I), which has yet to occur. The \$250,000 is secured by a letter of credit and is recorded as restricted cash on our balance sheets at December 31, 2003 and 2002. As a result of this termination agreement, in December 2002, the Company expensed \$4.8 million related to the delivery of lots H, J, K, and L, and recorded a prepaid for drug substance of \$2.4 million as of December 31, 2002, which was expected to be expensed upon delivery of lot I. However, the Company has not yet been satisfied that the lot was manufactured in accordance with a validation plan or that related documentation is adequate, and is currently discussing this with the contract manufacturer. Due to significant uncertainty over the timing and outcome of these discussions, the entire \$2.4 million prepaid amount was written off to research and development expense in 2003.

From 1994 to 1997, the Company entered into a series of agreements with The Regents of the University of California under which it obtained certain licenses to its protegrin technology under development. In consideration for these licenses, the Company has made certain payments totaling \$125,000, and agreed to pay The Regents of the University of California additional amounts and specified royalties upon occurrence of certain events related to the development of the technology. These events include drug approvals and product sales.

Table of Contents**NOTES TO FINANCIAL STATEMENTS (Continued)****11. Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amount used for income tax purposes. Significant components of the Company's deferred tax assets as follows (in thousands):

	December 31,	
	2003	2002
Net operating loss carryforwards	\$ 67,700	\$ 63,700
Research and development tax credit carryforwards	5,500	3,000
Capitalized research and development costs	7,500	8,200
Other, net		200
Total deferred tax assets	80,700	75,100
Valuation allowance	(80,700)	(75,100)
Net deferred tax assets	\$	\$

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$5.6 million, \$11.4 million and \$26.2 million during 2003, 2002 and 2001, respectively.

As of December 31, 2003, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$192.0 million, which expire in the years 2009 through 2023, and federal research and development credits of approximately \$3.3 million, which expire in the years 2009 through 2023. In addition, the Company had net operating loss carryforwards for state income tax purposes of approximately \$44.0 million, which expire in the years 2004 through 2013 and state research and development tax credits of approximately \$3.3 million, which do not expire.

Utilization of the Company's net operating loss may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss before utilization.

12. Quarterly Financial Data (Unaudited)

	2003				2002			
	First	Second	Third	Fourth	First	Second	Third	Fourth
(In thousands, except per share amounts)								
Operating loss	\$ (1,933)	\$ (2,395)	\$ (4,766)	\$ (4,415)	\$ (4,992)	\$ (8,858)	\$ (11,483)	\$ (10,220)
Net loss	(1,907)	(2,350)	(4,738)	(4,317)	(4,880)	(7,972)	(11,271)	(10,330)
Net loss applicable to common stockholders	(1,907)	(3,815)	(4,808)	(4,400)	(4,880)	(7,972)	(11,271)	(10,330)
Net loss per share applicable to common stockholders:								
Basic and diluted	\$ (0.58)	\$ (1.17)	\$ (1.46)	\$ (0.87)	\$ (1.73)	\$ (2.58)	\$ (3.59)	\$ (3.23)

Table of Contents

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

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

Changes in internal control over financial reporting: There was no change in our internal control over financial reporting during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Pursuant to General Instruction G to Form 10-K, the information required by Items 10, 11, 12, 13 and 14 of Part III is incorporated by reference from the Company's definitive Proxy Statement with respect to its 2004 annual meeting of stockholders, to be filed pursuant to Regulation 14A within 120 days after December 31, 2003.

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) 1. Financial Statements

The Financial Statements and Report of Independent Auditors are included in a separate section of this Annual Report on Form 10-K. See index to Financial Statements at Item 8 of this Form 10-K.

2. Financial Statement Schedules

All financial statement schedules are omitted because they were not required or the required information is included in the Financial Statements and the related notes. See index to consolidated financial statements at Item 8 of this Annual Report on Form 10-K.

3. Exhibit Index

See Exhibit Index on page 53 of this Annual Report on Form 10-K.

(b) Reports on Form 8-K

We filed a report on Form 8-K on October 9, 2003 concerning the issuance of a press release relating to (i) our private equity financing and related agreements, and (ii) a press release relating to the enrollment of patents in a clinical trial involving our product candidate, iseganan HCl.

We filed a report on Form 8-K on October 29, 2003 concerning the issuance of a press release relating to our third quarter financial results.

(c) Exhibits

See Exhibit Index on page 53 of this Annual Report on Form 10-K.

(d) Financial Statement Schedules

See (a)(2) above.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15 (d) 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 on this 19th day of March 2004.

INTRABIOTICS PHARMACEUTICALS, INC.

By /s/ HENRY J. FUCHS, M.D.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, jointly and severally, Henry J. Fuchs, M.D. his attorney in fact, each with the full power of substitution, for such person, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might do or could do in person hereby ratifying and confirming all that each of said attorneys-in-fact and agents, or his substitute, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ HENRY J. FUCHS</u>	President and Chief Executive Officer	March 19, 2004
Henry J. Fuchs, M.D.		
<u>/s/ DAVID J. TUCKER</u>	Principal Financial Officer	March 19, 2004
David J. Tucker		
<u>/s/ ERNEST MARIO</u>	Chairman of the Board	March 19, 2004
Ernest Mario, Ph.D.		
<u>/s/ KEVIN C. TANG</u>	Director	March 19, 2004
Kevin C. Tang		
<u>/s/ MARK L. PERRY</u>	Director	March 19, 2004
Mark L. Perry		
<u>/s/ GARY A. LYONS</u>	Director	March 19, 2004
Gary A. Lyons		

Table of Contents

Signature	Title	Date
<hr/>		
/s/ JERRY JACKSON	Director	March 19, 2004
<hr/>		
Jerry Jackson		
/s/ JACK S. REMINGTON	Director	March 19, 2004
<hr/>		
Jack S. Remington		

Table of Contents**EXHIBIT INDEX**

Exhibit Number	Description
3.1	Certificate of Amendment of Amended and Restated Certificate of Incorporation; and Amended and Restated Certificate of Incorporation.(12)
3.2	Bylaws.(1)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on April 10, 2003. (15)
3.4	Certificate of Designation filed with the Delaware Secretary of State on May 1, 2003.(15)
4.1	Amended and Restated Investor Rights Agreement dated October 15, 1999.(1)
4.2	Form of Stock Purchase Agreement by and between the Company and each selling stockholder, dated January 29, 2002.(4)
4.3	Form of Preferred Stock and Warrant Purchase Agreement, dated February 5, 2003, as amended on February 11, 2003.(11)
4.4	Form of Second Amendment to Preferred Stock and Warrant Purchase Agreement of February 5, 2003, dated April 10, 2003.(13)
4.5	Form of Warrant issued by the Company pursuant to Preferred Stock and Warrant Purchase Agreement of February 5, 2003, as amended of February 11, 2003 and April 10, 2003.(13)
4.6	Form of Common Stock and Warrant Purchase Agreement, dated October 6, 2003.(14)
4.7	Form of Warrant issued by the Company pursuant to the Common Stock and Warrant Purchase Agreement of October 6, 2003.(14)
10.1	Form of Indemnity Agreement.(1)
10.2	Amended and Restated 1995 Stock Option Plan, as amended on November 16, 2002.(10)(12)
10.2.2	Amended and Restated Form of Stock Option Agreement and Notice of Grant of Stock Options and Option Agreement.(1)(10)
10.3	2000 Equity Incentive Plan, as amended on February 11, 2003.(10)(12)
10.4	Purchase Supply Agreement by and between the Company and PolyPeptide Laboratories A/S dated January 3, 1997.(1)
10.5	Development Supply Agreement by and between the Company, PolyPeptide Laboratories A/S and Ferring Peptide Production AB dated January 3, 1997 and Amendment dated July 1, 1997.(1)
10.6	Second Amendment to the License Agreement by and between the Company and The Regents of the University of California dated June 12, 1996.(1)
10.7	Third Amendment to the License Agreement by and between the Company and The Regents of the University of California dated September 16, 1997.(1)
10.8	License and Supply Agreement by and between the Company and Biosearch Italia S.p.A. dated May 8, 1998.(1)
10.9	2000 Employee Stock Purchase Plan and related documents.(1)(10)
10.10	Loan and Security Agreement by and between the Company and Silicon Valley Bank, dated August 25, 1999.(1)
10.11	Research and Technology Agreement by and between the Company and New Chemical Entities dated January 24, 2001.(2)
10.12	Letter Agreement by and between the Company and Biosearch Italia dated May 18, 2001.(3)
10.13	First Amendment to Research and Technology Agreement by and between the Company and Albany Molecular Research Inc. (successor to New Chemical Entities Inc.) dated April 13, 2001.(3)

Table of Contents

Exhibit Number	Description
10.14	Letter Agreement by and between the Company and Albany Molecular Research Inc. (successor to New Chemical Entities Inc.) dated June 21, 2001.(3)
10.15	Senior Executive Severance Benefit Plan, as amended and restated on August 1, 2002.(8)(10)
10.16	Executive Severance Benefit Plan, as amended and restated on August 1, 2002.(8)(10)
10.17	Summary of Officer Incentive Bonus Plan.(3)(10)
10.18	Release Agreement by and between the Company and Diversa Corporation dated July 27, 2001, including Warrant to Purchase Common Stock of the Company and Registration Rights Agreement.(6)
10.19	Letter Agreement dated November 28, 2001 by and between the Company and Ken Kelley.(5)(10)
10.20	Loan Modification Agreement by and between the Company and Silicon Valley Bank, dated April 29, 2002.(7)
10.21	Loan Modification Agreement by and between the Company and Silicon Valley Bank, dated June 10, 2002.(7)
10.22	2002 Non-Officer Equity Incentive Plan and related documents, as amended on February 3, 2003.(12)
10.23	Master Services Agreement by and among the Company, PPD Development, LP and PPD Global Ltd., dated July 29, 2002.(8)
10.24	Lease Termination Agreement by and between the Company and EOP-Shoreline Technology Park, L.L.C., dated November 22, 2002, including Common Stock Purchase Agreement.(9)
10.25	Lease Termination Agreement by and between the Company and Bruce H. Carter and Keith M. Carter, dated October 31, 2002.(12)
10.26	Sublease Termination Agreement and Sublease by and between the Company and ReShape, Inc., dated October 31, 2002.(12)
10.27	Amendment and Assignment of Lease, Release and Assumption Agreement by and among the Company, PolyFuel, Inc. and 1245 Terra Bella Partners, LLC, dated December 20, 2002, including Warrant to Purchase Common Stock of the Company dated December 31, 2002.(12)
10.28	Termination of Development Supply Agreement and Purchase/Supply Agreement by and among the Company, PolyPeptide Laboratories A/S and PolyPeptide Laboratories AB, dated December 6, 2002.(12)
10.29	Lease Agreement by and between the Company and Embarcadero Corporate Center, dated February 10, 2003.(12)
10.30	Common Stock and Warrant Purchase Agreement, dated October 6, 2003 (the Purchase Agreement) by and among the Company and each Investor as defined therein.(14)
10.31	Form of warrant issued by the Company in favor of each Investor, as defined in the Purchase Agreement.(14)
23.1	Consent of Ernst & Young LLP, Independent Auditors
24.1	Power of Attorney. Reference is made to the signature page.
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).

Table of Contents

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

- (1) Incorporated by reference to exhibit to our Registration Statement on Form S-1 (File No. 333-95461) initially filed with the Securities and Exchange Commission on January 27, 2000 as subsequently amended.
- (2) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on May 16, 2001.
- (3) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on August 14, 2001.
- (4) Incorporated by reference to exhibit to our Registration Statement on Form S-3 (File No. 333-82934) filed with the Securities and Exchange Commission on February 15, 2002.
- (5) Incorporated by reference to exhibit to our Form 10-K (File No. 000-29993) filed with the Securities and Exchange Commission on February 15, 2002.
- (6) Incorporated by reference to exhibit to our Registration Statement on Form S-3 (File No. 333-89840) filed with the Securities and Exchange Commission on June 5, 2002.
- (7) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on August 14, 2002.
- (8) Incorporated by reference to exhibit to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on November 14, 2002.
- (9) Incorporated by reference to exhibit to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on November 27, 2002.
- (10) Management contract or compensatory plan, contract or arrangement.
- (11) Incorporated by reference to Appendix B to the Definitive Proxy Statement for the Special Meeting of Stockholders (File No. 000-29993) filed with the Securities and Exchange Commission on March 3, 2003.
- (12) Incorporated by reference to exhibit to our Form 10-K (File No. 000-29993) filed with the Securities and Exchange Commission on March 31, 2003.
- (13) Incorporated by reference to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on May 14, 2003.
- (14) Incorporated by reference to exhibit to our Form 8-K (File No. 000-29993) filed with the Securities and Exchange Commission on October 9, 2003.
- (15) Incorporated by reference to our Form 10-Q (File No. 000-29993) filed with the Securities and Exchange Commission on November 12, 2003.