SHEFFIELD PHARMACEUTICALS INC
Form 10-K405
March 29, 2002

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 (NO FEE REQUIRED)

Commission file number 1-12584

SHEFFIELD PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its Charter)

DELAWARE	13-3808303
(State of Incorporation)	(IRS Employee Identification Number)

14528 SOUTH OUTER FORTY ROAD STE 205 ST. LOUIS, MISSOURI	63017	(314) 579-9899
(Address of principal executive offices)	(Zip Code)	(Registrant's telephone, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Class	Name of each exchange on which registered
Common Stock. $.01 par value	American Stock Exchange

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

None

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 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. [X]Yes [ ] No

Indicate by check mark if disclosure of delinquent filers to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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 aggregate market value at March 25, 2002 of the voting stock of the registrant held by non-affiliates (based upon the closing price of $2.27 per share of such stock on the American Stock Exchange on such date) was approximately $48,072,000. Solely for the purposes of this calculation, shares held by the registrant's directors and executive officers and beneficial owners of 10% or more of the Company's Common Stock of the registrant have been excluded. Such exclusion should not be deemed a determination or an admission by the registrant that such persons are, in fact, affiliates of the registrant.

Indicate the number of shares outstanding of each of the registrant's classes of common equity, as of the latest practicable date: At

March 25, 2002, there were outstanding 29,068,712 shares of the registrant's Common Stock, $.01 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the Registrant's definitive proxy statement to be filed not later than April 30, 2002 pursuant to Regulation 14A are incorporated by reference in Items 10 through 13 of Part III of this Annual Report on Form 10-K.

PART I

The following contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the safe harbors created thereby. All forward-looking statements involve risks and uncertainty. Although the Company believes that the assumptions underlying the forward-looking statements contained herein are reasonable, any of the assumptions could be inaccurate, and therefore, the Company's actual results may differ materially from the results anticipated in the forward-looking statements. See "Business - Certain Risk Factors that May Affect Future Results, Financial Condition and Market Price of Securities" included herein for a discussion of factors that could contribute to such material differences. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the objectives and plans of the Company will be achieved.

ITEM 1. BUSINESS

THE COMPANY

Sheffield Pharmaceuticals, Inc. (formerly Sheffield Medical Technologies Inc.) ("Sheffield" or the "Company") was incorporated under Canadian law in October 1986. In May 1992, the Company became domesticated as a Wyoming Corporation pursuant to a "continuance" procedure under Wyoming law. In January 1995, the Company's shareholders approved the proposal to reincorporate the Company in Delaware, which was effected on June 13, 1995. The Company provides innovative, cost-effective pharmaceutical therapies by combining state-of-the-art pulmonary drug delivery technologies with existing and emerging therapeutic agents. The Company is developing a range of products to treat respiratory and systemic diseases in its proprietary pulmonary delivery systems, including the Premaire(R) Delivery System ("Premaire") and Tempo(TM) Inhaler ("Tempo"). The Company is in the development stage and, as such, has been principally engaged in the development of its pulmonary delivery systems. Sheffield believes these pulmonary delivery technologies will allow the Company to capitalize on the growing drug delivery market by providing both advanced respiratory treatments and patient-friendly alternatives for therapies that can currently be administered only by injection or other inconvenient means.

In 1997, the Company acquired the Premaire, a portable nebulizer-based pulmonary delivery system, through a worldwide exclusive license and supply arrangement with Siemens AG ("Siemens"). During the second half of 1998, the Company acquired the rights to a new generation propellant-based pulmonary delivery system, Tempo, from a subsidiary of Aeroquip-Vickers, Inc. ("Aeroquip-Vickers"). Additionally, during 1998, Sheffield licensed from Elan

Corporation, plc ("Elan") the Ultrasonic Pulmonary Drug Absorption System ("UPDAS"), a novel disposable unit dose nebulizer system, and Elan's Absorption Enhancing Technology ("Enhancing Technology"), a therapeutic agent to increase the systemic absorption of drugs. In October 1999, the Company licensed Elan's Nanocrystal(TM) technology to be used in developing certain inhaled steroid products.

BUSINESS STRATEGY

The Company's business strategy is to seek out opportunities to acquire and develop commercially attractive pharmaceutical products, primarily in the area of pulmonary drug delivery. The Company recognizes that no single technology in the area of pulmonary drug delivery will meet the needs of patients and providers of the wide variety of compounds (both for respiratory disease and systemic disease therapy) that may benefit therapeutically and commercially from pulmonary delivery. As a result, it remains the Company's goal to acquire or in-license a portfolio of pulmonary delivery technologies to meet the broadest based market opportunity. The Company intends to selectively enter into joint ventures or other forms of strategic alliances to access technology and compounds as well as defray or reduce significant development and manufacturing costs associated with these opportunities that otherwise might be borne by the Company. The Company will also retain certain commercial rights to these products.

The Company will continue to be opportunistic in the acquisition and/or in-licensing of technologies or products that meet the Company's strategic objectives. Such opportunities include: (1) technologies or products that meet the needs of healthcare providers and patients that are not currently served, (2) technologies or products that can effectively be developed when viewed in light of the commercial opportunity and competitive environment within the U.S. market, (3) technologies or products that will be of substantive interest to other companies with regard to co-development and co-marketing with limited incremental investment by the Company, and (4) products and technologies with the potential for marketing to a specialty group or limited physician audience. The Company plans to pay special attention to platform technologies that can be developed into multiple applications in varying therapeutic categories.

STRATEGIC ALLIANCES

The Company believes a less costly, more predictable path to commercial development of therapeutics can be achieved through the creative use of collaborations and alliances, combined with state-of-the-art technology and experienced management. The Company is applying this strategy to the development of both respiratory and systemic pharmaceutical products to be delivered through the Company's proprietary pulmonary delivery systems. Using these pulmonary delivery systems as platforms, the Company has established strategic alliances for developing its initial products.

The Company is developing a range of pharmaceutical products delivered by the Premaire to treat respiratory diseases. Products initially developed for respiratory disease therapy delivered through the Premaire include albuterol sulfate, ipratropium bromide, sodium cromoglycate and inhaled steroids. In June 1998, the Company sublicensed to Zambon Group SpA ("Zambon") worldwide marketing and development rights to respiratory products to be delivered by the Premaire in return for an equity investment in the Company (approximately 10%). From June 1998 to September 2001, Zambon funded the costs for the respiratory compounds being developed for delivery in the Premaire. In September 2001, the Company

amended its 1998 agreement with Zambon whereby Sheffield regained the rights to the Premaire previously granted to Zambon. As part of the amended agreement, Zambon provided a low-interest, $2.5 million loan to Sheffield to progress the development of the Premaire respiratory program. Upon commercialization, Zambon will be entitled to certain royalties on payments received by Sheffield for albuterol sulfate, ipratropium bromide and sodium cromoglycate sales for specified periods.

As part of a strategic alliance with Elan, a world leader in pharmaceutical delivery technology, the Company is developing therapies for systemic diseases to be delivered to the lungs using both the Premaire and Tempo. In 1998, the systemic applications of the Premaire and Tempo were licensed to Systemic Pulmonary Delivery, Ltd. ("SPD"), a wholly owned subsidiary of the Company. In addition, two Elan technologies, UPDAS and the Enhancing Technology, have also been licensed to SPD. The Company has retained exclusive rights outside of the strategic alliance to respiratory disease applications utilizing the Tempo technology and the two Elan technologies.

In addition to the above alliance with Elan, in 1999, the Company and Elan formed a joint venture, Respiratory Steroid Delivery, Ltd. ("RSD"), a 80.1% owned subsidiary of the Company and 19.9% owned by Elan, to develop certain inhaled steroid products to treat certain respiratory diseases using Elan's NanoCrystal(TM) dispersion technology. The inhaled steroid products being developed include a unit-dose-packaged steroid dispersion formulation for delivery using a conventional tabletop nebulizer, and a steroid dispersion formulation for delivery using the Premaire system.

Outside of these alliances, the Company owns the worldwide rights to respiratory disease applications of all of its technologies.

The Company is also currently in discussions with a number of pharmaceutical and biotechnology companies concerning potential collaborations for developing specific compounds (both respiratory and systemic) in the Tempo. Unlike the Premaire, Tempo is a technology that lends itself to individual product applications in the respiratory market. While the Tempo technology may be applicable to a wide range of respiratory products, the Company believes that a full line of products delivered by Tempo is not necessary for commercial success. The reverse is true with the Premaire, since one of the Premaire's primary competitive advantages is the delivery of a range of drugs in interchangeable cartridges used with the parent nebulizer device.

PULMONARY DELIVERY MARKET ENVIRONMENT

The Company competes in the pulmonary delivery market. The principal use of pulmonary delivery has been in the treatment of respiratory diseases such as asthma, chronic obstructive pulmonary disease ("COPD") and cystic fibrosis. There is significant advantage in aerosol therapy for respiratory disease. Pulmonary administration delivers the medication directly onto the lung's epithelial surfaces. In many cases, this means that drugs can be effective in very low doses -- reducing the side effects often associated with systemic administration. In 1998, industry sources estimate there were approximately 35.5 million asthma patients and 49.5 million COPD patients worldwide. These sources indicate that the number of newly diagnosed patients is growing at a rate in excess of 10% annually due to an increase in worldwide air pollution levels and the overall aging of the population. By the year 2005, the Company expects that there will be more than 19 million asthma patients in the United States alone.

In addition, the competitive marketplace has been significantly affected by the worldwide phase out of clorofluorocarbons ("CFCs") pursuant to the Montreal Protocol. CFCs are the propellants traditionally used in pressurized metered dose inhalers ("pMDIs"), which are the most common form of pulmonary delivery. Companies in the respiratory market have initiated

significant programs to redevelop existing products using alternative propellants, dry powders or aqueous-based nebulizers.

There is considerable interest in applying pulmonary delivery technology to systemic therapies that would benefit from the relatively easy administration to the circulatory system through the lungs. Work on pulmonary delivery of insulin by other pulmonary delivery companies has received significant public notice. There is a range of therapies that could provide a significant market opportunity if available in an inhaled delivered form.

Today, three types of devices are widely used in pulmonary drug administration: pressurized metered dose inhalers, dry powder inhalers, and nebulizers.

Pressurized Metered Dose Inhalers. Currently, pMDIs are the most commonly used pulmonary delivery system. It is estimated that in the United States over 80% of pulmonary drug delivery is via pMDI, with the majority of this use coming from adults with asthma and COPD.

The main components of a pMDI include a canister containing the drug mixed with propellant and surfactant, a mouthpiece that acts as the delivery conduit and the metering valve for the release of precise quantities of the drug. The initial velocity of particle

and propellant droplets as they leave an inhaler is very high -- approximately 2-7 meters per second -- resulting in wasted drug if the patient is not able to coordinate his/her breath with the delivery of aerosol into the mouth. A number of studies have demonstrated that as many as 80% of patients cannot accurately time their inspiration with the actuation of their inhaler which results in under medication and lack of compliance. Typically, less than 20% of metered drug actually reaches the lungs.

The primary advantages of a pMDI include its excellent storage and metering capability, small size, portability, fast usage time, and its availability for use with most respiratory drugs. Disadvantages of a pMDI include patient coordination issues and efficient dose delivery. Additionally, because the use of CFCs traditionally used in pMDIs are being phased out by international agreement (Montreal Protocol), alternative propellants and formulations are being developed. Over time, all current pMDI users will be required to move to a non-CFC pMDI or other alternative delivery systems. The majority of U.S. patients favor aerosol pMDIs although a sizable percentage may not coordinate them properly.

Dry Powder Inhalers. Dry powder inhalers ("DPIs") were introduced in the 1960s as single-dose inhalers. In these devices, the drug is loaded as a unit dose that is mechanically released as a powder for inhalation prior to each use. To date, these relatively cumbersome systems have been the primary form of DPI available in the United States, and account for approximately 1% of the total aerosol delivery market.

The inconvenience of the single dose DPI has been overcome outside of the U.S. with the development and introduction of multi-dose DPIs that can deliver up to 200 doses of medication. However, like the single dose systems, they are inspiratory flow rate dependent; that is, the amount of drug delivered to the lung depends on the patient's ability

to inhale.

Two of the most significant advantages of DPIs include (1) no hand-breath coordination is required as with pMDIs; and (2) they contain no CFCs. However, most require a high inspiratory flow rate, which can be problematic in younger patients or patients with compromised lung function. In addition, they often present difficulties for those with manual disabilities (e.g., arthritis) or limited vision and, depending upon the powder load delivered, they may induce acute bronchospasm in sensitive individuals. Additionally, multi-dose powder inhalers are subject to moisture sensitivity either from the environment or patient breath and have had difficulty meeting U.S. regulatory standards for dose-to-dose variation.

Nebulizers. The third widely used aerosol delivery system is the nebulizer. Jet nebulizers, which are the most commonly used nebulizer, work on a stream of compressed air or oxygen that is forced through a narrow tube lying just above the surface of the liquid to be nebulized. It takes approximately 10 to 15 minutes to nebulize this amount of liquid. Studies suggest keeping the duration of nebulization short, as longer durations are associated with poor compliance. During nebulization only about 10% of the drug is delivered to the lungs; about 80% gets trapped in the reservoir, tubing, mask or the patients mouth and throat; the rest is exhaled.

Nebulizers can be used for a wide range of patients, but are especially useful for those older and younger patients who cannot manage other inhaler devices. Nebulizers also play a key role in emergency room and intensive care treatment for patients with acute bronchospasm. Another feature exclusive to nebulizers is that a mixture of drugs can be administered in one sitting. However, currently approved nebulizers are bulky tabletop units that are time consuming, have a high initial cost (often in excess of the amount reimbursable by managed care) and can be noisy during operation.

PREMAIRE(R) DELIVERY SYSTEM

The Premaire system has been developed to provide the therapeutic benefit of nebulization with the convenience of pressurized pMDIs in one system. The Premaire was developed to meet specific needs within the respiratory market, particularly for pediatric and geriatric patients suffering from asthma and COPD.

Description of the Premaire

The Premaire is comprised of two main components: (1) a reusable, pocket-size inhaler unit developed and manufactured for the Company by Siemens; and (2) drug cartridges, called Dosators(TM), containing multiple doses of drug formulation assembled and filled by Chesapeake Biological Laboratories. The cartridges are an integral part of the total system. The cartridge plus each drug formulation will be the subject of a separate drug device combination New Drug Application ("NDA").

The basic technology of the system involves the rapid atomization of therapeutic agents using ultrasonic energy. This produces a concentrated soft mist of medication delivered through the mouthpiece over a one to two second period for inhalation. The key components of the technology are housed in the inhaler unit. They are the rechargeable battery-operated motor, ultrasonic horn and drug cartridge. The pocketsize Premaire allows for administration of a range of drugs in a single, simple-to-use, environmentally friendly delivery system. Each cartridge contains, depending on formulation, approximately a one-month supply of the drug.

To use the Premaire system, a patient simply selects the appropriate color-coded drug cartridge and places it into the chamber of the inhaler unit. Pressing the "on" button activates a small electrical motor that transports a precise dose of drug from the cartridge chamber to the ultrasonic horn -- transforming the solution into an aerosolized cloud. The patient's inspiratory breath carries this cloud of medication directly to the lungs where it is needed. The dose delivered by the Premaire is very accurate and consistent because: (1) the Premaire is designed to be inspiratory flow rate independent; that is, delivery of the drug does not depend upon the patient's ability to inhale forcefully, and (2) the Premaire does not require a high level of coordination between inspiration and actuation of the device. The patient's natural breath carries the medication directly to the lungs, minimizing the amount of drug deposited in the mouth and throat.

Premaire Advantages

The Company believes that the Premaire provides significant advantages over other drug delivery systems. It is particularly suited for younger and older asthma patients, as well as for older COPD patients who have difficulty using pMDIs and currently have to depend on larger, more time-consuming tabletop nebulizers for delivery of their medications. These potential advantages include:

Accuracy. The superior engineering and patient-friendly design of the Premaire is intended to provide minimal dose-to-dose variability. Patients can therefore expect to receive the right therapeutic dose consistently. Testing of the Premaire delivery system has shown that dose-to-dose variability with the Premaire is significantly better than the current FDA requirement.

Enhanced Patient Compliance. The pocketsize, portable Premaire unit is designed to combine the therapeutic benefits of nebulization with the convenience of pressurized metered dose inhalers. The drug dose is precisely measured and delivered in a minute, as compared to 10 to 15 minutes or more for the typical nebulizer. The device is easy to operate, requiring minimal coordination between actuation and inhalation for proper drug delivery. These benefits are expected to improve patient compliance with the proper administration of their respiratory medication. Another expected factor in enhanced patient compliance is the broad range of drugs that can be accommodated by the Premaire, allowing patients on multiple medications to rely on one simple delivery system.

Inspiratory Flow Rate Independence. Unlike most of the DPIs currently available (or in development), the Premaire is designed to achieve a consistent and significant level of drug deposition over a broad range of inspiratory flow rates. This is especially important in younger patients or patients with compromised lung function (e.g., during an asthma attack) that have a difficult time breathing normally.

Versatility. Many asthma and COPD patients are taking multiple inhalation medications. The Premaire accommodates drug cartridges to allow for the administration of a broad range of frequently used respiratory drugs in a single, simple-to-use delivery system. The system includes an early warning mechanism that signals when the batteries need recharging or when the dosator is not functioning

properly and a dose counter indicating when a new inhaler unit is required. These user-friendly features result in a simplified dosing procedure for both patients and their caregivers.

Pulmonary Targeting. The particle size of the inhaled medication affects the effectiveness of drug delivery to the lung. Generally, a drug is "respirable" if the particle size is between two and five microns. Larger particles tend to deposit in the inhaler or in the patient's mouth and throat. Smaller particles tend to be exhaled. Within the respirable range, the Premaire is designed to deliver particles specifically targeted for certain portions of the lungs; for example, the central lung for local treatment or the deep lung for enhanced absorption into the blood stream for systemic therapies.

Environmentally Friendly. CFCs, the most commonly used propellant for pMDI aerosols, are believed to adversely affect the Earth's ozone layer. They are subject to worldwide regulations aimed at eliminating their production and use within the decade under the Montreal Protocol. The Premaire does not use CFCs or any other type of ozone depleting propellant.

Economical. The Company believes that the Premaire offers significant value to the patient because it is designed to allow a single device to be used with a variety of respiratory medications available in cost-effective interchangeable cartridges. The inhaler unit itself is expected to have a life of up to two years. The initial cost of the inhaler unit is expected to be within the cost range that managed care providers will reimburse patients. The Company anticipates the combined cost to the patient of the device plus the drug filled cartridges will be comparable to the average cost per dose of the standard metered dose inhaler.

Premaire Product Pipeline in Development

The Company is implementing a broad development strategy for the Premaire. The Company is developing a range of widely used respiratory drugs for delivery in the Premaire. Initial drugs being developed for respiratory disease therapy include albuterol sulfate, ipratropium bromide, sodium cromoglycate, and budesonide, an inhaled bronchial steroid, each of which is described below.

As previously discussed, in June 1998, the Company sublicensed to Zambon worldwide marketing and development rights to respiratory products to be delivered by the Premaire. From June 1998 to September 2001, Zambon developed and funded the costs for the respiratory compounds being developed for delivery in the Premaire. In September 2001, the Company amended its 1998 agreement with Zambon whereby Sheffield regained the rights to the Premaire previously granted to Zambon. As a result, the sponsorship of the Premaire respiratory development programs was transferred from Zambon to the Company with the Food and Drug Administration ("FDA") being notified accordingly. Sheffield has reviewed all of the development work completed-to-date, identifying a number of deficiencies in the Zambon development program. To address these issues, Sheffield has made a number of internal management changes and moved the program to a group of highly experienced pulmonary clinical and regulatory experts. The Premaire device is currently in a to-be-marketed form and fully industrialized.

The following details the status of the respiratory applications being developed in the Premaire system:

ALBUTEROL SULFATE. Albuterol sulfate, a beta agonist, is a bronchodilator used as rescue therapy for patients with asthma and COPD. It is the largest selling respiratory compound with U.S. sales of over $500 million in all dosage forms. It is available in a metered

dose inhaler and nebulizer solution as well as solid and liquid dosage forms.

Status: Zambon initiated a Phase II clinical trial in December 1999 that compared the Premaire-albuterol sulfate to a conventional albuterol-pMDI. Findings from Phase II studies indicated that Premaire-albuterol and pMDI-albuterol were comparable in improving lung function in the 24 adult patients. An end of Phase II meeting was held in February 2002 with the FDA where the results of the development activities-to-date, specifically the results of the Phase II trial, were reviewed. The Company is currently reviewing the FDA's comments and recommendations, integrating the information into the plans for the Phase III trial and NDA submission. The Company expects to begin pivotal clinical trials for the albuterol sulfate program by the end of 2002.

BUDESONIDE. Budesonide is a corticosteroid, anti-inflammatory agent that treats the underlying inflammation in the lungs of asthma and COPD patients. It is currently available in a DPI, nebulizer respule and pMDI in Europe. Steroids are the fastest growing category in the respiratory market, growing at 20% per year.

Status: Preclinical formulation development work is currently underway. A formulation developed by Nanosystems has proven a feasible candidate for delivery in the Premaire. The formulation is dependent on a proprietary nanocrystaline dispersion of budesonide in an aqueous carrier. Tow other alternative formulation approaches are also under evaluation. Upon scale-up and production of clinical batches released under CMC protocol, an IND will be prepared for filing with the FDA, which is currently planned for the first half of 2003.

IPRATROPIUM BROMIDE. Ipratropium bromide is a bronchodilator used primarily to treat COPD patients. It is useful because of its anticholinergic properties, which reduce pulmonary congestion. It is available in a metered dose inhaler, nebulizer solution and a combination product with albuterol.

Status: Zambon initiated a Phase I/II clinical trial in Europe in January 2000 assessing the safety and efficacy compared to a commercially available ipratropium bromide product delivered by a pMDI and placebo in patients with COPD. The results of the study indicated that both Premaire-ipratropium bromide and pMDI-ipratropium were tolerated and improved lung function in the COPD patients. An Investigational New Drug Application ("IND") was filed by Zambon with the FDA in May 2000. During 2001, the IND was transferred to the Company. The Company does not intend to further develop this product on its own as the program has progressed to the point where a potential licensing partner would be in a position to take the product into clinical studies.

SODIUM CROMOGLYCATE. Sodium cromoglycate is a non-steroidal, anti-inflammatory drug used to reduce the underlying bronchial inflammation associated with asthma. It is extremely safe and it is most commonly used to treat pediatric patients. It is available in a pMDI and nebulizer solution.

Status: An IND was filed by Zambon with the FDA in July 2000.

No further development work is anticipated to be completed on this product, as the projected market opportunity for sodium cromoglycate is currently deemed too small to justify further progression.

OTHER RESPIRATORY THERAPIES. In addition to the drugs listed above, the Company continues to assess the market potential for certain other respiratory therapies. These therapies may include a combination of an anti-inflammatory and beta agonist, an anticholinergic and beta agonist, as well as antibiotics for cystic fibrosis treatments.

SYSTEMIC APPLICATIONS: Through its development alliance with Elan, the Company evaluated certain drugs for systemic treatment by pulmonary delivery through Premaire. By identifying a market opportunity for a rapid-acting, non-invasive treatment for breakthrough pain, the first drug to be tested for delivery in Premaire was morphine. The pain management market includes patients with cancer, post-operative, migraine headache and chronic persistent pain. Narcotic analgesics for treatment of these severe forms of pain are estimated to exceed $1.0 billion in worldwide sales in the year 2000.

Status: In July 1999, the Company completed a gamma scintigraphy/pharmacokinetic trial comparing morphine delivered using the Premaire to subcutaneous injection. The Premaire demonstrated good pulmonary deposition and very rapid absorption, more rapid peak blood levels vs. subcutaneous injection and low oral and throat deposition. As part of the development alliance with Elan, Elan has the first right of refusal on the development of any product developed by the joint venture. Elan has chosen not to license this product from the joint venture. As such, the joint venture continues to seek to attract a partner for the continued development and commercialization of this product.

TEMPO(TM) INHALER

Tempo, a new generation pMDI, was developed to correct major deficiencies associated with existing pMDI technology. pMDIs have provided convenient, safe, self-administered treatment for over 30 years and decreased the cost of therapy because the patient at home can use them with minimal medical supervision. However, proper use of current pMDIs requires training and precise execution of the delivery technique. For these reasons, many patients do not use their pMDIs in the prescribed manner to coordinate actuation and inhalation. Incorrect technique has been shown to result in little or no benefits from pMDI use in half of all adult patients and in a greater proportion of children. Moreover, because of these coordination issues, most children under age five cannot use a standard pMDI.

Even with correct technique, current pMDIs typically deliver less than 20% of the drug to the lungs of the patient. The remainder of the drug is wasted upon deposition on the back of the mouth, or by completely missing the airway. This results from: (1) the high linear

velocity (two to seven meters/second) of the aerosol jet as it discharges; (2) incomplete evaporation of the propellant leading to large size droplets that deposit in the mouth and larynx rather than reaching the lung; and (3) inadequate mixing resulting in a non-uniform distribution of drug particles in the inspiratory flow stream. Drug deposited in the mouth and throat can be swallowed and absorbed systemically or, in the case of inhaled steroids, may create a local concentration of the drug that causes immunosuppression response and the development of fungal infections. In addition, swallowing beta agonist

bronchodilators may result in adverse effects on heart rate, blood pressure, glucose and potassium.

From a therapeutic view, the most serious problem with pMDIs is inconsistency of delivery. With existing pMDIs the actual dose can vary from 0% to 300% of the intended dose. Patients may not receive sufficient drug to achieve a therapeutic effect, or they may overdose with undesirable side effects. These conditions can lead to the need for emergency treatment.

A major advantage for the Tempo technology is that it uses the same aerosol canisters and valves as are currently used in existing pMDIs. As a result, existing aerosol facilities will be able to produce canisters with formulations optimized for use in Tempo. The only additional step required is to place the aerosol canister in the "device" prior to final packaging. This results in a cost effective product and provides numerous benefits to patients. The device along with the canister is disposable when the canister is empty.

The Tempo technology features two improvements over existing pMDIs and dry powder inhalers. Fluid dynamics modeling, in-vitro and human trials indicate that up to 60% of drug emitted by the Tempo reaches the lungs with oral deposition reduced to approximately 15%. Because of this increase in efficiency, Tempo should require less drug per actuation than existing devices to achieve the same therapeutic effect. This may result in more unit doses per drug canister than a conventional pMDI, with less potential for adverse reactions.

Tempo also features a unique proprietary triggering mechanism that actuates at the correct time during inhalation. It is designed to automatically adjust to the patient's breathing pattern to accommodate differences in age and disease state. This synchronous trigger is designed to reduce patient coordination problems and enhance patient compliance.

Description of the Tempo

The Tempo technology utilizes a standard aerosol pMDI canister and metering valve, encased in a compact device that provides an aerosol flow-control chamber and a synchronized triggering mechanism. Manipulation of the discharged drug- containing aerosol cloud is key to optimization of the efficiency and consistency for pMDIs.

The Tempo design uses fluid dynamics to: (1) reduce the velocity of the drug relative to the inspiratory breath velocity (less than one meter/second); (2) increase residence time of the aerosol droplets before exiting the device to allow near complete evaporation of the propellant; (3) increase droplet dispersion and mixing, thus increasing evaporation and improving vapor fraction at every point along the flow path; (4) reduce the diameter of the drug particles at the exit plane of the device; (5) decrease inertia of droplets to reduce impaction; and (6) improve timing of dose discharge with inspiratory breath for increased drug deposition in lungs.

The unique features of Tempo are:

Aerosol Flow-Control Chamber. The aerosol flow-control chamber allows the patient to inhale through the device at a normal breathing rate, instead of a forced breath. The inspiratory breath establishes flow fields within the device that mix and uniformly disperse the drug in the breath. In the mouthpiece, nearly all the propellant is evaporated leaving only drug particles to be inspired, allowing a significant increase in the amount of drug delivered to the lungs. Only small amounts of drug deposit in the mouth and throat.

Synchronizing Trigger Mechanism. A triggering and timing mechanism that is synchronized with the patient's inspiratory breath controls the

discharge of the metering valve. Tempo can accommodate different inspiratory flow rates, so any patient can activate the triggering device. Similarly, the timing mechanism will automatically adjust to the flow generated by the patient, delaying or hastening discharge in proportion to the total volume passing through the flow control chamber. This feature accommodates differences in inspiratory flow characteristic of pulmonary disease states in children, adults and the infirm.

Tempo Advantages

The Company believes that the Tempo technology possesses many potential competitive advantages over other inhalation systems in both local respiratory and systemic applications. It is applicable to all age categories, eliminating the most troublesome problems of aerosol metered dose delivery. Increased efficiency allows for potential application to proteins and peptides formerly not considered as candidates for aerosol delivery.

The performance characteristics of the Tempo are expected to translate into multiple benefits, including:

Improved Drug Delivery Efficiency. A higher percentage of the drug emitted by the Tempo is delivered to the lungs than current inhalation systems while approximately 15% is lost through deposition in the mouth and throat. The improved delivery efficiency enhances efficacy, reduces side effects and provides greater consistency of dose administration.

Greater Patient Compliance. The Tempo reduces technique dependence for simple, consistent dose-to-dose delivery, resulting in improved compliance with prescribed therapy.

Broader Patient Base. The Tempo can be prescribed for a broader patient base since it is designed to be self-administered by children and the elderly as well as adult patients.

Pharmacoeconomic Benefit. The Tempo has increased delivery efficiency with less waste, so patients can receive more unit doses per standard canister. This allows for a lower drug cost per day in addition to reducing prescription and payer costs because fewer pharmacy visits are required.

Tempo Product Pipeline in Development

TEMPO SYSTEMIC THERAPIES. The development of systemic drugs using Tempo is being conducted as part of the Company's alliance with Elan. The initial product developed was targeted to address migraine headaches. The Company utilized ergotamine tartrate as a proof-of-principle product. Ergotamine, an alpha adrenergic blocking agent, is a therapy to stop or prevent vascular headaches such as migraines. Migraine headaches affect up to 30 million Americans. Worldwide annual drug sales for the migraine therapy market are in excess of $2.4 billion with many patients unable to get satisfactory relief from currently available therapies. In fact, it is estimated that absenteeism and medical expenses resulting from migraine total $50 billion annually. Current oral drug therapies for the treatment of migraine headaches have slow onset of action, resulting in a medical need that may be better satisfied through pulmonary delivery.

Status: In December 1999, the Company completed a gamma scintigraphy/pharmacokinetic trial comparing the Tempo to a conventional pMDI. The trial showed successful delivery of the drug to all regions of lung with significantly reduced mouth and throat deposition, and rapid drug absorption. As part of the development alliance with Elan, Elan has the first right of refusal on the development of any product developed by the joint venture. Elan has chosen not to license this product from the joint venture. As such, the joint venture continues to seek to attract a partner for the continued development and commercialization of this product.

As a result of the work performed on the ergotamine product noted above, Sheffield initiated a new development program for a novel formulation of dyhydroergotamine ("DHE") for pulmonary delivery in the Tempo for the treatment of specific types of migraines. Formulation work for this program is currently underway. The Company is also currently in discussions with a pharmaceutical company for the development and manufacturing of this product.

TEMPO RESPIRATORY THERAPIES. The Tempo has broad applicability across respiratory disease therapies since it utilizes basic pMDI delivery methods that are the most popular forms of respiratory delivery. The Tempo technology's ability to significantly minimize oral deposition makes it especially applicable to steroids and steroid combinations with which fungal overgrowth side effects are common. In addition, U.S. patients and physicians have indicated that they prefer metered dose aerosol delivery. The Tempo technology is positioned to take advantage of this built-in market preference for pMDIs with its potential for superior performance, reduced adverse reactions and cost-effectiveness. Inhaled steroids are the fastest growing segment of the respiratory market and the largest in Europe. The features of the Tempo directly minimize the aspects of inhaled steroids that remain a concern to patients and physicians. The market for inhaled steroids on a worldwide basis is approximately $2.0 billion.

Status: In September 2000, the Company completed a pilot study using the Tempo to deliver a patented respiratory drug used to treat asthma. The study measured the distribution of this respiratory drug delivered by Tempo compared to the distribution of this same drug delivered through a commercially available pMDI in 12 healthy volunteers. Results of this study demonstrated that Tempo significantly increased drug deposition in all regions of the lung. Tempo delivered approximately 200% more drug to the lungs, deposited approximately 75% less drug in the mouth, and increased dosing consistency by approximately 55% compared to the currently marketed form of this same drug. The Company is using the results of this study as a basis for conducting discussions for feasibility work and/or clinical studies with potential collaboration partners.

As with Premaire, there remain opportunities for developing Tempo for a range of therapies either directly by the Company or in collaboration with strategic partners. Unlike the Premaire, it is potentially advantageous for the Company to partner on a product-by-product basis, concentrating on prime partners to launch the system commercially and to aid in subsequent development with products developed specifically for exclusive commercialization by the Company.

INHALED STEROID PRODUCTS

In October 1999, the Company and Elan formed a separate joint venture to develop certain inhaled steroid products to treat certain respiratory diseases that will utilize Elan's Nanocrystal(TM) dispersion technology and Sheffield's pulmonary delivery systems. Because of the difficulties in formulating steroids for delivery through a solution-based inhalation system, only one steroid product is currently available in the United States for delivery through a nebulizer. The estimated worldwide market for inhaled steroids is $2 billion annually and growing at 20% per year. The products being formulated using Elan's Nanocrystal technology and the status of each are as

follows:

Unit-dose nebulizer program - This product is for inhalation delivery in a standard commercial tabletop device using the steroid budesonide, formulated using the NanoCrystal technology. A Phase I, double-blind safety and pharmacokinetic study of nebulized nanobudesonide in 16 healthy volunteers was satisfactorily completed at Thomas Jefferson University Hospital in February 2002. This study compared single doses of Pulmicort Respules, nanobudesonide and placebo. Data from the study is currently undergoing final data and statistical analysis.

Premaire nanobudesonide program - This product is for inhalation delivery using the Company's Premaire device. The joint venture is currently conducting formulation work on this product. See "Premaire Delivery System" above for further discussion of this product.

OTHER TECHNOLOGIES AND PROJECTS

Ultrasonic Pulmonary Drug Absorption System

The UPDAS(TM) is a novel ultrasonic pulmonary delivery system designed by Elan as a disposable unit dose nebulizer system. UPDAS was designed primarily for the delivery of proteins, peptides and other large molecules to the lungs for absorption into the bloodstream. Elan's preliminary research with UPDAS demonstrated unique atomization that may prevent denaturing of bioactive molecules and particle size distribution that meets the targets for local and systemic delivery. The Company is not conducting any development work related to this technology.

Absorption Enhancing Technology

As part of the same transaction in which the Company acquired UPDAS, the Company also acquired a worldwide exclusive license to Elan's Absorption Enhancing Technology. While not a delivery system itself, the Enhancing Technology is a therapeutic agent identified by Elan to increase the systemic absorption of drugs delivered to the lungs. The Enhancing Technology may be utilized in conjunction with the Company's other pulmonary delivery systems. The Company is not conducting any development work related to this technology.

Early Stage Research Projects

As part of the Company's focus on later stage pharmaceutical opportunities, the Company is seeking to out-license its portfolio of early stage medical research projects to companies that are committed to early stage biotechnology opportunities. The Company has determined that its early stage technologies do not fit the Company's pulmonary drug delivery strategy. Consequently, the Company plans to out-license these technologies while maintaining an interest in the technologies' promise without incurring the development costs associated with early stage research and development.

Because the Company is no longer funding these projects, it is at risk of losing its rights to certain of these technologies. There can be no assurance that the Company will be able to sell or license its rights to any of its remaining early stage research projects or realize any milestone payments or other revenue from those early stage research projects that have been previously divested.

In November 1997, the Company entered into a license arrangement for

some of its early stage technologies with Lorus Therapeutics, Inc. (formerly Imutec Pharma Inc.). The arrangement licenses rights to a series of compounds for the treatment of cancer, Kaposi's sarcoma and actinic keratosis to a newly formed company, NuChem Pharmaceuticals, Inc. ("NuChem") for which Lorus Therapeutics will provide funding and management of the development program. The Company holds a 20% equity interest in NuChem.

Work on the lead compounds by NuChem has progressed in the pre-clinical phase. In 1999, NuChem announced that the U.S. National Cancer Institute has agreed to undertake additional in vitro screening after initial evaluation of the compounds. In 2000, NuChem chose NC 381 as its lead anti-cancer drug for further studies in preparation for clinical trials. Preclinical toxicology studies are currently underway.

GOVERNMENT REGULATION

The Company's research and development activities and, ultimately, any production and marketing of its licensed products, are subject to comprehensive regulation by numerous governmental authorities in the United States and other countries. Among the applicable regulations in the United States, pharmaceutical products are subject to the Federal Food, Drug & Cosmetic Act, the Public Health Services Act, other federal statutes and regulations, and certain state and local regulations. These regulations and statutes govern the development, testing, formulation, manufacture, labeling, storage, record keeping, quality control, advertising, promotion, sale, distribution and approval of such pharmaceutical products. Failure to comply with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production, refusal by the government to approve marketing of the product and criminal prosecution.

A new drug may not be legally marketed for commercial use in the United States without FDA approval. In addition, upon approval, a drug may only be marketed for the indications, in the formulations and at the dosage levels approved by the FDA. The FDA also has the authority to withdraw approval of drugs in accordance with applicable laws and regulations. Analogous foreign regulators impose similar approval requirements relating to commercial marketing of a drug in their respective countries and may impose similar restrictions and limitations after approval.

In order to obtain FDA approval of a new product, the Company and its strategic partners must submit proof of safety, efficacy, purity and stability, and the Company must demonstrate validation of its manufacturing process. The testing and application process is expensive and time consuming, often taking several years to complete. There is no assurance that the FDA will act favorably or quickly in reviewing such applications. With respect to patented products, processes or technologies, delays imposed or caused by the governmental approval process may materially reduce the period during which the Company will have the exclusive right to exploit them. Such delays could also affect the commercial advantages derived from proprietary processes. As part of the approval process, the FDA reviews the Drug Master File (the "DMF") for a description of product chemistry and characteristics, detailed operational procedures for product production, quality control, process and methods validation, and quality assurance. As process development continues to mature, updates and modifications of the DMF are submitted.

The FDA approval process for a pharmaceutical product includes review of (i) chemistry and formulations, (ii) preclinical laboratory and animal studies, (iii) initial IND clinical studies to define safety and dose parameters, (iv) well-controlled IND clinical trials to demonstrate product efficacy and safety, followed by submission and FDA approval of a New Drug Application (the "NDA"). Preclinical studies involve

laboratory evaluation of the product and animal studies to assess activity and safety of the product. Products must be formulated in accordance with United States Good Manufacturing Procedures ("GMP") requirements and preclinical tests must be conducted by laboratories that comply with FDA regulations governing the testing of drugs in animals. The results of the preclinical tests are submitted to the FDA as part of the IND application and are reviewed by the FDA prior to granting the sponsor permission to conduct clinical studies in human subjects. Unless the FDA objects to an IND application, the application will become effective 30 days following its receipt by the FDA. There can be no certainty that submission of an IND will result in FDA authorization to commence clinical studies.

Human clinical trials are typically conducted in three sequential phases with some amount of overlap allowed. Phase I trials normally consist of testing the product in a small number of normal volunteers for establishing safety and pharmacokinetics using single and multiple dosing regiments. In Phase II, the continued safety and initial efficacy of the product are evaluated in a limited patient population, and appropriate dosage amounts and treatment intervals are determined. Phase III trials typically involve more definitive testing of the appropriate dose for safety and clinical efficacy in an expanded patient population at multiple clinical testing centers. A clinical plan, or "protocol," accompanied by the approval of the institution participating in the trials, must be submitted to the FDA prior to commencement of each clinical trial phase. Each clinical study must be conducted under the auspices of an Institutional Review Board (the "IRB") at the institution performing the clinical study. The IRB is charged with protecting the safety of patients in trials and may require changes in a protocol, and there can be no assurance that an IRB will permit any given study to be initiated or completed. In addition, the FDA may order the temporary or permanent discontinuation of clinical trials at any time. The Company must rely on independent investigators and institutions to conduct these clinical studies.

All the results of the preclinical and clinical studies on a pharmaceutical product are submitted to the FDA in the form of an NDA for approval to commence commercial distribution. The information contained in the DMF is also incorporated into the NDA. Submission of an NDA does not assure FDA approval for marketing. The application review process often requires 12 months to complete. However, the process may take substantially longer if the FDA has questions or concerns about a product or studies regarding the product. In general, the FDA requires two adequate and controlled clinical studies demonstrating efficacy with sufficient levels of statistical assurance. However, additional support may be required. The FDA also may request additional information relating to safety or efficacy, such as long-term toxicity studies. In responding to an NDA, the FDA may grant marketing approval, require additional testing and/or information, or deny the application. Accordingly, there can be no assurance about any specific time frame for approval, if any, of products by the FDA or foreign regulatory agencies. Continued compliance with all FDA requirements and conditions relative to an approved application, including product specifications, manufacturing process, labeling and promotional material, and record keeping and reporting requirements, is necessary throughout the life of the product. In addition, failure to comply with FDA requirements, the occurrence of unanticipated adverse effects during commercial marketing or the result of future studies, could lead to the need for product recall or other FDA-initiated actions that could delay further marketing until the products or processes are brought into compliance.

The facilities of each pharmaceutical manufacturer must be registered

with and approved by the FDA as compliant with GMP. Continued registration requires compliance with standards for GMP. In complying with GMP, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure technical compliance. In addition, manufacturers must comply with the United States Department of Health and Human Services and similar state and local regulatory authorities if they handle controlled substances, and they must be registered with the United States Drug Enforcement Administration and similar state and local regulatory authorities if they generate toxic or dangerous waste streams. Other regulatory agencies such as the Occupational Safety and Health Administration also monitor a manufacturing facility for compliance. Each of these organizations conducts periodic establishment inspections to confirm continued compliance with its regulations. Failure to comply with any of these regulations could mean fines, interruption of production and even criminal prosecution.

For foreign markets, a pharmaceutical company is subject to regulatory requirements, review procedures and product approvals, which, generally, may be as extensive, if not more extensive, as those in the United States. Although the technical descriptions of the clinical trials are different, the trials themselves are often substantially the same as those in the United States. Approval of a product by regulatory authorities of foreign countries must be obtained prior to commencing commercial product marketing in those countries, regardless of whether FDA approval has been obtained. The time and cost required to obtain market approvals in foreign countries may be longer or shorter than required for FDA approval and may be subject to delay. There can be no assurance that regulatory authorities of foreign countries will grant approval. The Company has no experience in manufacturing or marketing in foreign countries nor in matters such as currency regulations, import-export controls or other trade laws.

PATENTS AND TRADEMARKS

Premaire System Patents and Trademark

Under its agreement with Siemens for the technology underlying the Premaire system, the Company is responsible for jointly financing and prosecuting the U.S. patent applications for the benefit of the owners and licensors of this technology. To date, nine U.S. patents have issued, and five corresponding foreign patents have been published. The issued U.S. patents provide protection through 2017 for the Premaire device, the dosator cartridges and their combinations. Also, a U.S. trademark was granted in 2001 registering the Premaire brand name, as well as Dosator(TM), and Misthaler(TM).

Tempo System Patents

As of the December 31, 2001, three U.S. patents have issued and one has been allowed. Three corresponding foreign patents have been published. One U.S. and three foreign applications are in prosecution. The issued U.S. patents cover the Tempo flow control and triggering mechanism through 2018. The Company also received trademark protection in 2001 for the Tempo(TM) brand name.

Early Stage Research Technology Patents

Under its license agreements for its early stage research projects, the Company has been responsible for financing and prosecuting patent applications for the benefit of the owners and licensors of these technologies. While the Company holds, or has held, several U.S. and foreign patents and patent

applications for these early stage technologies, the Company expects to assign these patents and applications to future acquirers, if any, of these technologies. Because the Company does not intend to continue to pay for future patent fees on these early stage technologies, in the event that no acquirers are found for these technologies, the Company expects that it will allow some or all of these patents and patent applications to lapse or the rights may be returned to the licensors.

COMPETITION

The Company competes with approximately 25 other companies involved in developing and selling respiratory products for the U.S. market. Most of these companies possess financial and marketing resources and developmental capabilities substantially greater than the Company. Some of the products in development by other companies may be demonstrated to be superior to the Company's current or future products. Furthermore, the pharmaceutical industry is characterized by rapid technological change and competitors may complete development and reach the marketplace prior to the Company. The Company believes that competition in the respiratory category will be based upon several factors, including product efficacy, safety, reliability, availability, and price, among others.

SUBSIDIARIES

On January 10, 1996, Ion Pharmaceuticals, Inc. ("Ion"), was formed as a wholly owned subsidiary of the Company. At that time, Ion acquired the Company's rights to certain early stage biomedical technologies.

On April 17, 1997, CP Pharmaceuticals, Inc. ("CP") was formed for the purpose of acquiring Camelot Pharmacal, LLC ("Camelot"), a privately held pharmaceutical development company. The Company acquired Camelot on April 25, 1997.

As part of its strategic alliance with Elan, on June 30, 1998, the Company formed SPD as a wholly owned subsidiary. At that time, SPD acquired the Company's rights to the systemic applications of the Premaire and the Tempo. In addition, SPD acquired Elan's rights to the UPDAS and the Enhancing Technology. SPD is responsible for the development of systemic applications in both the Premaire and Tempo.

In addition to the above alliance with Elan, on October 18, 1999, the Company and Elan formed a new joint venture, RSD, to develop certain respiratory steroid products. The Company and Elan made equity investments in RSD representing an initial 80.1% and 19.9%, respectively, ownership in the joint venture. The joint venture is responsible for the development of the inhaled steroid products.

EMPLOYEES

As of March 25, 2002, the Company employed 16 persons, four of whom are executive officers.

CERTAIN RISK FACTORS THAT MAY AFFECT FUTURE RESULTS, FINANCIAL CONDITION AND MARKET PRICE OF SECURITIES

The following are some of the factors that could affect the Company's future results. They should be considered in connection with evaluating forward-looking statements contained in this report and otherwise made by the Company or on the Company's behalf, because these factors could cause actual results and conditions to differ materially from those projected in forward-looking statements.

We have experienced significant operating losses throughout our history and expect these losses to continue for the foreseeable future.

Our operations to date have consumed substantial amounts of cash and we have generated to date only limited revenues from contract research and licensing activities. We have incurred approximately $90.5 million of operating losses since our inception, including $9.7 million during the year ended December 31, 2001. Our operating losses and negative cash flow from operations are expected to continue in the foreseeable future. The Company expects that it will continue to have a high level of operating expenses, negative cash flow from operations and will be required to make significant up-front expenditures in connection with its product development activities. As a result, the Company anticipates additional operating losses for 2002 and that such losses will continue thereafter until such time, if ever, as the Company is able to generate sufficient revenues to sustain its operations. The independent auditors' report dated February 12, 2002, on the Company's consolidated financial statements stated that the Company has incurred recurring operating losses and has a working capital deficiency and that these conditions raise substantial doubt about its ability to continue as a going concern.

We will need additional financing, which if not available, could prevent us from funding or expanding our operations.

Cash available for funding our operations as of December 31, 2001 was $.9 million. As of such date, we had trade payables and accrued liabilities of $1.3 million, current research obligations of $.2 million and a note payable to Elan of $4 million. In addition,

committed and/or anticipated funding of research and development after December 31, 2001 is estimated at approximately $2.4 million, of which $2.0 million has been committed to be funded by Elan through the issuance of our Series E cumulative convertible preferred stock, which funds are required to be used by the Company to fund its portion of RSD's operating and development costs. Since December 31, 2001 we have received $1.0 million as a borrowing on the Loan and Security Agreement with Zambon, with an additional $.5 million available on April 1, 2002. We have also received $1.0 million from the issuance of 1,000 shares of Series E cumulative convertible preferred stock to fund our portion of RSD's costs. As of March 25, 2002, cash available for funding our operations was $1.2 million.

We need to raise substantial additional capital to fund our operations. The development of our technologies and proposed products will require a commitment of substantial funds to conduct costly and time-consuming research, preclinical and clinical testing, and to bring any such products to market. Our future capital requirements will depend on many factors, including continued progress in developing and out-licensing our pulmonary delivery technologies, our ability to establish and maintain collaborative arrangements with others and to comply with the terms thereof, receipt of payments due from partners under research and development agreements, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technology and the status of competitive products.

We intend to seek such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through

public or private equity or debt financings. Additional financing may not be available on acceptable terms or at all. If we raise additional funds by issuing equity securities, stockholders may be further diluted and such equity securities might have rights, preferences and privileges senior to those of our current stockholders. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize. If adequate funds are not available from operations or additional sources of funding, our business will suffer a material adverse effect.

If our common stock is delisted from the American Stock Exchange, the price of our common stock and its liquidity could decline.

Our common stock is listed for trading on the American Stock Exchange, or AMEX, under the symbol "SHM". We do not satisfy AMEX guidelines for continued listing, including a guideline that a listed company that has sustained losses from operations and/or net losses in three of its four most recent fiscal years, have stockholders' equity of at least $4,000,000. We had a net capital deficiency of $9.1 million at December 31, 2001. We also do not satisfy a guideline against continued losses for each of the issuer's five most recent fiscal years. Our continued failure to meet the listing guidelines has been regularly reviewed by AMEX and may ultimately result in our common stock being delisted from AMEX. If our common stock were delisted from AMEX, trading of our common stock, if any, would thereafter likely be conducted in the over-the-counter market, unless we were able to list our common stock on The Nasdaq Stock Market or another national securities exchange, which cannot be assured. If our common stock were to trade in the over-the-counter market it may be more difficult for investors to dispose of, or to obtain accurate quotations as to the market value of our common stock. In addition, it may become more difficult for us to raise funds through the sale of our securities.

In the event of the delisting of our common stock from the AMEX and our inability to list our common stock on The Nasdaq Stock Market or another national securities exchange, the regulations of the SEC under the Securities Exchange Act of 1934, as amended, require additional disclosure relating to the market for penny stocks. SEC regulations generally define a penny stock to be an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. A disclosure schedule explaining the penny stock market and the risks associated therewith is required to be delivered to a purchaser and various sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally institutions). In addition, the broker-dealer must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. If our securities become subject to the regulations applicable to penny stocks, the market liquidity for our securities could be severely affected. In such an event, the regulations on penny stocks could limit the ability of broker-dealers to sell our securities.

Our products are still in development and we may be unable to bring our products to market.

We have not yet begun to generate revenues from the sale of products. Our products will require significant additional development, clinical testing and investment prior to their commercialization. We do not expect regulatory approval for commercial sales of any of our products in the immediate future. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Such reasons include the

possibility that products will not be proven to be safe and efficacious in clinical trials, that they will not be able to meet applicable regulatory standards or obtain required regulatory approvals, that they cannot be produced in commercial quantities at reasonable costs or that they fail to be successfully commercialized or fail to achieve market acceptance.

If our products are not accepted by the medical community, our business will suffer.

Commercial sales of our products will substantially depend upon the products' efficacy and on their acceptance by the medical community. Widespread acceptance of our products will require educating the medical community as to the benefits and reliability of the products. Our products may not be accepted and, even if accepted, we are unable to estimate the length of time it would take to gain such acceptance.

We will be required to make royalty payments on products we may develop, reducing the amount of revenues with which we could fund ongoing operations.

The owners and licensors of the technology rights acquired by us are entitled to receive a certain percentage of all revenues received by us from commercialization, if any, of products in respect of which we hold licenses. Accordingly, in addition to our substantial investment in product development, we will be required to make substantial payments to others in connection with revenues derived from commercialization of products, if any, developed under licenses we hold. Consequently, we will not receive the full amount of any revenues that may be derived from commercialization of products to fund ongoing operations.

Our dependence on third parties for rights to technology and the development of our products could harm our business.

Under the terms of existing license agreements, we are obligated to make certain payments to our licensors. In the event that we default on the payment of an installment under the terms of an existing licensing agreement, our rights there under could be forfeited. As a consequence, we could lose all rights under a license agreement to the related licensed technology, notwithstanding the total investment made through the date of the default. Unforeseen obligations or contingencies may deplete our financial resources and, accordingly, sufficient resources may not be available to fulfill our commitments. If we were to lose our rights to technology, we may be unable to replace the licensed technology or be unable to do so on commercially reasonable terms, which would materially adversely affect our ability to bring products based on that technology to market. In addition, we depend on our licensors for assistance in developing products from licensed technology. If these licensors fail to perform or their performance is not satisfactory, our ability to successfully bring products to market may be delayed or impeded.

We face intense competition and rapid technological changes and our failure to successfully compete or adapt to changing technology could make it difficult to successfully bring products to market.

The medical field is subject to rapid technological change and innovation. Pharmaceutical and biomedical research and product development are rapidly evolving fields in which developments are expected to continue at a rapid pace. Reports of progress and potential breakthroughs are occurring with increasing frequency. Our success will depend upon our ability to develop and

maintain a competitive position in the research, development and commercialization of products and technologies in our areas of focus. Competition from pharmaceutical, chemical, biomedical and medical companies, universities, research and other institutions is intense and is expected to increase. All, or substantially all, of these competitors have substantially greater research and development capabilities, experience, and manufacturing, marketing, financial and managerial resources. Further, acquisitions of competing companies by large pharmaceutical or other companies could enhance such competitors' financial, marketing and other capabilities. Developments by others may render our products or technologies obsolete or not commercially viable and we may not be able to keep pace with technological developments.

We are subject to significant government regulation and failure to achieve regulatory approval for our products would severely harm our business.

Our ongoing research and development projects are subject to rigorous FDA approval procedures. The preclinical and clinical testing requirements to demonstrate safety and efficacy in each clinical indication (the specific condition intended to be treated) and regulatory approval processes of the FDA can take a number of years and will require us to expend substantial resources. We may be unable to obtain FDA approval for our products, and even if we do obtain approval, delays in such approval would adversely affect the marketing of products to which we have rights and our ability to receive product revenues or royalties. Moreover, even if FDA approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA, and a later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer. Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. Additional government regulation may be established which could prevent or delay regulatory approval of our products. Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Even if FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The time required to obtain such approval may be longer or shorter than that required for FDA approval. We have no experience in manufacturing or marketing in foreign countries nor in matters such as currency regulations, import-export controls or other trade laws. To date, we have not received final regulatory approval from the FDA or any other comparable foreign regulatory authority for any of our products or technologies.

Our failure to meet product release schedules would make it difficult to predict our quarterly results and may cause our operating results to vary significantly.

Delays in the planned release of our products may adversely affect forecasted revenues and create operational inefficiencies resulting from staffing levels designed to support the forecasted revenues. Our failure to introduce new products on a timely basis could delay or hinder market acceptance and allow competitors to gain greater market share.

If our intellectual property and proprietary rights are infringed, or infringe upon the rights of others, our business will suffer.

Our success will depend in part on our ability to obtain patent protection for our technologies, products and processes and to maintain trade

secret protection and operate without infringing the proprietary rights of others. The degree of patent protection to be afforded to pharmaceutical, biomedical or medical inventions is an uncertain area of the law. In addition, the laws of foreign countries do not protect our proprietary rights to the same extent as do the laws of the United States. We may not develop or receive sublicenses or other rights related to proprietary technology that are patentable, patents that are pending may be not issued, and any issued patents may not provide us with any competitive advantages and may be challenged by third parties. Furthermore, others may independently duplicate or develop similar products or technologies to those developed by or licensed to us. If we are required to defend against charges of patent infringement or to protect our own proprietary rights against third parties, substantial costs will be incurred and we could lose rights to certain products and technologies or be required to enter into costly royalty or licensing agreements.

We do not have any marketing or manufacturing capabilities and will likely rely on third parties for these capabilities in order to bring products to market.

We do not currently have our own sales force or an agreement with another pharmaceutical company to market all of our products that are in development. When appropriate, we may build or otherwise acquire the necessary marketing capabilities to promote our products. However, we may not have the resources available to build or otherwise acquire our own marketing capabilities, and we may be unable to reach agreements with other pharmaceutical companies to market our products on terms acceptable to us, if at all.

In addition, we do not intend to manufacture our own products. While we have already entered into two manufacturing and supply agreements related to the Premaire system and one related to the Tempo, these manufacturing and supply agreements may not be adequate and we may not be able to enter into future manufacturing and supply agreements on acceptable terms, if at all. Our reliance on independent manufacturers involves a number of risks, including the absence of adequate capacity, the unavailability of, or interruptions in, access to necessary manufacturing processes and reduced control over product quality and delivery schedules. If our manufacturers are unable or unwilling to continue manufacturing our products in required volumes, we will have to identify acceptable alternative manufacturers. The use of a new manufacturer may cause significant interruptions in supply if the new manufacturer has difficulty manufacturing products to our specifications. Further, the introduction of a new manufacturer may increase the variation in the quality of our products.

Healthcare reimbursement policies are uncertain and may adversely impact the sale of our products.

Our ability to commercialize human therapeutic and diagnostic products may depend in part on the extent to which costs for such products and technologies are reimbursed by private health insurance or government health programs. The uncertainty regarding reimbursement may be especially significant in the case of newly approved products. Reimbursement price levels may be insufficient to provide a return to us on our investment in new products and technologies. In the United States, government and other third-party payers have sought to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products approved for marketing by the FDA, including some cases of refusal to cover such approved products. Healthcare reform may increase these cost containment efforts. We believe that managed care organizations may seek to restrict the use of new products, delay authorization to use new products or limit coverage and the level of reimbursement for new products. Internationally, where national healthcare systems are prevalent, little if any funding may be available for new products, and cost containment and cost reduction efforts can be more pronounced than in the United States.

We may become subject to product liability claims and our product liability

insurance may be inadequate.

The use of our proposed products and processes during testing, and after approval, may entail inherent risks of adverse effects that could expose us to product liability claims and associated adverse publicity. Although we currently maintain general liability insurance, the coverage limits of our insurance policies may not be adequate. We currently maintain clinical trial product liability insurance of $2.0 million per event for certain clinical trials and intend to obtain insurance for future clinical trials of products under development. However, we may be unable to obtain or maintain insurance for any future clinical trials. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect upon us and our financial condition. We intend to require our licensees to obtain adequate product liability insurance. However, licensees may be unable to maintain or obtain adequate product liability insurance on acceptable terms and such insurance may not provide adequate coverage against all potential claims.

The price of biotechnology/pharmaceutical company stocks has been volatile which could result in substantial losses to our stockholders.

The market price of securities of companies in the biotechnology/pharmaceutical industries has tended to be volatile. Announcements of technological innovations by us or our competitors, developments concerning proprietary rights and concerns about safety and other factors may have a material effect on our business or financial condition. The market price of our common stock may be significantly affected by announcements of developments in the medical field generally or our research areas specifically. The stock market has experienced volatility in market prices of companies similar to us that has been unrelated to the operating results of such companies. This volatility may have a material adverse effect on the market price of our common stock.

Our ability to issue "blank check" preferred stock may make it more difficult for a change in our control.

Our certificate of incorporation authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined from time to time by the Board of Directors, without shareholder approval. In the event of issuance, such preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in our control and preventing shareholders from receiving a premium for their shares in connection with a change of control. We issued Series A and Series B cumulative convertible redeemable preferred stock in connection with private placements in February 1997 and April 1998, respectively. All of the Series A preferred stock was converted into common stock during 1998. On July 31, 1998, all of the Series B Preferred stock was redeemed for cash. We also issued shares of our Series C cumulative convertible preferred stock in connection with the consummation of an agreement with Elan International Services, Ltd. ("Elan International") in June 1998. In October 1999, in conjunction with a licensing agreement with Elan International, we issued shares of our Series D cumulative convertible exchangeable preferred stock and Series F cumulative convertible preferred stock. In addition, we also have a commitment from Elan International to purchase shares of Series E cumulative convertible non-exchangeable preferred stock at our option (subject to satisfaction of certain conditions). Except for the previously-mentioned purchase commitment for Series E preferred stock, and additional shares of Series C, D and E preferred

stock that may be payable as dividends to Elan International, as holder of the outstanding Series C, D and E preferred stock, we have no present intention to issue any additional shares of our preferred stock. As we are currently investigating raising additional equity financing, we may issue additional shares of our preferred stock in the near future.

We have granted anti-dilutions rights to The Tail Wind Fund Ltd. which may require us to issue additional shares to Tail Wind, make cash payments to Tail Wind and may hinder our ability to raise additional funds.

Pursuant to our December 2000 private placement with The Tail Wind Fund Ltd., until at least August 29, 2002, if we sell shares of our common stock or securities convertible into or exercisable for common stock for less than $3.5888 per share, we are obligated to issue to Tail Wind additional shares so that the number of shares purchased by Tail Wind in the December 2000 private placement plus the additional shares issued to Tail Wind equals the number of shares that Tail Wind could have purchased for $2,250,000 at the price per share at which the new shares are sold. The presence of these anti-dilution rights may negatively affect our ability to obtain additional financing. In addition, in the event that we are required to issue additional shares to Tail Wind, we may not issue an aggregate of over 5,630,122 shares of our common stock in total to Tail Wind in connection with the December 2000 private placement. If we would otherwise be required to issue more than 5,630,122 shares to Tail Wind, we must instead pay Tail Wind 105% of the cash value of such shares we do not issue.

We are obligated to issue additional securities in the future diluting our stockholders.

As of December 31, 2001, we had reserved approximately 6,185,469 shares of our common stock for issuance upon exercise of outstanding options and warrants convertible into shares of our common stock, including by our officers and directors. In addition, as of December 31, 2001, we had $2,000,000 principal amount of a convertible promissory note, 14,708 shares of our Series C preferred stock, 13,779 shares of our Series D preferred stock, 2,124 shares of our Series E preferred stock and 5,000 shares of our Series F preferred stock outstanding. Except for Series D Preferred Stock, each of the convertible securities provides for conversion into shares of our common stock at a discount to the market price at December 31, 2001. Our Series C, D, E and F preferred stock are convertible into 10,431,206 shares, 2,839,300 shares, 546,015 shares and 1,470,588 shares, respectively, of common stock. The convertible promissory note, including accrued interest is convertible into 1,487,291 shares of common stock. The exercise of options and outstanding warrants, the conversion of such other securities and sales of common stock issuable thereunder could have a significant dilutive effect on the market price of our common stock and could materially impair our ability to raise capital through the future sale of our equity securities.

ITEM 2. PROPERTIES

The Company's principal executive offices are located at 14528 South Outer Forty Road, Suite 205, St. Louis, Missouri 63017. These premises consist of approximately 6,193 square feet subject to a lease that expires December 14, 2002. The monthly rent for these premises is $10,838. The Company also maintains a research facility in Ann Arbor, Michigan, and leases a small office in Rochester, New York. The Company maintains no other laboratory, research or other facilities, but primarily conducts research and development in outside

laboratories under contracts with universities or research facilities. The Company believes that its existing office arrangements will be adequate to meet its reasonably foreseeable future needs.

ITEM 3. LEGAL PROCEEDINGS

There are no material legal proceedings against the Company or any of its subsidiaries.

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

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The following table sets forth the high and low sale prices of the Company's Common Stock on the American Stock Exchange (the "AMEX") for the periods indicated.

2001:	High	Low
Fourth Quarter	$4.750	$3.000
Third Quarter	4.110	2.680
Second Quarter	4.900	3.500
First Quarter	4.625	3.000

2000:	High	Low
Fourth Quarter	$6.625	$3.250
Third Quarter	6.875	4.250
Second Quarter	5.938	3.000
First Quarter	7.938	3.375

The closing sale price for the Company's Common Stock on the AMEX on March 25, 2002 was $2.27 per share. At March 25, 2002, there were approximately 401 holders of record of the Company's Common Stock.

The Company has never paid dividends on its Common Stock and does not intend to pay cash dividends on its Common Stock in the foreseeable future. The terms of the Company's Series C, D and E Preferred Stock generally prohibit the payment of cash dividends and other distributions on the Company's Common Stock unless full cumulative stock dividends on shares of such Series C, D and E Preferred Stock have been paid or declared in full. During 2001, the Company issued stock dividends totaling 996, 929, and 120 shares and cash dividends for fractional shares of $3,278, $603, and $1,422 on Series C, D and E Preferred Stock, respectively.

The following unregistered securities were issued by the Company during the quarter ended December 31, 2001:

	NUMBER OF SHARES

DATE OF SALE/ISSUANCE	DESCRIPTION OF SECURITIES ISSUED	SOLD/ISSUED/ SUBJECT TO OPTIONS OR WARRANTS	OFFERING/ EXERCISE PRICE PER SHARES($)	PURCH
October 9, 2001	Common Stock, $.01 par value	14,367	$1.1206	Advi cash

The issuance of these securities are claimed to be exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving a public offering. There were no underwriting discounts or commissions paid in connection with the issuance of any of these securities.

ITEM 6. SELECTED FINANCIAL DATA

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)

SELECTED FINANCIAL INFORMATION
(In dollars, except share information)

	Years Ended December 31,		
	2001	2000	1999
CONSOLIDATED STATEMENT OF OPERATIONS DATA:			
Revenues:			
Contract research revenue	$ 869,095	$ 501,572	$ 399,378
Sublicense revenue	5,000	5,000	--
Total revenues	874,095	506,572	399,378
Expenses:			
Acquisition of research and development in-process technology	--	--	15,000,000
Research and development	5,999,693	3,747,437	3,421,734
General and administrative	4,551,661	2,817,535	2,277,136
Total expenses	10,551,354	6,564,972	20,698,870
Loss from operations	(9,677,259)	(6,058,400)	(20,299,492)
Interest income	58,438	124,908	91,941

Interest expense	(318,642)	(224,360)	(162,237)
Realized gain on sale of marketable securities	79,706	239,629	--
Minority interest in loss of subsidiary	378,620	155,072	2,985,000
Net loss	$ (9,479,137)	$ (5,763,151)	$(17,384,788)
Basic and diluted net loss per common share	$ (.40)	$ (.27)(1)	$ (.68)(1)
Basic and diluted weighted average common shares outstanding	28,963,562	27,956,119	27,236,715
CONSOLIDATED BALANCE SHEET DATA:			
Working capital (net deficiency)	$ (4,160,823)	$ 3,439,120	$ 3,344,174
Total assets	2,056,278	5,450,657	5,048,655
Long-term debt & redeemable preferred stock	5,000,000	4,000,000	3,000,000
Accumulated deficit	(92,496,964)	(80,967,524)	(73,409,828)
Stockholders' equity (net capital deficiency)	$ (9,086,276)	$ (413,720)	$ 671,073

No cash dividends have been paid on Common Stock for any of the periods presented.

Basic net loss per share is based on net loss available to common stockholders divided by the weighted average common stock outstanding during the year.

See consolidated financial statements and accompanying footnotes.

(1) As discussed in Note 1 ("Summary of Significant Accounting Policies - Basic Net Loss per Share of Common Stock") to the consolidated financial statements, basic and diluted net loss per share for the years ended December 31, 2000 and 1999 have been restated to properly reflect cumulative preferred stock dividends payable in kind in calculating the net loss available to common stockholders.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(A DEVELOPMENT STAGE ENTERPRISE)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains certain forward-looking statements

within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the safe harbors created thereby. All forward-looking statements involve risks and uncertainty, including without limitation, risks set forth in Part I of the Company's Form 10-K for the year ended December 31, 2001.

The discussion and analysis below should be read in conjunction with the Financial Statements of the Company and the related Notes to Financial Statements included on pages 24-35 in this Form 10-K.

OVERVIEW

Sheffield Pharmaceuticals, Inc. ("Sheffield" or the "Company") provides innovative, cost-effective pharmaceutical therapies by combining state-of-the-art pulmonary drug delivery technologies with existing and emerging therapeutic agents. The Company is developing a range of products to treat respiratory and systemic diseases in its proprietary Premaire(R) Delivery System ("Premaire") and Tempo(TM) Inhaler ("Tempo"). The Company is in the development stage and, as such, has been principally engaged in the development of its pulmonary delivery systems.

In 1997, the Company acquired the Premaire, a portable nebulizer-based pulmonary delivery system, through a worldwide exclusive license and supply arrangement with Siemens AG ("Siemens"). During the second half of 1998, the Company acquired the rights to an additional pulmonary delivery technology, Tempo, from a subsidiary of Aeroquip-Vickers, Inc. ("Aeroquip-Vickers"). The Tempo technology is a new generation propellant-based pulmonary delivery system. Additionally, during 1998, Sheffield licensed from Elan Corporation, plc ("Elan") the Ultrasonic Pulmonary Drug Absorption System ("UPDAS"), a novel disposable unit dose nebulizer system, and Elan's Absorption Enhancing Technology ("Enhancing Technology"), a therapeutic agent to increase the systemic absorption of drugs. In October 1999, the Company licensed Elan's Nanocrystal(TM) technology to be used in developing certain inhaled steroid products.

Sheffield's lead drug delivery technology, the Premaire, is a patented, multi-dose nebulizer delivery system. The pocket-sized inhaled drug delivery system features an ultrasonic nebulizer that emits high-frequency sound waves that turn liquid medication into a fine cloud or soft mist. The Premaire combines the therapeutic benefits of nebulization with the convenience of pressurized metered dose inhalers, or pMDIs, in one patient-friendly device. The Premaire is comprised of a hand-held ultrasonic nebulizer and drug-filled cartridges that are inserted into the inhaler unit. The cartridges provide patients who must take multiple respiratory medications with a single, easy-to-use system. The Company believes the soft mist created by the Premaire provides multiple drug administration advantages over the high-velocity pMDIs and dry powder inhalers. Furthermore, the Premaire system is fast and portable as compared to conventional tabletop nebulizers, which are large, cumbersome and more time consuming to use. The Premaire system targets younger and older asthma patients, as well as older chronic obstructive pulmonary disease patients who have difficulty using pMDIs and currently depend on tabletop nebulizers for delivery of their medications.

Sheffield's Tempo is a patented, new generation pMDI that the Company believes has significant efficiency and performance advantages over standard pMDIs. The Tempo technology utilizes a standard aerosol pMDI canister, encased in a compact device that provides an aerosol flow-control chamber and a synchronized triggering mechanism. The aerosol flow-control chamber allows the patient to inhale through the device at a normal breathing rate, instead of a forced breath. The inspiratory breath establishes flow fields within the device that mix and uniformly disperse the drug in the breath. At the mouthpiece,

nearly all the propellant is evaporated leaving only drug particles to be inspired, allowing a significant increase in the amount of drug delivered to the lungs. The Tempo system, like the Premaire system, is designed to reduce patient coordination problems and enhance compliance with the prescribed treatment.

In June 1998, the Company sublicensed to Zambon Group SpA ("Zambon") worldwide marketing and development rights to respiratory products to be delivered by the Premaire in return for an equity investment in the Company (approximately 10%). From June 1998 to September 2001, Zambon funded the development costs for the respiratory compounds delivered by Premaire. In September 2001, the Company amended its 1998 agreement with Zambon whereby Sheffield regained the rights to the Premaire previously granted to Zambon. As part of the amended agreement, Zambon provided a low-interest, $2.5 million loan to Sheffield to progress the development of the Premaire respiratory program. Upon commercialization, Zambon will be entitled to certain royalties on payments received by Sheffield for albuterol, ipratropium and cromolyn sales for specified periods.

As part of a strategic alliance with Elan, the Company is developing therapies for non-respiratory diseases to be delivered to the lungs using both Tempo and Premaire. In 1998, the systemic applications of Premaire and Tempo were licensed to Systemic Pulmonary

Delivery, Ltd. ("SPD"), a wholly owned subsidiary of the Company. In addition, two Elan technologies, UPDAS(TM) and the Enhancing Technology, were also licensed to SPD. The Company retained exclusive rights outside of the strategic alliance to respiratory disease applications utilizing the Tempo technology and the two Elan technologies.

In addition to the above alliance with Elan, in 1999, the Company and Elan formed a joint venture, Respiratory Steroid Delivery, Ltd. ("RSD"), to develop certain inhaled steroid products to treat respiratory diseases using Elan's NanoCrystal technology. Currently, RSD is developing a solution-based unit-dose-packaged steroid formulation for delivery using a conventional tabletop nebulizer, and a solution-based steroid formulation for delivery using the Premaire.

CRITICAL ACCOUNTING POLICIES

Basis of Presentation

The Company is in the development stage and to date has been principally engaged in research, development and licensing efforts. The Company has generated minimal operating revenue and will require additional capital, which the Company intends to obtain through out-licensing of rights to its technology, as well as through equity and debt offerings, to continue to operate its business. The Company's ability to meet its obligations as they become due and to continue as a going concern must be considered in light of the expenses, difficulties and delays frequently encountered in developing a new business, particularly since the Company will focus on research, development and unproven technology that may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products to be profitable. Management believes that the Company's ability to meet its obligations as they become due and to continue as a going concern through December 2002 is dependent upon obtaining additional funding. The Company's

consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. Should the Company not be successful in obtaining sufficient funding, some of the assets and liabilities may not be satisfied at the current carrying values.

The consolidated financial statements include the accounts of Sheffield and its wholly owned subsidiaries, Systemic Pulmonary Delivery, Ltd. ("SPD"), Ion Pharmaceuticals, Inc., and CP Pharmaceuticals, Inc., and its 80.1% owned subsidiary, Respiratory Steroid Delivery, Ltd. ("RSD").

Deferred Tax Assets

As of December 31, 2001, the Company has approximately $21.2 million of deferred tax assets, the majority of which relates to net operating loss carryforwards that expire at various dates from 2007 to 2021 if not utilized. The realization of these assets is dependent upon the Company generating future taxable income. Due to the uncertainty of the amount, if any, of future taxable income that may be generated, the Company has recorded a valuation allowance for the entire deferred tax asset. Should the Company generate sufficient future taxable income before the net operating loss carryforwards expire, the benefit of the deferred tax asset will be realized at that time.

RESULTS OF OPERATIONS

Revenue

Contract research revenues primarily represented revenues earned from a collaborative research agreement with Zambon relating to the development of respiratory applications of Premaire. Contract research revenue was $869,095, $501,572 and $399,378 for the years ended December 31, 2001, 2000 and 1999, respectively. The increase of $367,523, or 73.3% from 2000 to 2001 reflects higher revenues associated with Premaire device development work and testing as the Company finalizes the to-be-marketed device prior to the start of Phase III Premaire-albuterol clinical trials. These higher revenues were partially offset by the Company no longer performing development work for Zambon in the third and fourth quarters of 2001, resulting from Sheffield regaining the Premaire respiratory rights in the third quarter of 2001. The increase of $102,194, or 25.6% from 1999 to 2000 reflects two additional Premaire respiratory programs in development in 2000 as compared to 1999 and certain nonrecurring Premaire device development work and testing completed during 2000. Costs of contract research revenue approximated such revenues and were included in research and development expenses. Future contract research revenues and expenses are dependent on obtaining additional collaborative agreements.

The Company's ability to generate material revenues is contingent on the successful commercialization of its technologies and other technologies and products that it may acquire, followed by the successful marketing and commercialization of such technologies through licenses, joint ventures and other arrangements.

Acquisition of Research & Development In-Process Technology

In 1999, the Company licensed certain pulmonary NanoCrystal technology from Elan for $15.0 million. This entire payment was expensed as the license agreement restricts the Company's use of the NanoCrystal technology to certain

respiratory steroid products that are currently research and development projects.

Research and Development

Research and development expenses were $6.0 million for the year ended December 31, 2001 compared to $3.7 million and $3.4 million for the years ended December 31, 2000 and 1999, respectively. The increase of $2.3 million, or 60.1%, primarily reflects higher expenses associated with the development of the Company's unit-dose inhaled steroid product reflecting increased formulation work and the start of a Phase I clinical trial during the fourth quarter ($1.2 million), costs associated with the Company's feasibility work associated with new product development in the area of polypeptides ($.5 million), higher costs related to the industrialization of the Tempo Inhaler ($.4 million), and increased design and development costs associated with finalizing the to-be-marketed Premaire device prior to the start of a Phase III albuterol-clinical trial ($.2 million). The increase of $.3 million, or 9.5%, from 1999 to 2000 primarily represents costs associated with the development by the Company's subsidiary, RSD, of three steroid products initiated during the fourth quarter of 1999 ($.7 million), formulation work begun during 2000 on a respiratory product to be delivered via the Tempo ($.5 million), modifications made to the Premaire to enhance its commercial appeal prior to the start of Phase III-albuterol clinical trials ($.3 million), and two additional Premaire respiratory programs in development in 2000 as compared to 1999 ($.1 million). These increases were partially offset by lower development costs on the Company's two systemic programs, a therapy for breakthrough pain delivered through the Premaire ($.3 million), and a migraine therapy delivered through the Tempo ($1.0 million).

The following details the status of each of the Company's development programs as of December 31, 2001:

Premaire Respiratory Program:

As a result of the Company regaining from Zambon the rights to the respiratory applications to the Premaire in September 2001, the sponsorship of the Premaire respiratory development programs was transferred from Zambon to the Company with the Food and Drug Administration ("FDA") being notified accordingly. In the fourth quarter of 2001, Sheffield reviewed all of the development work completed-to-date, identifying a number of deficiencies in the Zambon development program. To address these issues, Sheffield has made a number of internal management changes and moved the program to a group of highly experienced pulmonary clinical and regulatory experts. The Premaire device is currently in a to-be-marketed form and fully industrialized. As of December 31, 2001, the Company had spent $3.1 million on developing the respiratory products discussed below.

The Company's strategy is to out license the U.S. rights to the Premaire respiratory products to a third party which the Company anticipates concluding in 2003. As a result, the Company estimates a U.S. commercial launch of its first products in Premaire to occur in the last half of 2005 or first half of 2006. Sheffield will fund the continued development work for the Premaire respiratory products up through the period of outlicensing, currently estimated at approximately $10 million, after which time the licensee will assume funding responsibility for further development work.

Albuterol Sulfate. Zambon initiated a Phase II clinical trial in December 1999 that compared the Premaire-albuterol sulfate to a conventional albuterol-pMDI. Findings from Phase II studies indicated that Premaire-albuterol and pMDI-albuterol were comparable in improving

lung function in the 24 adult patients. An end of Phase II meeting was held in February 2002 with the FDA where the results of the development activities-to-date, specifically the results of the Phase II trial, were reviewed. The Company is currently reviewing the FDA's comments and recommendations, integrating the information into the plans for the Phase III trial and NDA submission. The Company expects to begin pivotal clinical trials for the albuterol sulfate program by the end of 2002.

Budesonide. Preclinical formulation development work is currently underway. A formulation developed by Nanosystems has proven a feasible candidate for delivery in the Premaire. The formulation is dependent on a proprietary nanocrystaline dispersion of budesonide in an aqueous carrier. Two other alternative formulation approaches are also under evaluation. Upon scale-up and production of clinical batches released under CMC protocol, an IND will be prepared for filing with the FDA, which is currently planned for the first half of 2003.

Ipratropium Bromide. Zambon initiated a Phase I/II clinical trial in Europe in January 2000 assessing the safety and efficacy compared to a commercially available ipratropium bromide product delivered by a pMDI and placebo in patients with COPD. The results of the study indicated that both Premaire-ipratropium bromide and pMDI-ipratropium were tolerated and improved lung function in the COPD patients. An Investigational New Drug Application ("IND") was filed by Zambon with the FDA in May 2000. During 2001, the IND was transferred to the Company. The Company does not intend to further develop this product on its own as the program has progressed to the point where a potential licensing partner would be in a position to take the product into clinical studies.

Sodium Cromoglycate. An IND was filed by Zambon with the FDA in July 2000. No further development work is anticipated to be completed on this product as the projected market opportunity for sodium cromoglycate is currently deemed too small to justify further progression.

Premaire Systemic Program:

Through its development alliance with Elan, SPD, the Company evaluated certain drugs for systemic treatment by pulmonary delivery through Premaire. By identifying a market opportunity for a rapid-acting, non-invasive treatment for breakthrough pain, the first drug to be tested for delivery in Premaire was morphine. In July 1999, the Company completed a gamma scintigraphy/pharmacokinetic trial comparing morphine delivered using the Premaire to subcutaneous injection. The Premaire demonstrated good pulmonary deposition and very rapid absorption, more rapid peak blood levels vs. subcutaneous injection and low oral and throat deposition. As part of the development alliance with Elan, Elan has the first right of refusal on the development of any product developed by the joint venture. Elan has chosen not to license this product from the joint venture. As such, the joint venture continues to seek to attract a partner for the continued development and commercialization of this product. The Company has spent $.4 million to date to develop this product and does not

anticipate incurring any future costs for further development until such time as a licensing partner is secured.

Tempo Respiratory Program:

In September 2000, the Company completed a pilot study using the Tempo to deliver an undisclosed, patented respiratory drug used to treat asthma. The study measured the distribution of this respiratory drug delivered by Tempo compared to the distribution of this same drug delivered through a commercially available pMDI in 12 healthy volunteers. Results of this study demonstrated that Tempo significantly increased drug deposition in all regions of the lung. Tempo delivered approximately 200% more drug to the lungs, deposited approximately 75% less drug in the mouth, and increased dosing consistency by approximately 55% compared to the currently marketed form of this same drug. As of December 31, 2001, the Company has incurred approximately $.9 million to-date on this study. The Company is using the results of this study as a basis for conducting discussions for feasibility work and/or clinical studies with potential collaboration partners.

Tempo Systemic Program:

The development of systemic drugs using Tempo is being conducted as part of the Company's alliance with Elan. The initial product developed was targeted to address migraine headaches. The Company utilized ergotamine tartrate as a proof-of-principle product. In December 1999, the Company completed a gamma scintigraphy/pharmacokinetic trial comparing the Tempo to a conventional pMDI. The trial showed successful delivery of the drug to all regions of lung with significantly reduced mouth and throat deposition, and rapid drug absorption. As part of the development alliance with Elan, Elan has the first right of refusal on the development of any product developed by the joint venture. Elan has chosen not to license this product from the joint venture. As such, the joint venture continues to seek to attract a partner for the continued development and commercialization of this product. As of December 31, 2001, the Company has spent $1.0 million to date to develop this product and does not anticipate incurring any future costs for further development until such time as a licensing partner is secured.

As a result of the work performed on the ergotamine product noted above, during 2001 Sheffield initiated a new development program for a novel formulation of dyhydroergotamine ("DHE") for pulmonary delivery in the Tempo for the treatment of specific types of migraines. Formulation work for this program is currently underway. As of December 31, 2001, the Company has incurred approximately $.1 million to-date related to this project. The Company is currently in discussions with a pharmaceutical company for the development and manufacturing of this product. Future costs related to this project are dependent, among other factors, the timing of securing a development partner. The Company estimates incurring approximately $3 million in 2002 related to the development of the DHE project.

Unit Dose Nebulizer Program:

As part of an alliance with Elan, RSD is developing a product for inhalation delivery in a standard commercial tabletop device using the steroid budesonide, formulated using the NanoCrystal technology. A Phase I, double-blind safety and pharmacokinetic study of nebulized nanobudesonide in 16 healthy volunteers was satisfactorily completed at Thomas Jefferson University Hospital in February 2002. This study compared single doses of Pulmicort Respules, nanobudesonide and

placebo. Data from the study is currently undergoing final data and statistical analysis. After such data has been analyzed, the Company plans on initiating discussions with potential partners regarding the outlicensing of this opportunity. As of December 31, 2001, the Company incurred approximately $2.1 million to-date on this project. Sheffield will fund the continued development work for this program up through the period of outlicensing, currently estimated at approximately $2.5 million, after which time it is anticipated that the licensee will assume funding responsibility for further development work.

General and Administrative Expenses

General and administrative expenses were $4.6 million for the year ended December 31, 2001 compared to $2.8 million and $2.3 million for the years ended December 31, 2000 and 1999, respectively. The increase of $1.8 million, or 61.5%, from 2000 to 2001 was primarily due to higher consulting costs and legal fees associated with expanded business development and merger and acquisition activities

in the area of licensing and partnering of the Company's delivery systems, as well as potential acquisitions of complementary pulmonary delivery technologies and companies. The increase of $.5 million, or 23.7%, from 1999 to 2000 primarily reflects higher consulting and legal costs associated with expanded business development activities.

Interest

Interest income was $58,438 for the year ended December 31, 2001 as compared to $124,908 and $91,941 for the years ended December 31, 2000 and 1999, respectively. The decrease of $66,470, or 53.2%, from 2000 to 2001 is primarily due to less cash available for investment and lower yields on those investments. The $32,967 increase in interest income in 1999 from 1998 was primarily due to larger balances of cash available for investment and higher average yields on those investments.

Interest expense was $318,642 for the year ended December 31, 2001 as compared to $224,360 and $162,237 for the years ended December 31, 2000 and 1999, respectively. The increase of $94,282, or 42.0%, from 2000 to 2001 resulted primarily from higher short-term borrowings reflecting the August 2001 $4.0 million promissory note with Elan Pharma International Ltd. ("Elan Pharma"). The increase of $62,123 from 2000 to 1999 resulted from a higher outstanding balance during 2000 on the Company's convertible promissory note with Elan, as well as a higher average interest rate on the note.

Realized Gain on Sale of Marketable Securities

Realized gain on sale of marketable securities was $79,706 and $239,629 for the years ended December 31, 2001 and 2000, respectively. These gains resulted from the sale of 283,188 and 300,000 shares for 2001 and 2000, respectively, of the Company's investment in Lorus Therapeutics, Inc. ("Lorus"). As of December 31, 2001, the Company had no remaining investment in Lorus.

Minority Interest in Subsidiary

Minority interest in loss of subsidiary was $.4 million for the year ended December 31, 2001 compared to $.2 million and $3.0 million for the years ended December 31, 2000 and 1999, respectively. RSD, a consolidated and 80.1%

owned subsidiary of the Company, incurred a loss of $1.9 million and $.8 million in 2001 and 2000, respectively. The $1.1 million increase from 2000 to 2001 resulted primarily from costs associated with initiation of a Phase I/II clinical study of the inhaled steroid product delivered using a tabletop nebulizer. RSD's loss of $15.0 million in 1999 resulted from the license of certain pulmonary NanoCrystal technology from Elan. The minority interest in loss of subsidiary represents Elan's portion, or 19.9%, of RSD's losses. Elan's investment in RSD, shown as minority interest in subsidiary on the consolidated balance sheets, was $0 at both December 31, 2001 and 2000, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2001, the Company had $.9 million in cash and cash equivalents compared to $3.0 million at December 31, 2000. The decrease of $2.1 million reflects $9.1 million of cash disbursements used primarily to fund operating activities and $.6 million to repurchase and retire 214,997 shares of the Company's Common Stock. These decreases in cash were partially offset by the receipt of a $1.0 million milestone advance from Zambon, $1.0 million from the issuance of 1,000 shares of the Company's Series E Cumulative Convertible Preferred Stock, $4.0 million from the proceeds of an unsecured promissory note from Elan Pharma, $1.0 million from the proceeds of a secured loan from Zambon, and $.5 million in net proceeds from the exercise of common stock options and warrants.

In September 2001, in connection with the amendment of its 1998 agreement with Zambon, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Zambon, pursuant to which Zambon agreed to lend the Company $2.5 million. The Company received $1.0 million upon signing of the Loan Agreement, with additional borrowings of $1.0 million and $.5 million to be made on January 1, 2002 and April 1, 2002, respectively. The Loan Agreement provides for interest on principal and annually compounded interest at a fixed rate of 2% per annum and is secured by certain security interests in respiratory products developed in the Premaire. One third of the principal balance, together with interest, is payable by the Company upon the Company's execution of an agreement with one or more third parties to develop, co-promote and/or sell certain products in North America, with all remaining unpaid principal and interest due on December 31, 2005. As part of the amendment of its 1998 agreement with Zambon, on October 17, 2001 the Company repurchased from Zambon 214,997 shares of common stock for $3.0233 per share ("Repurchase Price"). In addition, the Company received an option, expiring December 31, 2002, to repurchase the remaining shares of the Company's common stock held by Zambon at the Repurchase Price. In the event the Company completes a sublicense for the North American rights or a sublicense for the non-North American rights to certain Premaire respiratory products prior to December 31, 2002, the Company will be required to repurchase from Zambon 882,051 shares of the Company's common stock on each of the events.

In August 2001, the Company entered into a Note Purchase Agreement with Elan Pharma, pursuant to which Elan Pharma agreed to lend the Company $4 million. All borrowings under the Note Purchase Agreement are evidenced by an unsecured promissory note of the Company that provides for interest on principal and semi-annually compounded interest at a fixed rate of 10% per annum and a maturity of November 14, 2002, or upon the earlier occurrence of one or more specified events.

In October 1999, as part of a licensing agreement with Elan, the Company received gross proceeds of $17.0 million related to the issuance to Elan

of 12,015 shares of Series D Cumulative Convertible Exchangeable Preferred Stock and 5,000 shares of Series F Convertible Non-Exchangeable Preferred Stock. In turn, the Company made an equity investment of $12.0 million in a joint venture, RSD, representing an initial 80.1% ownership. The remaining proceeds from this preferred stock issuance were available for general operating purposes. As part of the agreement, Elan also committed to purchase, on a drawdown basis, up to an additional $4.0 million of the Company's Series E Preferred Stock, of which $2.0 million of such commitment remains outstanding. The proceeds from the Series E Preferred Stock are required to be utilized by the Company to fund its portion of RSD's operating and development costs.

In May 1999, in conjunction with the completion of its Phase I/II Premaire-albuterol trial, Zambon provided the Company with a $1.0 million interest-free advance against future milestone payments. In January 2001, the Company received an additional $1.0 million interest-free milestone advance resulting from the demonstration of the technical feasibility of delivering an inhaled steroid formulation in Premaire. The proceeds from these advances were not restricted as to their use by the Company. As part of the amendment of its 1998 agreement with Zambon, the terms of the milestone advances were modified in that the Company agreed to repay $1.0 million of the advance milestone payments upon the earlier of December 31, 2003, or upon the first regulatory approval for either albuterol or an inhaled steroid delivered in the Premaire. The remaining $1.0 million advance shall be repaid by the Company on the earlier of December 31, 2005, or the regulatory approval of the second product (albuterol or an inhaled steroid) delivered in the Premaire. Due to the modification in the repayment terms, the advances have been reclassified in the Company's balance sheet as long-term debt.

Since its inception, the Company has financed its operations primarily through the sale of securities and convertible debentures, from which it has raised an aggregate of approximately $84.0 million through December 31, 2001, of which approximately $30.0 million has been spent to acquire certain in-process research and development technologies, and $34.8 million has been incurred to fund certain ongoing technology research projects. The Company expects to incur additional costs in the future, including costs relating to its ongoing research and development activities, and preclinical and clinical testing of its product candidates. The Company may also bear considerable costs in connection with filing, prosecuting, defending and/or enforcing its patent and other intellectual property claims. Therefore, the Company will need substantial additional capital before it will recognize significant cash flow from operations, which is contingent on the successful commercialization of the Company's technologies. There can be no assurance that any of the technologies to which the Company currently has or may acquire rights can or will be commercialized or that any revenues generated from such commercialization will be sufficient to fund existing and future research and development activities.

As of March 25, 2002, the Company had $1.2 million in cash available to fund its operations. As stated above, the Company is to receive $.5 million on April 1, 2002 pursuant to its Loan Agreement with Zambon and the Company has an agreement to receive $1.0 million from Elan to fund the Company's portion of RSD's operating and development costs. Because the Company does not currently have, and does not expect to generate, significant cash flows from operations for at least the next few years, the Company will require additional funds to meet the costs of its development programs for 2002 and beyond. In an effort to meet its capital requirements, the Company is currently pursuing various financing alternatives including private offerings of its securities, debt financing, and collaboration and licensing arrangements with other companies. There can be no assurance that the Company will be able to obtain such additional funds or enter into such collaborative and licensing arrangements on terms favorable to the Company, if at all. The Company's development programs will be curtailed if future financings are not completed.

While the Company does not believe that inflation has had a material impact on its results of operations, there can be no assurance that inflation in the future will not impact financial markets which, in turn, may adversely affect the Company's valuation of its securities and, consequently, its ability to raise additional capital, either through equity or debt instruments, or any off-balance sheet refinancing arrangements, such as collaboration and licensing agreements with other companies.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The Company has no material market risk exposure.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Sheffield Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Sheffield Pharmaceuticals, Inc. and Subsidiaries (a development stage enterprise) as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity (net capital deficiency), and cash flows for each of the three years in the period ended December 31, 2001 and for the period October 17, 1986 (inception) through 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 consolidated financial position of Sheffield Pharmaceuticals, Inc. and Subsidiaries at December 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 and the period from October 17, 1986 (inception) through December 31, 2001, in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming that Sheffield Pharmaceuticals, Inc. and Subsidiaries will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses and has a working capital deficiency. Those conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial

statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As discussed in Note 1, the computation of basic and diluted net loss per share of common stock for the years ended December 31, 2000 and 1999 has been restated.

/s/ Ernst & Young LLP
St. Louis, Missouri
February 12, 2002

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)
CONSOLIDATED BALANCE SHEETS

ASSETS	D 2001
Current assets:	
Cash and cash equivalents (Note 1)	$ 859
Marketable equity securities (Notes 1 and 6)	
Milestone advance receivable (Note 5)	
Clinical supplies	427
Prepaid expenses and other current assets	86
Total current assets	1,372
Property and equipment (Note 1):	
Laboratory equipment	431
Office equipment	245
Leasehold improvements	25
Total at cost	702
Less accumulated depreciation and amortization	(355
Property and equipment, net	347
Patent costs, net of accumulated amortization of $20,216 and $9,287, respectively (Note 1)	308
Other assets	27

Total assets	$ 2,056

LIABILITIES AND STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

Current liabilities:	
Accounts payable	$ 856
Accrued liabilities	441
Sponsored research payable	235
Note payable (Note 5)	4,000
Total current liabilities	5,533
Convertible promissory note (Note 5)	2,000
Long-term debt (Note 5)	3,000
Other long-term liabilities	608
Commitments and contingencies	
Total liabilities	11,142
Minority interest in subsidiary (Note 1)	
Stockholders' equity (net capital deficiency) (Notes 3 & 4):	
Preferred stock, $.01 par value, authorized 3,000,000 shares:	
Series C cumulative convertible preferred stock, authorized 23,000 shares; 14,708 and 13,712 shares issued and outstanding at December 31, 2001 and 2000, respectively	
Series D cumulative convertible exchangeable preferred stock, authorized 21,000 shares; 13,799 and 12,870 shares issued and outstanding at December 31, 2001 and 2000, respectively	
Series E cumulative convertible non-exchangeable preferred stock, authorized 9,000 shares; 2,124 and 1,004 shares issued and outstanding at December 31, 2001 and 2000, respectively	
Series F convertible non-exchangeable preferred stock, 5,000 shares authorized; 5,000 shares issued and outstanding at December 31, 2001 and 2000	
Common stock, $.01 par value, authorized 100,000,000 shares; issued and outstanding 29,001,602 and 28,791,643 shares at December 31, 2001 and 2000, respectively	290
Additional paid-in capital	83,120
Other comprehensive income	
Deficit accumulated during development stage	(92,496
Total stockholders' equity (net capital deficiency)	(9,086
Total liabilities and stockholders' equity (net capital deficiency)	$ 2,056

See notes to consolidated financial statements.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2001, 2000 and 1999 and for the Period

from October 17, 1986 (inception) to December 31, 2001

	Years ended December 31,		
	2001	2000	1999
Revenues:			
Contract research revenue (Note 1)	$ 869,095	$ 501,572	$ 399,
Sublicense revenue (Note 6)	5,000	5,000	
Total revenues	874,095	506,572	399,
Expenses:			
Acquisition of research and development in-process technology (Note 6)	--	--	15,000,
Research and development	5,999,693	3,747,437	3,421,
General and administrative	4,551,661	2,817,535	2,277,
Total expenses	10,551,354	6,564,972	20,698,
Loss from operations	(9,677,259)	(6,058,400)	(20,299,
Interest income	58,438	124,908	91,
Interest expense	(318,642)	(224,360)	(162,
Realized gain (loss) on sale of marketable securities	79,706	239,629	
Minority interest in loss of subsidiary (Note 1)	378,620	155,072	2,985,
Loss before extraordinary item	(9,479,137)	(5,763,151)	(17,384,
Extraordinary item	--	--	
Net loss	$ (9,479,137)	$ (5,763,151)	$(17,384,
Preferred stock dividends	(2,084,392)	(1,830,094)	(1,036,
Accretion of mandatorily redeemable preferred stock	--	--	
Net loss - attributable to common shares	$(11,563,529)	$ (7,593,245)	$(18,421,
Basic and diluted weighted average common shares outstanding (Note 1)	28,963,562	27,956,119	27,236,
Basic and diluted net loss per share of common stock (Note 1):	$ (.40)	$ (.27)	$ (

See notes to consolidated financial statements.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)
For the Period from October 17, 1986 (Inception) to December 31, 2001

	Preferred Stock	Common Stock	No in c
Balance at October 17, 1986	$ --	$ --	$
Common stock issued	--	11,484,953	
Reincorporation in Delaware at $.01 par value	--	(11,220,369)	
Common stock subscribed	--	--	
Common stock options and warrants issued	--	--	
Issuance of common stock in connection with acquisition of Camelot Pharmacal, LLC	--	6,000	
Common stock options extended	--	--	
Accretion of issuance costs for Series A preferred stock	--	--	
Series C preferred stock issued	115	--	
Series C preferred stock dividends	4	--	
Comprehensive income (loss):			
Unrealized loss on marketable securities	--	--	
Net loss	--	--	
Comprehensive income (loss)	--	--	
Balance at December 31, 1998	119	270,584	
Common stock issued	--	2,504	
Series C preferred stock dividends	9	--	
Series D preferred stock issued	120	--	
Series F preferred stock issued	50	--	
Common stock warrants issued	--	--	
Comprehensive income (loss):			
Unrealized gain on marketable securities	--	--	
Net loss	--	--	
Comprehensive income (loss)	--	--	
Balance at December 31, 1999	298	273,088	
Common stock issued	--	15,738	
Repurchase and retirement of common stock	--	(910)	
Series C preferred stock dividends	9	--	
Series D preferred stock dividends	9	--	
Series E preferred stock issued	10	--	
Series E preferred stock dividends	--	--	
Common stock warrants issued	--	--	
Comprehensive income (loss):			
Unrealized loss on marketable securities	--	--	
Net loss	--	--	
Comprehensive income (loss)	--	--	
Balance at December 31, 2000	326	287,916	
Common stock issued	--	4,251	
Repurchase and retirement of common stock	--	(2,151)	

Series C preferred stock dividends	10	--	
Series D preferred stock dividends	9	--	
Series E preferred stock issued	10	--	
Series E preferred stock dividends	1	--	
Common stock warrants issued	--	--	
Comprehensive income (loss):			
Unrealized loss on marketable securities	--	--	
Net loss	--	--	
Comprehensive income (loss)	--	--	
Balance at December 31, 2001	$ 356	$ 290,016	$

	Other comprehensive income(loss)	Deficit accumulated during development stage	sto eq c de
Balance at October 17, 1986	$ --	$ --	$
Common stock issued	--	--	4
Reincorporation in Delaware at $.01 par value	--	--	
Common stock subscribed	--	--	
Common stock options and warrants issued	--	--	
Issuance of common stock in connection with acquisition of Camelot Pharmacal, LLC	--	--	
Common stock options extended	--	--	
Accretion of issuance costs for Series A preferred stock	--	(103,400)	
Series C preferred stock issued	--	--	1
Series C preferred stock dividends	--	(415,112)	
Comprehensive income (loss):			
Unrealized loss on marketable securities	(222,226)	--	
Net loss	--	(54,638,251)	
Comprehensive income (loss)	--	--	(5
Balance at December 31, 1998	(222,226)	(55,156,763)	
Common stock issued	--	--	
Series C preferred stock dividends	--	(868,277)	
Series D preferred stock issued	--	--	1
Series F preferred stock issued	--	--	
Common stock warrants issued	--	--	
Comprehensive income (loss):			
Unrealized gain on marketable securities	391,613	--	
Net loss	--	(17,384,788)	
Comprehensive income (loss)	--	--	(1
Balance at December 31, 1999	169,387	(73,409,828)	
Common stock issued	--	--	
Repurchase and retirement of common stock	--	--	
Series C preferred stock dividends	--	(934,045)	
Series D preferred stock dividends	--	(855,750)	
Series E preferred stock issued	--	--	
Series E preferred stock dividends	--	(4,750)	
Common stock warrants issued	--	--	
Comprehensive income (loss):			
Unrealized loss on marketable securities	(11,920)	--	
Net loss	--	(5,763,151)	
Comprehensive income (loss)	--	--	(

Balance at December 31, 2000	157,467	(80,967,524)	
Common stock issued	--	--	
Repurchase and retirement of common stock	--	--	
Series C preferred stock dividends	--	(999,278)	
Series D preferred stock dividends	--	(929,603)	
Series E preferred stock issued	--	--	
Series E preferred stock dividends	--	(121,422)	
Common stock warrants issued	--	--	
Comprehensive income (loss):			
Unrealized loss on marketable securities	(157,467)	--	
Net loss	--	(9,479,137)	
Comprehensive income (loss)	--	--	(
Balance at December 31, 2001	$ --	$(92,496,964)	$ (

See notes to consolidated financial statements.

SHEFFIELD PHARMACEUTICALS, INC. AND SUBSIDIARIES
(a development stage enterprise)
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2001, 2000 and 1999 and for the Period from October 17, 1986 (Inception) to December 31, 2001

	Years ended December		
	2001	2000	
Cash flows from operating activities:			
Net loss	$ (9,479,137)	$ (5,763,151)	$
Adjustments to reconcile net loss to net cash used by development stage activities:			
Issuance of common stock, stock options/warrants for services	126,741	207,202	
Depreciation and amortization	130,554	118,775	
Non-cash acquisition of research and development in-process technology	--	--	
(Gain) loss realized on sale of marketable securities	(79,706)	(239,629)	
Decrease (increase) in clinical supplies, prepaid expenses & other current assets	26,642	(395,035)	
Decrease (increase) in milestone advance receivable	1,000,000	(1,000,000)	
Increase in other assets	(72,320)	(64,089)	
Increase in accounts payable and accrued liabilities	352,646	615,636	
(Decrease) increase in sponsored research payable	--	(185,924)	
Other	(72,343)	59,973	
Net cash used by development stage activities	(8,066,923)	(6,646,242)	

Cash flows from investing activities:			
Proceeds from sale of marketable securities	249,661	419,674	
Acquisition of laboratory and office equipment, and leasehold improvements	(200,570)	(86,107)	
Other	--	--	
Net cash provided (used) by investing activities	49,091	333,567	
Cash flows from financing activities:			
Payments on debt and capital leases	(7,428)	(6,435)	
Net proceeds from issuance of:			
Debt	5,000,000	1,000,000	
Common stock	--	2,015,625	
Preferred stock	1,000,000	1,000,000	
Proceeds from exercise of warrants/stock options	485,452	1,784,185	
Repurchase and retirement of common stock	(642,842)	(313,189)	
Other	--	--	
Net cash provided by financing activities	5,835,182	5,480,186	
Net (decrease) increase in cash and cash equivalents	(2,182,650)	(832,489)	
Cash and cash equivalents at beginning of period	3,041,948	3,874,437	
Cash and cash equivalents at end of period	$ 859,298	$ 3,041,948	$
Noncash investing and financing activities:			
Common stock, stock options and warrants issued for services	$ 126,741	$ 207,202	$
Common stock redeemed in payment of notes receivable	--	--	
Acquisition of research and development in-process technology	--	--	
Common stock issued for intellectual property rights	--	--	
Common stock issued to retire debt	--	--	
Common stock issued to redeem convertible securities	--	--	
Securities acquired under sublicense agreement	--	--	
Equipment acquired under capital lease	--	--	
Notes payable converted to common stock	--	--	
Stock dividends	2,050,305	1,794,545	
Supplemental disclosure of cash information: Interest paid	$ 7,060	$ 2,940	$

See notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation - Sheffield Pharmaceuticals, Inc. ("Sheffield" or the "Company") a Delaware corporation, is focused on the development and commercialization of later stage pharmaceutical products that utilize the Company's unique proprietary pulmonary delivery technologies.

The accompanying consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company is in the development stage and to date has been principally engaged in research, development and licensing efforts. The Company has generated minimal operating revenue, sustained significant net operating losses, and requires additional capital that the Company intends to obtain through out-licensing of rights to its technology, as well as through equity and debt offerings, to continue to operate its business. The Company's ability to meet its obligations as they become due and to continue as a going concern must be considered in light of the expenses, difficulties and delays frequently encountered in developing a new business, particularly since the Company will focus on product development that may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products to be profitable. Management believes that the Company's ability to meet its obligations as they become due and to continue as a going concern through December 2002 is dependent upon obtaining additional funding. In an effort to meet its capital requirement, the Company will be evaluating various financing alternatives including private offerings of its securities, debt financing, and collaboration and licensing arrangements with other companies. However, the accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Principles of Consolidation - The consolidated financial statements include the accounts of Sheffield and its wholly owned subsidiaries, Systemic Pulmonary Delivery, Ltd. ("SPD"), Ion Pharmaceuticals, Inc., and CP Pharmaceuticals, Inc., and its 80.1% owned subsidiary, Respiratory Steroid Delivery, Ltd. ("RSD"). All significant intercompany transactions have been eliminated. Investments in affiliated companies that are 50% owned or less, and where the Company does not exercise control, are accounted for using the equity method.

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

Cash Equivalents - The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. Cash and cash equivalents include demand deposits held in banks, interest bearing money market funds, and corporate commercial paper with A1 or P1 short-term ratings.

Marketable Securities - Marketable securities consist of investments that can be readily purchased or sold using established markets. The Company's securities, which are classified as available-for-sale, are carried at market with unrealized gains and losses reported as a separate component of other comprehensive income within stockholders' equity.

Property and Equipment - Property and equipment are stated at cost. Depreciation is computed using the straight-line method over three or five year periods for office equipment, and five years for laboratory equipment. Assets under capital leases, consisting of office equipment and leasehold improvements, are amortized

over the lesser of the useful life or the applicable lease terms.

Patent Costs - Costs associated with obtaining patents, principally legal costs and filing fees, are capitalized and being amortized on a straight-line basis over the remaining lives of the respective patents. The Company periodically evaluates the carrying amount of these assets based on current licensing and future commercialization efforts, and if warranted, impairment would be recognized.

Contract Research Revenue - Contract revenue from collaborative research agreements is recorded when earned and as the related costs are incurred. Payments received that are related to future performance are deferred and recognized as revenue in the period in which they are earned.

Research and Development Costs - Research and development costs ("R & D costs") are expensed as incurred, except for fixed assets to which the Company has title, which are capitalized and depreciated over their estimated useful lives.

Income Taxes - The Company utilizes the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Fair Value of Financial Instruments - The carrying amounts of cash and cash equivalents, receivables, accounts payable, sponsored research payable and notes payable approximate fair value.

Basic Net Loss per Share of Common Stock - Basic net loss per share is calculated in accordance with Statement of Financial Accounting Standards ("SFAS") No. 128, Earnings Per Share. Basic net loss per share is based on net loss available to common stockholders divided by the weighted average common stock outstanding during the year. Potentially dilutive securities, such as stock options, warrants, convertible debt and preferred stock, have not been included in any years presented as their effect is antidilutive. The net loss available to common stockholders and basic and diluted net loss per share for the years ended December 31, 2000 and 1999 have been restated from amounts previously reported to properly reflect cumulative preferred stock dividends payable in kind. Such amounts may differ from dividends declared as reflected in the Statement of Stockholders' Equity. The effect of this restatement was to increase basic and diluted net loss per share from $.21 to $.27 and from $.64 to $.68 for the years ended December 31, 2000 and 1999, respectively.

Stock-Based Compensation - SFAS No. 123, Accounting for Stock-Based Compensation, defines a fair value method of accounting for stock options and similar equity instruments. As permitted by SFAS 123, the Company continues to account for employee stock options under Accounting Principal Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25"), and has disclosed in a note to the financial statements pro forma net loss and earnings per share as if the Company had applied the fair value method of accounting for its stock-based awards. Under APB 25, no expense is generally recognized at the time of option grant because the exercise price of the Company's employee stock option equals or exceeds the fair market value of the underlying common stock on the date of grant.

Comprehensive Income (Loss) - SFAS No. 130, Reporting Comprehensive Income, establishes standards for the reporting and display of comprehensive income and

its components in a full set of general purpose financial statements and applies to all enterprises. Other comprehensive income or loss shown in the consolidated statements of stockholders' equity at December 31, 2001, 2000 and 1999 is solely comprised of unrealized gains or losses on marketable securities. The unrealized loss on marketable securities during 2001 and 2000 includes reclassification adjustments of $79,706 and $239,629, respectively, for gains realized in income from the sale of the securities.

Segment Information - SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. The Company operates in one reportable segment as defined by SFAS No. 131.

Reclassifications - Certain amounts in the prior year financial statements and notes have been reclassified to conform to the current year presentation.

2. LEASES

The Company leases its office space and certain equipment under noncancelable operating and capital leases that expire at various dates through 2003. At December 31, 2001, assets held under capital leases consisting of office equipment were $11,397, net of accumulated amortization of $37,834. Future minimum lease payments under capital and operating leases at December 31, 2001 are as follows:

	Capital Leases	Operating Leases
2002	$ 9,375	$168,478
2003	774	2,463
Total minimum lease payments	10,149	$170,941
Less amount representing interest	(806)	
Present value of net minimum lease payments	9,343	
Less current maturities of capital lease obligations	(8,578)	
Capital lease obligations	$ 765	

Rent expense relating to operating leases for the years ended December 31, 2001, 2000 and 1999 was $226,759, $219,859, and $174,332, respectively.

3. STOCKHOLDERS' EQUITY

Preferred Stock

In June 1998, the Company issued 4,571,428 shares of Common Stock and 11,500 shares of Series C Cumulative Convertible Preferred Stock ("Series C Preferred Stock"), convertible into shares of Common Stock of the Company or of its wholly owned subsidiary, SPD, for $17.5 million pursuant to a definitive agreement with an affiliate of Elan Corporation, plc ("Elan"), Elan International Services, Ltd. ("Elan International"). The Series C Preferred Stock earns cumulative dividends payable in shares of Series C Preferred Stock at an annual rate of 7.0% on the stated value of each outstanding share of Series C Preferred Stock on the dividend date. Elan International also received a warrant to purchase 990,000 shares of Common Stock of the Company exercisable from December 31, 1998 through January 30, 2005 at an exercise price of $2.00 per share. Under the terms of the agreement, the Company, through SPD, acquired certain pulmonary delivery technologies for the sum of $12.5 million in cash (see Note 6). All of the outstanding Common Stock of SPD is pledged to Elan during the term of the agreement. Subject to certain conditions and the making of certain payments to the Company, Elan International has the option to acquire all or a portion of the outstanding stock of SPD. The net book value of SPD is $.1 million as of December 31, 2001. The Company issued stock dividends totaling 996 and 932 shares of Series C Preferred Stock and cash dividends for fractional shares of $3,278 and $2,045 for the years ended December 31, 2001 and 2000, respectively.

In October 1999, pursuant to a definitive agreement, the Company and Elan International formed RSD to develop certain respiratory steroid products. Under the terms of the agreement, the Company issued to Elan International 12,015 shares of Series D Cumulative Convertible Exchangeable Preferred Stock ("Series D Preferred Stock"), convertible into shares of Common Stock of the Company at $4.86 per Common Share or exchangeable for an additional 30.1% ownership interest in the new joint venture, for $12.0 million. The Series D Preferred Stock earns cumulative dividends payable in shares of Series D Preferred Stock at an annual rate of 7.0% on the stated value of each outstanding share of Series D Preferred Stock on the dividend date. The Company issued stock dividends totaling 929 and 855 shares of Series D Preferred Stock and cash dividends for fractional shares of $603 and $750 for the years ended December 31, 2001 and 2000, respectively. Elan International also has committed to purchase, on a drawdown basis, up to $4.0 million of the Company's Series E Cumulative Convertible Preferred Stock ("Series E Preferred Stock"), convertible into shares of Common Stock of the Company at $3.89 per Common Share. During 2001 and 2000, Elan International purchased a total of $2.0 million of the Series E Preferred Stock. The Series E Preferred Stock will be utilized by the Company to fund its portion of RSD's operating and development costs. The Series E Preferred Stock earns cumulative dividends payable in shares of Series E Preferred Stock at an annual rate of 9.0% on the stated value of each outstanding share of Series E Preferred Stock on the dividend date. The Company issued stock dividends totaling 120 and 4 shares of Series E Preferred Stock and cash dividends for fractional shares of $1,422 and $750 for the years ended December 31, 2001 and 2000, respectively. In addition to the above, the Company issued to Elan International 5,000 shares of Series F Convertible Non-Exchangeable Preferred Stock ("Series F Preferred Stock"), convertible into shares of Common Stock of the Company at $3.40 per Common Share, for $5.0 million. The proceeds of the Series F Preferred Stock were utilized by Sheffield for its own operating purposes. The holders of the Series F Preferred Stock may be entitled to receive dividends on a pari passu basis with the holders of Common Stock. As part of the transaction, Elan International also received a warrant to purchase 150,000 shares of Common Stock of the Company at an exercise price of $6.00 per share (see Note 6).

Common Stock

During 1998, the Company entered into an agreement with Zambon Group, SpA ("Zambon") for a sublicense to the Company's proprietary Premaire(R)

Delivery System ("Premaire"), a portable nebulizer-based pulmonary delivery system (see Note 6). Pursuant to an option agreement dated April 15, 1998, the Company issued 800,000 shares of Common Stock to Zambon for $650,000 in cash. On June 15, 1998, the Company entered into the definitive agreement, resulting in the issuance of an additional 1,846,153 shares of Common Stock to Zambon for $1.5 million. On October 17, 2001, as part of the September 28, 2001 amendment of the Company's 1998 agreement with Zambon, the Company repurchased from Zambon, 214,997 shares of common stock for $3.0233 per share ("Repurchase Price"). In addition, the Company received an option, expiring December 31, 2002, to repurchase the remaining shares of the Company's common stock held by Zambon at the Repurchase Price. In the event the Company completes a sublicense for the North American rights or a sublicense for the non- North American rights to the Premaire respiratory products prior to December 31, 2002, the Company will be required to repurchase from Zambon 882,051 shares of the Company's common stock on each of the events.

In December 2000, the Company entered into a stock purchase agreement with The Tail Wind Fund Ltd. ("Tail Wind"). Under the agreement, Sheffield issued and sold 626,950 shares of Common Stock and a warrant to purchase 112,500 shares of Common Stock at an exercise price of $4.9844 per share for total cash consideration of $2.3 million. The net proceeds from the transaction of $2.0 million

were available to be used for general corporate purposes. Pursuant to the stock purchase agreement, until at least August 29, 2002, if Sheffield sells shares of Common Stock or securities convertible into or exercisable for Common Stock for less than $3.5888 per share, Sheffield is obligated to issue to Tail Wind additional shares so that the number of shares purchased by Tail Wind in the December 2000 private placement plus the additional shares issued to Tail Wind equals the number of shares that Tail Wind could have purchased for $2.3 million at the price per share at which the new shares are sold. In addition, in the event that the Company is required to issue additional shares to Tail Wind, Sheffield may not issue an aggregate of over 5,630,122 shares of Common Stock in total to Tail Wind in connection with the December 2000 private placement. If the Company would otherwise be required to issue more than 5,630,122 shares to Tail Wind, Sheffield must instead pay Tail Wind 105% of the cash value of such shares the Company does not issue.

4. STOCK OPTIONS AND WARRANTS

Stock Option Plan - The 1993 Stock Option Plan (the "Option Plan") was adopted by the Board of Directors in August 1992 and approved by the stockholders at the annual meeting in December 1993. An amendment to the Option Plan increasing the number of shares of Common Stock available for issuance thereunder from 3 million shares to 4 million shares received stockholder approval on July 15, 1998. The Option Plan permits the grant to employees and officers of the Company of both incentive stock options and non-statutory stock options. The Option Plan is administered by the Board of Directors or a committee of the Board, which determines the persons to whom options will be granted and the terms thereof, including the exercise price, the number of shares subject to each option, and the exercisability of each option. The exercise price of all options for Common Stock granted under the Option Plan must be at least equal to the fair market value on the date of grant in the case of incentive stock options, and 85% of the fair market value on the date of grant in the case of non-statutory stock options. Options generally expire five to ten years from the date of grant and vest either over time or upon the Company's Common Stock attaining a set market price for a certain number of trading days. Certain employment agreements

provide for an immediate vesting of all unvested options held by the employee upon a change of control of the Company. Upon such a change of control, recognition of compensation expense may be triggered, the amount of which cannot be determined at this time. As of December 31, 2001, there are 709,700 shares available for grant under the Option Plan.

Restricted Stock Plan - The 1993 Restricted Stock Plan (the "Restricted Plan") was adopted by the Board of Directors in August 1992 and approved by the stockholders at the annual meeting in December 1993. The Restricted Plan authorized the grant of a maximum of 150,000 shares of Common Stock to key employees, consultants, researchers and members of the Company's Scientific Advisory Board. The Restricted Plan is administered by the Board of Directors or a committee of the Board, which determines the person to whom shares will be granted and the terms of such share grants. As of December 31, 2001, no shares have been granted under the Restricted Plan.

Directors Stock Option Plan - The 1996 Directors Stock Option Plan (the "Directors Plan") was adopted by the Board of Directors and approved by the stockholders on June 20, 1996. Under the Directors Plan, the maximum aggregate number of shares that may be optioned and sold is 500,000 shares of Common Stock. The Directors Plan initially granted each eligible director 15,000 stock options. To the extent that shares remain available, any new directors shall receive the grant of an option to purchase 25,000 shares. To the extent that shares remain available under the Directors Plan, on January 1 of each year commencing January 1, 1997, each eligible director shall be granted an option to purchase 15,000 shares. The exercise price of all options granted under the Directors Plan shall be the fair market value at the date of the grant. Options generally expire five years from the date of grant. As of December 31, 2001, there are 170,000 shares available for grant under the Directors Plan.

SFAS No. 123 requires pro forma information regarding net income and earnings per share as if the Company has accounted for its stock options granted subsequent to December 31, 1994, under the fair value method of SFAS No. 123. The fair value of these stock options is estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions for 2001, 2000, and 1999, risk-free interest rate ranging from 4.39% to 6.36%; expected volatility ranging from 0.628 to 0.874; expected option life of one to ten years from vesting and an expected dividend yield of 0.0%.

For purposes of pro forma disclosures, the estimated fair value of the stock options is amortized to expense over the options' vesting period. The Company's pro forma information is as follows:

	2001	2000	1999
Pro forma net loss	$ (12,479,299)	$ (10,036,410)	$ (18,843,61
Pro forma basic net loss per share of common stock	$ (.43)	$ (.36)	$ (.6

As discussed in Note 1, the net loss available to common stockholders and basic and diluted net loss per share for the years ended December 31, 2000 and 1999 have been restated to properly reflect cumulative preferred stock dividends payable in kind. As a result, the 2000 and 1999 pro forma basic net loss per share of common stock above have also been restated.

Transactions involving stock options and warrants are summarized as follows:

	Years Ended December 31,				
	2001		2000		
	Common Stock Options/Warrants	Weighted Average Exercise Price	Common Stock Options/Warrants	Weighted Average Exercise Price	Co Opti
Outstanding, January 1	6,921,629	$ 3.02	7,782,954	$ 2.59	
Granted	156,940	4.44	1,041,040	5.34	
Expired	250,000	2.99	660,820	2.90	
Exercised	558,100	1.73	1,241,545	2.32	
Canceled	85,000	3.21	--	--	
Outstanding, December 31	6,185,469	$ 3.18	6,921,629	$ 3.02	
Exercisable at end of year	4,525,969	$ 2.77	5,049,613	$ 2.57	

During the period January 1, 1999 through December 31, 2001, the exercise prices and weighted average fair value of options and warrants granted by the Company were as follows:

Year	Number of Options/Warrants	Exercise Price	Weighted Averag
1999	555,040	$0.82 - 6.00	$ 1.3
2000	1,041,040	$3.50 - 7.00	$ 3.3
2001	156,940	$3.58 - 5.25	$ 3.0

At December 31, 2001, outstanding warrants to purchase the Company's Common Stock are summarized as follows:

Range of Exercise Prices	Outstanding Warrants	Weighted Average Remaining Contractual Life (Years)	Weighted Avera
$1.38 - $2.00	1,054,910	3.37	$
$2.50 - $3.65	521,179	0.30	$
$4.00 - $6.13	384,080	4.04	$

Total	1,960,169	2.68	$

At December 31, 2001, outstanding options to purchase the Company's Common Stock are summarized as follows:

Range of Exercise Prices	Outstanding Options	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exer
$1.24 - $2.69	1,036,000	3.82	$ 1.74
$2.75 - $3.25	1,681,000	4.67	$ 2.80
$3.50 - $7.00	1,508,300	5.24	$ 4.79
Total	4,225,300	4.66	$ 3.25

5. NOTES PAYABLE AND LONG-TERM DEBT

Note Payable

In August 2001, the Company entered into a Note Purchase Agreement ("Note") with Elan Pharma International Ltd. ("Elan Pharma"), pursuant to which Elan Pharma agreed to lend the Company up to $4 million. All borrowings under the Note are evidenced by an unsecured promissory note of the Company providing for interest on principal and semi-annually compounded at a fixed rate of 10% per annum and a maturity of November 14, 2002, or upon the earlier occurrence of one or more specified events. The outstanding principal balance of the Note was $4.0 million at December 31, 2001.

Convertible Promissory Note

As part of the 1998 agreement with Elan, Elan agreed to make available to the Company a Convertible Promissory Note ("Convertible Note") that provides the Company the right to borrow up to $2.0 million, subject to satisfying certain conditions. No more than $500,000 may be drawn under the Convertible Note in any calendar quarter and at least one-half of the proceeds must be used to fund SPD's development activities. The principal outstanding under the Convertible Note bears interest at the prime rate plus 1% and, if not previously converted, matures on June 30, 2005. Prior to repayment, Elan has the right to convert all principal and accrued interest into shares of the Company's Common Stock at a conversion price of $1.75 per share. The outstanding principal balance of the Convertible

Note at December 31, 2001 and 2000 was $2.0 million, and accrued interest was $.6 million and $.4 million at December 31, 2001 and 2000, respectively.

Long-Term Debt

In September 2001, in connection with the amendment of its 1998 agreement with Zambon, the Company entered into a Loan and Security Agreement (the "Loan") with Zambon, pursuant to which Zambon agreed to lend the Company $2.5 million. The Company received $1.0 million upon signing of the Loan, with additional borrowings of $1.0 million and $.5 million to be made on January 1, 2002 and April 1, 2002, respectively. The Loan provides for interest on principal and annually compounded interest at a fixed rate of 2% per annum and is secured by certain security interests in respiratory products developed in the Premaire. One third of the principal balance, together with interest, is payable by the Company upon the Company's execution of an agreement with one or more third parties to develop, co-promote and/or sell certain products in North America, with all remaining unpaid principal and interest due on December 31, 2005. The outstanding principal balance of the Loan was $1.0 million at December 31, 2001. On January 1, 2002, the Company received the additional borrowing of $1.0 million as provided by the Loan.

In conjunction with the completion of the Phase I/II Premaire albuterol trial in 1999 and the demonstration of the technical feasibility of delivering an inhaled steroid formulation in the Premaire in 2000, Zambon provided the Company with two $1.0 million interest-free advances against future milestone payments. The second advance was received in January 2001 and was reflected in the accompanying financial statements as a milestone advance receivable at December 31, 2000. The proceeds from these advances were not restricted as to their use by the Company (see Note 6). As part of the amendment of its 1998 agreement with Zambon, the terms of all milestone advances received from Zambon were modified in that the Company shall repay $1.0 million of the advance milestone payments upon the earlier of December 31, 2003, or upon the first regulatory approval for either albuterol or an inhaled steroid delivered in the Premaire. The remaining $1.0 million advance shall be repaid by the Company on the earlier of December 31, 2005, or the regulatory approval of the second product (albuterol or an inhaled steroid) delivered in the Premaire. Due to the modification in the repayment terms, the advances, totaling $2.0 million at both December 31, 2001 and 2000, have been reclassified in the Company's balance sheet as long-term debt.

6. RESEARCH AND DEVELOPMENT AGREEMENTS

Pulmonary Delivery Technologies

In June 1998, the Company sublicensed to Zambon worldwide marketing and development rights to respiratory products to be delivered by the Premaire in return for an equity investment in the Company (approximately 10%). From June 1998 to September 2001, Zambon funded the development costs for the respiratory compounds delivered by Premaire. In September 2001, the Company amended its 1998 agreement with Zambon whereby Sheffield regained the rights to the Premaire previously granted to Zambon. Upon commercialization, Zambon will be entitled to certain royalties on payments received by Sheffield for albuterol, ipratropium and cromolyn sales for specified periods.

In June 1998, the Company issued certain equity securities pursuant to an agreement with Elan (see Note 3). Under the terms of the agreement, the Company, through its wholly owned subsidiary, SPD, acquired certain pulmonary delivery technologies from Elan for $12.5 million in cash. In July 1998, SPD acquired from Aeroquip-Vickers, Inc. a new generation propellant-based pulmonary delivery system called the Tempo(TM) Inhaler for $.9 million. The payments for these technologies were expensed during 1998 as acquired R&D in-process technology since the technologies acquired had not demonstrated technological feasibility and had no alternative future uses. SPD holds the rights to all systemic disease applications of the Tempo technology while Sheffield retains the rights to develop the respiratory disease applications of Tempo. The Company

is responsible for the development of these technologies. Pursuant to its agreement with Elan, at December 31, 2001, the Company was not committed to fund any additional costs related to SPD's systemic development programs.

In October 1999, the Company issued certain equity securities pursuant to an agreement with Elan (see Note 3). Under the terms of the agreement, the Company, through its majority owned subsidiary RSD, licensed certain pulmonary NanoCrystal(TM) technology from Elan for $15.0 million in cash. This payment was expensed as acquired R&D in-process technology as the license agreement restricts the Company's use of the NanoCrystal technology to certain respiratory steroid products that are currently research and development. The subsidiary is responsible for the development of certain respiratory steroid products. Pursuant to its agreement with Elan, at December 31, 2001, the Company was committed to fund $2.0 million to the subsidiary for the development of these products, which the Company will fund by the issuance of its Series E Preferred Stock.

Early Stage Technologies

The Company also is party to a number of license and research agreements, primarily with universities, hospitals, and research facilities, relating to early stage medical research projects that focus on the development of new compounds for the treatment of cancer, acquired immune deficiency syndrome and other diseases. As part of the Company's focus on later stage opportunities, the Company is seeking to out-license these projects. There can be no assurance that the Company will receive license fees or other payments related to these technologies. The Company believes these early stage technology license and research agreements will have no material impact on the financial position of the Company.

On November 20, 1997, the Company entered into a sublicense agreement with Lorus Therapeutics, Inc. (formerly Imutec Pharma Inc.) ("Lorus"). The agreement licenses rights to a series of clotrimazole-related compounds for the treatment of cancer, Kaposi's sarcoma and actinic keratosis to a newly formed company, NuChem Pharmaceuticals, Inc. ("NuChem"). In exchange, Lorus agreed to manage and fund the remaining development program. The Company is entitled to receive payments upon the completion of certain milestones in the development of these compounds and retains a 20% ownership interest in NuChem.

7. INCOME TAXES

At December 31, 2001, the Company had available net operating loss carryforwards for regular federal income tax purposes of approximately $50.9 million, of which $27.5 million will expire between 2007 and 2012, and $23.4 million will expire between 2018 and 2021, if not utilized. Utilization of the Company's net operating loss carryforwards may be subject to an annual limitation as a result of the "changes in ownership" provisions of the Internal Revenue Code Section 382. Future changes in ownership may limit net operating loss carryforwards generated in the year of change.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax asset at December 31, 2001 and 2000, which are considered noncurrent, are as follows:

DEFERRED TAX ASSETS	2001	2000
Net operating loss carryforwards	$ 19,348,000	$ 16,289,000
Costs capitalized for tax purposes	1,810,000	1,975,000
Deferred tax asset valuation allowance	(21,158,000)	(18,264,000)
Net deferred tax asset	$ --	$ --

The Company has recorded a valuation allowance for the entire deferred tax asset due to the uncertainty of its realization. The deferred tax asset will be amortized into taxable income over a useful life of 15 years.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA (CONTINUED)

Quarterly financial data for 2001 and 2000 is summarized below:

	Three Months End	
	Mar 31	Jun 30
2001:		
Total revenues	$ 180,747	$ 693,348
Operating loss	(1,623,295)	(2,360,545)
Net loss	(1,580,410)	(2,279,410)
Basic and diluted net loss per common share	(.07)	(.10)
2000:		
Total revenues	$ 121,170	$ 124,505
Operating loss	(1,475,577)	(1,449,671)
Net loss	(1,457,090)	(1,383,810)
Basic and diluted net loss per common share	(.07)	(.07)

Basic net loss per share is based on net loss available to common stockholders divided by the weighted average common stock outstanding during the quarter. The net loss available to common stockholders and basic and diluted net loss per share for the quarters ended September 30, 2001, June 30, 2001, and March 31, 2001, and for each of the quarters in 2000 have been restated from amounts previously reported to properly reflect cumulative preferred stock dividends payable in kind as discussed in Note 1 to the financial statements. The effect of this restatement was to increase basic and diluted net loss per share from $.09 to $.11, from $.08 to $.10 and from $.05 to $.07 for the quarters ended

September 30, 2001, June 30, 2001, and March 31, 2001, respectively, and from $.06 to $.07, from $.05 to $.06, from $.05 to $.07, and from $.05 to $.07 for the quarters ended December 31, 2000, September 30, 2000, June 30, 2000, and March 31, 2000, respectively.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

The information required by this Item is incorporated by reference to the Company's definitive proxy statement to be filed no later than April 30, 2002, pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the Company's definitive proxy statement to be filed no later than April 30, 2002, pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this Item is incorporated by reference to the Company's definitive proxy statement to be filed no later than April 30, 2002, pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated by reference to the Company's definitive proxy statement to be filed no later than April 30, 2002, pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934.

ITEM14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a)(1) Financial Statements

The following Financial Statements are included in Item 8 hereto:
Report of Independent Auditors
Consolidated Balance Sheets as of
December 31, 2001 and 2000
Consolidated Statements of Operations for the years
ended December 31, 2001, 2000 and 1999 and for the
period October 17, 1986 (inception) to December, 31
2001
Consolidated Statements of Stockholders' Equity (net
capital deficiency) for the period from October 17,
1986 (inception) to December 31, 2001

Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999 and for the period from October 17, 1986 (inception) to December 31, 2001
Notes to Financial Statements

(a)(2) Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto.

(a)(3) Exhibits:

NO.		REFERENCE
3.1	Certificate of Incorporation of the Company, as amended	(9)
3.2	By-Laws of the Company	(4)
4.1	Form of Common Stock Certificate	(2)
4.4	Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series C Cumulative Convertible Redeemable Preferred Stock.	(9)
4.5	Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series D Cumulative Convertible Exchangeable Preferred Stock.	(14)
4.6	Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series E Convertible Non-Exchangeable Preferred Stock.	(14)
4.7	Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series F Convertible Non-Exchangeable Preferred Stock.	(14)
10.6	Employment Agreement dated as of June 6, 1996 between the Company and Thomas M. Fitzgerald*	(3)
10.6A	Amendment dated October 1, 2002 to Employment Agreement between the Company and Thomas M. Fitzgerald.*	(1)

NO.		REFE
10.6.5	Employment Agreement dated as of November 16, 1998 between the Company and Scott Hoffmann*	(

10.6.5A	Amendment dated October 1, 2001 to Employment Agreement between the Company and Scott Hoffmann.*	
10.6.6	Employment Agreement dated as of August 3, 1998 between the Company and Thomas A. Armer*	
10.6.6A	Amendment dated October 1, 2001 to Employment Agreement between the Company and Thomas A. Armer.*	
10.8	1993 Stock Option Plan, as amended*	(
10.9	1993 Restricted Stock Plan, as amended*	(
10.10	1996 Directors Stock Option Plan*	
10.11	Agreement and Plan of Merger among the Company, Camelot Pharmacal, L.L.C., David A. Byron, Loren G. Peterson and Carl Siekmann dated April 25, 1997*	
10.12	Employment Agreement dated as of April 25, 1997 between the Company and David A. Byron*	
10.13	Employment Agreement dated as of April 25, 1997 between the Company and Loren G. Peterson, as amended*	
10.13A	Amendment dated October 1, 2001 to Employment Agreement between the Company and Loren G. Peterson.*	
10.14	Employment Agreement dated as of April 25, 1997 between the Company and Carl Siekmann*	
10.19	Form of Sublicense and Development Agreement between Sheffield Pharmaceuticals, Inc. and Inpharzam International, S.A. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.20	Securities Purchase Agreement, dated as of June 30, 1998, by and between Sheffield Pharmaceuticals, Inc. and Elan International Services, Ltd., which includes the Certificate of Designations of Series C Convertible Preferred Stock as Exhibit B. The Company agreed to furnish the disclosure schedules as well as Exhibits A and C, which were omitted from this filing, to the Commission upon request (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.21	Systemic Pulmonary Delivery, Ltd. Joint Development and Operating Agreement dated as of June 30, 1998 among Systemic Pulmonary Delivery, Ltd., Sheffield Pharmaceuticals,	(

NO.		REFE
	Inc. and Elan International Services, Ltd. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	
10.22	License and Development Agreement dated June 30, 1998 between Sheffield Pharmaceuticals, Inc. and Systemic Pulmonary Delivery, Ltd. and Elan Corporation plc. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.23	License and Development Agreement dated June 30, 1998 between Systemic Pulmonary Delivery, Ltd. and Sheffield Pharmaceuticals, Inc. and Elan Corporation, plc. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.24	License and Development Agreement dated June 30, 1998 between Elan Corporation, plc and Systemic Pulmonary Delivery, Ltd. and Sheffield Pharmaceuticals, Inc. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.25	Securities Purchase Agreement, dated as of October 18, 1999, by and between the Company and Elan (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.26	Subscription, Joint Development and Operating Agreement dated as of October 18, 1999 by and among Elan Pharma International Limited, Elan, the Company and Respiratory Steroid Delivery, Ltd. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.27	License Agreement, dated as of October 19, 1999, by and	(

between the Company and Respiratory Steroid Delivery, Ltd. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

NO.		REFE
10.28	License Agreement, dated as of October 19, 1999, by and between Elan Pharma International Limited and Respiratory Steroid Delivery, Ltd. (portions of this exhibit were omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.29	Registration Rights Agreement dated as of October 18, 1999 by and between Elan and the Company.	(
10.30	Securities Purchase Agreement dated as of December 29, 2000, by and between the Company and The Tail Wind Fund Ltd	(
10.31	Registration Rights Agreement dated as of December 29, 2000, by and between the Company and The Tail Wind Fund Ltd	(
10.32	Amendment to Sublicense and Development Agreement dated September 29, 2001, between Sheffield Pharmaceuticals, Inc. and Inpharzam International S.A.	(
10.33	Loan and Security Agreement dated September 29, 2001, between Sheffield Pharmaceuticals, Inc. and Inpharzam International, S.A.	(
10.34	Promissory Note dated September 29, 2001 issued to Inpharzam International, S.A.	(
10.35	Note Purchase Agreement dated August 14, 2001 between Sheffield Pharmaceuticals, Inc. and Elan Pharma International Ltd. (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).	(
10.36	Promissory Note dated September 29, 2001 issued to Elan Pharma International Ltd. (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's	(

	application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).
10.37	Separation Agreement dated as of February 18, 2002 between the Company and Carl Siekmann*
10.38	Separation Agreement dated as of February 18, 2002 between the Company and David A. Byron*
10.39	Indemnification Agreement dated January 23, 2002 between the Company and certain officers and directors.
21	Subsidiaries of Registrant
23.1	Consent of Ernst & Young LLP
24	Power of Attorney (Included on page 42 hereof)

* Management contracts or compensatory plans or arrangements.

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(1) Filed herewith.

(2) Incorporated by reference to the Company's Annual Report on Form 10-KSB for its fiscal year ended December 31, 1995 filed with the Securities and Exchange Commission.

(3) Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 1996 filed with the Securities and Exchange Commission.

(4) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997 filed with the Securities and Exchange Commission.

(5) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1997 filed with the Securities and Exchange Commission.

(6) Incorporated by reference to the Company's Annual Report on Form 10-KSB for the year ended December 31, 1996 filed with the Securities and Exchange Commission.

(7) Incorporated by reference to the Company's Registration Statement on Form S-3 (File No. 333-38327) filed with the Securities and Exchange Commission on October 21, 1997.

(8) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 17, 1997.

(9) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998 filed with the Securities and Exchange Commission.

(10) Incorporated by reference to Exhibit 3 of the Company's Current Report

on Form 8-K, dated April 17, 1998, filed with the Securities and Exchange Commission.

(11) Incorporated by reference to Exhibit 2 of the Company's Current Report on Form 8-K, dated June 22, 1998, filed with the Securities and Exchange Commission.

(12) Incorporated by reference to exhibits to the Company's Current Report on Form 8-K, dated July 16, 1998, filed with the Securities and Exchange Commission.

(13) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 1998 filed with the Securities and Exchange Commission.

(14) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 2, 1999.

(15) Incorporated by reference to the Company's Registration Statement on Form S-3 (File No. 333-54446) filed with the Securities and Exchange Commission on January 26, 2001.

(16) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 filed with the Securities and Exchange Commission.

(17) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 filed with the Securities and Exchange Commission.

(b) Reports on Form 8-K

(1) Current Report on Form 8-K filed with Securities and Exchange Commission on October 11, 2001 to announce the filing of a press release under Item 5, and Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2001 to announce under Item 5 the filing of exhibits.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SHEFFIELD PHARMACEUTICALS, INC.

Dated: March 28, 2002

/s/ Loren G. Peterson

Loren G. Peterson
President and Chief Executive Officer

POWER OF ATTORNEY

Sheffield Pharmaceuticals, Inc. and each of the undersigned do hereby appoint Loren G. Peterson and Thomas Fitzgerald and each of them severally, its or his or her true and lawful attorney to execute on behalf of Sheffield Pharmaceuticals, Inc. and the undersigned any and all amendments to this Annual Report and to file the same with all exhibits thereto and other

documents in connection therewith, with the Securities and Exchange Commission; each of such attorneys shall have the power to act hereunder with or without the other.

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

SIGNATURE	TITLE
/s/ Thomas M. Fitzgerald Thomas M. Fitzgerald	Chairman and Director
/s/ Loren G. Peterson Loren G. Peterson	Director, President and Chief Executive Officer (Principal Executiv
/s/ John M. Bailey John M. Bailey	Director
/s/ Digby W. Barrios Digby W. Barrios	Director
/s/ Todd C. Davis Todd C. Davis	Director
/s/ Scott A. Hoffmann Scott A. Hoffmann	Vice President, Finance and Administr Treasurer and Secretary (Principal Fi Principal Accounting Officer)