INTRABIOTICS PHARMACEUTICALS INC /DE
Form 10-K405
February 15, 2002

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SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

/x/ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2001

OR

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

For the transition period from _____ to _____

Commission File Number 0-29993

INTRABIOTICS PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**94-3200380**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
1245 Terra Bella Avenue, Mountain View, CA	**94043**
(Address of principal executive offices)	(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 /x/ 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. /x/

The number of shares outstanding of the registrant's Common Stock, par value $0.001 per share, as of February 4, 2002 was 35,750,592 shares. The aggregate market value of the Common Stock, held by non-affiliates of the registrant, based on the closing price on February 4, 2002 as reported by the Nasdaq National Market was approximately $121,552,000.

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 5, 2002 are incorporated by reference into this Form 10-K.

IntraBiotics Pharmaceuticals, Inc
Form 10-K
For the Year Ended December 31, 2001
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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 candidates; 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 terminology. These statements involve known and unknown risk 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", "Risks Related to Our Business" and "Management's Discussion and Analysis of Financial Conditions 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

IntraBiotics develops and intends to commercialize novel antimicrobial (antibacterial and antifungal) drugs for the prevention or treatment of serious diseases. Our clinical development programs focus on addressing medical problems for patients who currently have few or no satisfactory alternatives. Because our lead drug candidate, iseganan hydrochloride (HCl), uses novel mechanisms of action to kill bacteria and fungi, we expect it to be particularly useful in fighting serious infections that are not well treated by current therapies. In particular, iseganan's broad spectrum of antimicrobial activity (including activity against multi-drug resistant bacteria and yeast), its ability to kill microorganisms within minutes, and its low propensity to engender resistance make iseganan HCl a novel and potentially important advance.

Our current product portfolio includes iseganan HCl, which has three potential indications: reduction in incidence and severity of oral mucositis, prevention of ventilator-associated pneumonia and treatment of respiratory infections in cystic fibrosis patients. Iseganan HCl oral solution, previously referred to as Protegrin IB-367, is currently in phase III clinical trials for the reduction in the incidence and severity of ulcerative oral mucositis. Oral mucositis is a common debilitating side effect of cancer therapy and is characterized by severe mouth ulcers that often become infected. In addition, we have completed a phase I/IIa study of iseganan HCl oral solution for the prevention of ventilator-associated pneumonia and a phase I study of iseganan HCl solution for inhalation in cystic fibrosis patients. At this time we are focusing our resources on the two Phase III trials in the oral mucositis program.

On May 31, 2001, we implemented a restructuring plan intended to conserve capital and help direct financial and human resources to the development of iseganan HCl oral solution for the reduction in incidence and severity of oral mucositis in cancer patients. The strategic restructuring included a reduction in force of approximately 90 positions in research and administration, or 71% of our workforce of 127 employees. The restructuring also included the termination of certain research and development collaborations and the consolidation of operations into one existing facility in Mountain View, California.

On November 29, 2001, Kenneth J. Kelley, our Chief Executive Officer, President and Chairman of the Board of Directors, terminated his employment with us effective January 31, 2002. Under the terms of his Separation and Consulting Agreement, Mr. Kelley will remain a consultant with us through July 31, 2003, and receive ongoing severance payments in the aggregate amount of approximately

$550,000. In addition, a portion of Mr. Kelley's unvested options vested in January 2002, and the remaining options will continue to vest over the remainder of the consulting period.

Iseganan HCl Oral Solution for Reduction in Incidence and Severity of Ulcerative Oral Mucositis

Iseganan HCl is a synthetic analog of the Protegrin family of antibiotic peptides naturally found in mammals. Iseganan HCl destroys the cell membranes of bacteria and fungi, thus damaging the structural integrity of the microorganism. Iseganan HCl kills a wide variety of microorganisms, including bacteria and certain fungi, and is effective against many of the serious drug-resistant, disease-causing bacteria and yeast.

We are developing iseganan HCl oral solution for the reduction in incidence and severity of ulcerative oral mucositis as its first indication. Cancer patients who are undergoing aggressive chemotherapy or oral radiation treatment will swish iseganan HCl oral solution in their mouths several times per day while undergoing cancer therapy in an attempt to reduce the number of microorganisms in their mouth, thereby lessening the incidence and severity of the manifestations of oral mucositis. We believe iseganan HCl is well suited for the prevention of oral mucositis because it quickly kills the bacteria and fungi found in the mouth and because it is formulated as a rinse, a method of application which is familiar to, and convenient for patients.

In clinical trials, iseganan HCl oral solution has been well tolerated and is not detectably absorbed into the bloodstream. In January 2001, we completed enrollment in the first of our randomized double blind, placebo-controlled phase III clinical trials to further assess the safety and efficacy of iseganan HCl oral solution in patients receiving aggressive chemotherapy. However, we discovered that nearly one third of the patients treated in the trial received one or more treatments of both iseganan and placebo medication due to an error on the part of subcontractor that was managing the drug dispensing. We believe that as a result of this error, the trial underestimated the impact of iseganan and, it failed to reach statistical significance in the primary endpoint. The study demonstrated a 30% increase in the proportion of patients who did not experience ulcerative oral mucositis ($p = 0.067$). Iseganan HCl oral solution did meet several additional endpoints including that of mouth pain

($p < 0.05$). In addition, this study demonstrated that iseganan HCl oral solution continues to be well tolerated.

Our second phase III clinical trial evaluating the safety and efficacy of iseganan HCl oral solution for the prevention of oral mucositis in patients receiving radiotherapy for cancer of the head and neck completed enrollment in December 2001. We anticipate the announcement of results from the second phase III oral mucositis trial in cancer patients receiving radiotherapy for head and neck cancer in the second quarter of 2002.

We have initiated enrollment in a third phase III clinical trial evaluating the safety and efficacy of iseganan HCl oral solution for the reduction in incidence and severity of ulcerative oral mucositis in patients receiving aggressive chemotherapy. We expect to announce the results from this trial in the fourth quarter of 2002.

If our phase III trials are successful, we intend to submit the results to the FDA to support regulatory approval of the product. However, we cannot be certain that iseganan HCl oral solution will prove to be safe or effective in reducing the incidence and severity of ulcerative oral mucositis in cancer patients receiving either chemotherapy and/or radiotherapy, will receive regulatory approvals, or will be successfully commercialized.

Iseganan HCl Oral Solution for Prevention of Ventilator-Associated Pneumonia

Iseganan HCl oral solution is also a potential new drug for prevention of ventilator-associated pneumonia. Phase I and IIa trials of iseganan HCl oral solution in mechanically ventilated patients

evaluating safety and antimicrobial activity have been completed. Single doses of iseganan HCl were well tolerated, and iseganan reduced the levels of oral microbial flora by more than 100-fold. The phase IIa study evaluating the safety and antimicrobial efficacy of iseganan HCl oral solution administered for up to five days demonstrated that iseganan HCl oral solution was well tolerated and provided a significant antimicrobial effect. The results are encouraging and support further development of iseganan HCl oral solution for the prevention of ventilator-associated pneumonia. However, we cannot be certain that iseganan HCl oral solution will prove to be safe or effective in the prevention of ventilator-associated pneumonia, will receive regulatory approvals, or will be successfully commercialized. In addition, we are currently focusing our resources on the oral mucositis program and are not expending significant resources on the ventilator-associated pneumonia program.

Iseganan HCl Solution for Inhalation for Treatment of Respiratory Infections

We believe iseganan HCl may be effective in treating respiratory infections in cystic fibrosis (CF) patients. Iseganan HCl has been formulated as a solution for inhalation by patients with CF. Since iseganan is a broad spectrum, rapidly acting antimicrobial agent with a low propensity to engender antimicrobial resistance, we believe iseganan HCl is well suited for this indication.

Two phase I studies of iseganan HCl solution for inhalation, one administered as a single dose and the second administered up to five doses, have enabled us to establish the dose tolerance and further develop the formulation for this product. 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, will receive regulatory approvals, or will be successfully commercialized. In addition, we are currently focusing our resources on the oral mucositis program and are not expending significant resources on the program for respiratory infections in CF patients.

Ramoplanin Ointment for the Eradication of Nasal *Staphylococcus Aureus*

We have evaluated the safety and efficacy of ramoplanin ointment and other topical formulations for the reduction in nasal carriage of *Staphylococcus aureus (S. aureus)* in a phase I study. Nasal carriers of *S. aureus* have an increased risk of developing surgical wound infections. The dosage forms evaluated to date have not demonstrated a sufficient reduction in the *S. aureus* levels. We have developed new formulations designed to achieve the targeted reduction. The commercialization and development rights for this formulation of ramoplanin will be returned to Biosearch Italia on April 1, 2002, unless we provide evidence prior to March 31, 2002 that we have diligently carried out development activity enabling us to initiate clinical developments by December 31, 2002. We cannot be certain that topical forms of ramoplanin will prove to be safe or effective in eradication of nasal *S. aureus*, will receive regulatory approvals, or will be successfully commercialized.

Our Preclinical Research Programs

Prior to our reduction in force, we were conducting research focused on discovering and developing compounds with novel chemical structures and mechanisms of antimicrobial activity against bacteria or fungi. We have filed patent applications on these compounds. We currently have two programs in the preclinical research stage, IB-880 and IB-863, which we intend to out-license for further research and development.

Strategic Relationships

Albany Molecular Research, Inc., Albany, New York

In January 2001, we entered into a renewable, two-year research and technology licensing agreement for the discovery of new anti-infective therapies with New Chemical Entities, Inc. (now

Albany Molecular Research, Inc.) (AMRI). On June 21, 2001, we terminated our collaborative research and technology agreement with AMRI due to our intention to focus our resources elsewhere. Under the terms of this termination agreement, we paid AMRI $300,000.

Biosearch Italia S.p.A., Gerenzano, Italy

In May 1998, we entered into a license agreement with Biosearch Italia, under which we have exclusive rights in the U.S. and Canada to develop and commercialize products containing certain formulations of ramoplanin for the treatment or prevention of human disease.

On May 29, 2001, we announced an amendment to this agreement. Under the new terms of the agreement, Biosearch Italia reimbursed us for ongoing clinical trial expenses during a two-month transition period, starting June 1 and ending July 31, 2001. During this period, Biosearch Italia assumed responsibility for the clinical development of ramoplanin oral powder at its own expense. In exchange for our clinical development expenses and efforts to date, we will receive a royalty on future net sales of ramoplanin in North America, if it is successfully developed. All of our future milestone payments and obligations were waived by Biosearch Italia for the development of oral formulations of ramoplanin. We retain the rights for the development and commercialization of topical formulations of ramoplanin. These rights will revert to Biosearch Italia on April 1, 2002, unless we provide evidence prior to March 31, 2002 that we have diligently carried out development activity enabling us to initiate clinical developments by December 31, 2002.

Cetek Corporation, Framingham, Massachusetts

On June 7, 2001, we terminated our research collaboration agreement with Cetek Corporation. There were no financial charges associated with this termination.

Diversa Corporation, San Diego, California

In January 2001, we entered into a strategic drug discovery, development and licensing agreement with Diversa Corporation to identify novel types of antimicrobial drugs.

On July 27, 2001, we terminated the agreement with Diversa. Under the terms of the termination agreement, we paid an aggregate of $2.45 million to Diversa during 2001. In addition, we issued a warrant to Diversa for the purchase 700,000 shares of our common stock at an exercise price of $2.00 per share, exercisable immediately for a period of four years.

PolyPeptide Laboratories A/S, Hillerød, Denmark

In January 1997, we entered into both a Development Supply Agreement and a Purchase Supply Agreement with PolyPeptide Laboratories A/S, for the development of manufacturing processes for iseganan HCl and for the clinical and commercial manufacture and supply of iseganan HCl, as a bulk drug substance. Under the Development Supply Agreement, we make payments to PolyPeptide upon achievement of certain development milestones and upon receipt of materials to be used in clinical trials. As of December 31, 2001, these payments totaled $8.0 million. Under the Purchase Supply Agreement, we will pay PolyPeptide for set volumes and at set prices.

The Development Supply Agreement will terminate after certain files relating to iseganan HCl are ready for submission to the FDA in connection with a new drug application. PolyPeptide is currently manufacturing iseganan HCl exclusively for us. However, under certain circumstances, we can transfer the manufacturing process to a third party if we choose.

The Regents of the University of California

In April 1994, we entered a license agreement with The Regents of the University of California, under which we have exclusive rights to develop and commercialize Protegrin-based products. In addition to a licensing fee, we are obligated to make payments to the Regents upon the occurrence of specific development milestones. These milestone payments are anticipated to total $200,000 if all research and development goals are achieved. We will also make royalty payments to the Regents based on sales of Protegrin-based products.

We may terminate the agreement upon written notice. We are obligated to diligently pursue the development of Protegrin-based products or the Regents may terminate the agreement.

Manufacturing

We intend to use contract manufacturers to prepare our drugs instead of developing this capability internally. We have contracted with PolyPeptide as a single source for supply of bulk drug substance iseganan HCl for use in the clinical trials. PolyPeptide has manufactured the peptide on a pilot scale to our specifications. The manufacturing process was scaled up at the proposed commercial facility in advance of the commencement of our phase III clinical trial. Scale up to commercial scale is ongoing. PolyPeptide is an established world leader in peptide manufacturing. We have selected a contract manufacturer for final formulation for commercialization. By using third-party manufacturers we can leverage their expertise and capital investment.

If our contract manufacturers are unable or fail to produce the required quantities of our drug candidate for clinical use on a timely basis, at commercially reasonable prices, our current and future clinical trials and our product development efforts will be delayed. If these facilities become unavailable for any reason, if our contract manufacturers fail to comply with the FDA's current good manufacturing practices, or if our contract manufacturers terminate their agreements with us, we would need to find an alternative source for manufacturing our drug candidates. Contract manufacturers often encounter difficulties in scaling up production, including problems involving production yields, quality control, quality assurance and shortage of qualified personnel. If our contract manufacturers are unable to scale up production to meet our commercial needs, our revenues may be adversely affected.

Intellectual Property

We own two U.S. patents directed to iseganan. Together, these patents contain claims to compositions of matter, pharmaceutical compositions and methods of use, including the treatment or prevention of oral mucositis. These patents expire no earlier than 2013. In addition, we are either the owner or exclusive licensee from The Regents of the University of California of seven other U.S. patents directed to related antimicrobial peptides and/or their uses. Applications directed to iseganan and the related antimicrobial peptides, as well as their uses, are either pending or have issued in major foreign jurisdictions. We also own two pending U.S. applications directed to specific uses of iseganan.

In addition, we own several pending U.S. and international patent applications directed to certain antifungal and antibacterial compounds and their uses, including the IB-863 Series of antifungal compounds and the IB-880 Series of antibacterial compounds.

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 or discontinue sales.

Marketing and Sales

We currently plan to market and sell our initial products through a direct or contracted sales force in the U.S. and Canada. We believe that a relatively small sales force of fewer than 100 sales representatives can be used to commercialize iseganan HCl oral solution for the reduction in incidence and severity of ulcerative oral mucositis because prescribing decisions will be made by a small group of physicians, specifically hematologist/oncologists administering high dose chemotherapy and radiation oncologists administering orally directed radiotherapy. We plan to begin hiring this sales force upon successful completion of phase III trials. This sales force will initially target the largest hospitals and cancer centers in the U.S. We cannot guarantee that we will develop a sales force with the necessary technical expertise and distribution capabilities.

We are also evaluating opportunities to partner with other pharmaceutical companies to develop and commercialize our products. We cannot guarantee that we will successfully develop or commercialize our product candidates, achieve significant market penetration, or generate any revenues from our products.

Competition

Currently, there is no FDA approved drug for oral mucositis. Doctors routinely prescribe mouthwashes containing salt water or sodium bicarbonate. Traditional antibacterial and antifungal drugs, topical anesthetics or antihistamines may also added for the symptomatic relief of oral mucositis, although most clinical trials have demonstrated no effectiveness of these remedies in comparison to salt water or sodium bicarbonate. Ice chips may also provide patients some soothing comfort. Narcotics are often used to reduce the patient's pain and nourishment may be supplemented, either intestinally or intravenously.

There are additional means of addressing oral mucositis currently under development in the pharmaceutical industry. For example, growth factors may be administered to patients to reestablish the protective barrier in the mouth to keep microorganisms out of the tissue. Additionally, we are aware of other antimicrobial drugs in earlier stages of clinical development for the prevention of oral mucositis.

Our competitors include fully integrated pharmaceutical companies and biotechnology companies. We are aware that several of these companies are actively engaged in research and development in the areas related to cancer therapy and antibiotic development, including some companies that address the same disease indications as we address. 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 cannot guarantee that we can effectively compete with these other pharmaceutical and biotechnology companies. We believe the principal bases for competition for our drug candidates are effectiveness, price and reimbursement status, ease of administration and side effect profile.

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 exemption will automatically become 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 exemption 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 exemption 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. Phase III 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 guarantee that phase I, phase II, or phase III testing will be completed successfully within any specified period of time, if 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 preclinical 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 our facilities or 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.

Iseganan has received fast-track designation by the FDA. The FDA's fast-track program is intended to facilitate the development of drugs intended for the treatment of serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs for such conditions. Under this program, the FDA can, for example, review portions of a new drug application for a fast-track product before the entire application is complete, thus potentially beginning the review process at an earlier time. The fast track designation may be withdrawn by FDA if the development program ceases to have the potential to address an unmet medical need for a life-threatening or serious condition. We cannot guarantee that the FDA will not withdraw the fast-track status, that any fast-track designation would affect the time of review, or that the FDA will approve the new drug application submitted for any of our drug candidates, whether or not fast-track designation is granted. Additionally, the FDA approval of a fast-track product can include restrictions on the product's use or distribution (such as permitting use only for specified medical procedures or limiting distribution to physicians or facilities with special training or experience). Approval of fast-track products can be conditional with a requirement for additional clinical studies after approval.

FDA procedures also provide priority review of new drug applications submitted for drugs that, compared to currently marketed products, offer a significant improvement in the treatment, diagnosis, or prevention of a disease. The FDA is supposed to review new drug applications that are granted priority status more quickly than new drug applications given standard status. FDA's current goal is to act on 90% of priority new drug applications within six months of receipt. We anticipate seeking priority review of iseganan HCl oral solution. We cannot guarantee that the FDA will grant priority review status in any instance, that priority review status would affect the review time, or that the FDA will approve the new drug application submitted for any of our drug candidates, whether or not priority review status is granted.

Under certain circumstances, the FDA provides periods of marketing exclusivity for new drugs that are the subject of an approved new drug application. Iseganan 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 (four years, in some cases) after approval of our product. We cannot be sure, however, that, iseganan HCl oral solution will qualify for marketing exclusivity. Among other reasons, until recently, antibiotics were not able to obtain such exclusivity, and the new law making antibiotics eligible for exclusivity includes a transition provision that could lead the FDA to conclude that certain of our antibiotic products are not eligible for marketing exclusivity. Additionally, even if a product is approved and granted exclusivity, that 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 a new regulatory system in the European Union, 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.

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 guarantee that any of our products will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

Employees

As of December 31, 2001, we had 31 full-time employees, 23 of whom were engaged in product development and research activities and eight of whom were engaged in general and administrative activities. Many of our current employees hold post-graduate degrees, including three with M.D. and six with Ph.D. degrees. Our employees are not represented by a collective bargaining agreement.

RISKS RELATED TO OUR BUSINESS

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

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

We have never generated revenue from product sales and have incurred significant net losses in each year since inception. We incurred net losses of $23.1 million in 1999, $45.6 million in 2000 and $67.4 million for the year ended December 31, 2001. As of December 31, 2001, our accumulated deficit was approximately $165.8 million. We expect to continue to incur substantial additional losses for the foreseeable future primarily as a result of increases in clinical trial costs, and we may never become profitable. In addition, we expect to incur further costs to commercialize iseganan HCl oral solution, previously referred to as Protegrin IB-367 Rinse. To date, we have financed our operations primarily through the private sale of equity securities, funds received from a terminated collaboration agreement, the proceeds of equipment financing arrangements and our initial public offering of common stock in March 2000. We will receive product revenues only if we complete clinical trials with respect to one or more products, receive regulatory approvals and successfully commercialize such products.

We may be forced to raise capital sooner than currently anticipated 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 believe that our cash balances and cash equivalents net of restricted cash of approximately $28.0 million, at December 31, 2001, in addition to approximately $17.5 million received in January and February 2002 will be sufficient to meet our operating and capital requirements for at least the next 12 months. However, we have based this estimate on assumptions that may prove to be wrong. For the years ended December 31, 2001, 2000 and 1999, net cash used for operating activities was $53.6 million, $50.4 million, and $25.1 million, respectively. In May 2001, we implemented a restructuring plan in order to conserve our cash reserves. Our future liquidity and capital requirements will depend on many factors, including the timing, delay, cost, extent and results of clinical trials, payments associated with

manufacturing scale-up, the costs and timing of regulatory approvals, the costs of establishing sales, marketing and distribution capabilities and costs associated with researching drug candidates, securing in-licensing opportunities and conducting pre-clinical research.

We believe that additional financing will be required in the future to fund our operations. 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 some or all of our product development efforts or be forced to cease operations. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Collaborative arrangements may require us to relinquish our rights to certain of our technologies, drug candidates or marketing territories.

We depend on the outcome of our clinical trials and if they are unsuccessful, we may not be able to commercialize our products and generate product revenue.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through preclinical research and clinical trials that our drug candidates are safe and effective for use in humans. If we are unable to demonstrate the safety and efficacy of iseganan HCl oral solution in phase III clinical trials, we may be unable to obtain regulatory approval from the FDA or to commercialize the drug candidate, and we will be unable to generate product revenue from that candidate for that indication. Clinical trials are expensive and time-consuming to conduct, and the timing and outcome of these trials is uncertain. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. A number of companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

In addition, if we have delays in clinical trials or the FDA approval process or if we need to perform more or larger clinical trials, our product development costs will increase and our ability to generate product revenue will be delayed. For example, in January 2001, we discovered that a contract vendor dispensed placebo and active drug in error to approximately one-third of the patients in our phase III clinical trial for iseganan HCl oral solution. As a result, we are conducting an additional phase III clinical trial, which has delayed our FDA approval process.

Our commencement and completion of clinical trials may be delayed by many factors, including:

- slower than expected rate of patient recruitment;
- inability to adequately obtain data about patients after their treatment;
- additional regulatory requests;
- inability to manufacture sufficient quantities of materials used for clinical trials; or
- unforeseen safety issues.

If the delays are substantial, the increase in product development expenses could cause our losses to increase and diminish the commercial potential for our products candidates.

If our collaborative partners assisting in our clinical trials fail to appropriately manage our clinical trials, the trials could be delayed or could fail.

We rely on contract research organizations, including PharmaNet, Inc., to assist us in managing and monitoring our clinical trials. The FDA may inspect some of our clinical investigational sites, our collaborative partner's records and our facility and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that the trials were not in compliance with good clinical practices, we may be required to repeat the clinical trials. If our contract

research organizations fail to perform under our agreements with them, we may face delays in completing our clinical trials or failure of our clinical program.

In January 2001, an error on the part of one of our subcontractors that was managing the drug dispensing, led to a dispensing error in both of our phase III clinical trials of iseganan HCl oral solution. We believe that as a result of this error, the clinical trial failed to demonstrate the efficacy of iseganan HCl oral solution for the reduction in incidence and severity of oral mucositis in patients receiving chemotherapy at the levels of statistical significance typically required by the FDA. As a result, we are conducting an additional phase III clinical trial and our timing for the FDA approval process has been delayed.

If our single-source third party manufacturers fail to produce clinical or commercial quantities of our drug candidates, we may not have sufficient quantities of our drug candidates to meet demand.

We rely on a single source of contract manufacturers, PolyPeptide Laboratories A/S and Patheon, Inc., to manufacture the bulk drug substance and formulated drug product on a commercial scale, respectively. While we maintain a limited inventory of our drug, we depend on contract manufacturers to produce our products for use in our clinical trials. Our contract manufacturers have limited experience in manufacturing iseganan HCl in quantities sufficient for commercialization and may have difficulty in scaling up production. If our contract manufacturers are unable or fail to produce the required quantities of iseganan HCl 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.

Our third-party manufacturers and we are required to register manufacturing facilities with the FDA and foreign regulatory authorities. If these facilities become unavailable for any reason or if our contract manufacturers fail to comply with the FDA's current good manufacturing practices or if our contract manufacturers terminate their agreements with us, we would have to find an alternative source for manufacturing our drug candidates. There are, on a worldwide basis, a limited number of contract facilities in which our drug candidates can be produced according to current good manufacturing practice regulations. In addition, the manufacturing processes for iseganan HCl are extremely complex and proprietary. If we are unable to continue having iseganan manufactured by our current contract manufacturers, we do not know if we could engage another contract manufacturer when needed or on acceptable terms, if at all.

If we fail to obtain FDA approvals for our products, we will be unable to commercialize our drug candidates.

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

delay or prevent the successful commercialization of our drug candidate;

diminish our competitive advantage; and

defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive preclinical and clinical data and supporting information must be submitted to the FDA for each indication to establish safety and effectiveness in order to secure FDA approval. We have limited experience in obtaining such approvals, and cannot be certain when, if ever, we will receive these regulatory approvals.

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

Development and commercialization of competitive products could reduce or prevent sales of our products and reduce revenue.

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 our drug candidate. If we are unable to compete successfully with our drug candidate, physicians may not recommend and patients may not buy our drug, which would cause our product revenue to decline.

There are several drugs commercially available or under development that might compete with iseganan HCl oral solution. There is one approved device, Radiacare, and several drugs in early stage clinical trials for prevention or treatment of oral mucositis. These include one antimicrobial agent, triclosan, and two growth factors, keratinocyte growth factor and keratinocyte growth factor-2. GM-CSF is also under development in radiotherapy-induced oral mucositis. The companies sponsoring these trials have successfully commercialized products in the past. In addition, there may be products under development of which we are unaware for the prevention or the treatment of oral mucositis.

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

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

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

obtain patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

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

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

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

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

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. Although we are not currently a party to any lawsuits, third parties may assert infringement or other intellectual property claims against us. We may have to pay substantial damages, including treble damages, for past infringement if it is ultimately determined that our products infringe a third party's proprietary rights. The defense and prosecution of intellectual property suits, U.S. Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the U.S and internationally are costly and time-consuming to pursue and their outcome is uncertain. If we become involved in any of these proceedings, we will incur substantial expense and the efforts of our technical and management personnel will be significantly diverted. An adverse determination may result in the invalidation of our patents, subject us to significant liabilities or require us to seek licenses that may not be available from third parties on satisfactory terms, or at all. Our stock price could decline based on any public announcements related to litigation or interference proceedings initiated or threatened against us.

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

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

demonstration of clinical efficacy and safety;

cost-effectiveness;

convenience and ease of administration;

potential advantage over alternative treatment methods; and

marketing and distribution support.

Physicians will not recommend our products until such time as clinical data or other factors demonstrate the safety and efficacy of our drugs as compared to other treatments. In practice,

competitors may be more effective in marketing their drugs. Even if the clinical safety and efficacy of our product is established, physicians may elect not to recommend its use. For example, physicians may be reluctant to prescribe widespread use of our products because of concern about developing bacterial strains that are resistant to our drugs, or because of the cost of our drug.

If we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to perform these services, we will be unable to commercialize our drug products.

We do not currently have marketing, sales or distribution capabilities. Initially we intend to establish a direct marketing and sales force in the U.S. and Canada. We intend to enter into arrangements with third parties to market and sell most of our products outside of the U.S. and Canada. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, we would be unable to commercialize these drug products. We must develop a marketing and sales force with technical expertise and distribution capabilities to market any of our products directly. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will be lower than if we marketed the products directly.

The failure to recruit and retain key personnel may delay our ability to complete, develop and commercialize iseganan HCl oral solution.

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, we may be delayed in our product development and commercialization efforts. We do not maintain key person life insurance and do not have employment agreements with our management and technical staff. In order to pursue product development, marketing and commercialization plans, we will need to hire additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, marketing and finance. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

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

Directors, executive officers, principal stockholders and affiliated entities own a portion of our capital stock and may be able to exert significant control over our activities.

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 40% of our outstanding common stock. These stockholders, if acting together, may be able to significantly influence any matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions.

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

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

These provisions:

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

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

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

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

limit who may call stockholder meetings.

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

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

The market prices for securities of biotechnology companies in general have been highly volatile and our stock may be subject to volatility. 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 of technological innovations or new commercial products by our competitors or us;

developments concerning proprietary rights;

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

regulatory developments in the U.S. or foreign countries;

litigation;

significant short selling in our common stock;

economic and other external factors; and

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

Item 2. Properties

We are currently leasing two adjacent facilities on Terra Bella Avenue, in Mountain View, California. These facilities provide approximately 16,000 and 18,000 square feet, respectively. The leases on these facilities, containing laboratory and office space, expire in July 2004. In October 2001, we sublet one of these facilities on Terra Bella Avenue. This sublease expires in December 2002.

In addition, we leased additional facilities in May 2000 and May 2001. These two facilities, containing laboratory and office space, on Stierlin Court in Mountain View, California, provide approximately 58,000 and 66,000 square feet, respectively. These leases will expire in 2011. The first of these two facilities was taken back by the landlord in October 2001 as part of our restructuring, with no continuing obligation to us. The second building is currently being marketed for sublease.

Item 3. Legal Proceedings

We are currently not a party to any legal proceedings. The previously disclosed arbitration between IntraBiotics and a contract vendor relating to a dispensing error in the iseganan HCl oral solution

phase III clinical trial was resolved amicably on January 21, 2002, and we received a cash payment of $3.6 million.

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

Not applicable.

Part II

Item 5. Market for the 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. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

	High	Low
1st Quarter ended March 31, 2000	$ 15.75	$ 15.00
2nd Quarter ended June 30, 2000	$ 26.69	$ 6.63
3rd Quarter ended September 30, 2000	$ 31.88	$ 14.50
4th Quarter ended December 31, 2000	$ 16.50	$ 9.56
1st Quarter ended March 31, 2001	$ 10.25	$ 2.06
2nd Quarter ended June 30, 2001	$ 3.37	$ 1.25
3rd Quarter ended September 30, 2001	$ 1.82	$ 1.00
4th Quarter ended December 31, 2001	$ 2.73	$ 1.23

As of February 4, 2002, there were 172 holders of record of common stock. Certain record holders are represented by brokers and other institutions on behalf of stockholders. We estimate that included within the holders of record are approximately 2,500 beneficial owners of common stock. As of February 4, 2002, the closing price for our common stock was $3.40.

USE OF PROCEEDS FROM REGISTERED SECURITIES

The Company's Registration Statement on Form S-1 filed pursuant to the Securities Act of 1933 (No. 333-95461) was declared effective on March 27, 2000. The Company incurred related offering costs of approximately $9.2 million during the year ended December 31, 2000, of which $7.9 million represented underwriting discounts and commissions. All initial public offering costs were direct or indirect payments to others. The net offering proceeds to the Company after all expenses were approximately $103.3 million.

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. Furthermore, in August 2001, we entered into a term loan agreement with Silicon Valley Bank that includes a restriction on paying dividends.

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,				
	2001	2000	1999	1998	1997
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Revenues:					
Contract revenue	$	$	$ 7,863	$ 5,357	$ 3,507
License fee and milestone revenue				1,000	2,000
Total revenues			7,863	6,357	5,507

	Year ended December 31,				
Operating expenses:					
Research and development	38,034	39,152	26,102	21,997	8,103
General and administrative	9,202	11,560	6,082	2,533	1,960
Restructuring and other charges	21,956				
Total operating expenses	69,192	50,712	32,184	24,530	10,063
Operating loss	(69,192)	(50,712)	(24,321)	(18,173)	(4,556)
Interest income	2,843	5,699	1,372	963	575
Interest expense	(1,110)	(563)	(166)	(172)	(94)
Other income	93				
Net loss	$ (67,366)	$ (45,576)	$ (23,115)	$ (17,382)	$ (4,075)
Basic and diluted net loss per share	$ (2.29)	$ (2.02)	$ (21.62)	$ (20.89)	$ (6.39)
Shares used to compute basic and diluted net loss per share	29,432	22,512	1,069	832	638
Pro forma basic and diluted net loss per share (unaudited)		$ (1.67)	$ (1.27)		
Shares used to compute pro forma basic and diluted net loss per share (unaudited)		27,231	18,172		

	As of December 31				
	2001	2000	1999	1998	1997
	(In thousands)				
Cash, cash equivalents, restricted cash deposits and short-term investments	$ 35,470	$ 86,065	$ 31,429	$ 29,869	$ 20,779
Working capital	29,629	86,142	25,743	21,279	18,851
Total assets	42,465	108,288	35,958	32,099	24,987
Long term obligations, less current portion	5,000	8,309	1,725	867	1,036
Accumulated deficit	(165,816)	(98,450)	(52,874)	(29,759)	(12,377)
Total stockholders' equity	26,212	89,955	27,914	22,498	19,765

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 "Risks Related To Our Business" and elsewhere in this Form 10-K. 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. develops and intends to commercialize new antibacterial and antifungal drugs for the prevention or treatment of serious infectious diseases. We have initiated expanded human clinical trials to test for efficacy and safety, known as phase III trials, for iseganan HCl oral solution, previously referred to as Protegrin IB-367 Rinse, for the reduction in the incidence and severity of ulcerative oral mucositis, a side effect of anti-cancer therapies. In May 2001, we presented the results on one phase III trial for patients undergoing aggressive chemotherapy. Due to a contractor error in dispensing study medication, nearly one third of the study patients received a mixture of drug and placebo, which we believe resulted in an underestimate of the impact of iseganan HCl oral solution. We believe that as a result of this error, the study demonstrated insufficient statistical significance on its primary endpoint and we are repeating the trial. As a consequence, we restructured our business in May 2001 to maximize the likelihood of success in registering this potential product. The restructuring had the following main elements:

A significant reduction in our workforce of approximately 90 positions in research and administrations, or 71% of our workforce of 127 employees at May 31, 2001;

The termination of several collaboration agreements, including agreements with Diversa Corporation and Albany Molecular Research, Inc., and a restructuring of our ramoplanin license agreement with Biosearch Italia S.p.A.;

Downsizing and termination of lease obligations with a reduction of occupied space from 158,000 square feet in four buildings to 16,000 square feet in one building, and a reduction in leased space from 158,000 square feet in four buildings to approximately 100,000 square feet in three buildings. We sublet 18,000 and intend to sublease about 66,000 of the remaining 100,000 square feet;

Write down of assets; and

Restructuring of our bank debt.

During the second half of 2001, we completed the majority of this restructuring effort and focused on iseganan HCl phase III trials for oral mucositis. We have completed enrollment of patients in a phase III trial for patients undergoing radiotherapy for head and neck cancer and expect to announce the results of that trial in the second quarter of 2002. We are currently enrolling patients in the repeat phase III trial for patients undergoing aggressive chemotherapy and assuming that enrollment in the trial progresses according to plan, we expect to announce results of that trial in the fourth quarter of 2002.

We have also completed two earlier stage trials for other indications of iseganan HCl to prevent pneumonia in patients requiring breathing assistance from a mechanical ventilator and to treat respiratory infections in patients with cystic fibrosis. The data from each of these trials support the advancement to the next stage of human clinical testing for each of these two products, however, in order to focus on iseganan HCl oral solution for oral mucositis, we continue to delay the advancement of these programs pending additional financial resources.

Since commencing operations in 1994, we have not generated any revenue from product sales, and we have funded our operations primarily through the private sale of equity securities, funds received from a terminated collaboration agreement, the proceeds of equipment financing arrangements and our initial public offering of common stock in March 2000. We have incurred a loss in each year since inception, and we expect to incur substantial losses for at least the next several years. We expect that

losses may fluctuate, and that such fluctuations may be substantial. At December 31, 2001 our accumulated deficit was approximately $165.8 million. We will need to raise additional funds in the future to continue our operations.

Results of Operations

Comparison of Years Ended December 31, 2001 and 2000

Revenues

IntraBiotics had no product sales or contract revenue for the year ended December 31, 2001 and 2000. We do not anticipate any product revenue in the near future.

Operating Expenses

Research and Development

Research and development expenses decreased to $38.0 million for the year ended December 31, 2001 compared to $39.2 million for the same period in 2000. As we have advanced our products into later stage clinical trials, our related expenses generally have increased. The decrease in clinical trial costs in 2001 is a result of a significant reduction in our research expenditures in an effort to focus our resources on our iseganan HCl development program, especially following the restructuring implemented in May 2001. In the second half of 2001, research and development expenses were $12.5 million (relating to the iseganan HCl for the prevention of oral mucositis program) compared to $25.5 million in the first half of 2001. These costs include salaries for research and development personnel, contractor and clinical trial site fees, building and equipment costs, supplies, administrative expenses and allocations of corporate costs. In 2001, approximately 50% of research and development expenses were for various contractor and clinical trial site fees. Included in research and development expenses are non-cash stock compensation charges of $1.5 million and $1.8 million in 2001 and 2000, respectively.

We are developing iseganan HCl oral solution for the reduction in incidence and severity of ulcerative oral mucositis as its first indication. We announced the results of a phase III clinical trial in May 2001. A second phase III clinical trial evaluating the safety and efficacy of iseganan HCl oral solution for the prevention of oral mucositis in patients receiving radiotherapy for cancer of the head and neck completed enrollment in December 2001. We anticipate the announcement of results from the second phase III oral mucositis trial in cancer patients receiving radiotherapy for head and neck cancer in the second quarter of 2002. We have initiated enrollment in a third phase III clinical trial evaluating the safety and efficacy of iseganan HCl oral solution for the reduction in incidence and severity of ulcerative oral mucositis in patients receiving aggressive chemotherapy. We expect to announce the results from this trial in the fourth quarter of 2002.

If our phase III trials are successful, we intend to submit the results to the FDA to support regulatory approval of the product. However, we cannot be certain that iseganan HCl oral solution will prove to be safe or effective in reducing the incidence and severity of ulcerative oral mucositis in cancer patients receiving either chemotherapy and/or radiotherapy, will receive regulatory approvals, or will be successfully commercialized.

We have also completed phase I/IIa clinical trials evaluating the potential of iseganan HCl oral rinse for the prevention of ventilator-associated pneumonia and phase I trials evaluating the potential of iseganan HCl inhalation for the treatment of respiratory infections in cystic fibrosis patients. Significant additional research and development expenses will be required to conduct further clinical investigations for these programs. These programs are currently on hold pending the availability of additional resources.

During 2001, we commenced a research and technology licensing agreement with New Chemical Entities, Inc. (now Albany Molecular Research, Inc.(AMRI)) and with Diversa Corporation. In conjunction with the May 2001 restructuring, we terminated our restructured research and licensing collaborations with AMRI, Biosearch Italia, S.p.A., Cetek Corporation and Diversa Corporation. The total costs incurred in 2001 in conjunction with these collaborations was $4.5 million of which, approximately $1.75 million was charged to research and development and $2.75 was charged to restructuring. In addition, we issued 700,000 warrants to Diversa Corporation valued at $560,000 which was also charged to restructuring.

Research and development expenses may increase in the future if we are able to advance new and existing product candidates into later stages of clinical development. The commencement and completion of our clinical trials may be delayed 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 or unforeseen safety issues. As a result, our research and development expenses may also fluctuate. Our future capital requirements will depend on many factors, including the timing, cost, extent and results of clinical trials, payments associated with manufacturing scale-up, the costs and timing of regulatory approvals, costs associated with researching drug candidates, securing in-licensing opportunities and conducting pre-clinical research.

General and Administrative

General and administrative expenses decreased to $9.2 million for the year ended December 31, 2001, compared to $11.6 million for the same period in 2000. The decrease was primarily attributed to the restructuring in May 2001 with a large percentage attributable to costs related to headcount. In the second half of 2001, general and administrative expenses were $2.3 million compared to $6.9 million in the first half of 2001. These costs include salaries for administrative personnel, outside contractors, legal fees, accounting fees, building and equipment costs, supplies and general administrative expenses. Included in general and administrative expenses are non-cash stock compensation charges of $1.4 million and $1.4 million in 2001 and 2000, respectively.

During November 2001, the Company entered into an agreement to modify the vesting of one officer's unvested stock options so that a portion of the officer's unvested options would vest upon his termination in January 2002, and the remaining options would continue to vest over a consulting period. In connection with this modification, compensation expense of $413,000, including the amortization of $408,000 of previously recorded deferred stock compensation associated with the awards, was recorded in general and administrative expense in the year ended December 31, 2001. We expect to continue to record consulting expense through July 31, 2003 related to the periodic revaluation of these stock options as they vest in accordance with EITF 96-18. In addition, in 2002 and 2003, we will amortize the remaining deferred stock compensation originally recorded in connection with these options, of approximately $169,000.

Stock Compensation

In connection with the grant of certain stock options to employees, we recorded no deferred compensation for the year ended December 31, 2001, compared to $722,000 for the same period in 2000. Deferred compensation represents the difference between the deemed fair value of the common stock for financial reporting purposes and the exercise price of these options at the date of grant. In connection with the termination of various employees, several stock options were cancelled, and therefore we recorded a reduction of deferred compensation of $2.9 million for the year ended December 31, 2001. Deferred compensation is presented as a reduction of stockholders' equity and is amortized over the vesting period of the applicable options.

We recorded $2.9 million of stock compensation expense for the year ended December 31, 2001, compared to $3.2 million of stock compensation expense for the same period in 2000. The research and development stock compensation expense for the year ended December 31, 2001 was $1.5 million, compared to $1.8 million for the same period in 2000. The general and administrative stock compensation expense for the year ended December 31, 2001 was $1.4 million, compared to $1.4 million for the same period in 2000. The decrease in stock compensation expense for the year ended December 31, 2001 compared to the same period in 2000 is due to the cancellation of stock options as a result of the termination of employees, offset in part by the amortization of deferred compensation on stock options and expense associated with awards of common shares and restricted stock rights during 2001.

Restructuring and other charges

As a result of the restructuring plan, we recorded restructuring charges of $10,121,000 and asset write down charges of $11,835,000 for a total of $21,956,000 in the second quarter of 2001. The $10,121,000 restructuring charge was for costs incurred in work force reduction of $2,911,000, the termination of collaboration agreements of $4,060,000 and facilities consolidation $3,150,000.

For the year ended December 31, 2001, we paid $8,877,000 of the restructuring charges in cash, primarily in severance costs to approximately 90 employees, rent payments on vacant buildings, and termination fees on collaboration agreements. We also expensed $560,000 for warrants issued as part of a collaboration agreement termination.

The strategic restructuring included a reduction in force of approximately 90 positions in research and administration, or 71% of our previous workforce of 127 employees. All of the terminated employees have left as of December 31, 2001. The estimated costs for terminated employees were reduced by $236,000 in the fourth quarter of 2001, as no remaining severance amounts are payable. As of December 31, 2001, we had 31 full-time employees largely focusing on drug development of iseganan HCl, including a small number of support staff.

The restructuring also includes the termination of certain research and development collaborations and the consolidation of operations into one existing facility in Mountain View, California. The estimated costs associated with terminated collaboration agreements were increased by $483,000 in the fourth quarter of 2001. There are no remaining amounts payable for such agreements and costs.

We vacated three facilities in Mountain View, California comprising 142,000 square feet and continue to occupy one facility with 16,000 square feet. One of the vacated facilities has been sub-leased during 2001, and another was taken back by the landlord, with no continuing obligation to us. In the fourth quarter of 2001, an adjustment was made to increase restructuring charges associated with facilities consolidation by $1,930,000 for additional costs related to the one remaining vacant facility. At December 31, 2001, $2,861,000 remains in accrued

restructuring charges related to this facility, representing an additional one year of rent and expenses associated with the lease on the facility, based on our best estimate of the period for which the facility will remain vacant prior to sub-lease. We expect to incur the remaining restructuring obligation over the next year.

Additionally, we wrote down to estimated fair value $11,835,000 of leasehold improvements, laboratory equipment, computers and other assets that are no longer being used as part of the restructuring plan. 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, and as a result recognized a gain of $2,177,000 in the fourth quarter of 2001 in restructuring and other charges in the statement of operations.

Interest Income and Expense

Interest income decreased to $2.8 million for the year ended December 31, 2001 from $5.7 million for the same period in 2000. The decrease in interest income resulted from the decrease in average cash and investment balances.

Interest expense increased to $1.1 million for the year ended December 31, 2001 from $563,000 for the same period in 2000. The increase was primarily attributed to an increase in the average debt outstanding in 2001 compared to 2000. See Liquidity and Capital Resources below for a description of our financing obligations at December 31, 2001.

Net Loss

For the year ended December 31, 2001 we incurred a net loss of $67.4 million compared to a net loss of $45.6 million in 2000. This increase was primarily due to the restructuring and other charges of $22.0 million incurred on May 31, 2001. Excluding these charges, the net loss in 2001 was $45.4 million. The net loss in the second half of 2001 was $14.3 million compared to $31.1 million in the first half of 2001, excluding the $22.0 million restructuring and other charges.

Comparison of Years Ended December 31, 2000 and 1999

Revenues

IntraBiotics had no product sales or contract revenue for the year ended December 31, 2000 compared to $7.9 million of contract revenue for the same period in 1999. Revenue in 1999 was generated under a prior agreement with Pharmacia and Upjohn S.p.A., which terminated in July 1999. We will not recognize any additional revenue under this agreement. We do not anticipate any product revenue in the near future.

Operating Expenses

Research and Development

Research and development expenses increased to $39.2 million for the year ended December 31, 2000 compared to $26.1 million for the same period in 1999. As we advanced our products into later stage clinical trials, our related expenses increased significantly. The increase was primarily attributable to higher personnel and payroll expenses, development milestone fees, clinical trial activity, consulting expenses and deferred compensation amortization expense.

We added two collaborative research and license agreements in 2000. We entered into a collaborative research and license agreement in January 2000, with NAEJA Pharmaceutical Inc. to perform research activities for initial non-clinical and pre-clinical research of products including manufacturing scale-up work. As of December 31, 2000, total payments of $1.5 million were made and expensed under this agreement. In November 2000, the agreement was terminated effective May 2001. Also in 2000, we continued our collaborative research and license agreement with BioSource Pharm, Inc. to conduct fermentation, chemical design, synthesis, and/or modification activities to IB-880 and IB-863 compounds. In May 2000, we extended the agreement and increased the scope of research for which we increased our quarterly payment to $125,000. As a result, we made and expensed a total of $450,000 in payments to BioSource in 2000 compared to $225,000 in 1999.

We had agreements with two companies to provide drug substance for our clinical trials in 2000. We made and expensed $2.5 million in milestone payments to Biosearch Italia S.p.A for the commencement of phase III clinical studies for ramoplanin oral powder in 2000 compared to none in 1999. We also incurred and expensed milestone payments of $120,000 in 2000 and $760,000 in 1999 to PolyPeptide Laboratories A/S to develop a manufacturing process for our drug substance iseganan HCl.

PolyPeptide plans to manufacture the majority of our bulk product requirements for development and commercialization of iseganan HCl.

General and Administrative

General and administrative expenses increased to $11.6 million for the year ended December 31, 2000, compared to $6.1 million for the same period in 1999. The increase was primarily attributed to increased personnel and payroll expenses, consulting, legal, professional, travel and other expenses associated with increased business development activities, cost of being a public company and deferred compensation amortization expense.

Stock Compensation

In connection with the grant of certain stock options to employees prior to the initial public offering, we recorded deferred compensation of $722,000 for the year ended December 31, 2000, compared to $12.5 million for the same period in 1999. Deferred compensation represents the difference between the deemed fair value of the common stock for financial reporting purposes and the exercise price of these options at the date of grant. Deferred compensation is presented as a reduction of stockholders' equity and is amortized over the vesting period of the applicable options.

We expensed $3.2 million of deferred compensation for the year ended December 31, 2000, compared to $981,000 of deferred compensation for the same period in 1999. The research and development deferred compensation amortization expense for the year ended December 31, 2000 was $1.8 million, compared to $648,000 for the same period in 1999. The general and administrative deferred compensation amortization expense for the year ended December 31, 2000 was $1.4 million, compared to $333,000 for the same period in 1999.

Interest Income and Expense

Interest income increased to $5.7 million for the year ended December 31, 2000 from $1.4 million for the same period in 1999. The increase in interest income resulted from the increase in average cash and investment balances primarily due to our prior financing activities.

Interest expense increased to $563,000 for the year ended December 31, 2000 from $166,000 for the same period in 1999. The increase was primarily attributed to additional financing obligations.

Net Loss

The net loss for the year ended December 31, 2000 was $45.6 million compared to a net loss of $23.1 million in 1999. The increase in net loss was due to increased research and development expenses and increased general and administrative expenses.

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, 2001, we had net operating loss carryforwards for federal and state income tax purposes of approximately $152.0 million and $27.0 million, respectively. We also had federal and state research and development tax credits of approximately $2.5 million and $1.7 million, respectively. If not utilized, the net operating losses and credits will expire in the years 2002 through 2021. 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 9 of the Notes to the Financial Statements included in Item 8 of this Form 10-K for further information.

Liquidity and Capital Resources

On February 1, 2002, we sold 5,900,000 shares of common stock in a private placement resulting in net cash proceeds of approximately $13.9 million. In January 2002 we also received cash of $3.6 million in settlement of our arbitration with a contract vendor relating to a drug dispensing error in iseganan HCl oral solution phase III clinical trials. In the initial public offering, which was completed in March 2000 we sold 7,500,000 shares of common stock at a price of $15.00 per share. Net proceeds from the initial public offering were approximately $103.3 million. Prior to our initial public offering, we had financed our operations primarily through private placements of preferred stock and warrants, funds received from our prior collaboration with Pharmacia & Upjohn S.p.A. and the proceeds of equipment financings. As of December 31, 1999, we had raised aggregate net proceeds from the sale of preferred stock and warrants of $79.6 million. Prior to termination of the Pharmacia & Upjohn S.p.A. agreement, we received an aggregate of $21.4 million in cash payments under this agreement, of which $1.7 million of unused development funding was returned to Pharmacia & Upjohn S.p.A. in 2000.

Cash, cash equivalents, restricted cash and short-term investments were $35.5 million at December 31, 2001, compared to $86.1 million at December 31, 2000. On December 31, 2001, the Company had restricted cash of $7.5 million compared to $1.4 million at year end 2000. The $7.5 million of restricted cash consists of three major components as follows:

Certificates of Deposit guaranteeing standby letter of credit for product supplies	$ 3.0
Security Deposits for real estate leases	2.0
Certificate of Deposit supporting our line of credit	2.5
Total restricted cash	$ 7.5

Net of restricted cash, our cash, cash equivalents and short-term investments on December 31, 2001 were $28.0 million compared to $84.7 million and $31.1 million at year end 2000 and 1999, respectively.

Net cash used for operating activities was $53.6 million for the year ended December 31, 2001, $50.4 million for the year ended December 31, 2000 and $25.1 million for the year ended December 31, 1999. The increase from 2000 to 2001 was a result of increased net losses, primarily due to the restructuring plan implemented in May 2001. The increase from 1999 to 2000 was primarily the result of increased net losses, increased prepaid expenses for clinical trials and changes to accrued liabilities, accrued clinical liabilities, amount payable to a contract partner, and deferred revenue.

Net cash provided by (used for) investing activities was $44.7 million for the year ended December 31, 2001, $(42.7) million for the year ended December 31, 2000 and $(15.1) million for the year ended December 31, 1999. The increase in cash provided by investing activities in 2001 from a use of cash in 2000 was primarily due to the maturities of short-term investments used to fund our operations. The increase in cash used for investing activities from 1999 to 2000 was primarily attributable to an increase in the purchases of short-term investments, net of maturities of $20.4 million, and an increase in capital expenditures of $7.2 million.

Net cash provided by (used in) financing activities was $(2.1) million for the year ended December 31, 2001, $113.5 million for the year ended December 31, 2000 and $28.8 million for the year ended December 31, 1999. The cash used in financing activities in 2001 was primarily due to payments on financing obligations partially offset by proceeds from financing obligations. The cash provided by financing activities for the year ended December 31, 2000 was due to the issuance of common stock, including net proceeds of $103.3 million from the initial public offering, and proceeds of $10.8 million from equipment lease financing arrangements, partially offset by payments on these obligations.

In August 2001, we refinanced all existing financing obligations by entering into a new line of credit of $2.5 million and a term loan agreement of $7.5 million with Silicon Valley Bank. The term loan is secured by our assets and requires monthly principal repayments of $150,000. The interest rate on these loans varies depending on the prime rate. At December 31, 2001, the balance drawn on the line of credit was $2.5 million, fully secured by a certificate of deposit. On December 31, 2001, the term loan had an outstanding balance of $6.9 million. These loans include various financial covenants, a performance covenant and various negative covenants, as well as a restriction on paying dividends.

In December 2000, we entered into an equipment financing agreement to finance up to $7.6 million of equipment. The interest rate varied according to U.S. Treasury rates. In December 2000, we completed two draws against this arrangement. The first draw was for $3.8 million with a loan term of 36 months and an average annual interest rate of 9.98%. The second draw was for $945,000 with a term of 48 months and an average annual interest rate of 9.64%. In March 2001, a third draw was completed for $1.2 million with a term of 48 months and an average annual interest rate of 9.64%. The remaining $1.7 million expired on July 31, 2001. In August 2001, these loans were repaid in full.

In March 2000, we also completed two draws against an equipment financing agreement entered into in March 1999. The first draw was for $861,000 with a loan term of 43 months and an average annual interest rate of 10.99%. The second draw was for $222,000 with a loan term of 37 months and an average annual interest rate of 9.98%. In August 2001, these loans were repaid in full.

In August 1999, we entered into a term loan agreement with Silicon Valley Bank for $5,000,000, with an interest rate of 9.55%. The loan agreement had a revolving draw period expiring in August 2000. In August 2000, $5,000,000 was drawn under this financing arrangement. As at December 31, 2001 all obligations under these borrowings were fully paid off through the line of credit and term loan with Silicon Valley Bank mentioned above.

We have an obligation to pay ongoing severance payments to our former Chief Executive Officer during 2002 and 2003 totaling approximately $550,000.

We expect to continue to incur substantial operating losses. We believe that existing capital resources and interest income will be sufficient to fund our operations for at least the next 12 months. 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 research and development activities.

Until we can generate sufficient cash from our operations, which we do not expect for the foreseeable future, we expect to finance future cash needs through private and public financings, including equity financings. We cannot be certain that additional funding will be available when needed or on favorable terms. If funding is not available, we may need to delay or curtail our development and commercialization activities to a significant extent.

Critical Accounting Policies

Our discussion and analysis of its financial condition and results of operations is based upon its financial statements, which have been prepared in accordance with accounting principles generally

accepted in the U.S. 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 on-going basis, we evaluate these estimates, including those related to clinical trial accruals, restructuring 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 may differ from these estimates under different assumptions or conditions.

We review long-lived assets, including leasehold improvements and property and equipment for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Long lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of the carrying amount or fair value less the cost to sell.

Recent Accounting Pronouncements

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 141, "Business Combinations", or "SFAS 141", and Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets", or "SFAS 142". SFAS 141 requires the use of the purchase method for all business combinations initiated after June 30, 2001, and provides new criteria for determining whether an acquired intangible asset should be recognized separately from goodwill. SFAS 142 eliminates the amortization of goodwill and replaces it with an impairment only model. Upon adoption, goodwill related to acquisitions completed before the date of adoption would be subject to the new provisions of SFAS 141; amortization of any remaining book value of goodwill would cease and the new impairment-only approach would apply. The impairment-only approach does not apply to the treatment of other intangible assets. The provisions of SFAS 141 and SFAS 142 will be effective for fiscal years beginning after December 15, 2001. We do not believe adoption of these statements will have a material impact on our results of operations, financial position, or cash flows.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" or "SFAS 144" that is applicable to financial statements issued for fiscal years beginning after December 15, 2001, with transition provisions for certain matters. The FASB's new rules on asset impairment supersede FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of", and provides a single accounting model for long-lived assets to be disposed of. We do not believe adoption of this statement will have a material impact on our results of operations, financial position, or cash flows.

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. We own financial instruments that are sensitive to market risks as part of our investment portfolio. To minimize this risk, we maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including money market funds and commercial paper. The average duration of all our investments in fiscal 2001 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, 2001 and 2000. 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, 2001 and 2000 (in thousands).

	Total Cost	Fair Market Value	Average Interest Rate
Available for sale securities:			
December 31, 2001	$	$	
December 31, 2000	$ 45,525	$ 45,711	7.10%

All short-term investments held by us as of December 31, 2000 matured in 2001.

Item 8. Financial Statements and Supplementary Data

IntraBiotics Pharmaceuticals, Inc.

Index To Financial Statements

Report of Ernst & Young LLP, Independent Auditors

Balance Sheets As of December 31, 2001 and 2000

Statements of Operations for the Three Years Ended December 31, 2001

Statement of Stockholders' Equity for the Three Years Ended December 31, 2001

Statements of Cash Flows for the Three Years Ended December 31, 2001

Notes to Financial Statements

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, 2001 and 2000, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. 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, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Palo Alto, California
February 1, 2002

/s/ Ernst & Young LLP

INTRABIOTICS PHARMACEUTICALS, INC.

BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2001	**2000**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,982	$ 38,983
Restricted cash deposits	7,488	1,371
Short-term investments		45,711
Other current assets, primarily prepayments and deposits	5,412	10,101

	December 31,	
Total current assets	40,882	96,166
Property and equipment, net	1,540	12,056
Other assets	43	66
Total assets	$ 42,465	$ 108,288
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 339	$ 1,680
Accrued clinical costs	1,663	3,236
Accrued employee liabilities	579	625
Accrued restructuring charges	2,861	
Deferred rent	618	234
Other accrued liabilities	818	620
Current financing obligations	4,375	3,629
Total current liabilities	11,253	10,024
Long-term financing obligations	5,000	8,309
Stockholders' equity		
Preferred stock, $0.001 par value:		
5,000,000 convertible shares authorized at December 31, 2001 and 2000; no shares outstanding at December 31, 2001 and 2000		
Common stock, $0.001 par value:		
50,000,000 shares authorized at December 31, 2001 and 2000; 29,798,203 and 29,196,240 shares issued and outstanding at December 31, 2001 and 2000, respectively	30	29
Additional paid-in capital	196,575	198,388
Deferred stock compensation	(4,577)	(10,198)
Accumulated other comprehensive income (loss)		186
Accumulated deficit	(165,816)	(98,450)
Total stockholders' equity	26,212	89,955
Total liabilities and stockholders' equity	$ 42,465	$ 108,288

See accompanying notes.

INTRABIOTICS PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year ended December 31,		
	2001	**2000**	**1999**

	Year ended December 31,		
Revenues:			
Contract revenue	$	$	$ 7,863
Total revenues			7,863
Operating expenses:			
Research and development	38,034	39,152	26,102
General and administrative	9,202	11,560	6,082
Restructuring and other charges	21,956		
Total operating expenses	69,192	50,712	32,184
Operating loss	(69,192)	(50,712)	(24,321)
Interest income	2,843	5,699	1,372
Interest expense	(1,110)	(563)	(166)
Other income	93		
Net loss	$ (67,366)	$ (45,576)	$ (23,115)
Basic and diluted net loss per share	$ (2.29)	$ (2.02)	$ (21.62)
Shares used to compute basic and diluted net loss per share	29,432	22,512	1,069
Pro forma basic and diluted net loss per share (unaudited)		$ (1.67)	$ (1.27)
Shares used to compute pro forma basic and diluted net loss per share (unaudited)		27,231	18,172

See accompanying notes.

INTRABIOTICS PHARMACEUTICALS, INC.

STATEMENT OF STOCKHOLDERS' EQUITY

(In thousands)

	Convertible Preferred Stock	Common Stock	Additional Paid-In Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 1998	$ 52,152	$ 1	$ 1,249	$ (1,145)	$	$ (29,759)	$ 22,498
Issuance of 338 shares of common stock upon exercise of options for cash			93				93
Issuance of 846 shares of Series G convertible preferred stock for cash	2,580						2,580
	24,877						24,877

	Convertible Preferred Stock	Common Stock	Additional Paid-In Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Issuance of 6,250 shares of Series H convertible preferred stock and warrants to purchase 1,250 shares of Series H convertible preferred stock for cash (net of issuance costs of $123)							
Deferred stock compensation			12,486	(12,486)			
Amortization of deferred stock compensation				981			981
Net loss and comprehensive loss						(23,115)	(23,115)
Balances at December 31, 1999	79,609	1	13,828	(12,650)		(52,874)	27,914
Conversion of preferred stock to 19,742 shares of common stock at the initial public offering	(79,609)	20	79,589				
Initial public offering of 7,500 shares of common stock for cash (net of issuance costs of $9,221)		7	103,272				103,279
Issuance of 532 shares of common stock upon exercise of options for cash		1	549				550
Issuance of 34 shares of common stock upon net exercise of warrants							
Issuance of 49 shares of common stock for the employee stock purchase plan for cash			403				403
Issuance of warrants to purchase 10 shares of common stock			25				25
Deferred stock compensation			722	(722)			
Amortization of deferred stock compensation				3,174			3,174
Comprehensive loss:							
Net loss						(45,576)	(45,576)
Unrealized gain on securities					186		186
Comprehensive loss							(45,390)
Balances at December 31, 2000		29	198,388	(10,198)	186	(98,450)	89,955
Issuance of 543 shares of common stock upon exercise of options for cash		1	434				435
Stock compensation for consultant services			5				5
Issuance of 30 shares of common stock for the employee stock purchase plan for cash			36				36
Issuance of warrants to purchase 700 shares of common stock			560				560
Issuance of 29 shares of common stock for employee services			39				39
Amortization of deferred stock compensation				2,734			2,734
Cancellation of stock options			(2,887)	2,887			
Comprehensive loss:							

	Convertible Preferred Stock	Common Stock	Additional Paid-In Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Net loss						(67,366)	(67,366)
Unrealized gain on securities					(186)		(186)
Comprehensive loss			&n				