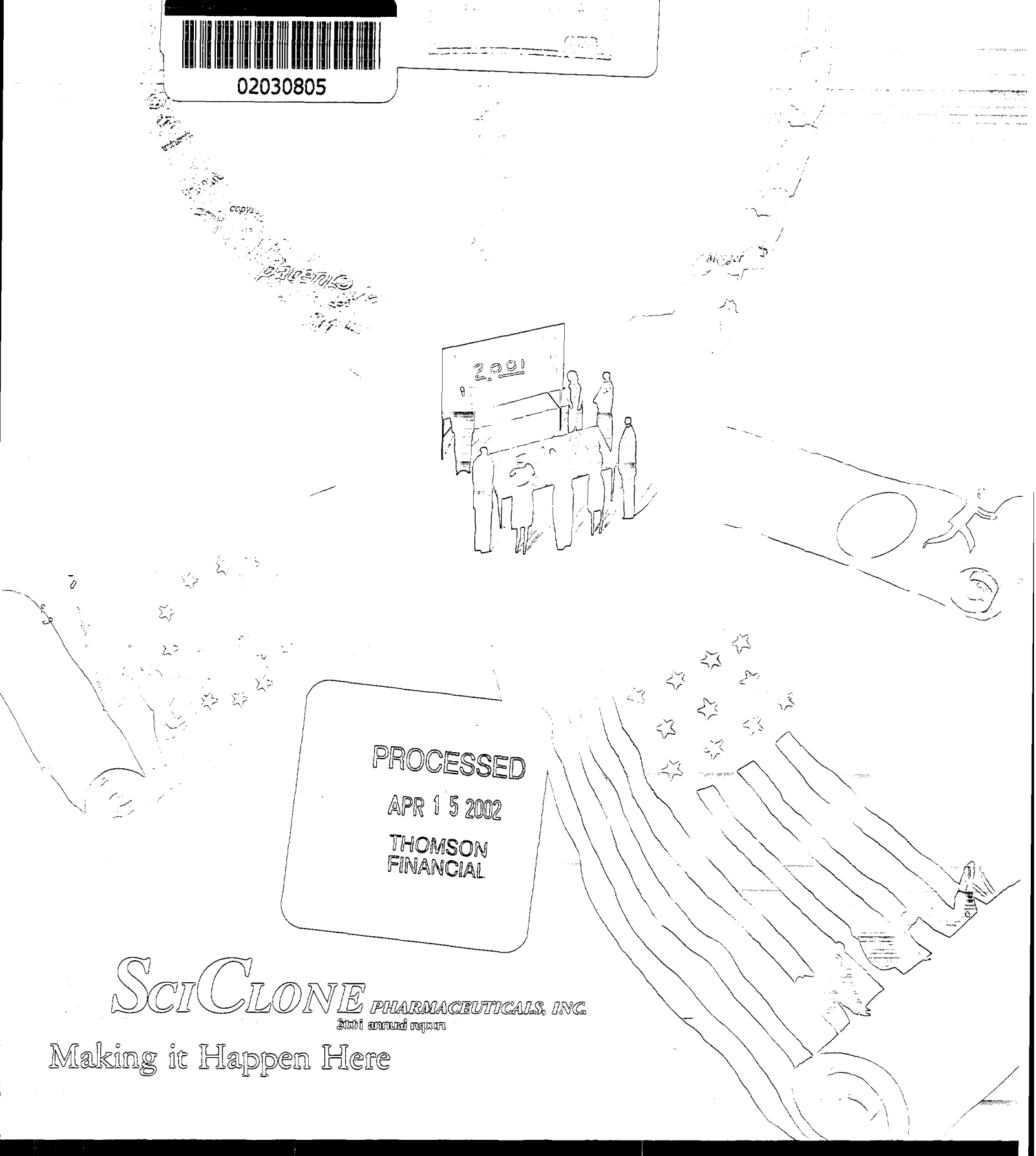


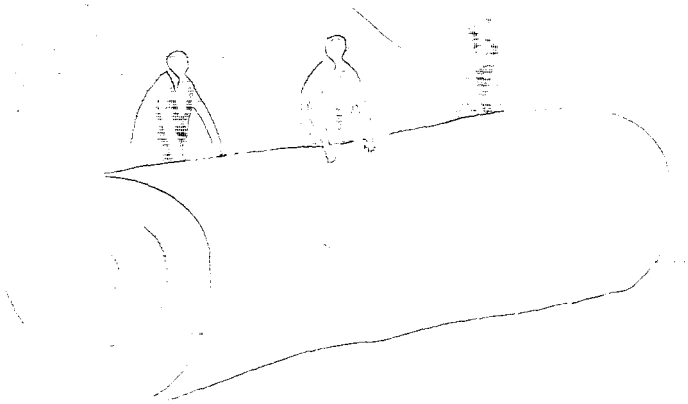
SciClone Pharmaceuticals, Inc.

2001 annual report

Making it Happen Here

From there

SciClone has been making it happen overseas by developing a successful international business with growing international sales, a strong financial position, solid strategic partnerships, and protected intellectual property. SciClone's lead immune system enhancer drug ZADAXIN® has been approved in 26 countries, with additional approvals anticipated, and has been administered without side effects or toxicities to over 10,000 patients.



...to here

SciClone is now focused on making it happen at home with company resources dedicated to phase 3 clinical trials for ZADAXIN in the U.S. and late-stage clinical programs for ZADAXIN in Japan and Europe. These programs target regulatory approval for ZADAXIN in the world's major pharmaceutical markets.

Dear Fellow Shareholders:

Our current late-stage clinical programs, particularly our phase 3 hepatitis C trials for ZADAXIN in the U.S., are the most important endeavors in the history of this company. Every employee at SciClone worldwide shares the goals associated with bringing these programs to fruition and is united in a single-minded commitment to reaching these goals. Our objective in the near future is to advance SciClone into the forefront of the biopharmaceutical industry, establishing the company as one of the few key players in the multibillion dollar worldwide market for hepatitis treatments and providing a platform for sustainable and dramatic earnings growth in the future.

2001 was a pivotal year for SciClone. We put in place all the pieces necessary to begin our ZADAXIN phase 3 hepatitis C clinical trials in the U.S. We successfully negotiated a phase 2–3 European ZADAXIN cancer program with our European partner and we established a new subsidiary, SciClone Japan K.K., to take on the responsibilities and rewards of finishing our ZADAXIN phase 3 hepatitis B trial in Japan.

These late-stage clinical trials in the U.S., Europe and Japan are now our key focus and the drivers of SciClone's future value. Building on the experience of successfully establishing an international business, we are now clearly focused on replicating that success in the U.S., Europe and Japan, targeting the commercial registration of ZADAXIN in these markets.

ZADAXIN has a unique mechanism of action, which simultaneously stimulates the body's cellular immune response and directs that response toward virally-infected or malignant cells, and a strong safety profile with no observed significant side effects or toxicities in over 10,000 patients. We believe these factors position ZADAXIN as an immune system enhancer with significant commercial potential both as a monotherapy and in combination with existing anti-viral and anti-cancer therapies.

Phase 3 U.S. Hepatitis C Trials Full Speed Ahead

SciClone has the exclusive patent for the use of ZADAXIN in the treatment of hepatitis C in the U.S. until 2015 and in Europe and Japan until 2012. We have developed and assembled compelling phase 2 U.S. and European data for the use of ZADAXIN in hepatitis C. We have gained extensive experience from the substantial commercial usage of ZADAXIN overseas where it is approved in 26 countries. We have recruited world-class investigators who are excited about the clinical program. We have secured cost-effective access to what we believe is the best possible combination therapy with a free supply of Roche's Pegasys® brand of pegylated interferon. We have aligned ourselves with a strong European partner, Sigma-Tau, who is contributing to our U.S. program and funding ZADAXIN's European development. Most importantly, with the help of Roche and other companies, our world-class Hepatitis Advisory Board and our Principal Investigators, we have developed what we believe is the best possible trial design to establish the data necessary for presentation to the U.S. Food and Drug Administration (FDA) and the European and Japanese drug regulatory organizations.

During 2001, we qualified and established 20 investigational sites for each of our two 500 patient U.S trials (a total of 1,000 patients). These clinical trials will enroll non-responders to current therapy for hepatitis C, the most difficult patients to treat. We obtained Investigational Review Board (IRB) approval at these sites and engaged a leading clinical research organization (CRO) to assist with site management, quality control and data collection. Pharmacy operations were set up to randomize drug and placebo administration and to label, monitor and deliver combination drugs and controls for blinded administration. Patients were screened by investigators for eligibility. We remain on target to complete all treatment and follow-up before the end of 2004.

"These late-stage clinical trials in the U.S., Europe and Japan are now our key focus and the drivers of SciClone's future value."

Donald R. Sellers
President and Chief Executive Officer

Other Milestones

Our primary focus in 2001 was to successfully complete all the preparatory work necessary to inject the first patients in our phase 3 hepatitis C trials in the U.S. in early 2002. However, we also had several other notable accomplishments during 2001. These initiatives also should contribute to both our near-term and longer-term goals for building shareholder value, and include:

- Establishment of a wholly owned Japanese subsidiary and completion of enrollment of more than 300 patients in our phase 3 trial for hepatitis B in Japan. We have already reported positive preliminary results from the first one-third of these patients at the beginning of 2002, and expect treatment, follow-up and analysis to be completed for all patients by the end of this year;
- Initiation of two U.S. phase 2 advanced-stage liver cancer trials using ZADAXIN in combination with transarterial chemoembolization (TACE) and radio frequency ablation (RFA), the two most commonly used treatment procedures for hepatocellulor carcinoma;
- A signed agreement committing our European partner Sigma-Tau to fund and conduct a phase 2-3 clinical cancer program and implement a European hepatitis C regulatory strategy using our U.S. data. This cancer program will be aimed at European ZADAXIN registration for malignant melanoma and also at providing data for similar registrations in the U.S. and Japan. Sigma-Tau also funded $2.7 million toward our phase 3 U.S. hepatitis C trials and pledged an additional $1 million upon completion of patient enrollment;
- Publication of new data about ZADAXIN's mechanism of action in treating hepatitis C, hepatitis B, and certain cancers;
- New ZADAXIN approvals for hepatitis B in India, hepatitis B and hepatitis C in Mexico, and as a cancer chemotherapy adjuvant in the Philippines;
- Grant of patent allowances for hepatitis C in Japan, for additional use in hepatitis B in the U.S., and for new analogs of ZADAXIN in the U.S.; and
- Receipt of Orphan Drug Status in Europe for CPX, our protein-repair drug candidate for cystic fibrosis.

Our financial performance was again solid during 2001. International ZADAXIN sales for the year were $13,831,000 with consecutive quarterly growth. Although 2001 sales to our importers were down slightly from 2000, total ZADAXIN use in the Chinese market, measured as sales from our distributors to end users, increased by 43% for the year. This is the basis for sales growth moving into 2002 and we expect this growth to continue. Our net loss grew to $6,232,000, reflecting the $8,561,000 in R&D expenses for our late-stage clinical programs. Further increases in R&D expense will come almost exclusively from our U.S. clinical program, as the clinical work in Japan is nearly completed and Sigma-Tau will fund the European trials.

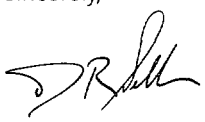
Goals for 2002

We believe 2002 will be even more productive and exciting. Goals we have targeted include:

- Completing enrollment of the 1,000 patients in our two phase 3 hepatitis C trials in the U.S.;
- Finishing treatment, follow-up, and analysis of the patients in our phase 3 hepatitis B trial in Japan;
- Commencing European trials for malignant melanoma;
- Continuing progress in international sales and regulatory approvals, as well as international phase 2 and 4 clinical work; and
- Continuing to explore and expand the scientific knowledge base which explains ZADAXIN's role in enhancing the immune response.

We believe these accomplishments, as well as those that precede them, should add significant value to our company as we focus on our ultimate goals. We thank you for your continued support.

Sincerely,

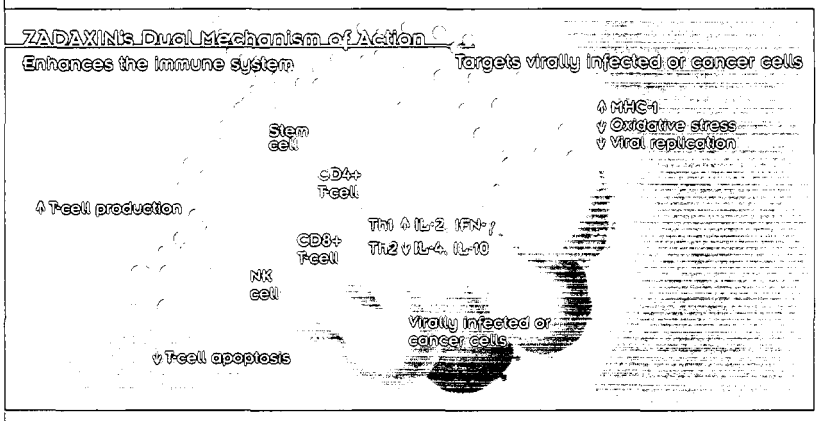


Donald R. Sellers
President and Chief Executive Officer
Managing Director, SciClone International

ZADAXIN

Dual Mechanism of Action

ZADAXIN is a synthetic preparation of a natural peptide, thymosin alpha 1, that is shown to be an important and highly specific key to activating a Th1-directed immune response. ZADAXIN promotes stem cell maturation into helper T-cells and differentiation of those cells into the Th1 subset by increasing the production of cytokines such as IL-2 and gamma interferon. In addition, studies suggest that ZADAXIN also increases the number and function of cytotoxic T-cells and natural killer cells.



In addition to the immune-enhancing effects of ZADAXIN, there are also more direct anti-viral and anti-cancer effects. ZADAXIN enhances the expression of class I MHC molecules on diseased human cells, which leads to increased recognition of those cells as a target for an appropriately coordinated immune response. ZADAXIN also decreases oxidative stress, which dramatically decreases viral replication.

The Immune System

The immune system has many layers of complexity. Disease-causing agents which circulate in the blood are usually quickly recognized as "foreign" by the body's humoral, or antibody-based, immune component. By contrast, diseases which primarily alter the body's cells, such as hepatitis C, hepatitis B, certain cancers and HIV, require a predominantly cellular immune response. These chronic diseases remain the most resistant to therapeutic intervention and are at the frontier of current medical investigation.

The cellular immune response encompasses T-lymphocytes differentiated into T-helper cells of two types, referred to as "Th1" and "Th2" subsets. Studies have shown that Th1 cells are fundamental to the eradication of hepatitis C. Conversely, when T-cells are predominantly placed into the Th2 mode, the hepatitis C virus is able to evade the body's immune response and the disease becomes chronic. Thus, compounds which drive the immune response toward a Th1 profile could be highly effective in fighting chronic viral infection.

Strategic Goal

SciClone's strategic goal, based on the broad therapeutic potential of its lead drug ZADAXIN, is to become the preeminent provider of immune system enhancers as monotherapies or as critical components of combination drug therapies for infectious diseases and cancer. ZADAXIN has produced no significant side effects in more than 10,000 patients to date in both clinical and commercial use for many different diseases, including viral diseases (hepatitis C and B) and certain cancers. This safety profile combined with its unique mechanism of action ideally positions ZADAXIN as the immune system enhancer of choice.

Hepatitis C

PROGRAM FOR THE U.S., EUROPE & JAPAN

Hepatitis C virus (HCV) is one of the most serious viral diseases in the U.S., Europe and Japan. Complications from HCV include cirrhosis, liver failure and liver cancer. Deaths related to HCV are expected to triple by 2010, exceeding the estimated deaths caused by HIV (the virus which causes AIDS). No vaccine exists and the current standard of care, a combination of alpha interferon and the antiviral drug ribavirin, is effective in only about 50% of all patients.

There are at least six different "strains" (genotypes) of HCV. Some strains, such as type 3, are easier to treat and others, such as type 1, are extremely difficult to treat. For patients that are infected with HCV genotype 1 and carry a high viral load (more than half of the 4 million patients infected in the U.S.), current therapy is only effective in 30% of patients.

For the 50% of all patients that take alpha interferon and ribavirin therapy for one year and do not respond to treatment ("non-responders"), repeat treatment with a combination of alpha interferon and ribavirin has a mere 8% success rate. By comparison, in previous clinical studies, the combination of ZADAXIN and alpha interferon was successful in treating 22% of non-responders, the most difficult to treat group of patients.

Hepatitis C Statistics

- **Total U.S. market of $1+ billion, doubling by 2004**
- **Less than 4% of 4 million carriers in U.S. being treated**
- **10,000 deaths annually (expected to triple by 2010)**
- **500,000 non-responders to treatment by 2005**
- **Average treatment cost of $17,000 annually for existing therapy**

SciClone's U.S. phase 3 hepatitis C trials are focused on non-responders to interferon or interferon plus ribavirin. The trials consist of two 500-patient, multicenter and randomized, double-blinded studies–a rigorous trial design preferred by the FDA and using a patient number which is intended to produce statistically significant results for U.S., European and Japanese regulatory approval. ZADAXIN is being administered in combination with Pegasys, F. Hoffmann LaRoche's brand of pegylated alpha

interferon, a longer acting form of interferon, which is currently under regulatory review. This combination will be compared to the control group which will receive a placebo plus Pegasys. These trials are designed to show the benefit of the ZADAXIN and Pegasys combination.

Patients will be randomly assigned to one of the two 12-month courses of treatment and then followed for a 6-month observation period. This is consistent with the U.S. FDA standard for demonstrating sustained response and ideal for ZADAXIN's mechanism of action and historical efficacy data versus standard treatment. SciClone hopes to complete patient enrollment and have all patients begin treatment by the end of 2002.

Pegasys, pegylated interferon alfa-2a, will be supplied by Roche at no cost to SciClone. Sigma-Tau, SciClone's European partner, is providing significant funding for the trials and will use the U.S. data as the basis for European hepatitis C registration.

Hepatitis B

Program for Japan & the Far East

Hepatitis B (HBV) remains a very serious health problem in Japan and throughout the developing world, particularly in Asia, and often leads to cirrhotic complications and progression to liver cancer. In the last decade, Japan became the world's largest single market for alpha interferon as a treatment for hepatitis B (and C) despite modest efficacy and serious side effect concerns which now limit interferon's use in the treatment of hepatitis B. The nucleoside analogue lamivudine recently became the hepatitis B drug of choice upon Japanese approval, but it too is raising concerns about sustained efficacy, the possibility of severe rebound viral hepatitis after cessation of therapy, and the high incidence of lamivudine-generated resistant mutant HBV. All of this leaves an enormous market opportunity for new HBV treatment regimens in Japan.

Hepatitis B Statistics

- 350 million carriers worldwide
- Highly prevalent in Asia where disease is most often acquired from the mother
- Less than 10% of 31.5 million carriers in Japan being treated

SciClone's phase 3 trial in Japan uses ZADAXIN as a monotherapy for HBV. The study is designed to assess response after 18 months (6 months of treatment and an additional 12 months of follow-up observation) to establish proof of a true sustained response.

Preliminary data on approximately one-third of the more than 300 patients indicate that, after 6 months of therapy and 12 months of follow-up, 24% demonstrated a successful interruption of viral replication, as measured by sustained seroconversion of hepatitis B e-antigen (loss of HBeAg and the development of antibody to HBeAg). By comparison, published data on lamivudine, the drug most widely used for treatment of hepatitis B worldwide, indicate that lamivudine induced sustained HBeAg seroconversion in 16% of Asian patients treated for one year.

SciClone expects the remaining two-thirds of patients in the ZADAXIN study to complete the 6-month treatment plus 12-month follow-up period and analysis by the end of 2002.

The company believes that significant final efficacy and safety results will contribute to Japanese commercial registration efforts and be a highly visible benefit to SciClone's marketing efforts in the Far East and other global markets where ZADAXIN already is approved for HBV or where such approval is pending.

Oncology

Program for the U.S., Europe & Japan

SciClone believes ZADAXIN's mechanism of action and highly specific role in activating and directing immune response is applicable for various cancers as well as for viral infection and anticipates oncology as the next large market opportunity for ZADAXIN.

SciClone and Sigma-Tau are collaborating to execute an oncology program concurrent with SciClone's own hepatitis registration efforts. SciClone will continue its U.S. phase 2 program for liver cancer while Sigma-Tau will fund and manage a formal European phase 2-3 oncology program, initially focused on European registration for malignant melanoma. All ZADAXIN oncology data will be pooled for European, U.S. and Japanese commercial registration efforts.

Hepatocellular Carcinoma

SciClone's current U.S. efforts consist of two separate phase 2 combination therapy trials for hepatocellular carcinoma (HCC), a common result of untreated or progressive HCV and HBV.

Hepatocellular Carcinoma Statistics

- One of the most prevalent malignancies in the world with 1 million new cases annually
- 6,000 new cases diagnosed in U.S. each year
- Median survival for patients with advanced disease is less than 8 months

With early identification, HCC is treated with reasonable success by surgery or liver transplantation. In later stages, prognosis is poor. Systemic chemotherapy has produced disappointing results. Localized chemotherapy, administered by a procedure called transarterial chemoembolization (TACE), has achieved higher response rates, but is not always an option for technical or clinical reasons. More recently, a procedure called radio frequency ablation (RFA), which destroys tumors by radio waves via a probe-bearing needle, has emerged as an additional alternative. TACE and RFA remain the current standard of care for late-stage, non-surgical HCC.

During 2001, SciClone initiated two phase 2 U.S. trials, one combining ZADAXIN with TACE and one combining ZADAXIN with RFA. The goal with both trials is to see whether ZADAXIN-specific immune enhancement may prolong survival. Patients in the ZADAXIN arm of each trial will receive 6 months of treatment and 12 months of follow-up observation.

Malignant Melanoma

Sigma-Tau's European oncology program, with a commitment for phase 2, phase 3 and commercial registration efforts, initially is focused on malignant melanoma, another cancer indication in which ZADAXIN has shown potential. No proven life-prolonging therapy for late-stage malignant melanoma yet exists.

Malignant Melanoma Statistics

- One of the deadliest forms of cancer
- 50,000 new melanoma cases diagnosed annually
- Median survival for late-stage patients is 5 months

Sigma-Tau's phase 2 malignant melanoma trials are based on the success of previous European pilot studies conducted and published by independent researchers. In these studies, 23 of the 46 late-stage patients showed a complete or partial response when ZADAXIN was added to the current standard combination therapy, the anticancer drug dacarbazine (DTIC) and alpha interferon. Moreover, the median survival for participating patients was 12.5 months, more than double the historical average.

CPX for Cystic Fibrosis

PROGRAM FOR THE U.S.

While ZADAXIN is SciClone's current focus, the company continues to develop CPX, a novel protein-repair therapy for cystic fibrosis (CF). An initial phase 2 U.S. study suggested the need for reformulation of the drug for better absorption in the unique digestive environment of the CF patient, and thus additional toxicology and early human studies. Development activities aimed at new phase 2 studies continue.

Forward-looking statements

The information in this annual report contains forward-looking statements including future demand for ZADAXIN and other drugs in our pipeline and its impact on SciClone's sales and earnings growth, future regulatory approvals of ZADAXIN and other drugs in our pipeline, the production of statistically significant results from our U.S. phase 3 hepatitis C trials for U.S., European and Japanese marketing applications and the timing and completion of our clinical trials and programs, including completion of enrollment, treatment and follow-up for our phase 3 hepatitis C trials in the U.S., completion of treatment, follow-up and analysis for our phase 3 hepatitis B trials in Japan and commencement of clinical trials for malignant melanoma in Europe. Words such as "expects," "plans," "believe," "may," "will," "anticipated," "intended" and variations of these words or similar expressions are intended to identify forward-looking statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors including, the speed which patients are enrolled in trials and programs, progress or failure of clinical trials, the failure of our partners to carry out commitments to SciClone, the potential for receipt of inconclusive or contradictory data from clinical trials or data unsupportive of a regulatory filing, future actions by the U.S. Food and Drug Administration or equivalent regulatory authorities in other countries, unexpected adverse results to patients during the trials and programs and other events that could prolong the studies or result in unanticipated expense, as well as other risks and uncertainties described in SciClone's filings with the Securities and Exchange Commission, including our annual report on Form 10-K for the fiscal year ended December 31, 2001 contained herein and quarterly report on Form 10-Q for the quarterly period ended September 30, 2001.

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2001,

or

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

For the transition period from to .

Commission file number 0-19825

SciClone Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

California	94-3116852
(State or other jurisdiction of Incorporation or organization)	*(I.R.S. Employer Identification No.)*
901 Mariner's Island Boulevard San Mateo, California	94404
(Address of principal executive offices)	*(Zip Code)*

(650) 358-3456
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, no par value
(Title of Class)

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

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately $137,930,000 as of March 13, 2002, based upon the closing sale price of the Registrant's Common Stock on The Nasdaq National Market on such date. Shares of Common Stock held by each executive officer and director have been excluded from the calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 13, 2002, there were 32,671,204 shares of the Registrant's Common Stock outstanding.

Part III incorporates by reference from the definitive proxy statement for the Registrant's 2002 Annual Meeting of Shareholders to be filed with the Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form.

NOTE REGARDING FORWARD-LOOKING STATEMENTS:

This Annual Report on Form 10-K contains 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. These forward-looking statements are based on our current expectations, estimates and projections about our industry, management's beliefs and certain assumptions made by us. Words such as "anticipates," "expects," "intends," "plans," "believes" or similar expressions are intended to identify forward-looking statements and our forward looking statements include those statements we make regarding the timing and outcome of clinical trails, anticipated sales and research and development expense levels. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors including, but not limited to, those described under the caption "Risk Factors" in this Annual Report on Form 10-K and our other SEC filings discuss some of the important risk factors that may affect our business, results of operations and financial condition. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

PART I

Item 1. *Business*

Overview

SciClone Pharmaceuticals, Inc. ("SciClone" or the "Company") develops and commercializes pharmaceutical and biological therapeutic compounds that are acquired or in-licensed at the stage of late pre-clinical or early clinical development. SciClone's strategic goal, based on the broad therapeutic potential of its lead drug ZADAXIN, is to become the preeminent worldwide provider of immune system enhancers, or ISEs, as monotherapies and as critical components of combination drug therapies for infectious diseases and cancer. ZADAXIN has been approved for sale primarily as a monotherapy for hepatitis B in 26 countries with additional approvals anticipated and has been administered without observed significant side effects or toxicities to over 10,000 patients worldwide. Currently, SciClone is targeting major market regulatory approval for ZADAXIN by focusing on its U.S. hepatitis C phase 3 clinical trials, Japanese hepatitis B phase 3 clinical trial and European cancer phase 2-3 clinical trials in collaboration with SciClone's European partner, Sigma-Tau, S.p.A.

ZADAXIN is a synthetic preparation of a natural peptide, thymosin alpha 1, that enhances the body's Th1 immune response. There are no reports of significant side effects in more than 10,000 patients to date, in both clinical trial and commercial use for several different diseases, including viral diseases (hepatitis C and B) and cancers (hepatocellular carcinoma and malignant melanoma). This safety profile, combined with its unique mechanism of action, ideally positions ZADAXIN as the immune system enhancer of choice for use in combination therapies for infectious diseases and cancer. Other drugs in SciClone's pipeline are intended to protect and expand this franchise, and to address the protein-based disorder that causes cystic fibrosis.

While SciClone has obtained ZADAXIN marketing approvals in 26 countries overseas, the Company's clinical development strategy has been to focus on hepatitis C as the first indication for commercial registration of ZADAXIN in the U.S. In Europe, SciClone's collaboration partner Sigma Tau is pursuing regulatory approval for ZADAXIN for oncology indications with a phase 2-3 clinical program, initially focused on malignant melanoma. In addition, Sigma Tau will pursue regulatory approval in Europe for ZADAXIN as a therapy for hepatitis C using data from SciClone's phase 3 clinical trials in the U.S. SciClone is also developing ZADAXIN for use as a therapy for hepatitis B in Japan. SciClone produces ZADAXIN for current commercial sales through contract manufacturers in Western Europe and most of the company's current sales are to importing agents in the People's Republic of China for distribution in that country. In the U.S., SciClone anticipates moving toward entering into a marketing collaboration in the later stages of its phase 3 clinical trials when the Company believes the product should have enhanced partnering value, though there is no assurance such a partnering arrangement can be successfully achieved.

ZADAXIN

ZADAXIN, an immune system enhancer, is a synthetic preparation of thymosin alpha 1, an immune system peptide that occurs naturally and whose activities increasingly are being recognized to regulate the body's immune response to viral infection or malignancy. Published scientific and clinical studies have shown that ZADAXIN's activities include helping to stimulate, maintain and direct the body's antiviral and anticancer immune response — to both target the intended affected cells and to enhance the immune system's capabilities for cell-specific eradication.

Disease-causing agents which remain circulating in the blood usually are quickly recognized and eliminated by the body's humoral, or antibody-based, immune component. ZADAXIN's critical role in the immune response is played out in the more complicated realm of cellular immunity, when certain of the body's own cells need to be the target of an immune response because of infection or malignancy, even though the immune system does not recognize these cells as foreign. Diseases requiring a cellular immune response, such as HIV, hepatitis C and cancer, have generally been the most resistant to therapeutic intervention to date, and remain at the frontier of current medical investigation.

Humoral and cellular immune response to some degree "cross-regulate" each other, with cytokine production determining which holds precedence. ZADAXIN seems to be an important regulator of these responses. Increasingly, studies have suggested that ZADAXIN enhances the maturation of stem cells and their differentiation into mature CD4, CD8, T and natural killer cells. ZADAXIN increases the Th1 subset of CD4 cells (which favors cellular immunity) by increasing the production of cytokines such as IL-2 and gamma interferon. ZADAXIN also enhances the expression of class I MHC molecules on diseased human cells, which leads to increased recognition and their destruction by CD8 cells.

Studies also have demonstrated that hepatitis C is able to evade the body's immune response leading to chronic viral infection if the body's immune response is "switched" to the Th2 mode. A Th1 response, on the other hand, is fundamental to hepatitis C eradication. Current treatments for hepatitis C, such as alpha interferon, actually induce a counter-regulatory increase in Th2 cytokine production. The addition of ZADAXIN counterbalances this Th2 cytokine production process. There are no reports that ZADAXIN has produced any serious, adverse side effects in more than 3,000 patients in various clinical trials to date and in thousands more in commercial use, thereby suggesting that ZADAXIN should not add to the toxicity profile of a multi-drug regimen.

SciClone's proprietary position for ZADAXIN is protected by patents in the U.S., Europe, Japan and various other countries, either alone or in combination with a variety of other drugs, for its use as a treatment for hepatitis C, hepatitis B and for certain cancers. For use as a treatment for hepatitis C, patent coverage extends to 2015 in the U.S. and to 2012 in the European Union and in Japan.

Hepatitis C (HCV)

The Centers for Disease Control estimate that up to 4 million people in the U.S. are infected by HCV, and no vaccine for it has been developed. There are approximately 40,000 new cases each year. While only 30 percent of those infected are initially symptomatic, in approximately 85 percent the infection becomes chronic, and some 70 percent suffer from complications of chronic liver disease. HCV currently causes 8,000 to 10,000 deaths per year in the U.S. These numbers are expected to triple by 2010. As a rapidly mutating RNA virus (like HIV), there already are at least six different genotypes, or "strains", of HCV. Genotype 1 is the most difficult to treat and is the most common variant in the U.S., infecting approximately 75 percent of all patients.

Current year-long treatment regimens can cost more than $17,000 per patient in the U.S., with the total therapeutic market in the U.S. and Europe estimated to be $2 billion and expected to grow to $4-5 billion by 2004. Alpha interferon has been the backbone of treatment, predominantly used in combination with the antiviral ribavirin (the combination treatment is marketed by Schering-Plough under the tradename "Rebetron™"). Alpha interferon can induce relatively severe toxicity, and ribavirin introduces additional toxicities of its own. Many patients cannot, or will not, tolerate a full-year regimen of alpha interferon and

ribavirin. More recently, longer acting forms of alpha interferon, pegylated alpha interferon, have been developed by Schering-Plough and by F. Hoffmann La-Roche under the tradenames "Peg-Intron™" and "Pegasys™", respectively. Even in its pegylated form, which stays in the bloodstream longer allowing for less frequent dosing and more consistent viral suppression, alpha interferon plus ribavirin is effective in eliminating the virus in the long-term in only about 50 percent of patients and the side effect profile is severe. Moreover, the effectiveness of current therapy is highly dependent on the genotype of the infecting virus and the viral load, or level of virus present in the patient. For genotype 1 patients with a high viral load, which characterizes about half of all HCV patients in the U.S., current therapy is effective in only about 30 percent of the cases. Patients that fail to respond to therapy seldom respond to a second 12-month regimen of the same treatment. The success rate for treating non-responders with non pegylated alpha interferon plus ribavirin is only approximately 8 percent. In early clinical studies, the combination of ZADAXIN and alpha interferon, when used to treat non-responders, achieved a 22 percent response rate. We believe that this improvement is clinically significant and have designed and implemented our U.S. phase 3 hepatitis C clinical program based on these data.

ZADAXIN, we believe, represents the closest new opportunity for improving the treatment for hepatitis C patients in the foreseeable future. Based upon our review of the market, virtually nothing else is on the horizon in a similar advanced clinical stage of development. We redesigned and timed the implementation of our phase 3 U.S. clinical program of ZADAXIN to use it in combination with the newest form of interferon, pegylated alpha interferon.

Clinical Development Strategy

Our clinical development strategy for ZADAXIN in the U.S. has been to select an indication where ZADAXIN may add the greatest efficacy compared to current standard treatment, where the likelihood of expedited review is greatest due to a lack of an approved treatment, where the initial patient population supports the greatest financial return upon successful registration and where SciClone has a strong intellectual property position for the use of ZADAXIN. Results from clinical trials suggest that using ZADAXIN with interferon produces better results than using interferon independently or interferon with ribavirin for the treatment of hepatitis C in primary non-responders. Thus, we have focused our phase 3 clinical trials on hepatitis C non-responders (no virological response at the end of a standard course of therapy) to interferon or to interferon plus ribavirin.

Non-responders typically have high viral loads of HCV genotype 1, which is also characteristic of half of all HCV patients in the U.S. We estimate that there are approximately 200,000 patients in the U.S. alone who have failed to respond to treatment using interferon independently or interferon in combination with ribavirin and that this patient group will grow to approximately 500,000 identifiable non-responders by 2005. Non-responders are a commercially attractive initial target market for ZADAXIN. Such patients generally are motivated to seek treatment, are already identified by their physicians, are in the health care and insurance systems, and their number is growing as more new patients seek and ultimately fail first-time therapy for HCV.

The phase 3 U.S. clinical trials consist of two 500-patient, multicenter, randomized, double-blinded studies, and the trials are designed to provide the data and safeguards required to file a successful marketing application if the data demonstrate clinical benefit. Patients in equal numbers are being assigned to a one-year course of ZADAXIN plus pegylated interferon or to a course of pegylated interferon plus placebo. Primary endpoints are a sustained virological response and an improvement in the liver histological activity index measured six months after the end of the 12-month therapy, consistent with the U.S. Food and Drug Administration, or the FDA, standard for demonstrating sustained response to HCV therapy. Efficacy data at the end of the 12-month treatment period will be included as a secondary endpoint of the trial.

The Pegasys brand of pegylated interferon for both trials is being provided at no cost to us by F. Hoffmann La-Roche, which receives the right to use the data resulting from the trials but does not receive any marketing rights to ZADAXIN or the combination therapy. The costs of this U.S. study are also supported, without any U.S. marketing rights, by our European partner, Sigma-Tau. In early 2002 Sigma-Tau

contributed $2.7 million and will make an additional $1 million milestone payment when the 1,000 patients are recruited in our U.S. clinical trials. We expect to begin patient enrollment in the early part of the second quarter of 2002. Under this plan the treatment and observation periods for the first patients would be completed by the end of 2003 and for all patients in the phase 3 clinical trials by mid-2004, though there is no assurance that patients can be recruited to plan.

We believe that oncology will be another large market opportunity for ZADAXIN as the immune system enhancer of choice in certain cancer multi-drug treatments. ZADAXIN's mechanism of action stimulates and directs the body's immune response toward many forms of malignant cells. In addition, use of ZADAXIN has not demonstrated any serious, adverse side effects in combination with many known anticancer drugs. In comparison, most anticancer drugs are normally highly toxic which complicates the efficacy of many combination treatments often raising prohibitive safety issues and hindering patient compliance.

Our clinical strategy in oncology is to implement a broad phase 2 clinical program with leading cancer investigators in the U.S. and Europe concurrent with the phase 3 HCV clinical and registration program. We intend to generate a substantial body of published phase 2 data in specific cancers where ZADAXIN has shown preclinical or early clinical potential as a component of therapy in order to determine the feasibility and design of pivotal phase 3 trials in oncology. We are currently sponsoring two phase 2 U.S. trials for liver cancer, which is a common result of untreated or progressive hepatitis C or hepatitis B. ZADAXIN is being combined with transarterial chemoembolization (TACE) or with radio frequency ablation (RFA), the two most common procedures for hepatocellular carcinoma (HCC) patients whose tumors cannot be treated either by surgery or by liver transplantation. The studies are designed to duplicate the survival benefits that were demonstrated in our European phase 2 HCC studies. HCC accounts for more than 80 percent of all primary liver tumors and is the most prevalent fatal malignancy in the world, with an annual incidence of approximately one million new cases. In the U.S., there are some 4,000 to 6,000 new cases of HCC diagnosed each year. ZADAXIN's use also has been investigated with promising early results in malignant melanoma, and non-small cell lung cancer.

International Strategy

While U.S. clinical efforts are at the forefront of our current activities, our commercialization strategy has always been global. Our initial target markets for ZADAXIN have been in emerging growth countries. ZADAXIN is now approved for sale in 26 countries, including China, India and Mexico. ZADAXIN is approved principally for the treatment of hepatitis B and hepatitis C, and also in certain countries as a vaccine adjuvant for patients with weakened immune systems and as an adjuvant to chemotherapy for the treatment of various cancers. Additional marketing approvals are pending in significant hepatitis markets such as Turkey, Hong Kong and Indonesia. Commercial activities in these countries, and most significantly in China, have played an important role in our early development. We believe that the demonstration of continued progress in this international sales program will significantly increase the value of any future development or marketing alliance to our shareholders. Overseas efforts also provide invaluable experience in the successful marketing and sales of ZADAXIN, particularly in economically challenged conditions.

Together with Sigma-Tau, we are engaged in a regulatory development strategy for ZADAXIN targeting a pan-European hepatitis C registration intended to run concurrently with U.S. registration efforts. Sigma-Tau has exclusive marketing rights for ZADAXIN in most Western European countries. Sigma-Tau will fund the ZADAXIN European hepatitis C regulatory efforts utilizing the U.S. phase 3 clinical trial data that SciClone will provide to Sigma-Tau. In addition, Sigma-Tau will fund and conduct phase 2-3 oncology clinical trials in Europe. Combination therapy of ZADAXIN with the cytotoxic agent dacarbazine (DTIC) for the treatment of malignant melanoma is the first clinical effort of this collaboration, and the clinical trial is expected to commence in 2002.

In Japan, we are conducting a phase 3 clinical trial in over 300 patients using ZADAXIN as a monotherapy for the treatment of hepatitis B (HBV). In March 2002 we announced positive preliminary data on the first evaluated one-third of these patients indicating that, after 6 months of therapy and 12 months of follow up, 24% demonstrated a successful interruption of viral replication, as measured by sustained

seroconversion of hepatitis B e-antigen (loss of HBeAg and the development of antibody to HBeAg). By comparison, published data on lamivudine, the drug most widely used for treatment of hepatitis B worldwide, indicate that lamivudine is capable of inducing sustained HBeAg seroconversion in 16% of Asian patients that took the drug for one year. Over two-thirds of the patients in the trial have already completed the therapy and follow-up evaluation periods. The remaining patients are scheduled to complete the therapy and evaluation periods by the end of 2002. There are approximately 31.5 million carriers of HBV in Japan, of which approximately 10 percent are chronically infected.

We also will continue to supply ZADAXIN to qualified investigators outside of the U.S. and Europe for non-company sponsored hepatitis and cancer studies. For example, currently, leading oncology researchers in Australia are studying ZADAXIN in combination with dendritic cell-based vaccination for malignant melanoma, the first pure immunotherapy combination study for ZADAXIN in cancer. Malignant melanoma is one of the most prevalent cancers in Australia. Worldwide, there are at least 50,000 new cases of malignant melanoma diagnosed each year, and there currently is no effective treatment.

Second Generation Immune System Enhancers

In 1999, we acquired exclusive rights to a new class of immunomodulators which in preclinical studies enhanced the immune system in a manner similar to ZADAXIN. At least one of these compounds, SCV-07, has the potential to be orally active (ZADAXIN is administered as a subcutaneous injection). With the $300,000 grant awarded by the U.S. Civilian Research and Development Foundation's "Next Steps to Market Program", several preclinical and clinical studies of SCV-07 treatment in tuberculosis, or TB, have been conducted in collaboration with Verta Ltd., a biotechnology company located in St. Petersburg, Russia. These studies have shown potential for efficacy in this difficult to treat and emerging disease. SCV-07 and its related class of compounds are covered by a composition of matter patent in the U.S. as well as for their use as immunomodulators. We have also obtained a Notice of Allowance for a U.S. composition of matter patent for various analogs of ZADAXIN that we have determined could have proprietary therapeutic or biologic distinctions from its current "natural synthetic" formulation, such as length of circulation in the blood or alternative delivery techniques.

CPX for Cystic Fibrosis

While ZADAXIN is SciClone's clear current focus, the Company continues to develop CPX, a novel small molecule protein-repair therapy for cystic fibrosis, or CF, a common fatal genetic disorder among Caucasians. Current treatments for CF address only the symptoms, which ultimately include a build-up of viscous mucus in the lungs that harbor infections and which lead to death in most patients. We licensed CPX from the National Institutes of Health (NIH) after the gene encoding for the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) protein was identified. In preclinical studies conducted at the NIH utilizing several different approaches to examine the efficacy of CPX, including the use of cells explanted from cystic fibrosis patients, CPX demonstrated the ability to repair the two principal protein defects underlying the cause of CF in most patients at the cellular level: it enables the defective protein to travel through the cell and reach the epithelial cell membrane, a process called "trafficking", and improves an originally impaired transport of chloride ions across the cell membrane. Because of erratic digestive absorption patterns in CF patients our first U.S. phase 2 trial aimed at demonstrating this protein repair activity in CF patients did not produce the sustained circulatory drug levels required to assess efficacy. We reformulated CPX to prepare for additional toxicology and early human studies. Development activities aimed at new Phase 2 studies continue. We have been granted Orphan Drug Status for CPX in both the U.S. and Europe, protecting market exclusivity. The NIH has granted us an exclusive license for a class of related compounds, one of which, DAX, is another protein-repair candidate. DAX currently is in preclinical development.

Marketing and Sales

Assuming FDA, European and Japanese regulatory approval, we plan to market ZADAXIN in the U.S., Europe and Japan in collaboration with larger pharmaceutical companies. In the U.S., SciClone anticipates moving toward entering into a marketing collaboration in the later stages of its phase 3 clinical trials when the

Company believes the product should have enhanced partnering value, though there is no assurance such a partnering arrangement can be successfully achieved. Outside these territories we plan to market ZADAXIN through our established broad distribution network.

In our ZADAXIN markets in Asia (excluding Japan), Latin America, the Middle East and Eastern Europe, we conduct medical education and clinical trial programs targeting the leading specialists (e.g. hepatologists, immunologists and oncologists) at the leading hospitals in each of our markets. Local importers/distributors assist us with regulatory submissions to the ministries of health and are responsible for the importation, inventory, physical distribution and invoicing of ZADAXIN. Our wholly owned international subsidiary, SciClone Pharmaceuticals International Ltd., which we refer to as SPIL, is a Cayman Islands registered company that is based in Hong Kong and has international offices in Beijing, Hong Kong, Shanghai, and Singapore. SPIL manages a distribution center in Hong Kong that we use as the center for receiving ZADAXIN from our European contract manufacturer and for distributing it to our currently approved markets. We have established distribution arrangements with local pharmaceutical wholesale/distribution companies covering 54 countries outside of the U.S., Western Europe, and Japan. In those markets where ZADAXIN is approved in Asia, Latin America and the Middle East, we have established or plan to establish in the near term ZADAXIN marketing programs. ZADAXIN sales in our currently approved markets and pending markets are and will be managed by SPIL employees. SciClone also has wholly owned subsidiaries in Italy and Japan.

The People's Republic of China is currently our largest single market for ZADAXIN representing approximately 89%, 86% and 87% of our product sales for the years ended December 31, 2001, 2000 and 1999, respectively. China is the world's most populous nation and also has the largest population of hepatitis B, hepatitis C and liver cancer patients. Like most developing countries, China generally does not provide patient cost reimbursement for relatively expensive therapies such as ZADAXIN, however, SPIL has successfully established and expanded the use of ZADAXIN in China in recent years. SPIL employs a medical education team of approximately 60 to promote physicians' knowledge of ZADAXIN and its use. Distribution of ZADAXIN to hospital pharmacies and physicians in China is through four licensed distributors who purchase the product through four importing agents. These importing agents are well established government licensed importers in China. SPIL sells ZADAXIN to the importing agents on a no returns basis except under limited terms regarding product quality, and sales are in U.S. dollars.

Manufacturing

We do not intend to acquire or establish our own dedicated manufacturing facilities for any of our products at this time. We believe there are numerous facilities in compliance with FDA current Good Manufacturing Practices (cGMP), or the foreign equivalent of such standards, available for contract manufacturing. We have entered into exclusive contract manufacturing and supply agreements to produce ZADAXIN and CPX. These manufacturers are supplying the ZADAXIN and CPX required for our current and planned clinical trial activities, and have demonstrated, with respect to ZADAXIN, the capability to supply commercial quantities of the drug to fulfill our expected near term commercial requirements. We believe that, in the event of the termination of an agreement with any single supplier or manufacturer, we would likely be able to enter into arrangements with other suppliers or manufacturers on similar terms. We monitor production runs of our products and maintain our own quality assurance audit programs.

For the U.S. and Japanese clinical trials ZADAXIN is manufactured to cGMP in the U.S. For Europe and all currently approved markets ZADAXIN is manufactured to cGMP standards in Europe.

Patents and Proprietary Rights

We are either a patentee or exclusive licensee of composition of matter, process and use patents and pending applications related to thymosin alpha 1 or thymalfasin, the generic name, of ZADAXIN, in the U.S. and abroad.

We are the exclusive licensee of foreign patents directed to the thymosin alpha 1 composition of matter which are owned by F. Hoffmann-La Roche AG and the Board of Regents of the University of Texas System.

Most of these foreign composition of matter patents have expired. However, we are a patentee of a number of composition of matter patents and applications directed to analogs and derivatives of thymosin alpha 1 which have been granted in the U.S. and numerous international markets. We are seeking numerous other proprietary rights for thymosin alpha 1. We are either a patentee or exclusive licensee and are directing prosecution of use and process patents related to the method of making and therapeutic uses of thymosin alpha 1.

We are also a co-patentee of patents and pending applications covering numerous uses of thymosin alpha 1. Patents covering use of thymosin alpha 1 for treatment of hepatitis C have been issued in the U.S., a majority of European countries and numerous international markets and extend to 2015 in the U.S. and 2012 in the European Union and Japan. Patents for the use of thymosin alpha 1 in treating hepatitis C in non-responders to interferon treatment have been issued in the U.S. and various international markets. Patents have been issued in the U.S. and various international markets covering the use of thymosin alpha 1 to treat decompensated liver disease. Patents which we own covering the use of thymosin alpha 1 to treat hepatitis B carriers with minimal disease have been issued in the U.S., Japan, China and other international markets. We are the exclusive licensee of patents which have been issued in the U.S., Japan and other international markets covering the treatment of hepatitis B using thymosin alpha 1 and in the U.S., a majority of European countries, Japan and other international markets which cover the use of thymosin alpha 1 to treat small cell and non-small cell lung cancer. Several corresponding additional patent applications have been issued or patent applications are pending in other countries for each of the above named indications.

Our process patents are directed to methods of making thymosin alpha 1 and have issued in the U.S., a majority of European countries, Japan, Canada, Hong Kong, Taiwan and South Korea.

We are the exclusive licensee of an issued U.S. patent covering the use of CPX to treat cystic fibrosis, as well as an issued U.S. patent and pending foreign patent applications covering DAX and other CPX analogs and their use in treating cystic fibrosis.

We are the exclusive licensee of an issued U.S. patent covering the composition of matter of SCV-07 and related compounds, as well as similar pending foreign patent applications.

In addition to patent protection, we intend to use other means to protect our portfolio of proprietary rights. Certain marketing exclusivity periods may be available under regulatory provisions in certain countries including the U.S., European Union countries and Japan, which benefits the holder of the first marketing approval for new chemical entities or their equivalents for a given indication and we are pursuing such rights. Orphan drug protection has been or will be sought where available, granting additional market exclusivity. We hold an orphan drug product designation for thymosin alpha 1 for hepatocellular carcinoma, hepatitis B and DiGeorge Anomaly in the U.S. Recognition and protection of trademarks for thymosin alpha 1 is being accomplished through worldwide filing of trademark applications for ZADAXIN and other trademarks which appear on the commercial packaging of the product and are used in promotional literature. Copyrights for the commercial packaging may provide us with means to take advantage of procedures available in certain countries to exclude counterfeit products or genuine but unauthorized products from entering a particular country by parallel importation. We have also implemented anti-counterfeiting measures on commercial packaging and plans to register the packaging with customs departments in countries where such procedures exist.

We are pursuing similar types of protection for CPX, where applicable. We hold an orphan drug product designation for CPX to treat cystic fibrosis in the U.S. and Europe.

We also rely upon trade secrets, which we seek to protect, in part, by entering into confidentiality agreements with our employees, consultants, corporate partners, suppliers and licensees.

Sponsored Research and Development

For the years ended December 31, 2001, 2000 and 1999, we expended $8,561,000, $4,182,000 and $4,604,000, respectively, in our sponsored research and development activities.

Competition

In the area of immune system enhancer therapy, we believe that we participate in an important and growing therapeutic niche, stimulating an immune system response in a disease state often characterized by an inadequate immune response. ZADAXIN is a product that has demonstrated a unique safety profile among immunomodulatory agents. ZADAXIN has shown in clinical trials that it can be added safely and effectively to existing anti-viral and anti-cancer therapies. We believe that this "cocktail" approach to anti-viral and anti-cancer therapy will become more popular in the future. We believe that ZADAXIN's suggested mechanism of action will encourage it to be used in new multiple combination therapies over time. We anticipate that as newer and better directed anti-viral and anti-cancer therapies are developed there will continue to be a need for an immune system enhancement component and this in turn may create new opportunities for ZADAXIN. Competition with ZADAXIN may be reduced because ZADAXIN, administered in combination with numerous anti-viral and anti-cancer agents, is expected to be complementary rather than competitive to these agents in enhancing the immune system. We expect that continuing advancements in and increasing awareness of the use of immune system enhancer therapy to fight some cancer and infectious diseases may create new competitors as well as numerous new opportunities for expanded use of ZADAXIN. We know of no other immune system enhancer therapy that has ZADAXIN's combination of clinically evident safety and efficacy. In addition, SCV-07 shows early signs of having many of the immune system enhancer qualities of ZADAXIN, but in an orally available form.

Competition among therapeutic treatments for the diseases and cancers is intense. Numerous alternative methods to treat viral diseases and cancers exist and new treatments will be developed. All of these will compete with each other and ZADAXIN for therapeutic use. The principal therapy for hepatitis C is year long treatment with interferon alpha plus ribavirin. For hepatitis B, the main therapies are lamivudine or interferon alpha. We believe that in many cases ZADAXIN will prove itself complementary to these other therapies.

Government Regulation

Regulation by governmental authorities in the U.S. and foreign countries is a significant factor in the manufacturing of products for us and the marketing of our products, as well as in ongoing research and development activities and in preclinical and clinical trials and testing related to our products. When our products are manufactured, tested or sold in the U.S., they will be regulated in accordance with the Federal Food, Drug, and Cosmetic Act, commonly referred to as the FD&C Act and the U.S. Public Health Service Act. The standard process required by the FDA before a pharmaceutical agent may be marketed in the U.S. includes: (i) preclinical laboratory and animal tests; (ii) submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may commence; (iii) adequate well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication, and adequate data to support the Chemistry, Manufacturing and Controls aspect of the process which will ensure reproducible product quality batch after batch; (iv) submission to the FDA of a New Drug Application, or NDA, with respect to drugs, or Biologics License Application, or BLA, for biological products; and (v) FDA approval of the NDA prior to any commercial marketing, sale or shipment of the drug. In addition to obtaining FDA approval for each product, each domestic manufacturing establishment must be registered with the FDA. Domestic manufacturing establishments are subject to inspections by the FDA and by other federal, state and local agencies and must comply with current U.S. Good Manufacturing Practices, or cGMP.

The steps required before a new drug or biological product may be distributed commercially in the U.S. generally include:

- conducting appropriate preclinical laboratory evaluations of the product's chemistry, formulation and stability, and animal studies to assess the potential safety and efficacy of the product;
- submitting the results of these evaluations and tests to the FDA, along with manufacturing information and analytical data, in an IND;

- making the IND effective after the resolution of any safety or regulatory concerns of the FDA;
- obtaining approval of Institutional Review Boards, or IRBs, to introduce the drug into humans in clinical studies;
- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the drug product candidate for the intended use, typically in the following three sequential, or slightly overlapping stages:
  - *Phase 1:* The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion;
  - *Phase 2:* The drug is studied in patients to identify possible adverse effects and safety risks, to determine dose tolerance and the optimal dosage, and to collect initial efficacy data; and
  - *Phase 3:* The drug is studied in an expanded patient population at multiple clinical study sites, to confirm efficacy and safety at the optimized dose, by measuring a primary endpoint established at the outset of the study, and comparing it to that of established therapies, if any; and when required
  - *Phase 4:* The drug is studied in an expanded patient population in a post-approval setting for continued monitoring of safety and sometimes continued efficacy
- submitting the results of preliminary research, preclinical studies, and clinical studies as well as chemistry, manufacturing and control information on the drug to the FDA in a NDA or BLA; and
- obtaining FDA approval of the NDA or BLA prior to any commercial sale or shipment of the drug product.

In approving an NDA or BLA, the FDA may require further post-marketing studies, referred to as phase 4 studies. When used in connection with trials and filings in other countries, terms such as "phase 1," "phase 2," "phase 3," "phase 4," "new drug application" and "marketing application" refer to what we believe are comparable trials and filings in these other countries.

Congress has amended the FD&C Act to facilitate and expedite the development and review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. These provisions, which combine existing FDA expedited approval and accelerated approval procedures, set forth a new procedure for designation of a drug as a "fast track product." Concurrent with or after a NDA is filed, the sponsor may request designation as a fast track product, and the FDA will respond within 60 days.

If the FDA designates a product for fast track review, the FDA is obligated to take such actions as are appropriate to facilitate and expedite review of the application. Another advantage of fast track designation is that sponsors may submit, and the FDA may commence review of, portions of an application before the complete application is submitted, provided that a schedule for submission of the completed application is provided. The sponsor of a fast track product also may seek and obtain FDA approval based upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit. A product approved on this basis is subject to rigorous postmarket compliance requirements. For example, the sponsor may be required to conduct post-approval studies to validate or confirm the endpoint or may be required to submit copies of all promotional materials 30 days prior to their dissemination. The FDA may withdraw approval of a fast track product if, for example, the sponsor fails to conduct required post-approval studies or disseminates false or misleading promotional materials.

Even after initial FDA approval has been obtained, further studies, including post-marketing studies, may be required to provide additional data on the product's risks, benefits, and optimal use, and will be required to gain approval for the use of the product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including changes in indication, labeling, or a change in manufacturing facility, a NDA or BLA supplement may be required to be submitted to the FDA. Pursuant to

recent amendments to the FD&C Act, major manufacturing changes, defined as changes that have substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a product as they may relate to the safety and effectiveness of the product, require the submission of a supplement and approval by the FDA prior to distribution of the product made using the change. Moderate changes are defined as having moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the product's safety or effectiveness. Some moderate changes, such as a move to a different manufacturing site for the manufacture or processing of any drug product, in-process material, or drug substance, require submission of a supplement to the FDA at least 30 days before the distribution of the product made using the change. Other moderate changes, including a move to a different manufacturing site for the manufacture or processing of the final intermediate, may occur when the FDA receives the supplement. The manufacturer must describe minor changes, defined as having minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness, in the next required annual report to the FDA.

The orphan drug provisions of the FD&C Act provide incentives to drug and biologics manufacturers to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the U.S. or, for a disease that affects more than 200,000 individuals in the U.S., where the sponsor does not realistically anticipate its product becoming profitable without benefits under the provisions. Under these provisions, a manufacturer of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven year period of marketing exclusivity for that product for the orphan indication. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same use. We have been granted orphan designation by the FDA for ZADAXIN for chronic active hepatitis B, DiGeorge Anomaly and hepatocellular carcinoma, and for CPX for cystic fibrosis.

Orphan drug legislation was recently introduced into the European Union, or EU, pursuant to the Orphan Medicinal Products Regulation. Orphan medicinal products are those products designed to diagnose, treat or prevent a condition which occurs so infrequently that the cost of developing and bringing the product to the market would not be recovered by the expected sale of the product. In the EU, the criterion for designation is a prevalence of the relevant condition in no more than 5 per 10,000 of the population. The legislation, consistent with that already in place in the United States, aims to provide incentives for the development of orphan medicinal products which include, amongst others, a reduction in the fees payable in respect of the marketing authorization application, protocol assistance for clinical trials in support of the application, and marketing exclusivity once the authorization is granted. In the EU, marketing exclusivity is granted to products with an orphan drug designation for a period of 10 years during which the EU will not accept another application for a marketing authorization for the same therapeutic indication in respect of a similar medicinal product, unless the second applicant can show its product is safer, more effective or otherwise clinically superior. A similar medicinal product is defined as a medicinal product containing a similar active substance as contained in the authorized orphan medicinal product.

In March 2001, we were granted orphan drug status throughout the EU for CPX for the treatment of cystic fibrosis. However, it should be noted that, as in the U.S., the granting of orphan drug status in the EU does not affect the likelihood of success of obtaining regulatory approval or marketing authorization for the relevant product in any way.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or DPCPTRA, a sponsor may be granted marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or new clinical studies were used to support the marketing application. This marketing exclusivity would prevent a third party from obtaining FDA approval for a similar or identical drug through an Abbreviated New Drug Application, or ANDA, which is the application form typically used by manufacturers seeking approval of a generic drug, or 505(b)(2) application. The DPCPTRA also allows a patent owner to extend the term of the patent for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval with the maximum patent extension term

being five years. Once a drug is granted some form of marketing exclusivity, the recently enacted FDA Modernization Act provides an additional six months of marketing exclusivity for certain pediatric research conducted at the written request of the FDA.

We may seek the benefits of orphan, DPCPTRA, or fast track provisions, but we cannot assure you that we will be able to obtain any such benefits.

We are subject to foreign regulations governing human clinical trials and pharmaceutical sales. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries is required prior to the commencement of marketing of our products in those countries. The approval process varies from country to country and the time required for approval may be longer or shorter than that required for FDA approval. In general, foreign countries use one of three forms of regulatory approval process. In one form, local clinical trials must be undertaken and the data must be compiled and submitted for review and approval. In Japan, for example, the process is time consuming and costly because clinical trials and preclinical studies must be conducted in Japan. A second form of approval process requires clinical trial submissions, but permits use of foreign clinical trials and typically also requires some form of local trial as well. A third form of approval process does not require local clinical trials, but rather contemplates submission of an application including proof of approval by countries that have clinical trial review procedures. Thus, a prior approval in one or more of the U.S., Japan, most European Union countries or Australia, among others, is often sufficient for approval in countries using this third form of approval process.

In addition to required foreign approvals, the FDA regulates the export of drugs or bulk pharmaceuticals from the U.S. In general, a drug that has been approved for commercial sale in the U.S. may be exported for commercial sale. In 1996, the U.S. Congress passed export reform legislation that provides that an unapproved drug may be exported to a "listed country" for investigational purposes without FDA authorization if exported in accordance with laws of the foreign country, and in accordance with the export requirements. The listed countries include Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and countries in the European Union and the European Economic Area. Export of drugs to an unlisted country for clinical trial purposes continues to require FDA approval. We have obtained, where necessary, FDA approval for all exports of ZADAXIN from the U.S. for clinical trial purposes, and will seek to obtain FDA approval, where necessary, for any future shipments from the U.S. to any unlisted country. The export reform legislation further provides that an unapproved drug can be exported to any country for commercial purposes without prior FDA approval, provided that the drug (i) complies with the laws of that country, and (ii) has valid marketing authorization or the equivalent from the appropriate authority in a listed country. Export of drugs not approved in the U.S. that do not have marketing authorization in a listed country continue to require FDA export approval..

Pursuant to the Prescription Drug User Fee Act ("PDUFA") of 1992, as amended in 1997, manufacturers of drugs and biologics generally are required to pay three types of user fees: (1) a one-time application fee for approval of an NDA or BLA; (2) an annual product fee imposed on prescription drugs and biologics after FDA approval; and (3) an annual establishment fee imposed on facilities used to manufacture prescription drugs and biologics. The fee rates for 2001 were: (1) $309,647 for an application requiring clinical data, or $154,823 for an application not requiring clinical data; (2) $145,989 for the establishment fee; and (3) $21,892 for the product fee. The fee rates for 2002 are: (1) $313,320 for an application requiring clinical data, or $156,660 for an application not requiring clinical data; (2) $140,109 for the establishment fee; and (3) $21,630 for the product fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the drug also includes a non-orphan indication. PDUFA will expire on October 1, 2002, and is in the process of being re-authorized, but re-authorization is not certain.

Among the conditions for NDA or BLA approval in the U.S. is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to cGMP. In complying with standards

set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance.

We are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with research work and preclinical and clinical trials and testing. The extent of government regulation that might result from future legislation or administrative action in these areas cannot be accurately predicted.

As the preceding discussion indicates, the research, preclinical development, clinical development, manufacturing, marketing and sales of pharmaceuticals, including ZADAXIN and CPX, are subject to extensive regulation by governmental authorities. Products we develop cannot be marketed commercially in any jurisdiction in which they have not been approved. The process of obtaining regulatory approvals is lengthy, uncertain and requires the expenditure of substantial resources. For example, in some countries where we contemplate marketing ZADAXIN, the regulatory approval process for drugs not previously approved in countries that have established clinical trial review procedures is uncertain and this uncertainty may result in delays in granting regulatory approvals. In addition, in certain countries such as Japan, the process for obtaining regulatory approval is typically more time consuming and more costly than in other major markets. We are currently pursuing regulatory approvals of ZADAXIN in the U.S., Japan, and in a number of other countries, and in the EU through our collaborator Sigma-Tau, and regulatory approval of CPX in the U.S.

Third Party Reimbursement

ZADAXIN is a relatively expensive therapeutic product. The amount of product utilized by the patient depends on the disease and the related dose and length of treatment, and the cost will typically be several thousands of U.S. dollars for a course of therapy. ZADAXIN is currently sold principally in countries without broad government provided health care reimbursement programs or adequate and widely distributed private health insurers and other third party payor organizations. The lack of third party reimbursement impedes the exposure and availability of ZADAXIN to the broad affected patient populations in our currently approved markets. We believe that, in addition to regulatory marketing approvals, inclusion of ZADAXIN in drug insurance programs and government drug cost reimbursement programs in the U.S., Europe and Japan is essential to the commercial success of the product.

Employees

As of December 31, 2001, we had 84 employees, 18 in the U.S., and 66 in foreign offices. We consider our relations with our employees to be satisfactory. We expect to hire other experienced professionals in 2002 to address, among other things, expanded clinical, regulatory, manufacturing and marketing activities.

We also have engaged the services of numerous experienced consultants worldwide with pharmaceutical and business backgrounds to assist in our product development and ZADAXIN commercialization activities. We plan to leverage our key personnel by continuing to make extensive use of clinical research organizations, contract laboratories, development consultants and collaborations with pharmaceutical companies to develop and market our products.

Recent Developments

As part of SciClone's collaborative agreement with Sigma-Tau, in January 2002 SciClone received from Sigma-Tau a $2,685,000 payment which will be recognized evenly as contract revenue over the period of our U.S. hepatitis C clinical development activities, estimated at two years beginning in the second quarter of 2002. This payment is part of the $3.7 million Sigma-Tau has agreed to pay us to help fund the U.S. hepatitis C clinical trials. The remaining $1 million will be earned upon completion of patient enrollment in these clinical trials.

Executive Officers of the Registrant

As of March 5, 2002, the executive officers of the Company, who are elected by and serve at the discretion of the Board of Directors, were as follows:

Name	Age	Position
Donald R. Sellers	57	President, Chief Executive Officer, and Director, SciClone Pharmaceuticals, Inc.; Managing Director, SciClone Pharmaceuticals International Ltd.
Alfred R. Rudolph, M.D	54	Chief Operating Officer
Richard A. Waldron	48	Chief Financial Officer

Donald R. Sellers has served as the Company's Chief Executive Officer since April 1996 and as President and Director since January 1996. From May 1993 to present, he has also served as Managing Director, SciClone Pharmaceuticals International Ltd., the international arm of the Company. From 1990 to 1993, Mr. Sellers was Corporate Vice President of Getz Bros., a U.S.-based international trading company, as well as President of one of its Japanese operations. From 1983 to 1990, Mr. Sellers was employed by Sterling Drug International, initially as Vice President of Marketing and Operations in Asia and later as President of its Latin American Andina Group. Mr. Sellers began his pharmaceutical career in 1973 with Pfizer as Country Manager, Vietnam and Hong Kong, and he later worked with the Revlon Healthcare Group as Director of Worldwide Exports and Pacific Area Director. Mr. Sellers spent five years in Military Intelligence serving with Special Forces and as a Counter-Intelligence Special Agent. He has an AB degree from Lafayette College and a Masters of International Management degree with honors from the American Graduate School of International Management.

Alfred R. Rudolph, M.D. joined the Company in April 1997 as Chief Technical Officer and was promoted to Chief Operating Officer in August 1997. From January 1995 to September 1995, Dr. Rudolph was President and Chief Operating Officer of Neptune Pharmaceuticals, Inc., a marine-based natural product screening company. Dr. Rudolph was Senior Vice President of T Cell Sciences, Inc., a biotechnology company, from December 1991 to September 1994 and was Vice President, Medical Affairs from March 1990 to December 1991. Dr. Rudolph was Director of Clinical Operations at Cetus Corporation from 1984 to 1989, and Clinical Assistant Professor of Medicine at University of California, San Francisco ("UCSF") during this period. Prior to that, he worked at Bristol Myers in cancer drug development. His fellowship training in Hemotology-Oncology was done at Syracuse University.

Richard A. Waldron joined the Company in March 2001 as Chief Financial Officer. Prior to joining SciClone he was Vice President and Chief Financial Officer from June 1999 to August 2000 for Genelabs Technologies, Inc., a biotechnology company. From July 1995 through March 1999 he was Vice President and Chief Financial Officer of GeneMedicine, Inc., a biotechnology company engaged in gene therapy. From 1990 to 1995, he was a managing director and the head of finance for technology-based companies at Rauscher Pierce Refsnes, Inc., an investment banking firm. From 1985 to 1990, he was a senior vice president responsible for health care investment banking at Cowen & Company. Mr. Waldron received his M.B.A. degree with honors from Harvard University and his A.B. degree magna cum laude in Economics from Princeton University.

There are no family relationships among any of the directors or executive officers of the Company.

Item 2. *Properties*

We currently lease approximately 14,768 square feet of office space at our headquarters in San Mateo, California and limited office space in Beijing, Hong Kong, Rome, Shanghai, Singapore and Tokyo. We believe that our existing facilities will be adequate for our current needs and that additional space will be available as needed.

Item 3. *Legal Proceedings*

None

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

No matter was submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2001.

PART II

Item 5. *Market for the Registrant's Common Equity and Related Shareholder Matters*

Our Common Stock trades on The Nasdaq National Market under the symbol "SCLN."

The following table sets forth the high and low sale prices per share for the quarterly periods indicated, as reported by The Nasdaq National Market. The quotations shown represent inter-dealer prices without adjustment for retail markups, markdowns, or commissions, and may not necessarily reflect actual transactions.

	Price Range Common Stock	
	High	Low
2001		
4th quarter	$ 3.45	$2.50
3rd quarter	5.13	2.50
2nd quarter	5.83	3.77
1st quarter	7.75	3.69
2000		
4th quarter	$11.13	$2.50
3rd quarter	14.19	9.50
2nd quarter	15.25	5.81
1st quarter	22.75	5.06

In April 1999, we completed a $1,000,000 private placement of 445,000 shares of restricted common stock to the Sigma-Tau Group, an accredited investor and one of the leading pharmaceutical companies in Southern Europe, in reliance upon Regulation D of the Securities Act of 1933, as amended. The Sigma-Tau Group was not granted any registration rights covering resale of the shares.

On July 2, 1999, we completed a $2,000,000 (before deducting expenses) private placement to strategic institutional and other accredited investors in reliance upon Regulation D of the Securities Act of 1933, as amended. The offering consisted of units of 1,370,145 shares of common stock and redeemable warrants to purchase 1,370,145 shares of common stock. Each unit was priced at $1.46 and consisted of one share of common stock and one five-year redeemable warrant to purchase one share of common stock at an exercise price of $1.33 per share. In addition, we issued to our placement agents an aggregate of 183,179 five-year redeemable warrants to purchase 183,179 shares of common stock at an exercise price of $1.66 per share.

On July 21, 1999, we completed a $4,000,000 (before deducting expenses) private placement to strategic institutional investors led by Brown Simpson Asset Management and The New York Life Insurance Company, all accredited investors, in reliance upon Regulation D of the Securities Act of 1933, as amended. The offering consisted of units of 2,515,934 shares of common stock and redeemable warrants to purchase 2,515,934 shares of common stock. Each unit was priced at $1.59 and consisted of one share of common stock and one five-year redeemable warrant to purchase one share of common stock at an exercise price of $1.72 per share. In addition, we issued to our placement agents an aggregate of 345,932 five-year redeemable warrants to purchase 345,932 shares of common stock at an exercise price of $1.83 per share.

In January 2000, we completed a private placement to Brown Simpson Asset Management, an accredited investor, in reliance upon Regulation D of the Securities Act of 1933, as amended. Brown Simpson purchased. 1,000,000 shares of our common stock at a price of $6.00 per share, a slight premium to market, and five-year warrants to purchase 800,000 shares of common stock at an exercise price of $7.00 per share. As of December 31, 2001, none of these warrants had been exercised.

In March 2000, we completed a private placement to Italy-based Sigma-Tau Group, an accredited investor, in reliance upon Regulation D of the Securities Act of 1933, as amended. Sigma-Tau purchased 198,072 shares of our common stock at $15.14 per share and five-year warrants to purchase 400,000 shares of our common stock. Warrants for 200,000 shares are exercisable at a price of $15.67 per share and warrants for 200,000 shares are exercisable at a price of $31.33 per share. The shares issued to Sigma-Tau were "restricted securities," that is Sigma Tau was not permitted to sell any of the shares purchased in this private placement until March 2, 2001. In addition, Sigma-Tau was not granted any registration rights covering resale of the shares or the shares issuable upon exercise of the warrants.

In March/April 2000, we received approximately $8,606,000 in connection with exercises of outstanding warrants to purchase 4,597,690 shares of common stock.

In December 2000, we completed a $4 million senior unsecured convertible note with an investment affiliate of UBS AG, an accredited investor, in reliance upon Regulation D of the Securities Act of 1933, as amended. The $4 million note is convertible into 407,610 shares of our common stock at a fixed conversion price of $9.8133 per share. The note will accrue interest at a rate of 6% per year and will mature in December 2005. The note was not convertible prior to December 2001. We also received $900,000 for granting the investor the right to purchase, at any time up to the maturity date, approximately $5.9 million of senior unsecured convertible notes due December 2005. The $900,000 was accounted for as an increase to shareholders' equity. If issued, the notes will bear no interest (zero coupon) and will be convertible into 407,610 shares of our common stock at a fixed conversion price of $14.5066 per share.

In March 2001, we completed a $1.6 million senior unsecured convertible note with an investment affiliate of UBS AG., an accredited investor, in reliance upon Regulation D of the Securities Act of 1933, as amended. The $1.6 million note is convertible into 276,530 shares of our common stock at a fixed conversion price of $5.7860 per share. The note will accrue interest at a rate of 6% per year and will mature in March 2006. The note is not convertible prior to March 21, 2002. We also received approximately $354,000 for granting the investor the right to purchase, at any time up to the maturity date, approximately $2.4 million of senior unsecured convertible notes due March 2006. The $354,000 was accounted for as an increase to shareholders' equity. If issued, the notes will bear no interest (zero coupon) and will be convertible into 276,530 shares of our common stock at a fixed conversion price of $8.5532 per share.

As of March 15, 2002, there were approximately 350 holders of record and approximately 19,250 beneficial holders of our common stock.

We have not paid any dividends during the fiscal years ended December 31, 2000 and 2001 on our common stock and currently intend to retain any future earnings for use in our business.

Item 6. *Selected Consolidated Financial Data*

This section presents selected historical financial data for each of the last five fiscal years and is qualified by reference to and should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

	2001	2000	1999	1998	1997
Statements of Operations data:					
Product sales	$13,831,000	$15,357,000	$9,091,000	$ 3,625,000	$ 2,223,000
Contract/grant revenue	—	—	307,000	100,000	—
Total revenue	13,831,000	15,357,000	9,398,000	3,725,000	2,223,000
Cost of product sales	2,742,000	3,113,000	1,761,000	1,036,000	990,000
Gross margin	11,089,000	12,244,000	7,637,000	2,689,000	1,233,000
Operating expenses:					
Research and development	8,561,000	4,182,000	4,604,000	9,293,000	8,642,000
Sales and marketing	8,764,000	7,720,000	5,503,000	5,123,000	3,988,000
General and administrative	3,897,000	3,538,000	3,386,000	3,982,000	3,819,000
Total operating expenses	21,222,000	15,440,000	13,493,000	18,398,000	16,449,000
Loss from operations	(10,133,000)	(3,196,000)	(5,856,000)	(15,709,000)	(15,216,000)
Writedown of note receivable from former officer	—	—	—	(5,944,000)	—
Income from payment on note receivable from former officer	3,497,000	400,000	20,000	—	—
Interest and investment income	751,000	1,066,000	157,000	514,000	1,321,000
Interest and investment expense	(334,000)	(36,000)	—	(21,000)	(174,000)
Other income (expense), net	(13,000)	49,000	212,000	89,000	72,000
Net loss	(6,232,000)	(1,717,000)	(5,467,000)	(21,071,000)	(13,997,000)
Deemed dividend on issuance of preferred stock	—	—	—	(3,143,000)	—
Net loss attributable to common stockholders	(6,232,000)	(1,717,000)	(5,467,000)	(24,214,000)	(13,997,000)
Basic and diluted net loss per share	$ (0.19)	$ (0.06)	$ (0.26)	$ (1.48)	$ (0.85)
Weighted average shares used in computing basic and diluted net loss per share	32,356,287	29,904,924	21,162,936	16,335,096	16,472,765
Balance Sheet data:					
Cash, cash equivalents and investments	$16,468,000	$22,497,000	$3,621,000	$ 5,410,000	$ 12,901,000
Working capital	26,930,000	30,281,000	7,091,000	3,845,000	7,416,000
Total assets	32,096,000	36,167,000	13,124,000	11,727,000	19,196,000
Redeemable preferred stock	—	—	—	848,000	—
Total shareholders' equity	22,774,000	28,077,000	9,301,000	6,428,000	15,724,000

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the "Selected Consolidated Financial Data" and our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Annual Report on Form 10-K contain forward-looking statements which involve risks and uncertainties. See "Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

During the periods encompassed by this Annual Report on Form 10-K, we have devoted substantially all of our resources to our ZADAXIN and CPX product development programs and our ZADAXIN commercialization activities. We conduct our research and product development efforts through a combination of internal and collaborative programs. In addition to internal management and staff, we rely upon arrangements with universities, other clinical research sites and contract research organizations for a significant portion of our product development efforts. Oversight of all external and collaborative programs are conducted by our executive officers and other staff from our headquarters located in San Mateo, California.

From commencement of operations through December 31, 2001, we incurred a cumulative net loss of approximately $123 million. We expect our sales, gross margin and operating expenses to increase over the next several years as we expand our sales, research and development, clinical testing and marketing capabilities. Our ability to achieve and sustain operating profitability is primarily dependent on the initiation, execution and completion of new ZADAXIN clinical trials, securing regulatory approvals for ZADAXIN in additional countries, particularly in the U.S., Europe and Japan, successfully launching ZADAXIN, if approved, in those countries, increasing ZADAXIN sales in approved markets, and developing and maintaining ZADAXIN corporate partnering arrangements in the U.S., Europe and Japan. In addition, other factors may also impact our ability to achieve and sustain operating profitability, including manufacturing costs of ZADAXIN, our ability to obtain additional financing to support our operations, long-term product development and commercialization programs, acquiring rights to additional drugs, and entering into and extending agreements for product development and commercialization, where appropriate.

Our operating results may fluctuate from quarter to quarter and these fluctuations may be substantial as a result of, among other factors, the number, timing, costs and results of preclinical and clinical trials of our products, market acceptance of ZADAXIN and the timing of large orders for ZADAXIN, the regulatory approval process, the timing of FDA or international regulatory approvals, and the acquisition of additional product rights and the funding, if any, provided as a result of corporate partnering arrangements. Setbacks in the launch, sale or distribution of ZADAXIN, preclinical or clinical development of our products, the regulatory approval process or relationships with collaborative partners, and any shortfalls in revenue or earnings from levels expected by securities analysts, among other developments, in the past had, and could in the future have, an immediate and significant adverse effect on the trading price of our common stock in any given period.

Critical Accounting Policies

General

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout management's Discussion and Analysis of Financial Condition and Results of Operations where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 1 in the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K. The Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United Sates, that requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of our financial statements, and the reported amounts of revenue

and expenses during the reporting period. On an on-going basis, we evaluate the relevance of our estimates. We base our estimates on historical experience and on various other market specific assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. There can be no assurance that actual results will not differ from those estimates.

Revenue Recognition

The Company recognizes revenue from product sales at the time of shipment and recognizes contract/ grant revenue over the period services are performed. The People's Republic of China, currently ZADAXIN's largest market, like Japan and certain other Asian markets, uses a tiered method to import and distribute products. The distributors make the sales in the country, but the product is imported for them by licensed importers. We recognize revenue on sales to principal importing agents who then resell to distributors inside China. Sales to customers (importing agents or distributors) are recognized at time of shipment when title to the products is transferred to them. There are no significant customer acceptance requirements or post shipment obligations on the part of the Company. The importing agents and distributors do not have contractual rights of return except under limited terms regarding product quality. Payments to us by the importing agents and distributors are not contingent upon sale to the end user by the import agents or distributors.

To date we have not recorded estimated reductions to revenue for expected sales returns. If conditions become more competitive in any of the markets served by ZADAXIN or if other circumstances change, we may take actions to record product return estimates that would result in a reduction of future revenue at the time the return estimate is changed.

Accounts Receivable

We are required to estimate the collectibility of our trade receivables. A considerable amount of judgment is required in assessing the ultimate realization of these receivables including the current credit-worthiness of each customer. Our ability to collect outstanding receivables from our customers is critical to our operating performance and cash flows. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. For the year ended December 31, 2001, importing agents in China accounted for 89% of the Company's product sales and accounted for 86% and 87% of our product sales for the years ended December 31, 2000 and 1999, respectively. As of December 31, 2001, approximately $8,653,000 or, 91% of our accounts receivable were attributable to these four customers in China. The Company performs on-going credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. We maintain reserves for credit losses, and such losses have been within our expectations. We recognize reserves for bad debts ranging from 25% to 100% based on the length of time the receivables are past due.

Inventories

We are required to state our inventories at the lower of cost or realizable market value. In assessing the ultimate realization of inventories, we are required to make judgments as to future demand requirements and compare that with the current and committed inventory levels. It is possible that changes in inventory reserves may be required in the future due to a change in market conditions.

Impairment of Intangible Assets

At December 31, 2001, we had net intangible assets of $1,091,000 related to ZADAXIN product rights and had never recorded any impairment losses related to intangible assets. In assessing the recoverability of our intangible assets we must make assumptions regarding estimated future cash flows and other factors to

determine the fair value of the respective assets. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets not previously recorded.

Research and development expenses

Research and development expenditures are charged to operations as incurred including accruals for estimated clinical and preclinical study costs. Our late-stage clinical programs in the U.S. and Japan will increase our research and development expenditures significantly over the next several years. Contract research organization management fees are expensed monthly, while remaining clinical program activity generally is expensed on a straight-line basis over the life of the individual contract or study. We monitor patient enrollment levels and related activity to the extent possible and adjust our estimates accordingly, however, if management has underestimated activity levels associated with various studies at a given point in time, we could underestimate our actual research and development expenses.

Results of Operations

Product sales were $13,831,000, $15,357,000 and $9,091,000 for the years ended December 31, 2001, 2000 and 1999, respectively. The decrease in sales from 2000 to 2001 was mostly due to a large sale of ZADAXIN to a new customer in China during the third quarter of 2000. As of March 2002, ZADAXIN is approved for sale in 26 countries worldwide. For the year ended December 31, 2001, importing agents in China accounted for 89% of our product sales and accounted for 86% and 87% for the years ended December 31, 2000 and 1999, respectively. Sales emphasis is concentrated in China because, as one of our more developed markets, marketing expenditures can result in rapid benefits in sales and profits compared to newer markets which require investment and development spending. We expect ZADAXIN sales to increase both in our existing approved markets and in new markets once regulatory approvals are secured and ZADAXIN is launched. The level of this sales increase is dependent upon increased ZADAXIN market penetration in our existing approved markets, additional ZADAXIN marketing approvals and the successful launch of ZADAXIN in new markets. Although we remain optimistic regarding the prospects of ZADAXIN, we cannot assure you that we will achieve sales increases, maintain existing sales levels, or ever achieve significant levels of sales or that we will receive additional ZADAXIN market approvals. Revenue results are difficult to predict, and any shortfall in revenue or any delay in recognizing revenue could cause our operating results to vary significantly from quarter to quarter and could result in future operating losses.

Cost of product sales was $2,742,000, $3,113,000 and $1,761,000 for the years ended December 31, 2001, 2000 and 1999, respectively. We expect cost of product sales to vary from quarter to quarter, depending upon the level of ZADAXIN sales, the absorption of fixed product-related costs, and any charges associated with excess or expiring finished product.

Gross margin was $11,089,000, $12,244,000 and $7,637,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Gross profit margin was 80% in 2001, 80% in 2000 and 81% in 1999. We expect to maintain approximately the same gross margin going forward, however, there can be no assurance that it will not decrease.

In 2001, 2000 and 1999, research and development (R&D) expenses represented approximately 40%, 27% and 34%, respectively, of our total costs and expenses. The major components of R&D expenses consist of personnel costs, including salaries and benefits, clinical studies performed by contract research organizations, materials and supplies, and overhead allocations consisting of various support and facilities related costs. Our research and development activities are also separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs include Phase 1, 2, and 3 clinical trials as well as expanded access programs. Pharmaceutical development costs consist of product formulation and chemical analysis. During 2001, we recorded approximately $2.8 million on research, $5.0 million on clinical development, and $0.8 million on pharmaceutical development activities. This compares to expenses in 2000 of approximately $2.4 million on research, $0.5 million on clinical development, and $1.3 million on pharmaceutical development activities and

expenses in 1999 of approximately $2.7 million on research, $1 million on clinical development, and $0.9 million on pharmaceutical development activities.

Research and development expenses were $8,561,000, $4,182,000 and $4,604,000 for the years ended December 31, 2001, 2000 and 1999, respectively. The increase in 2001 over 2000 was to support our late-stage clinical programs in the U.S. and Japan. The initiation and continuation of ZADAXIN, CPX and other product clinical development programs has had and will continue to have a significant effect on our research and development expenses and is expected to require us to seek additional capital resources. The decrease in 2000 over 1999 was primarily attributable to decreased clinical trial expenses related to CPX and consulting fees. We are currently sponsoring two phase 2 clinical trials using ZADAXIN for treatment in liver cancer development work to support a new phase 2 trial using CPX for treatment in cystic fibrosis, and two phase 3 U.S. trials using ZADAXIN plus pegylated interferon for treatment in hepatitis C in U.S. We are conducting a phase 3 clinical trial using ZADAXIN as a monotherapy for the treatment of hepatitis B in Japan. We are conducting several preclinical and clinical studies of SCV-07 for treatment in tuberculosis in Russia. Major components of research and development expenses consist of personnel costs, including salaries and benefits, clinical development performed by contract research organizations, preclinical work, pharmaceutical development, materials and supplies, third party research funding and overhead allocations consisting of various administrative and facilities related costs. Due to the uncertain nature of the trial process, it is not possible to determine the timing of completion or total cost expected to be incurred for each trial. CPX expenditures are expected to decrease from the level in 2001, while ZADAXIN expenditures will increase and account for most of our development expenditures. In general, we expect product research and development expenses to increase significantly over the next several years and to vary substantially from quarter to quarter as we pursue our strategy of initiating additional preclinical and clinical trials and testing, acquiring product rights, and expanding regulatory activities.

Sales and marketing expenses were $8,764,000, $7,720,000 and $5,503,000 for the years ended December 31, 2001, 2000 and 1999, respectively. The increase over these years is related to increased payroll expenses and expenses for advertising and conferences associated with the expansion of our markets for ZADAXIN. We expect sales and marketing expenses to increase in the next several quarters and years as we expand our commercialization and marketing efforts and pursue additional strategic collaborations.

General and administrative expenses were $3,897,000, $3,538,000 and $3,386,000 for the years ended December 31, 2001, 2000 and 1999, respectively. This increase was attributable to greater general and administrative activities to support an increased level of research and development on our late-stage clinical programs. In the near term, we expect general and administrative expenses to vary quarter to quarter as we augment our general and administrative activities and resources to support increased expenditures on preclinical and clinical trials and testing, and regulatory, pre-commercialization and marketing activities.

Income from payment on a note receivable from a former officer was approximately $3,497,000, $400,000 and $20,000 for the years ended December 31, 2001, 2000 and 1999, respectively. In July 1997, the Company loaned to the former officer $5,944,000 in exchange for a promissory note and the pledge of 1,882,500 shares of SciClone Common Stock as collateral for such loan. During 1998 it was determined that the value of the collateral underlying the loan was more than temporarily impaired and that a writedown of the book value of the note would be required. For accounting purposes, the Company wrote off the entire remaining book value in a non-cash charge to earnings in the fourth quarter of 1998. Under a new agreement in 1999, the 1,882,500 shares of SciClone common stock held as collateral were retired and the value of these shares at that date was applied as a credit against the total indebtedness of the former officer. After applying a credit for the retired stock of $3,142,000, the officer entered into a new note in the amount of $3,615,000. The note has been fully repaid.

Interest and investment income was approximately $751,000, $1,066,000, and $157,000 for the years ended December 31, 2001, 2000 and 1999, respectively. The decrease in 2001 over 2000 was due to lower average invested cash balances and lower interest rates. The increase in 2000 over 1999 was due to higher average invested cash balances.

Interest and investment expense was approximately $334,000, $36,000 and $0 for the years ended December 31, 2001, 2000 and 1999, respectively. The increase over the years was from the interest accrued on senior unsecured convertible notes that we have with an investment institution.

Other income (expense) was approximately $(13,000), $49,000 and $212,000 for the years ended December 31, 2001, 2000 and 1999, respectively. In 1999, we recognized other income of approximately $262,000, related to a gain generated on a loan foreclosure.

Liquidity and Capital Resources

At December 31, 2001, 2000 and 1999, we had $16,468,000, $22,497,000 and $3,621,000, respectively, in cash, cash equivalents and short-term investments. The short-term investments consist primarily of highly liquid marketable securities. Under our lease agreement, we are required to have a line of credit in the amount of $633,000. This line of credit is secured by a certificate of deposit that totaled $633,000 at December 31, 2001.

Net cash used in operating activities totaled $12,008,000, $5,917,000 and $8,929,000 for the years ended December 31, 2001, 2000, and 1999, respectively. Net cash used in operating activities for the year ended December 31, 2001 was greater than the net loss primarily due to a gain of $3,497,000 related to collection of a note receivable, which had previously been written off in 1998, from a former officer, an increase in inventory and a decrease in accounts payable and other accrued expenses. Net cash used in operating activities for the year ended December 31, 2000 was greater than the net loss primarily due to increases in accounts receivable and inventory. These amounts were partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable. Net cash used in operating activities for the year ended December 31, 1999 was greater than the net loss due to an increase in accounts receivable and a decrease in amounts owed to third parties for clinical trials. These amounts were partially offset by increases in accrued compensation and employee benefits and accounts payable and other accrued expenses.

Net cash used in investing activities of $450,000 for the year ended December 31, 2001 related to the net purchase of $351,000 in marketable securities and $99,000 in equipment and furniture. Net cash used in investing activities of $430,000 for the year ended December 31, 2000 related to the net purchase of $331,000 in marketable securities partially offset by the purchase of $99,000 in equipment and furniture. Net cash provided by investing activities of $349,000 for the year ended December 31, 1999 related to the net sale of $391,000 in marketable securities partially offset by the purchase of $42,000 in equipment and furniture.

Net cash provided by financing activities totaled $5,995,000, $24,886,000 and $7,189,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Net cash provided by financing activities for the year ended December 31, 2001 consisted of $1,600,000 in proceeds from the issuance of a convertible note, $544,000 in net proceeds from the issuance of common stock, $354,000 for granting an investor the right to purchase approximately $2,400,000 of senior unsecured convertible notes, and $3,497,000 from the payment on a note receivable from a former officer Net cash provided by financing activities for the year ended December 31, 2000 consisted of approximately $5,326,000 from a private placement of common stock and warrants to institutional investors, approximately $8,606,000 from the exercise of outstanding warrants to purchase common stock by institutional and accredited investors, approximately $191,000 from the issuance of common stock under our employee stock purchase plan, approximately $3,100,000 from a private placement of 198,072 of common stock to Sigma-Tau, our partner for the development and marketing of ZADAXIN in Europe, approximately $2,363,000 from the exercises of outstanding options under our employee stock option plans, $4,000,000 from the issuance of a convertible note and $900,000 for granting investors the right to purchase approximately $5,900,000 of senior unsecured convertible notes and $400,000 from the payment on a note receivable from a former officer. Net cash provided by financing activities for the year ended December 31, 1999 consisted of approximately $5,430,000 from the issuance of common stock and warrants to institutional and accredited investors in two private placements, $235,000 from the payment in full of a note receivable from our President and Chief Executive Officer approximately $1,504,000 from the issuance of common stock under our employee stock purchase plan, exercise of warrants and issuance of restricted common stock to Sigma-Tau, and $20,000 from the payment on a note receivable from a former officer.

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Long Term Debt	$ 5,600,000	—	—	$5,600,000	—
Operating Leases	$ 5,315,000	$1,311,000	$2,734,000	$1,270,000	—
Total Contractual Cash Obligations	$10,915,000	$1,311,000	$2,734,000	$6,870,000	—

Other Commercial Commitments	Total Amounts Committed	Amount of Commitment Expiration Per Period			
		Less than 1 year	1-3 years	4-5 years	Over 5 years
Letter of Credit.....	$633,000	$633,000	—	—	—

In January 2000, we completed a private placement of common stock and immediately exercisable common stock warrants to an institutional investor which resulted in gross proceeds of approximately $6,100,000. If the warrants issued in connection with this private placement are fully exercised, we will receive an additional $5,600,000. In March 2000, we completed a $3,100,000 private placement to Sigma-Tau consisting of 198,072 shares of restricted common stock and warrants for 400,000 shares of common stock, which, if fully exercised, will result in additional gross proceeds of $9,400,000. In March and April 2000, an aggregate of 4,597,690 other common stock warrants were exercised resulting in aggregate gross proceeds of approximately $8,606,000. In December 2000, we completed a $4 million senior unsecured convertible note with an investment affiliate of UBS AG. The $4 million note is convertible into 407,610 shares of our common stock at a fixed conversion price of $9.8133 per share. The note will accrue interest at a rate of 6% per year and will mature in December 2005. We also received $900,000 for granting the investor the right to purchase at any time up to the notes' maturity date approximately $5.9 million of senior unsecured convertible notes due December 2005. If issued, the notes will bear no interest (zero coupon) and will be convertible into 407,610 shares of our common stock at a fixed conversion price of $14.5066 per share. We may elect in lieu of delivering convertible notes to deliver the respective number of shares of common stock. In March 2001, we received $1.6 million under a senior unsecured convertible note with an investment affiliate of UBS AG. The $1.6 million note is convertible into 276,530 shares of our common stock at a fixed conversion price of $5.7860 per share. The note will accrue interest at a rate of 6% per year and will mature in March 2006. We also received $354,000 for granting the investor the right to purchase at any time up to the notes' maturity date approximately $2.4 million of senior unsecured convertible notes due March 2006. If issued, the notes will bear no interest (zero coupon) and will be convertible into 276,530 shares of our common stock at a fixed conversion price of $8.5532 per share. We may elect in lieu of delivering convertible notes to deliver the respective number of shares of common stock.

Besides the last note receivable payment from a former officer, there are no officers or directors that were involved in related party transactions in 2001.

Management believes ZADAXIN product sales should continue to increase and remain a valuable source of capital generation. The initiation and continuation of U.S. clinical development programs, however, is expected to require additional funding either from a collaborative partner or through equity or debt financing. The timing, achievement and sustainability of our operating profitability and capital requirements may change depending upon numerous factors, including the level of ZADAXIN product sales, the timing and amount of manufacturing costs related to ZADAXIN, the availability of complementary products, technologies and businesses, the initiation and continuation of preclinical and clinical trials and testing, particularly in the U.S., the timing of regulatory approvals, developments in relationships with existing or future collaborative partners and the status of competitive products. Without additional financing, or sales growth beyond management's expectations, or a combination thereof, management believes its existing capital resources and interest on funds available are adequate to maintain its current and planned operations through the end of 2002. The Company is actively reviewing alternatives for equity debt financings and potential partnering activities.

Income Taxes

At December 31, 2001, we had net operating loss carryforwards for federal income tax purposes of approximately $59,700,000 which expire in the years 2006 through 2021. The difference between the cumulative losses for financial reporting purposes and federal income tax purposes is primarily attributable to losses incurred by our foreign subsidiaries. At December 31, 2001, we had federal tax credit carryforwards of approximately $3,200,000 which expire in the years 2009 through 2021.

Because of the "change in ownership" provisions of the Internal Revenue Code, a portion of our net operating loss carryforwards and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods. As a result of the annual limitation, a portion of these carryforwards may expire before ultimately becoming available to reduce future income tax liabilities.

Recent Accounting Pronouncements

The Financial Accounting Standards Board issued Statements of Financial Accounting Standards, No. 141, "Business Combinations", (SFAS 141) and No. 142, "Goodwill and Other Intangible Assets", (SFAS 142) in June 2001. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subjected to annual impairment tests in accordance with these statements. Other intangible assets will continue to be amortized over their useful economic lives. These statements are effective for combinations initiated after July 1, 2001 and SFAS 142 applies to assets related to acquisitions prior to that date as of January 1, 2002. Based on current circumstances, we believe the application of the new rules will not have a material impact on our consolidated financial statements.

The Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (SFAS 144) in August 2001. The statement addresses financial accounting and reporting of the impairment or disposal of long-lived assets. SFAS 144 is effective for fiscal years beginning after December 15, 2001, with earlier application encouraged. Based on current circumstances, we believe application of the new rules will not have a material impact on our consolidated financial statements.

Risk Factors

You should carefully consider the risks described below, together with all of the other information included in this Report on Form 10-K, before making an investment decision. Each of these risk factors could adversely affect our business, financial condition, and operating results as well as adversely affect the value of an investment in our common stock.

Our phase 3 program in the U.S. for the approval of ZADAXIN in combination with pegylated interferon for the treatment of hepatitis C may fail, which will harm our business.

We conservatively designed a phase 3 study program based on the use of ZADAXIN in combination with pegylated interferon. There can be no assurances that the results from our previous phase 2 and phase 3 hepatitis C studies which enabled us to produce this design will carryover to the trials involving a combination of ZADAXIN and pegylated interferon and any resulting data may be insufficient to demonstrate efficacy under FDA guidelines. We may not be able to enroll patients quickly enough to meet our expectations for completing the trial. The independent use of the pegylated form of interferon may perform better than anticipated. If that results, our efforts to market and sell ZADAXIN in combination with pegylated interferon will be impaired.

We may not be able to successfully develop or commercialize our products.

Many of our products are in the development stage and will require the commitment of substantial resources, devoted to extensive research, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. We cannot assure you that commercially viable products will result from these efforts. We face significant technological risks inherent in developing these

products. We may also abandon some or all of our proposed products before they become commercially viable. We have limited experience in conducting and managing U.S. clinical trials and we rely, in part, on third parties, particularly clinical research organizations and our development partners, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completing, or failure to complete, these clinical trials if third parties fail to perform their obligations to us. If any of our products, even if developed and approved, cannot be successfully commercialized in a timely manner, our business will be harmed and the price of our stock may decline.

We have not yet sold any product other than ZADAXIN. Our future revenue growth depends on increased market acceptance and commercialization of ZADAXIN in additional countries, particularly in the U.S., Europe and Japan. If we fail to successfully market ZADAXIN, or if we cannot commercialize this drug in the U.S. and other additional markets, our revenue and operating results will suffer. Our future revenue will also depend in part on our ability to develop other commercially viable and accepted products. Market acceptance of our products will depend on many factors, including our ability to convince prospective customers and prospective strategic partners that our products are an attractive alternative to other treatments and therapies, and manufacture products in sufficient quantities with acceptable quality and at an acceptable cost.

If we fail to satisfy and comply with governmental regulations or if government regulations change, our business will suffer.

All new drugs, including our products, which have been developed or are under development, are subject to extensive and rigorous regulation by the FDA, and comparable agencies in state and local jurisdictions and in foreign countries. These regulations govern, among other things, the development, testing, manufacturing, labeling, storage, pre-market approval, importation, advertising, promotion, sale and distribution of our products. These regulations change from time to time and new regulations may be adopted. For example, in prior years, legislation has been introduced in the U.S. Congress that would restrict the duration of the marketing exclusivity of an orphan drug. There can be no assurances that this type of legislation will not be reintroduced and passed into law, or that the benefits of the existing statute will remain in effect. Our failure to satisfy and comply with regulations adopted by the FDA, and comparable agencies in state and local jurisdictions and in foreign countries, may delay or stop approval of our drugs. In particular, such failure can, among other things, result in warning letters, fines, suspensions of regulatory approvals, product recalls or seizures, operating restrictions, injunctions, total or partial suspension of production, civil penalties, and criminal prosecutions. Furthermore, additional government regulation may be established or imposed by legislation or otherwise, which could prevent or delay regulatory approval of ZADAXIN or any of our other future products. Adverse events related to our products in any of our existing or future markets could cause regulatory authorities to withdraw market approval for such products, if any, or prevent us from receiving market approval in the future. There is no assurance that ZADAXIN, or any of our other products, will demonstrate efficacy sufficient to obtain approval by the FDA or its counterpart regulatory agencies in other countries.

Satisfaction of government regulations may take several years and the time needed to satisfy them varies substantially, based on the type, complexity and novelty of the pharmaceutical product. As a result, government regulation may cause us to delay the introduction of, or prevent us from marketing, our existing or potential products for a considerable period of time and to impose costly procedures upon our activities. If regulatory approval of our products is granted, such approval may impose limitations on the indicated uses for which our products may be marketed. The pegylated interferon we will use in our phase 3 program in the U.S. has not yet been approved by the FDA. If this pegylated interferon is not approved by the FDA, we would need to conduct an additional trial with an approved form, resulting in additional delays and expenses.

If we fail to obtain regulatory approvals for our products in countries where we have targeted regulatory approval, we may not be able to sustain or increase our revenues and our stock price may decline.

The research, preclinical and clinical development, manufacturing, marketing and sale of ZADAXIN and our other drug candidates are subject to extensive regulation by governmental authorities. ZADAXIN

and any other products we may sell in countries outside the U.S. must be approved by the foreign counterparts of the FDA before they can be sold in any jurisdiction. Obtaining regulatory approval is time-consuming and expensive. In some countries where we are contemplating marketing and selling ZADAXIN, the regulatory approval process for drugs that have not been previously approved in countries with established clinical trial review procedures is uncertain, and this may delay the grant of regulatory approvals for ZADAXIN. In addition, to secure these regulatory approvals, we will need, among other things, to demonstrate favorable results from additional clinical trials of ZADAXIN and the safety and efficacy of CPX as a treatment for cystic fibrosis in preclinical and clinical trials. There can be no assurance that we will ultimately obtain regulatory approvals in our targeted countries in a timely and cost-effective manner or at all. Our failure to obtain the required regulatory approvals so that we can develop, market and sell our products in countries where we currently do not have such rights may limit our revenues.

Even if we are able to complete the clinical trials we have sponsored or are planning in a timely or cost-effective manner, these trials may not fulfill the applicable regulatory approval criteria, in which case we will not be able to obtain regulatory approvals in these countries. Failure to obtain additional regulatory approvals will harm our operating results. In addition, adverse results that occur in our clinical trials could result in restrictions on the use of ZADAXIN.

We will need to obtain additional capital to support our long-term product development and commercialization programs.

Our ability to achieve and sustain operating profitability depends in large part on our ability to commence, execute and complete clinical programs for, and obtain additional regulatory approvals for ZADAXIN and other drug candidates, particularly in the U.S., Europe and Japan, increase ZADAXIN sales in existing markets, and launch ZADAXIN in new markets. We cannot assure you that we will ever achieve significant levels of sales or that we will receive additional ZADAXIN market approvals.

Our current sales levels of ZADAXIN are not expected to generate all the funds we anticipate will be needed to support our current plans for product development including our U.S. phase 3 clinical trials for ZADAXIN. We will need to obtain additional financing to support our product development and commercialization programs. We may seek additional funds through public and private stock offerings, arrangements with corporate partners, borrowings under lease lines of credit or other sources. If we cannot raise the necessary funds, we will have to reduce our capital expenditures, curtail or delay our phase 3 clinical trials, scale back our development of new products, reduce our workforce and out-license to others products or technologies that we otherwise would seek to commercialize ourselves.

The amount of capital we will need will depend on many factors, including: the timing, location, scope and results of ongoing and planned preclinical studies and clinical trials; the cost of manufacturing or obtaining preclinical and clinical materials; the timing and cost involved in applying for and obtaining FDA and international regulatory approvals; whether we elect to establish additional partnering arrangements for development, sales, manufacturing, and marketing of our products; the level of future ZADAXIN sales; expense levels for our international sales and marketing efforts; our ability to establish and maintain strategic arrangements for development, sales, manufacturing and marketing of our products; competing technological and market developments; the costs involved in filing, prosecuting and enforcing patent claims; and whether any or all of our outstanding common stock warrants are exercised and the timing and amount of these exercises.

Many of the foregoing factors are not within our control. If we need to raise additional funds and such funds are not available on reasonable terms, we may be required to delay or cancel our product development and commercialization programs. Any additional equity financing will be dilutive to shareholders, and any debt financing, if available, may include restrictive covenants.

We have a history of operating losses and an accumulated deficit. We expect to continue to incur losses in the near term and may never achieve profitability.

We have experienced significant operating losses since our inception and as of December 31, 2001, we had an accumulated deficit of approximately $123,000,000. We expect our operating expenses to increase over the next several years as we plan to dedicate substantially all of our resources to expanding our development, testing and marketing capabilities, particularly in the U.S., and we may never achieve profitability. Our failure to achieve profitability may cause our stock price to decline.

We are dependent on the sale of ZADAXIN in foreign countries, particularly China, and if we experience difficulties in our foreign sales efforts, our financial condition will be harmed.

Our financial condition in the near term is highly dependent on the sale of ZADAXIN in foreign countries. If we experience difficulties in our foreign sales efforts, our business will suffer and our financial condition will be harmed. Substantially all of our ZADAXIN sales are to customers in the People's Republic of China. Sales of ZADAXIN in China may be limited due to its low average income, lack of patient cost reimbursement, poorly developed infrastructure, and existing and potential competition from other products, possibly including generics. China uses a tiered method to import and distribute finished pharmaceutical products. At each port of entry, and prior to moving the product forward to the distributors, government licensed importing agents must process and evaluate each shipment to determine whether such shipment satisfies China's quality assurance requirements. In order to efficiently manage this process, the importing agents place relatively few orders from time to time over any six month period and each order is typically for large quantities. Therefore, our sales to an importing agent can vary substantially from quarter to quarter depending on the size and timing of the orders, which has in the past and may in the future cause our quarterly results to fluctuate. Because we use four importing agents in China, our account receivable from any one importing agent is material and if we were unable to collect receivables from any importer, our business and cash-flow would be adversely affected, at least in the short term.

In addition, our ZADAXIN sales and operations in other parts of Asia, as well as in Latin America and the Middle East, are subject to a number of risks, including: difficulties and delays in obtaining pricing approvals and reimbursement, product health registrations and importation permits; unexpected changes in regulatory requirements; difficulties in staffing and managing foreign operations; long payment cycles; difficulties in accounts receivable collection; difficulties in enforcing our proprietary rights; currency fluctuations; adverse or deteriorating economic conditions; and potential adverse tax consequences.

We do not have product sales in the U.S. with which to offset any decrease in our revenue from ZADAXIN sales in Asia, Latin America and the Middle East. In addition, some countries in these regions, including China, regulate pharmaceutical prices and pharmaceutical importation. These regulations may reduce prices for ZADAXIN to levels significantly below those that would prevail in an unregulated market, limit the volume of product which may be imported and sold, or place high import duties on the product, any of which may limit the growth of our revenues or cause them to decline.

We have limited sales, marketing and distribution capabilities, which may adversely affect our ability to successfully commercialize our products.

We currently have limited sales, marketing and distribution capabilities, and we anticipate that we will be relying on third-party collaborators to sell, market and distribute our products for the foreseeable future. If our arrangements with these third parties are not successful, or if we are unable to enter into additional third-party arrangements, we may need to substantially expand our sales, marketing and distribution force. Our efforts to expand may not succeed, or we may lack sufficient resources to expand in a timely manner, either of which will harm our operating results. In addition, if we are able to further expand our sales, marketing and distribution capabilities, we will begin competing with other companies that have experienced and well funded operations. If we cannot successfully compete with these larger companies, our revenues may not grow and our business may suffer.

If we are not able to establish and maintain adequate manufacturing and supply relationships, the development and sale of our products could be impaired.

To be successful, our products must be manufactured in commercial quantities, in compliance with regulatory requirements and at an acceptable cost. We may not be able to maintain the long-term manufacturing relationships we currently have with our suppliers. Manufacturing interruptions could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions could also impede commercialization of our products, including sales of ZADAXIN in approved markets, and impair our competitive position. Any of these developments would harm our business.

In some countries, a manufacturing change may require additional regulatory approvals. If we do not obtain the required regulatory approvals for a manufacturing change in a timely fashion, new ZADAXIN marketing approvals may be delayed or sales may be interrupted until the manufacturing change is approved. Either of these results will harm our business.

In addition, manufacturing, supply and quality control problems may arise as we, either alone or with subcontractors, attempt to scale-up our manufacturing procedures. We may not be able to scale-up in a timely manner or at a commercially reasonable cost, either of which could cause delays or pose a threat to the ultimate commercialization of our products and harm our business.

If we do not obtain rights to additional products from third parties, our prospects for future revenue may decline.

We are only actively pursuing clinical development of ZADAXIN and CPX at this time. If we do not advance SCV-07 and DAX, the other products to which we have in-licensed rights, from preclinical into clinical development, we may lose the rights to these products. We may also have a shortage of drugs to develop and commercialize if we do not license or otherwise acquire rights to additional drugs. Any shortage in the number of drugs that we are able to develop and commercialize may reduce our prospects for future revenue.

Commercialization of some of our products depends on collaborations with others. If our collaborators are not successful, or if we are unable to find future collaborators, we may not be able to properly develop and commercialize our products.

We depend in part on our distributors and business partners to develop and/or promote our drugs, and if they are not successful in their efforts or fail to do so, our business will suffer. We generally do not have control over the amount and timing of resources that our business partners devote to ZADAXIN and they have not always performed as or when expected. If they do not perform their obligations as we expect, particularly obligations regarding clinical trials, our development expenses would increase and the development and/or sale of our products could be limited or delayed, which could cause our business to suffer and our stock price to decline. In addition, our relationships with these companies may not be successful. Disputes may arise over ownership rights to intellectual property, know-how or technologies developed with our collaborators, and we may not be able to negotiate similar additional arrangements in the future to develop and commercialize ZADAXIN or other products.

If we fail to protect our products, technologies and trade secrets, we may not be able to successfully use, manufacture or market and sell our products, or we may fail to advance or maintain our competitive position.

Our success depends significantly on our ability to obtain and maintain meaningful patent protection for our products and technologies, to preserve our trade secrets and to avoid infringing on the proprietary rights of third parties. Our pending patent applications may not result in the issuance of patents in the future. Our patents or patent applications may not have priority over others' applications. Our existing patents and additional patents, if any, that issued, may not provide a competitive advantage to us or may be invalidated or circumvented by our competitors. Others may independently develop similar products or design around

patents issued or licensed to us. Patents issued to, or patent applications filed by, other companies could harm our ability to use, manufacture or market our products or maintain our competitive position with respect to our products. Many of our patents relating to ZADAXIN have expired, and we have rights to other patents and patent applications relating to ZADAXIN under exclusive licenses. If we breach the terms of any of these licenses, we could lose our rights to these patents and patent applications.

Our commercial success also depends in part on us not infringing valid, enforceable patents or proprietary rights of third parties, and not breaching any licenses that may relate to our technologies and products. We are aware of third-party patents that may relate to our products. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. Our efforts to defend against any of these claims, even if unmeritorious, would require us to devote resources and attention that could have been directed to our operation and growth plans. In addition, these actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in a patent action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

Pharmaceuticals are either not patentable or have only recently become patentable in some of the countries in which we have exclusive rights to ZADAXIN. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.

If appropriate opportunities become available, we may attempt to acquire products, product candidates or businesses that we believe fit strategically with our business. We currently have no commitments or agreements with respect to material acquisitions. If we do undertake any transaction of this sort, the process of integrating an acquired product, product candidate or business may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for our ongoing business development plans. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in in-process research and development expenses, potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or impairment of goodwill and amortization or impairment of other intangible assets, which could adversely affect our business, financial condition and results of operations.

We may lose market share or otherwise fail to compete effectively in the intensely competitive biopharmaceutical industry.

Competition in the biopharmaceutical industry is intense and we expect that competition to increase. Our success depends on our ability to compete. We believe that the principal competitive factors in this industry include the efficacy, safety, price, therapeutic regimen, manufacturing quality assurance, and patents associated with a given drug. Our competitors include biopharmaceutical companies, biotechnology firms, universities and other research institutions, both in the U.S. and abroad, that are actively engaged in research and development of products in the therapeutic areas we are pursuing, particularly hepatitis C, hepatitis B, cancer, and cystic fibrosis. Competitors are currently marketing drugs for hepatitis C, hepatitis B and cancer, or have products in late-stage clinical trials.

Most of our competitors, particularly large biopharmaceutical companies, have substantially greater financial, technical, regulatory, manufacturing, marketing and human resource capabilities than we do. Most of them also have extensive experience in undertaking the preclinical and clinical testing and in obtaining the regulatory approvals necessary to market drugs. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated with our competitors. Where comparable products are marketed by other companies price is a competitive factor. Increased competitive pressure could lead to intensified price-based competition resulting in lower prices and margins, which would hurt our operating results.

We currently rely on sales of ZADAXIN as a treatment for hepatitis C and hepatitis B as our primary source of revenue. However, several large biopharmaceutical companies have substantial commitments to alpha interferon, an approved drug for treating hepatitis B and hepatitis C, and to lamivudine, an approved drug to treat hepatitis B. We cannot assure you that we will compete successfully against our competitors or that our competitors, or potential competitors, will not develop drugs or other treatments for hepatitis C, hepatitis B, cystic fibrosis, cancer and other diseases that will be superior to ours. However, in the area of immune system enhancer therapy, we anticipate that our competition for ZADAXIN may be reduced by the fact that ZADAXIN, administered in combination with numerous antiviral and anti-cancer agents, is expected to be complementary rather than competitive to these agents in enhancing the immune system. We believe that we can position ZADAXIN as a complementary rather than competitive drug to many therapies, but cannot guarantee that we will be successful in this endeavor. We expect continuing advancements in and increasing awareness of the use of immune system enhancer therapy to fight cancer and infectious diseases and that this may create new competitors as well as numerous new opportunities for expanded use of ZADAXIN worldwide. We cannot assure you that we will be able to meet these objectives, however.

If third-party reimbursement is not available or patients cannot otherwise pay for ZADAXIN, we may not be able to successfully market ZADAXIN.

Our ability to successfully commercialize our products may depend in part on the extent to which coverage and reimbursement to patients for our products will be available from government health care programs, private health insurers and other third party payors or organizations. Significant uncertainty exists as to the reimbursement status of new therapeutic products, such as ZADAXIN, and we cannot assure you that third party insurance coverage and reimbursement will be available for therapeutic products we might develop. In most of the emerging markets in which we sell ZADAXIN or intend to sell ZADAXIN, reimbursement for ZADAXIN under government or private health insurance programs is not yet widely available. The failure to obtain third-party reimbursement for our products, particularly in the U.S., Europe and Japan, will harm our business. In the U.S., proposed health care reforms could limit the amount of third-party reimbursement available for our products. We cannot assure you that additional limitations will not be imposed in the future on drug coverage and reimbursement. In many emerging markets where we have marketing rights to ZADAXIN, government resources and per capita income may be so low that our products will be prohibitively expensive. In these countries, we may not be able to market our products on economically favorable terms, if at all.

Efforts by governmental and third-party payors to contain or reduce health care costs could cause us to reduce the prices at which we market our drugs, which will reduce our gross margins and may harm our business. Various governments and third-party payors are trying to contain or reduce the costs of health care through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could cause us to reduce the prices at which we market our drugs, which will reduce our gross margins and may harm our business.

If the current economic slowdown in the U.S. causes the economies of other countries, particularly those in Asia, Latin America and the Middle East to experience a slowdown or recession, our business will suffer.

The U.S. is the world's largest consumer and as such, the current economic slowdown in the U.S. may adversely affect the economies of other countries, including the developing countries in Asia, Latin America

and the Middle East from which we derive all of our revenues. If the economic conditions in the U.S. continue or worsen, these developing countries may also experience an economic slowdown or recession, which would likely result in a decrease of sales of ZADAXIN. Any decrease in sales of ZADAXIN would harm our operating results, delay our efforts to achieve profitability, and likely cause our stock price to decline.

If we lose key personnel or are unable to attract and retain additional, highly skilled personnel required for the expansion of our activities, our business will suffer.

We are highly dependent upon our ability to attract and retain qualified personnel because of the specialized, scientific and international nature of our business. There is intense competition for qualified management, scientific and technical personnel in the pharmaceutical industry, and we may not be able to attract and retain the qualified personnel we need to grow and develop our business globally. In addition, numerous key responsibilities at SciClone are assigned to a small number of individuals. If we are unable to attract and retain qualified personnel as needed or promptly replace those employees who are critical to our product development and commercialization, the development and commercialization of our products would adversely be affected. At this time, we do not maintain "key person" life insurance on any of our key personnel.

We may be subject to product liability lawsuits and our insurance may be inadequate to cover damages.

Clinical trials or marketing of any of our current and potential products may expose us to liability claims from the use of these products. We currently carry product liability insurance. However, we cannot be certain that we will be able to maintain insurance on acceptable terms for clinical and commercial activities or that the insurance would be sufficient to cover any potential product liability claim or recall. If we fail to have sufficient coverage, our business, results of operations and cash flows could be adversely affected.

If we are unable to comply with environmental laws and regulations, our business may be harmed.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We currently maintain a supply of hazardous materials at our facilities. In the event of an accident, we could be liable for any damages that result, and the liability could exceed our resources. While we outsource our research and development programs involving the controlled use of biohazardous materials, if in the future we conduct these programs ourselves, we might be required to incur significant cost to comply with the environmental laws and regulations.

The price of our common stock has experienced substantial volatility and may fluctuate due to factors beyond our control.

As a result of the September 11, 2001 events in Pennsylvania, New York City and Washington, D.C., U.S. and global economies have weakened, which may result in a decrease in our revenues and cause our stock price to decline. Further, high profile corporate governance and accounting problems and resulting corporate failures have eroded investor confidence. In the wake of these events, U.S. and global capital markets have experienced a period of extreme volatility, and this may continue for some time.

In addition, there has been significant volatility in the market prices for publicly traded shares of pharmaceutical and biotechnology companies, including ours. The following factors may have an adverse impact on the market price of our common stock: significant negative changes in the major equity market indices; announcements of technical or product developments by us or our competitors; governmental regulation; health care legislation; public announcements regarding advances in the treatment of the disease states that we are targeting; public announcements from government officials relating to the biotechnology or pharmaceutical industries; patent or proprietary rights developments; changes in third-party reimbursement policies for our products; and fluctuations in our operating results. In addition, the price of our common stock may not remain at or exceed current levels.

If the current war on terrorism causes economic slowdowns in the economies of certain countries our business will suffer.

The United States and its allied nations are aggressively attacking terrorism with military and economic actions. If these actions lead to economic slowdowns in the economies of developing countries in Asia, Latin America and the Middle East from which we currently derive all of our product revenue, then our sales could decrease. Any decrease in sales would harm our operating results, delay our efforts to achieve profitability, and likely cause our stock price to decline.

Our indebtedness may result in future liquidity problems.

As of December 31, 2001, we had $5.6 million in convertible notes payable, of which $4.0 million were issued in the quarter ended December 31, 2000 and $1.6 million were issued in the quarter ended March 31, 2001. This increased indebtedness has and will continue to impact us by increasing interest expense and making it more difficult to obtain additional financing. The notes are payable five years after issuance unless converted into common stock at the sole discretion of the holder. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result which would negatively impact our future prospects. As of December 31, 2001 we had cash and short-term investments of $16.5 million.

Substantial sales of our stock or convertible securities may impact the market price of our common stock.

As of December 31, 2001, stock options for 4,926,857 shares of common stock were outstanding, of which options for 3,457,061 shares were exercisable, and there were warrants exercisable for 1,970,500 shares of common stock outstanding. Two issues of convertible notes payable as of December 31, 2001 were convertible into a total of 684,140 shares of common stock beginning one year from date of issuance of the notes. In addition, the investors were given the right to purchase senior unsecured convertible notes due December 2005 and March 2006. If issued, the additional notes will bear no interest (zero coupon) and will be convertible into 684,140 shares of our common stock. Upon exercise of options or warrants, or conversion of the notes, these issued shares of common stock will be freely tradable.

Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock. Similarly, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our shareholders will be reduced and the price of our common stock may fall.

Issuing preferred stock with rights senior to those of our common stock could adversely affect holders of common stock.

Our charter documents give our board of directors the authority to issue additional series of preferred stock without a vote or action by our shareholders. The board also has the authority to determine the terms of preferred stock, including price, preferences and voting rights. The rights of holders of our common stock may be adversely affected by the rights granted to holders of preferred stock. For example, a series of preferred stock may be granted the right to receive a liquidation preference — a pre-set distribution in the event of a liquidation — that would reduce the amount available for distribution to holders of common stock. In addition, the issuance of preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock. As a result, common shareholders could be prevented from participating in transactions that would offer an optimal price for their shares.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short-term securities and maintain an average maturity of less than one year. A hypothetical 60 basis point increase in interest rates would result in an approximate $92,448 decrease (0.6%) in fair value of our available-for-sale securities. This potential change is based on sensitivity analyses performed on our financial position at December 31, 2001. Actual results may differ materially.

Item 8. *Financial Statements and Supplementary Data*

SCICLONE PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

Consolidated Financial Statements at December 31, 2001 and 2000 and for each of the Three Years in the period ended December 31, 2001

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Shareholders
SciClone Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of SciClone Pharmaceuticals, Inc. as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the financial statement schedule listed in the index at Item 14(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 SciClone Pharmaceuticals, Inc. at December 31, 2001 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

Palo Alto, California
January 24, 2002

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,518,000	$ 21,981,000
Restricted short-term investments	633,000	316,000
Other short-term investments	317,000	200,000
Accounts receivable, net of allowances of $638,000 in 2001 and $394,000 in 2000	8,792,000	8,621,000
Inventories	4,059,000	2,020,000
Prepaid expenses and other current assets	1,333,000	1,233,000
Total current assets	30,652,000	34,371,000
Property and equipment, net	167,000	214,000
Other assets	1,277,000	1,582,000
Total assets	$ 32,096,000	$ 36,167,000
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,575,000	$ 2,327,000
Accrued compensation and employee benefits	960,000	787,000
Accrued clinical trials expense	296,000	202,000
Accrued professional fees	633,000	665,000
Other accrued expenses	258,000	109,000
Total current liabilities	3,722,000	4,090,000
Convertible notes payable	5,600,000	4,000,000
Shareholders' equity:		
Preferred stock, no par value; issuable in series; 10,000,000 shares authorized; none outstanding	—	—
Common stock, no par value; 75,000,000 shares authorized; 32,474,150 shares in 2001 and 32,209,286 shares in 2000 issued and outstanding	145,713,000	144,815,000
Accumulated other comprehensive income	39,000	8,000
Accumulated deficit	(122,978,000)	(116,746,000)
Total shareholders' equity	22,774,000	28,077,000
Total liabilities and shareholders' equity	$ 32,096,000	$ 36,167,000

See notes to consolidated financial statements.

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2001	2000	1999
Revenues:			
Product sales	$13,831,000	$15,357,000	$ 9,091,000
Contract/grant revenue	—	—	307,000
Total revenues	13,831,000	15,357,000	9,398,000
Cost of product sales	2,742,000	3,113,000	1,761,000
Gross margin	11,089,000	12,244,000	7,637,000
Operating expenses:			
Research and development	8,561,000	4,182,000	4,604,000
Sales and marketing	8,764,000	7,720,000	5,503,000
General and administrative	3,897,000	3,538,000	3,386,000
Total operating expenses	21,222,000	15,440,000	13,493,000
Loss from operations	(10,133,000)	(3,196,000)	(5,856,000)
Income from payment on note receivable from former officer	3,497,000	400,000	20,000
Interest and investment income	751,000	1,066,000	157,000
Interest and investment expense	(334,000)	(36,000)	—
Other income (expense), net	(13,000)	49,000	212,000
Net loss	$(6,232,000)	$(1,717,000)	$(5,467,000)
Basic and diluted net loss per share	$ (0.19)	$ (0.06)	$ (0.26)
Weighted average shares used in computing basic and diluted net loss per share	32,356,287	29,904,924	21,162,936

See notes to consolidated financial statements.

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY

	Common Stock		Accumulated other comprehensive income	Accumulated deficit	Total shareholders' equity
	Shares	Amount			
Balance at December 31, 1998	21,534,056	$115,981,000	$ 9,000	$(109,562,000)	$ 6,428,000
Retirement of common stock from former officer	(1,882,500)	—	—	—	—
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	361,427	581,000	—	—	581,000
Issuance of common stock bonus	411,330	565,000	—	—	565,000
Issuance of common stock in asset purchase	50,297	69,000	—	—	69,000
Issuance of common stock to vendors	153,223	189,000	—	—	189,000
Issuance of common stock from private placements	4,331,079	6,430,000	—	—	6,430,000
Conversion of preferred stock to common stock	299,483	513,000	—	—	513,000
Net loss	—	—	—	(5,467,000)	(5,467,000)
Net unrealized loss on available-for-sale securities	—	—	(7,000)	—	(7,000)
Total comprehensive loss					(5,474,000)
Balance at December 31, 1999.	25,258,395	124,328,000	2,000	(115,029,000)	9,301,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	5,752,819	11,160,000	—	—	11,160,000
Issuance of common stock from private Placements	1,198,072	8,427,000	—	—	8,427,000
Issuance of rights to purchase convertible note	—	900,000	—	—	900,000
Net loss	—	—	—	(1,717,000)	(1,717,000)
Net unrealized gain on Available-for-sale securities	—	—	6,000	—	6,000
Total comprehensive loss					(1,711,000)
Balance at December 31, 2000.	32,209,286	144,815,000	8,000	(116,746,000)	28,077,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	264,864	544,000	—	—	544,000
Issuance of rights to purchase convertible note	—	354,000	—	—	354,000
Net loss	—	—	—	(6,232,000)	(6,232,000)
Net unrealized gain on available-for-sale securities	—	—	31,000	—	31,000
Total comprehensive loss					(6,201,000)
Balance at December 31, 2001.	32,474,150	$145,713,000	$39,000	$(122,978,000)	$22,774,000

See notes to consolidated financial statements.

SCICLONE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2001	2000	1999
Operating activities:			
Net loss	$ (6,232,000)	$(1,717,000)	$(5,467,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	556,000	529,000	626,000
Non-cash income from the foreclosure of loan from former officer	—	—	(242,000)
Non-cash gain on equity securities	(52,000)	—	—
Gain from payment on note receivable from former officer	(3,497,000)	(400,000)	(20,000)
Changes in operating assets and liabilities:			
Accounts receivable	(171,000)	(4,278,000)	(3,042,000)
Inventory	(2,039,000)	(939,000)	272,000
Prepaid expenses and other assets	(205,000)	621,000	(51,000)
Accounts payable and other accrued expenses	(603,000)	466,000	441,000
Accrued clinical trials expense	94,000	(57,000)	(2,144,000)
Accrued professional fees	(32,000)	(199,000)	134,000
Accrued compensation and employee benefits	173,000	57,000	564,000
Net cash used in operating activities	(12,008,000)	(5,917,000)	(8,929,000)
Investing activities:			
Purchase of property and equipment	(99,000)	(99,000)	(42,000)
Proceeds from sale of marketable securities	—	—	400,000
Payment on purchase of marketable securities	(351,000)	(331,000)	(9,000)
Net cash provided by (used in) investing activities	(450,000)	(430,000)	349,000
Financing activities:			
Proceeds from issuance of common stock, net	898,000	20,486,000	6,934,000
Payment on notes receivable from former and current officers	3,497,000	400,000	255,000
Proceeds from issuance of convertible note	1,600,000	4,000,000	—
Net cash provided by financing activities	5,995,000	24,886,000	7,189,000
Net increase (decrease) in cash and cash equivalents	(6,463,000)	18,539,000	(1,391,000)
Cash and cash equivalents, beginning of year	21,981,000	3,442,000	4,833,000
Cash and cash equivalents, end of year	$ 15,518,000	$21,981,000	$ 3,442,000
Supplemental schedule of non-cash financing and investing activities:			
Issuance of common stock in lieu of bonus	$ —	$ —	$ 565,000
Issuance of common stock for professional fees	$ —	$ —	$ 189,000
Issuance of common stock in asset purchase	$ —	$ —	$ 69,000
Conversion of preferred stock to common stock	$ —	$ —	$ 513,000
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 308,000	$ —	$ —

See notes to consolidated financial statements.

Note 1 — The Company and Summary of Significant Accounting Policies

The Company

SciClone Pharmaceuticals, Inc. ("SciClone" or the "Company") develops and commercializes pharmaceutical and biological therapeutic compounds that are acquired or in-licensed at the stage of late pre-clinical or early clinical development. The Company's current product development and commercial activities are focused on hepatitis B, hepatitis C, cancer and cystic fibrosis.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, SciClone Pharmaceuticals International Limited, SciClone Italy S.R.L. and SciClone Japan K.K. SciClone Pharmaceuticals International Limited is registered in the Cayman Islands with its principal office located in Hong Kong. SciClone Italy S.R.L. is registered in Italy with its principal office located in Rome. SciClone Japan K.K. is registered in Japan with its principal office located in Tokyo. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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 and Investments

Cash equivalents consist of highly liquid investments with original maturities of three months or less. All cash equivalents are carried at cost plus accrued interest, which approximates market value.

Under the Company's lease agreement, the Company is required to maintain a letter of credit in the amount of $633,000 in favor of the lessor. This letter of credit is secured by a certificate of deposit in the amount of $633,000.

The Company classifies it's entire investment portfolio as available-for-sale and records these investments at fair value, as determined by available market information, on the balance sheet. The portfolio primarily consists of U.S. Government securities and short-term and long-term debt instruments. Unrealized holding gains or losses are included in accumulated other comprehensive income. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in investment income along with interest earned. Realized gains or losses, determined on the basis of specific identification, and declines in value judged to be other than temporary are also included in investment income. Management believes the credit risk associated with these investments is limited due to the nature of investments.

For the years ended December 31, 2001, 2000 and 1999, net unrealized gains (loss) of approximately $31,000, $6,000 and $(7,000), respectively, were charged to accumulated other comprehensive income. For the years ended December 31, 2001, 2000 and 1999, net realized gains (loss) were less than $1,000 for all years.

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Depreciation is provided over the estimated useful lives of the respective assets (three to five years) on the straight-line basis. Depreciation expense for the years ended December 31, 2001, 2000 and 1999 was $146,000, $120,000 and $184,000, respectively.

Other Income

In January 1999, the Company foreclosed on loans extended to one of its former executive officers and board members and was in possession of the real property securing the loans. The Company recorded the net value of the property in assets available-for-sale at approximately $1,184,000, the related assumed mortgage liability in other current liabilities at approximately $942,000, and other income of approximately $242,000. In November 2000, the Company sold the property and recorded an additional $21,000 in other income from the sale.

Other Assets

Other assets include the following:

	December 31,	
	2001	2000
Intangible product rights	$ 2,456,000	$2,456,000
Accumulated amortization	(1,365,000)	(955,000)
	1,091,000	1,501,000
Other	186,000	81,000
	$ 1,277,000	$1,582,000

Product rights acquired are being amortized over six years (See Note 5). The Company identifies and records impairment losses, as circumstances dictate, on intangible product rights when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

In July 1998 the Company acquired the worldwide rights to ZADAXIN from Alpha 1 Biomedicals, Inc. ("A1B"), which rights A1B had licensed from Hoffmann-LaRoche, Inc. and F. Hoffmann-LaRoche AG, for approximately $1,800,000. The transaction eliminated the Company's royalty obligation to A1B with respect to all sales of ZADAXIN after the acquisition date. The A1B transaction allowed SciClone to market ZADAXIN worldwide, except in Italy, Spain and Portugal, where Sclavo S.p.A. ("Sclavo"), an international pharmaceutical entity, owned exclusive marketing rights. In April 1998, the Company acquired ZADAXIN rights for Italy, Spain and Portugal from Sclavo for approximately $1,400,000.

In connection with the foregoing transactions, the Company estimated the fair market value of the intangible assets purchased to be approximately $2,456,000 and wrote off the remaining $700,000.

Although the Company has a history of operating and cash flow losses, the Company believes that there is no impairment to the intangible assets because ZADAXIN was approved for sale in 26 countries as of March 15, 2002, principally as a treatment for hepatitis B or hepatitis C. Based on the Company's anticipated financial results for ZADAXIN sales from 2001 to 2005, it has determined that the net present value of the future cash flows exceed the carrying amount of the asset.

Foreign Currency Translation

The Company has determined the U.S. dollar to be the functional currency for its wholly owned subsidiary. Adjustments resulting from translation and foreign currency transactions are included in results of operations and have not been significant.

Revenue Recognition

The Company recognizes revenue from product sales at the time of shipment and recognizes contract/grant revenue when services have been performed. There are no significant customer acceptance requirements or post shipment obligations on the part of the Company. Sales to importing agents or distributors are recognized at time of shipment when title to the product is transferred to them, and they do not have contractual rights of return except under limited terms regarding product quality. However, the Company will replace products that have expired or are deemed to be damaged or defective when delivered. Payments by the importing agents and distributors are not contingent upon sale to the end user by the importing agents or distributors.

Contract revenue for research and development is recorded as earned based on the performance requirements of the contract. Nonrefundable contract fees for which no further performance obligations exist, and there is no continuing involvement by SciClone, are recognized on the earlier of when the payments are received or when collection is assured.

Revenue associated with substantive performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements. Revenue under research and development cost reimbursement contracts is recognized as the related costs are incurred.

Research and Development

Research and development expenditures are charged to operations as incurred. Major components of research and development expenses consist of personnel costs, including salaries and benefits, clinical development performed by contract research organizations, preclinical work, pharmaceutical development, materials and supplies, third party research funding and overhead allocations consisting of various administrative and facilities related costs. Our research and development activities are also separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs include Phase 1, 2, and 3 clinical trials as well as expanded access programs. Pharmaceutical development costs consist of product formulation and chemical analysis.

Contract research organization management fees are expensed monthly, while remaining clinical program activity generally is expensed on a straight-line basis over the life of the individual contract or study. The Company monitors patient enrollment levels and related activity to the extent possible and adjusts estimates accordingly.

Shipping and Handling Costs

Costs related to shipping and handling are included in cost of sales for all periods presented.

Advertising Expenses

The Company accounts for advertising costs as expense in the period in which they are incurred and are included in marketing expenses for all periods presented. Advertising expense for the years ended December 31, 2001, 2000 and 1999 were $233,000, $204,000, and $188,000, respectively.

Income Taxes

Income tax expense is based on reported results of operations before extraordinary items and income taxes. Deferred income taxes reflect the impact of temporary differences between the amount of assets and liabilities recognized for financial reporting purposes and such amounts recognized for tax purposes. These

deferred taxes are measured by applying current tax laws. Based on the Company's lack of earnings history, deferred tax assets have been fully offset by a valuation allowance.

Retirement Benefits

The Company has a pre-tax savings plan covering substantially all U.S. employees, which qualifies under Section 401(k) of the Internal Revenue Code. Under the plan, eligible employees may contribute a portion of their pre-tax salary, subject to certain limitations. The Company contributes and matches 50% of the employee contributions, up to 15% of the employee's salary. Company contributions, which can be terminated at the Company's discretion, were $73,000, $58,000 and $17,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

Net Loss Per Share

Basic net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period. The weighted average number of shares excludes shares held as collateral against a former officer's loan which shares were retired in 1999. Diluted net loss per share equals basic net loss per share given the Company's history of net losses.

Had the Company been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as an additional 6,897,357, 6,396,577 and 9,822,008 shares in 2001, 2000 and 1999, respectively, related to outstanding options and warrants not included in the calculation of basic net loss per share.

Accounting for Stock-Based Compensation

The Company accounts for its stock option and employee stock purchase plans under the provisions of Accounting Principles Board Opinion 25 ("APB 25") and related Interpretations. Accordingly, the Company does not recognize compensation expense in accounting for its stock option and employee stock purchase plans for awards to employees and directors.

Warrants issued in connection with equity and debt arrangements and equity instruments issued to non-employees are valued using the Black-Scholes option valuation model. Warrants issued to placement agents and similar parties in connection with equity financing are accounted for as stock issuance costs with an equal amount recorded as additional paid-in capital. Warrants issued to purchasers of the Company's equities are not specifically accounted for as their value is a sub-component of additional paid-in capital. The fair value of warrants issued in connection with debt arrangements, if material, is accounted for as a debt discount and amortized as additional interest expense over the term of the related debt.

Reporting Comprehensive Income (Loss)

The Company reports unrealized gains or losses on the Company's available-for-sale securities in comprehensive income (loss). For the years ended December 31, 2001, 2000 and 1999, total comprehensive loss attributable to common shareholders amounted to $6,201,000, $1,711,000 and $5,474,000, respectively.

Segment Information

The Company operates in one segment (see Note 9).

Concentration of Credit Risk

The People's Republic of China, like Japan and certain other Asian markets, uses a tiered method to import and distribute products. The distributors make the sales in the country, but the product is imported for

them by licensed importers. In 1997, the Company sold to one principal importing agent who then resold to four distributors inside the People's Republic of China. Reflecting the expansion and stability of the Company's sales to the People's Republic of China in 1998, the Company began working extensively with a second importing agent in addition to the agent used in 1997. In 2000, the Company began selling to a third importing agent and in 2001 the Company began selling to a fourth importing agent. This enabled the expansion of sales to the four distributors. For the year ended December 31, 2001, importing agents in China accounted for 89% of the Company's product sales. As of December 31, 2001, approximately $8,653,000, 91% of the Company's accounts receivable were attributable to these four customers in China. The Company performs on-going credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company maintains reserves for credit losses, and such losses have been within management's expectation. The Company recognizes reserves for bad debts ranging from 25% to 100% based on the length of time the receivables are past due.

Recent Accounting Pronouncements

The Financial Accounting Standards Board issued Statements of Financial Accounting Standards, No. 141, "Business Combinations", (SFAS 141) and No. 142, "Goodwill and Other Intangible Assets", (SFAS 142) in June 2001. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subjected to annual impairment tests in accordance with these statements. Other intangible assets will continue to be amortized over their useful economic lives. These statements are effective for combinations initiated after July 1, 2001 and apply to assets related to acquisitions prior to that date as of January 1, 2002. Based on current circumstances, management believes the application of the new rules will not have a material impact on the Company's consolidated financial statements.

The Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (SFAS 144) in August 2001. The statement addresses financial accounting and reporting of the impairment or disposal of long-lived assets. SFAS 144 is effective for fiscal years beginning after December 15, 2001, with earlier application encouraged. Based on current circumstances, management believes application of the new rules will not have a material impact on the Company's consolidated financial statements.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year's presentation. The reclassifications did not have a material impact on our consolidated financial statements.

Note 2 — Available-for-sale Securities

The following is a summary of available-for-sale securities:

	Available-for sale securities		
	Amortized Cost	Gross Unrealized Gains (Losses)	Estimated Fair Value
December 31, 2001:			
Certificate of deposit	$ 865,000	$ —	$ 865,000
Corporate obligations	10,858,000	6,000	10,864,000
Corporate equity securities	51,000	33,000	84,000
	$11,774,000	$39,000	$11,813,000
December 31, 2000:			
Certificate of deposit	$ 507,000	$ —	$ 507,000
Corporate obligations	$18,482,000	$ —	$18,482,000
Corporate equity securities	—	8,000	8,000
	$18,989,000	$ 8,000	$18,997,000

As of December 31, 2001, the total available-for-sale securities are included as follows, $10,897,000, in cash and cash equivalents, $633,000, in restricted short-term investments and $283,000 in other short-term investments. As of December 31, 2000, the total available for sale securities are included as follows, $18,482,000, in cash and cash equivalents, $317,000, in restricted short-term investments and $198,000 in other short-term investments. As of December 31, 2001 and 2000 all available-for-sale securities had maturities of 12 months or less.

Note 3 — Inventories

Inventories are stated at the lower of cost (first-in, first-out basis) or market. Inventories consisted of the following:

	December 31,	
	2001	2000
Raw materials	$2,759,000	$ 815,000
Work in progress	1,269,000	1,015,000
Finished goods	431,000	420,000
Reserve	(400,000)	(230,000)
	$4,059,000	$2,020,000

Note 4 — Property and Equipment

Property and equipment consisted of the following:

	December 31, 2001	December 31, 2000
Office furniture and fixtures	$ 120,000	$ 328,000
Office equipment	465,000	894,000
Leasehold improvements	108,000	96,000
	693,000	1,318,000
Less accumulated depreciation	(526,000)	(1,104,000)
Net property and equipment	$ 167,000	$ 214,000

Note 5 — Collaborative Agreements

In April 1999, the Company licensed to Sigma-Tau semi-exclusive ZADAXIN development and marketing rights in Italy and Spain, and exclusive rights in Switzerland. In March 2000, this license was expanded and amended to include all of the countries in the European Union and Sigma-Tau was made exclusive licensee in these countries.

In September 1998, the Company acquired all rights of Sclavo to ZADAXIN in Italy, Spain and Portugal, including Sclavo's marketing approval for ZADAXIN in Italy as an influenza vaccine adjuvant. The purchase price consisted of $297,000 in cash, 375,000 shares of the Company's common stock, and warrants to purchase 375,000 shares of common stock at an exercise price of $4.125 per share, which warrants were exercised in January 2000.

Pursuant to its 1994 license agreement with A1B, the Company obtained worldwide marketing, development and manufacturing rights to ZADAXIN, with the exception of Italy, Spain and Portugal. In April 1997, SciClone entered into an arrangement with A1B to administer the sublicense activities of the A1B licensee for Italy, Spain and Portugal. Under this 1997 agreement, the Company also acquired control of A1B's patent portfolio for ZADAXIN. In December 1997, SciClone and A1B entered into an Asset Purchase Agreement pursuant to which the Company acquired A1B's worldwide rights to ZADAXIN, which rights A1B licensed from Hoffmann-LaRoche, Inc. and F. Hoffmann-LaRoche AG, and eliminated the Company's and its current and future sublicensees' royalty obligations to A1B with respect to future sales of ZADAXIN. In July 1998, the Company and A1B closed the Asset Purchase Agreement. In accordance with the agreement, the Company issued to A1B 600,000 shares of common stock and loaned to A1B $210,000 in exchange for the assets described above.

In connection with the foregoing transactions with Sclavo and A1B, the Company estimated the fair market value of the intangible assets purchased to be approximately $2,456,000 and wrote off the remaining $700,000.

In August 1997 the Company entered into a ZADAXIN Patent License Agreement with The Fitzsimons Army Medical Center of the U.S. Army (the "Army"). The Company is obligated to pay the Army a minimum annual royalty, and upon commercialization of ZADAXIN for treatment of chronic hepatitis C in certain countries. The Company will be obligated to pay the Army a royalty based on a percentage of ZADAXIN net sales revenue.

In October 1996, the Company entered into an agreement with Schering-Plough K.K., giving Schering-Plough K.K. exclusive marketing rights to ZADAXIN in Japan. Under the agreement Schering-Plough K.K. initiated development of ZADAXIN as a monotherapy for the treatment of hepatitis B and hepatitis C.

Historically, Schering-Plough K.K. managed the development process and the parties shared certain development expenses. In 2001, the Company exercised its right to participate directly in the development process and now manages the process through its wholly owned subsidiary, SciClone Japan K.K., using a Japanese clinical research organization and Schering-Plough K.K. as a consultant. Schering-Plough K.K. continues to have exclusive marketing rights to ZADAXIN in Japan.

In April 1996, the Company acquired an exclusive license to CPX, a synthetic compound, from the National Institutes of Health ("NIH"). The NIH developed CPX as a potential treatment for cystic fibrosis. Under this license agreement, the Company is obligated to pay the NIH a minimum annual royalty payment and, upon product approval, the NIH will receive a milestone payment in addition to royalties based on a percentage of CPX net sales revenue.

Note 6 — Income Taxes

The Company uses 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. Deferred tax assets and liabilities are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The domestic and foreign components of loss before income tax at December 31 are as follows:

	2001	2000	1999
Domestic	$(4,445,000)	$(3,287,000)	$(4,968,000)
Foreign	(1,787,000)	(1,570,000)	(499,000)
Loss before income tax expense	$(6,232,000)	$(1,717,000)	$(5,467,000)

Significant components of the Company's deferred tax assets at December 31 are as follows:

	2001	2000
Assets		
Net operating loss carryforwards	$ 21,158,000	$ 20,057,000
R&D credit carryforwards	3,462,000	2,847,000
Note receivable written off for financial reporting	1,275,000	1,069,000
Other	1,553,000	1,741,000
Gross deferred tax assets	27,448,000	25,714,000
Valuation allowance	(27,448,000)	(25,714,000)
Total deferred tax assets	$ —	$ —

The valuation allowance increased by approximately $1,734,000, $3,774,000 and $1,200,000 in the years ended December 31, 2001, 2000 and 1999, respectively. Deferred tax assets relating to carryforwards as of December 31, 2001 include approximately $6,265,000 associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to shareholders' equity. The Company did not have any deferred tax liabilities at December 31, 2000 or 2001.

At December 31, 2001, the Company has net operating loss carryforwards for federal income tax purposes of approximately $59,700,000 which expire in the years 2006 through 2021. The difference between the cumulative losses for financial reporting purposes and federal income tax purposes is primarily attributable to losses incurred by the Company's foreign subsidiaries. At December 31, 2001, the Company has federal tax credit carryforwards of approximately $3,200,000, which expire in the years 2009 through 2021.

Because of the "change in ownership" provisions of the Internal Revenue Code, a portion of the Company's net operating loss carryforwards and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods. As a result of the annual limitation, a portion of these carryforwards may expire before ultimately becoming available to reduce future income tax liabilities.

As a result of net operating losses and valuation allowances, the Company did not record any state income tax expense for the years ended December 31, 2001, 2000 and 1999.

Note 7 — Commitments and Contingencies

Leases

The Company leases its main office facility under a non-cancelable operating lease agreement which expires in August 2005. The lease is for a period of five years and requires the Company to pay insurance and taxes and its pro-rata share of operating expenses. The Company also leases various office facilities abroad under non-cancelable lease agreements, expiring in 2001. Rental expense in 2001, 2000 and 1999 was $1,296,000, $498,000 and $398,000, respectively. Minimum future rental commitments amount to $1,311,000 in 2002, $1,349,000 in 2003, $1,385,000 in 2004 and $1,270,000 in 2005.

Royalties

Under the August 1997 ZADAXIN Patent License Agreement with The Fitzsimons Army Medical Center of the U.S. Army (the "Army"), the Company is obligated to pay the Army a minimum annual royalty, and upon commercialization of ZADAXIN for treatment of chronic hepatitis C in certain countries. The Company will be obligated to pay the Army a royalty based on a percentage of ZADAXIN net sales revenue.

Under the April 1996 CPX license agreement with the NIH, the Company is obligated to pay the NIH a minimum annual royalty and, upon commercialization of CPX, the Company will be obligated to pay the NIH a royalty based on a percentage of CPX net sales revenue. During 2001, 2000 and 1999 the Company paid $30,000, $10,000 and $10,000, respectively, related to the minimum annual royalty.

Convertible Notes Payable

In March 2001, the Company issued a $1.6 million senior unsecured convertible note with an investment affiliate of UBS AG. The $1.6 million note is convertible into 276,530 shares of common stock at a fixed conversion price of $5.7860 per share. The note will accrue interest at a rate of 6% per year and will mature in March 2006. The note is convertible after March 21, 2002. The Company also received $354,000 for granting the investor the right to purchase, at any time up to the notes' maturity date, approximately $2.4 million of senior unsecured convertible notes due March 2006. If issued, the notes will bear no interest (zero coupon) and will be convertible into 276,530 shares of common stock at a fixed conversion price of $8.5532 per share. The Company may elect in lieu of delivering convertible notes to deliver the respective number of shares of common stock.

In December 2000, the Company issued a $4 million senior unsecured convertible note with an investment affiliate of UBS AG. The $4 million note is convertible into 407,610 shares of common stock at a fixed conversion price of $9.8133 per share. The note will accrue interest at a rate of 6% per year and will mature in December 2005. The Company also received $900,000 for granting the investor the right to purchase, at any time up to the notes' maturity date, approximately $5.9 million of senior unsecured convertible notes due December 2005. If issued, the notes will bear no interest (zero coupon) and will be convertible into 407,610 shares of common stock at a fixed conversion price of $14.5066 per share. The Company may elect in lieu of delivering convertible notes to deliver the respective number of shares of common stock.

Note 8 — Shareholders' Equity

Common Stock, Preferred Stock and Warrants

In March 2000, the Company licensed to Sigma-Tau exclusive development and marketing rights to ZADAXIN in Europe. In addition, the Company completed a $3,100,000 million private placement to Sigma-Tau consisting of 198,072 shares of common stock, five-year immediately exercisable warrants to purchase 200,000 shares of common stock at $15.67 per share and five-year immediately exercisable warrants to purchase 200,000 shares of common stock at $31.33 per share. Sigma-Tau has no registration rights with respect to the shares purchased or issuable upon exercise of the warrants. As of December 31, 2001, none of the foregoing warrants had been exercised.

In January 2000, the Company completed a $6,100,000 private placement to Brown Simpson Asset Management which purchased 1,000,000 shares of common stock at a price of $6.00 per share, a slight premium to market, and five-year immediately exercisable warrants to purchase 800,000 shares of common stock at an exercise price of $7.00 per share. As of December 31, 2001, none of these warrants had been exercised.

On July 21, 1999, the Company completed a $3,620,000 private placement to strategic institutional investors. The offering consisted of units of 2,515,934 shares of common stock and immediately exercisable warrants to purchase 2,515,934 shares of common stock. Each unit was priced at $1.59 and consisted of one share of common stock and one five-year immediately exercisable warrant to purchase one share of common stock at an exercise price of $1.72 per share. In connection with this private placement, the Company's placement agents received five-year immediately exercisable warrants to purchase 345,933 shares of common stock at an exercise price of $1.83 per share. As of December 31, 2001, none of the warrants were outstanding and, all of the 2,515,934 investor warrants had been exercised for aggregate proceeds to the Company of approximately $4,327,000.

On July 2, 1999, the Company completed a $1,810,000 private placement to strategic institutional and accredited investors. The offering consisted of units of 1,370,145 shares of common stock and immediately exercisable warrants to purchase 1,370,145 shares of common stock. Each unit was priced at $1.46 and consisted of one share of common stock and one five-year immediately exercisable warrant to purchase one share of common stock, at an exercise price of $1.33 per share. In connection with this private placement, the Company's placement agents received five-year immediately exercisable warrants to purchase 183,179 shares of common stock, at an exercise price of $1.66 per share. As of December 31, 2001, none of the warrants were outstanding, all of the 1,370,145 investor warrants had been exercised for aggregate proceeds to the Company of approximately $1,822,000.

In May 1999, the Company issued 411,330 shares of common stock to the Company's employees in lieu of cash bonuses.

In April 1999, Sigma-Tau paid $1,000,000 for 445,000 shares of the Company's unregistered common stock. Sigma-Tau was not granted any registration rights covering resale of the shares.

In June 1998, the Company entered into an agreement with an institutional investor for an equity line which allowed the Company to access up to $32 million through sales of its common stock over a two-year period, subject to certain limitations. The decision to draw any funds and the timing for any such draw was solely at the Company's discretion. The Company was not obligated to draw any minimum amount under the equity line and did not draw any amounts under the equity line. As a commitment fee to the investor, the Company issued five-year warrants to purchase 300,000 shares of its common stock at an exercise price of $3.50 per share and five-year warrants to purchase 200,000 shares of its common stock at an exercise price of $5.53 per share. The Company cancelled the equity line in November 1999. As of December 31, 2001, none of the foregoing warrants had been exercised.

In April 1998, the Company sold 661,157 shares of Series C preferred stock at $6.05 per share and received $3,931,000 in net proceeds from the offering. In the second quarter ended June 30, 1998, the Company recognized a deemed dividend in the amount of $3,143,000 in connection with the issuance of the Series C preferred stock. This amount was computed in accordance with EITF Appendix D-60, "Accounting for the Issuance of Convertible Preferred Stock and Debt Securities with a Non-detachable Conversion Feature" ("EITF D-60"), because the Series C preferred stock had a beneficial conversion feature at the date of issuance that allowed it to be converted to common stock at a discount to the common stock's market price at the date of issuance. This amount increased net loss per share attributable to common shareholders and was calculated as required by the SEC. As of December 31, 1998 all but 58,356 shares of Series C preferred stock were converted into 3,168,404 shares of common stock. In January 1999, 46,922 of the remaining 58,536 shares were converted into 299,483 shares of common stock and 11,434 of such remaining shares of Series C preferred stock were redeemed at a conversion price of approximately $0.95 per common share. As a result, there are no shares of Series C preferred stock outstanding. In conjunction with the offering, the Company granted to the investors five-year warrants to purchase 100,000 shares of common stock at an exercise price of $5.67 per share. As of December 31, 2001, none of the warrants were outstanding, the remaining 37,500 of the 100,000 investor warrants had been exercised for aggregate proceeds to the Company of approximately $213,000.

Stock Award Plans

In August 1991, the Board of Directors and shareholders of the Company approved the 1991 Stock Plan (the "1991 Plan") and reserved 1,300,000 shares for issuance thereunder. In May 1993, the Board of Directors and shareholders of the Company approved a 2,150,000 increase in the shares reserved under the 1991 Plan. The 1991 Plan permits the award of incentive or nonqualified stock options and shares of common stock under restricted stock purchase agreements. In January 1992, the Board of Directors and shareholders of the Company approved the 1992 Stock Plan (the "1992 Plan") and reserved 240,000 shares for issuance thereunder. The 1992 Plan permits the award of incentive or nonqualified stock options which must be exercised in cash. In June 1995, the Board of Directors and the shareholders of the Company approved the 1995 Equity Incentive Plan (the "1995 Plan") and reserved 1,250,000 shares for issuance thereunder. The 1995 Plan permits the award of incentive or nonqualified stock options and shares of common stock under restricted stock awards. In May 1997, the Board of Directors and shareholders of the Company approved a 750,000 increase in the shares reserved under the 1995 Plan. In June 1998 and June 2000, the Board of Directors and shareholders of the Company approved increases of 1,500,000 and 1,250,000, respectively, in the shares reserved under the 1995 Plan.

Under the 1991, 1992 and 1995 Plans, options are exercisable upon conditions determined by the Board of Directors and expire ten years from the date of grant. Options are generally granted at fair market value on the date of grant and vest over time, generally four years.

In June 1995, the Board of Directors and the shareholders of the Company approved the Nonemployee Director Stock Option Plan (the "Nonemployee Director Plan") and reserved 250,000 shares for issuance thereunder. The Nonemployee Director Plan automatically grants nonqualified stock options to nonemployee directors upon their appointment or first election to the Company's Board of Directors ("Initial Grant") and annually upon their reelection to the Board of Directors at the Company's Annual Meeting of Shareholders ("Annual Grant"). The options are granted at fair market value on the date of grant. Initial Grants vest annually over a period of three years. Annual Grants vest monthly over a period of one year. In June 2000, the Board of Directors and shareholders of the Company approved a 250,000 increase in the shares reserved under the Nonemployee Director Plan.

In July 1996, the Board of Directors and shareholders of the Company approved the 1996 Employee Stock Purchase Plan (the "ESPP") and reserved 500,000 shares for issuance thereunder. All full-time

employees are eligible to participate in the ESPP. Under the terms of the ESPP, employees can choose to have up to 15% of their salary withheld to purchase the Company's common stock. The purchase price of the stock is 85% of the lower of the fair market value as of the first trading day of each quarterly participation period, or of the fair market value as of the last trading day of each quarterly participation period. Under the ESPP, the Company sold 33,009, 144,505 and 47,038 shares to employees in 2001, 2000 and 1999, respectively.

The following table summarizes the stock option activity under the 1991, 1992 and 1995 plans and the Nonemployee Director Plan:

	Shares Available for Grant	Shares Under Option	Weighted Average Exercise Price of Shares Under Plan
Balance at December 31, 1998	2,300,933	3,548,978	$4.92
Options canceled	1,195,985	(1,195,985)	4.43
Options granted	(2,243,062)	2,243,062	1.38
Options exercised	—	(34,238)	1.03
Balance at December 31, 1999	1,253,856	4,561,817	3.34
1995 Plan shares reserved	1,250,000	—	—
Nonemployee Director Plan shares reserved	250,000	—	—
Options canceled	56,366	(56,366)	1.43
Options granted	(931,250)	931,250	10.46
Options exercised	—	(1,010,624)	2.48
Balance at December 31, 2000	1,878,972	4,426,077	5.00
Options canceled	93,697	(93,697)	7.27
Options granted	(946,800)	946,800	3.98
Options exercised	—	(231,605)	1.83
Plan shares expired	—	(120,718)	—
Balance at December 31, 2001	1,025,869	4,926,857	$4.86

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2001:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 1.22 - $ 1.59	1,123,738	7.37	$1.40	1,067,650	$1.40
$ 1.75 - $ 3.68	1,370,001	7.98	3.07	582,849	2.43
$ 3.69 - $ 5.38	918,929	5.61	5.01	806,427	5.04
$ 5.50 - $10.50	767,964	5.25	6.96	665,277	6.78
$10.75 - $10.75	645,225	8.64	10.75	233,858	10.75
$12.50 - $12.50	101,000	1.66	12.50	101,000	12.50
	4,926,857	6.93	4.86	3,457,061	4.41

Pro forma information regarding net loss and net loss per share is required by SFAS 123 and has been determined as if the Company had accounted for its stock awards under the fair value method of that Statement. The fair value for the options was 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 rates of 4.00%, 6.00% and 6.00%, respectively; dividend yields of 0%; volatility factors of the expected market price of the Company's common stock of 0.96 for 2001 and 0.97 for 2000 and 0.91 for 1999 and a weighted average expected life of the option of 3.94 years for 2001, 3.90 years for 2000 and 3.92 years for 1999. The weighted average estimated fair value of options granted was $2.72 for 2001, $7.31 for 2000, and $0.93 for 1999. The fair value for the employee stock purchases was also estimated using the Black-Scholes model with the following assumptions for 2001, 2000 and 1999: risk-free interest rate of 4.00%, 6.00% and 6.00%, respectively; dividend yield of 0%; expected volatility of 0.96, 0.97 and 0.91, respectively, and expected life of 0.25 years. The weighted average estimated fair value of the employee stock purchase plan shares purchased was $1.86 for 2001, $1.96 for 2000, and $0.55 for 1999.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock awards have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in the Company's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options and stock purchases.

Had compensation expense for the Company's option and employee purchase plans been determined based on the fair value at the grant date for awards in 2001, 2000 and 1999 consistent with the provisions of SFAS 123, the Company's net loss and net loss per share would have been adjusted to the pro forma amounts for the years ended December 31 indicated below:

	2001	2000	1999
Net loss — as reported	$(6,232,000)	$(1,717,000)	$(5,467,000)
Net loss — pro forma	$(8,988,000)	$(3,679,000)	$(7,896,000)
Net loss per share — as reported	$ (0.19)	$ (0.06)	$ (0.26)
Net loss per share — pro forma	$ (0.28)	$ (0.12)	$ (0.37)

The effects of applying SFAS 123 for pro forma disclosures are not likely to be representative of the effects on reported net loss for future years.

Reserved Shares

As of December 31, 2001, the Company had reserved shares of common stock for future issuance as follows:

Options outstanding	4,926,857
Warrants outstanding	1,970,500
	6,897,357

Note 9 — Significant Geographic Information

The Company operates in one business segment, the development and commercialization of specialist-oriented proprietary drugs for the treatment of chronic and life threatening diseases. Currently, the Company's principal focus has been the development and commercialization of ZADAXIN and the development of CPX.

The Chief Executive Officer has been identified as the Chief Operating Decision Maker ("CODM") because he has final authority over resource allocation decisions and performance assessment. The CODM does not receive discrete financial information about the individual components.

The Company's domestic operations primarily consist of product development. The Company's wholly owned international subsidiary, SciClone Pharmaceuticals International Ltd., is based in Hong Kong and is engaged in sales and marketing and product distribution worldwide.

Information regarding geographic areas is as follows at December 31:

	Product Sales	Long Lived Assets	Net Assets
2001:			
U.S	$ —	$ 61,000	$ 8,407,000
China	12,325,000	103,000	13,968,000
Other	1,506,000	3,000	399,000
Total	$13,831,000	$167,000	$22,774,000
2000:			
U.S	$ —	$101,000	$17,063,000
China	13,174,000	106,000	10,973,000
Other	2,183,000	7,000	41,000
Total	$15,357,000	$214,000	$28,077,000
1999:			
U.S	$ —	$153,000	$ 3,535,000
China	7,906,000	72,000	5,726,000
Other	1,185,000	10,000	40,000
Total	$ 9,091,000	$235,000	$ 9,301,000

Two customers accounted for 10% or more of total revenues (46% and 29%) for the year ended December 31, 2001. Two customers accounted for 10% or more of total revenues (63%, and 16%) for the year ended December 31, 2000. One customer accounted for 10% or more of total revenues (77%) for the year ended December 31, 1999. No other customer accounted for more than 10% of revenues during these years.

Note 10 — Selected Quarterly Financial Data (unaudited)

	Three Months Ended			
	March 31	June 30	September 30	December 31
2001:				
Product sales	$ 3,113,000	$ 3,250,000	$3,580,000	$ 3,888,000
Cost of product sales	$ 598,000	$ 636,000	$ 714,000	$ 794,000
Gross margin	$ 2,515,000	$ 2,614,000	$2,866,000	$ 3,094,000
Net loss	$(2,125,000)	$(2,219,000)	$ (173,000)	$(1,715,000)
Basic and diluted net loss per share	$ (0.07)	$ (0.07)	$ (0.01)	$ (0.05)
2000:				
Product sales	$ 3,499,000	$ 4,206,000	$4,675,000	$ 2,977,000
Cost of product sales	$ 735,000	$ 849,000	$ 914,000	$ 616,000
Gross margin	$ 2,764,000	$ 3,357,000	$3,761,000	$ 2,361,000
Net loss	$ (875,000)	$ (589,000)	$ (137,000)	$ (117,000)
Basic and diluted net loss per share	$ (0.03)	$ (0.02)	$ (0.00)	$ (0.00)

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

Not Applicable.

PART III

Item 10. *Directors and Executive Officers of the Registrant*

The information required by Item 401 of Regulation S-K is incorporated by reference from the definitive proxy statement for the Company's 2002 Annual Meeting of Shareholders to be filed with the Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form (the "Proxy Statement") under the caption "ELECTION OF DIRECTORS — Nominees." Information relating to the executive officers of the Company is set forth in Part I of this report under the caption "Executive Officers of the Registrant."

The information required by Item 405 of Regulation S-K is incorporated by reference from the Proxy Statement under the caption "EXECUTIVE COMPENSATION AND OTHER MATTERS — Section 16(a) Beneficial Ownership Reporting Compliance."

Item 11. *Executive Compensation*

The information required by this Item is incorporated by reference from the Proxy Statement under the captions "EXECUTIVE COMPENSATION AND OTHER MATTERS," "COMPENSATION COMMITTEE REPORT ON EXECUTIVE COMPENSATION," "ELECTION OF DIRECTORS — Compensation of Directors" and "STOCK PERFORMANCE GRAPH."

Item 12. *Security Ownership of Certain Beneficial Owners and Management*

The information required by this Item is incorporated by reference from the Proxy Statement under the caption "STOCK OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT."

Item 13. *Certain Relationships and Related Transactions*

The information required by this Item is incorporated by reference from the Proxy Statement under the caption "EXECUTIVE COMPENSATION AND OTHER MATTERS — Certain Relationships and Related Transactions."

PART IV

Item 14. *Exhibits, Financial Statement Schedules and Reports on Form 8-K*

(a) The following documents are filed as part of this Report:

(1) *Financial Statements.* The following financial statements of the Company are contained on pages 33 — 53 of this Report on Form 10-K:

Report of Ernst & Young LLP, Independent Auditors.

Consolidated Balance Sheets at December 31, 2001 and 2000.

Consolidated Statements of Operations for each of the three years in the period ended December 31, 2001.

Consolidated Statement of Shareholders' Equity for each of the three years in the period ended December 31, 2001.

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2001.

Notes to Consolidated Financial Statements.

(2) *Financial Statement Schedules*

The following schedule is filed as part of this Report:

Schedule II — Valuation and Qualifying Accounts for each of the three years in the period ended December 31, 2001.

All other schedules have been omitted because they are either inapplicable or the required information has been given in the consolidated financial statements or the notes hereto.

(3) *Exhibits.*

Refer to Item 14(c) below.

(b) **Reports on Form 8-K.**

None

(c) **Exhibits.**

Exhibits (numbered in accordance with Item 601 of Regulation S-K):

Exhibit Number	Description
3(i).1(1)	Restated Articles of Incorporation.
3(i).2(2)	Certificate of Amendment of Restated Articles of Incorporation.
3(i).3(14)	Certificate of Determination.
3(i).4(20)	Certificate of Determination Regarding the terms of the Series C Preferred Stock.
3(ii).1(1)	Bylaws.
3(ii).2(2)	Certificate of Amendment of Bylaws.
4.2(14)	Rights Agreement dated as of July 25, 1997 between the Registrant and Chase Mellon Shareholder Services, L.L.C.
4.3(21)*	6% Convertible Note dated as of December 7, 2000 by the Registrant in favor of UBS AG, London Branch.
4.4(21)*	Option Agreement dated as of October 26, 2000 by and between the Registrant and UBS AG, London Branch.
4.5(21)*	Amendment No. 1 to Option Agreement dated as of December 19, 2000 by and between the Registrant and UBS AG, London Branch.
4.6(22)*	6% Convertible Note dated as of March 21, 2001 by the Company in favor of UBS AG, London Branch.
4.7(22)*	Option Agreement dated as of February 16, 2001 by and between the Company and UBS AG, London Branch.
4.8(22)*	Amendment No. 1 to Option Agreement dated as of March 21, 2001 by and between the Company and UBS AG, London Branch.
10.7(2)**	Registrant's 1991 Stock Plan, together with forms of agreements thereunder.
10.8(1)**	Registrant's 1992 Stock Plan, together with forms of agreements thereunder.
10.10(1)	Lease, dated September 10, 1991, between the Registrant and Spieker-Singleton68 concerning property, located at 901 Mariners Island Boulevard, San Mateo, California, as amended (the "Spieker Lease").
10.11(7)	Amendment No. 4 to Spieker Lease, dated October 4, 1994.
10.12(9)	Amendment No. 7 to Spieker Lease, dated November 14, 1995.
10.13(8)**	Registrant's 1995 Equity Incentive Plan, together with forms of agreement thereunder.
10.14(8)**	Registrant's 1995 Nonemployee Director Stock Option Plan, together with forms of agreement thereunder.

Exhibit Number	Description
10.16(21)	Second Amendment of Employment Agreement dated December, 2000 between the Registrant and Donald R. Sellers.
10.17(10)	License Agreement effective April 19, 1996 between the Registrant and the National Institute of Health Office of Technology Transfer.
10.19(11)	Amendment No. 8 to Spieker Lease, dated August 26, 1996.
10.20(21)	Amendment No. 14 to Spieker Lease dated November 21, 2000.
10.21(15)	Alpha Rights Acquisition Agreement by and between the Registrant and Alpha 1 Biomedicals, Inc., dated December 17, 1997.
10.22(16)*	Expanded and Amended Alpha 1 License, Distributorship and Supply Agreement by and between the Company and Sigma-Tau Industrie Farmadeutiche Riunite S.p.A. dated as of March 3, 2000.
10.23(17)	Preferred Stock Investment Agreement by and among the Company, Halifax Fund, L.P., Themis Partners L.P. and Heracles Fund dated as of March 27, 1998.
10.24(17)	Registration Rights Agreement by and among Registrant, Halifax Fund, L.P., Themis Partners L.P. and Heracles Fund dated as of April 1, 1998.
10.26(18)	Warrant to purchase up to 200,000 shares of Common Stock of the Company issued to Cheyenne LLC dated as of June 30, 1998.
10.27(18)	Registration Rights Agreement by and between the Company and Cheyenne LLC dated as of June 30, 1998.
10.28(19)	Acquisition Agreement between the Company and Sclavo S.p.A. dated April 20,1998.
10.29(19)	First Amendment to Acquisition Agreement between the Company and Sclavo S.p.A., dated April 20, 1998.
10.30(19)	Stock Purchase Warrant to purchase up to 375,000 shares of Common Stock of the Company issued to Sclavo S.p.A. dated September 3, 1998.
10.31(22)*	Registration Rights Agreement by and between the Company and UBS AG, London Branch dated as of February 16, 2001.
10.32(21)	Change in Control Agreement between the Company and Alfred Rudolph dated as of November 19, 1999.
10.33(21)	Change in Control Agreement between the Company and Donald R. Sellers dated as of November 19, 1999.
10.34	Change in Control Agreement between the Company and Richard A. Waldron dated as of April 30, 2001.
21.1	Subsidiaries of Registrant.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Powers of Attorney. See page 58.

* Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200, 80(b)(4), 200.83 and 230.46.

** Management compensatory plan or arrangement.

(1) Incorporated by reference from the Company's Registration Statement on Form S-1 (No. 33-45446), declared effective by the Commission on March 17, 1992.

(2) Incorporated by reference from the Company's Registration Statement on Form S-8 (No. 33-66832) filed with the Commission on August 3, 1993.

(7) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1994.

(8) Incorporated by reference from the Company's Registration Statement on Form S-8 (No. 33-80911) filed with the Commission on December 28, 1995.

(9) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1995.

(10) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.

(11) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.

(14) Incorporated by reference from the Company's Current Report on Form 8-K filed on October 14, 1997.

(15) Incorporated by reference from the Company's Current Report on Form 8-K filed on January 26, 1998.

(16) Incorporated by reference from the Company's Form 8-K filed on April 20, 2000.

(17) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1998.

(18) Incorporated by reference to the Company's Current Report on Form 8-K filed on July 23, 1998.

(19) Incorporated by reference from the Company's Quarterly Report on Form 10-Q on November 17, 1998.

(20) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1997.

(21) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

(22) Incorporated by reference from the Company's Quarterly Report on Form 10-Q on May 15, 2001.

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.

SCICLONE PHARMACEUTICALS, INC.

By: /s/ DONALD R. SELLERS
Donald R. Sellers
President and Chief Executive Officer

Date: March 22, 2002

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Donald R. Sellers and Richard A. Waldron, and each of them, his attorneys-in-fact and agents, each with the power of substitution and resubstitution, for him in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary, to be done in connection therewith, as fully as to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitute or substitutes, may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ DONALD R. SELLERS (Donald R. Sellers)	President and Chief Executive Officer, Director Principal Executive Officer	March 22, 2002
/s/ RICHARD A. WALDRON (Richard A. Waldron)	Chief Financial Officer Principal Financial Officer	March 22, 2002
/s/ IVAN B. HUI (Ivan B. Hui)	Corporate Controller Principal Accounting Officer	March 22, 2002
/s/ JOHN D. BAXTER, M.D. (John D. Baxter, M.D.)	Director	March 22, 2002
/s/ EDWIN C. CADMAN, M.D. (Edwin C. Cadman, M.D.)	Director	March 22, 2002
/s/ JERE E. GOYAN, PH.D. (Jere E. Goyan, Ph.D.)	Chairman of Board of Directors	March 22, 2002
/s/ ROLF H. HENEL (Rolf H. Henel)	Director	March 22, 2002
/s/ JON S. SAXE (Jon S. Saxe)	Director	March 22, 2002
/s/ DEAN S. WOODMAN (Dean S. Woodman)	Director	March 22, 2002

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

SCICLONE PHARMACEUTICALS INC.

Description	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Deductions	Balance at End of Period
Year Ended December 31, 2001					
Reserves and allowances deducted from asset accounts:					
Allowance for uncollectable accounts	$394,000	$244,000	$ —	$ —	$638,000
Inventory reserve	$230,000	$170,000	$ —	$ —	$400,000
Year Ended December 31, 2000					
Reserves and allowances deducted from asset accounts:					
Allowance for uncollectable accounts	$ 74,000	$320,000	$ —	$ —	$394,000
Inventory reserve	$ 81,000	$149,000	$ —	$ —	$230,000
Year Ended December 31, 1999					
Reserves and allowances deducted from asset accounts:					
Allowance for uncollectable accounts	$ 76,000	$ —	$ —	$ 2,000	$ 74,000
Inventory reserve	$129,000	$ —	$ —	$48,000	$ 81,000

Corporate Officers

Donald R. Sellers
President and Chief Executive Officer
Managing Director, International
SciClone Pharmaceuticals International Ltd.

Alfred R. Rudolph, M.D.
Chief Operating Officer

Richard A. Waldron
Chief Financial Officer

Corporate Management

Donald R. Sellers
President and Chief Executive Officer

Alfred R. Rudolph, M.D.
Chief Operating Officer

Richard A. Waldron
Chief Financial Officer

Eduardo B. Martins, M.D., Ph.D.
Medical Director

Cynthia W. Tuthill, Ph.D.
Vice President, Scientific Affairs

Sriram Vemuri, Ph.D.
Vice President, Product Development
and Manufacturing

Randy J. McBeath
Director of Marketing

International Management

Donald R. Sellers
Managing Director

Hans P. Schmid
Vice President, Finance, Administration and
Business Development

Chung-Ying Tam
Vice President and Regional Managing Director,
Greater China

Kenneth R. Cowan
Regional Managing Director, Middle East,
Africa and Eastern Europe

Craig B. Varden
Regional Managing Director, Pacific Rim

Board of Directors

Jere E. Goyan, Ph.D.
Chairman, SciClone Pharmaceuticals, Inc.
President, Goyan and Hart Associates
Former U.S. FDA Commissioner

Donald R. Sellers
President and Chief Executive Officer
SciClone Pharmaceuticals, Inc.
Managing Director, International
SciClone Pharmaceuticals International Ltd.

John D. Baxter, M.D.
Professor of Medicine
University of California, San Francisco

Edwin C. Cadman, M.D.
Dean, John A. Burns School of Medicine,
University of Hawaii

Rolf H. Henel
Partner, Naimark & Associates, Inc.
Retired President of Cyanamid International—
Lederle Division

Jon S. Saxe
Former President of Protein Design Labs, Inc.
Former President and CEO of Synergen, Inc.
Former Vice President of Hoffmann-LaRoche, Inc.

Dean S. Woodman
Former Managing Director, ING Barings, LLC
Founding Partner of Robertson Stephens

Headquarters

SciClone Pharmaceuticals, Inc.
901 Mariner's Island Blvd., Suite 205
San Mateo, California 94404-1573
Telephone: (650) 358-3456
or (800) SCICLONE

International Locations

Beijing, Hong Kong, Rome, Shanghai,
Singapore, and Tokyo.

Website

You can obtain recent press releases
and other corporate information
by visiting SciClone's websites at
http://www.sciclone.com and
http://www.scicloneinternational.com.

Additional Information

If you need additional assistance or information regarding the company, or would like to receive a free copy of the company's 10-Q report filed with the Securities and Exchange Commission, please contact SciClone's Investor Relations Department at (650) 358-3437 or send an e-mail message to investorrelations@sciclone.com.

Stock Listing and Price of Common Stock

SciClone's common stock trades on the Nasdaq National Market® under the symbol "SCLN".

On March 15, 2002, the last reported sales price of SciClone's common stock, as reported by the Nasdaq National Market, was $4.17 per share.

Transfer Agent

Communications concerning transfer requirements, lost certificates, changes of address and other similar inquiries should be directed to SciClone's transfer agent:

Mellon Investor Services LLC
P.O. Box 3315
South Hackensack, New Jersey 07606-1915
Telephone: (800) 356-2017
www.melloninvestor.com

Annual Meeting

The 2002 Annual Meeting of Shareholders will be held on Thursday, May 30, 2002 beginning at 10:00 a.m. local time at the Hilton Garden Inn, 2000 Bridgepointe Circle, San Mateo, California 94404. Detailed information about the meeting is contained in the Notice of Annual Meeting of Shareholders and Proxy Statement sent with a copy of the Annual Report to each shareholder of record as of April 2, 2002.

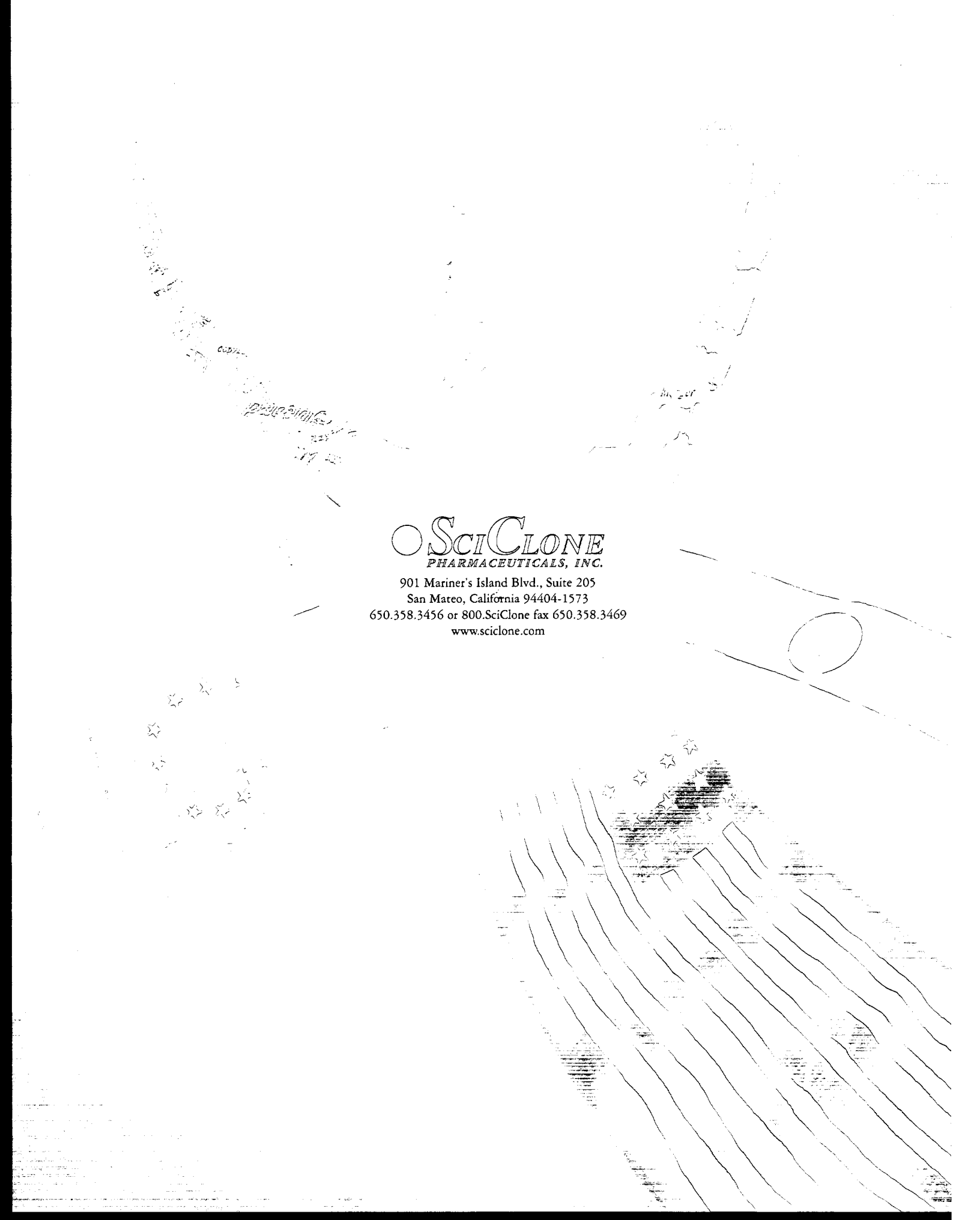
Corporate Counsel

Gray Cary Ware & Freidenrich LLP
San Francisco, California

Independent Auditors

Ernst & Young LLP
Palo Alto, California

Designed by Curran & Connors, Inc. / www.curran-connors.com



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