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FINANCIAL

Carol Spence was diagnosed with an extremely aggressive case of hepatitis C (genotype 1) in March 2000.

Carol did not respond to the standard hepatitis C drug treatment regimen, her treatment was discontinued, and in early 2001 she joined the hundreds of thousands of Americans called "non-responders."

On the advice of her doctor, Carol began a new treatment regimen which included ZADAXIN in July 2001.

As of January 2003, Carol is now considered a sustained responder, a patient that completes treatment successfully and continues to have no evidence of hepatitis C.

August 15, 2002

Mr. Donald R. Sellers  
President and Chief Executive Officer  
SciClone Pharmaceuticals, Inc.  
901 Mariner's Island Blvd., Suite 205  
San Mateo, California 94404

Dear Mr. Sellers:

How can I ever thank you? On behalf of the many people in whose lives you are making such a difference, I send an endless amount of appreciation.

In 2000, I was diagnosed with a very aggressive case of hepatitis C. At that time, I had an ALT of 1178, AST of 912, and viral load in excess of 32 million. My physician prescribed the then-accepted drug regimen for the treatment of hepatitis C, which consisted of interferon and ribavirin. After three months, it was clear that I was a pathetic non-responder, and treatment was discontinued.

In July of 2001, my physician suggested a new drug treatment which included ZADAXIN injections in conjunction with pegylated interferon and ribavirin. Within an extremely short period of time, my liver enzymes were well within the normal range (averaging 15), and my viral load was undetected. Those levels continued for the entire year of treatment and remain so to this day. Treatment ended June 29th of this year.

Again, I thank you for the large contribution you have made to, and in, my life. I would love to be able to give back to the SciClone family which has helped me so tremendously and would be more than willing to help in any way to spread the word, pass along my success story, and in short, just plain brag about what SciClone is doing in the pharmaceutical world.

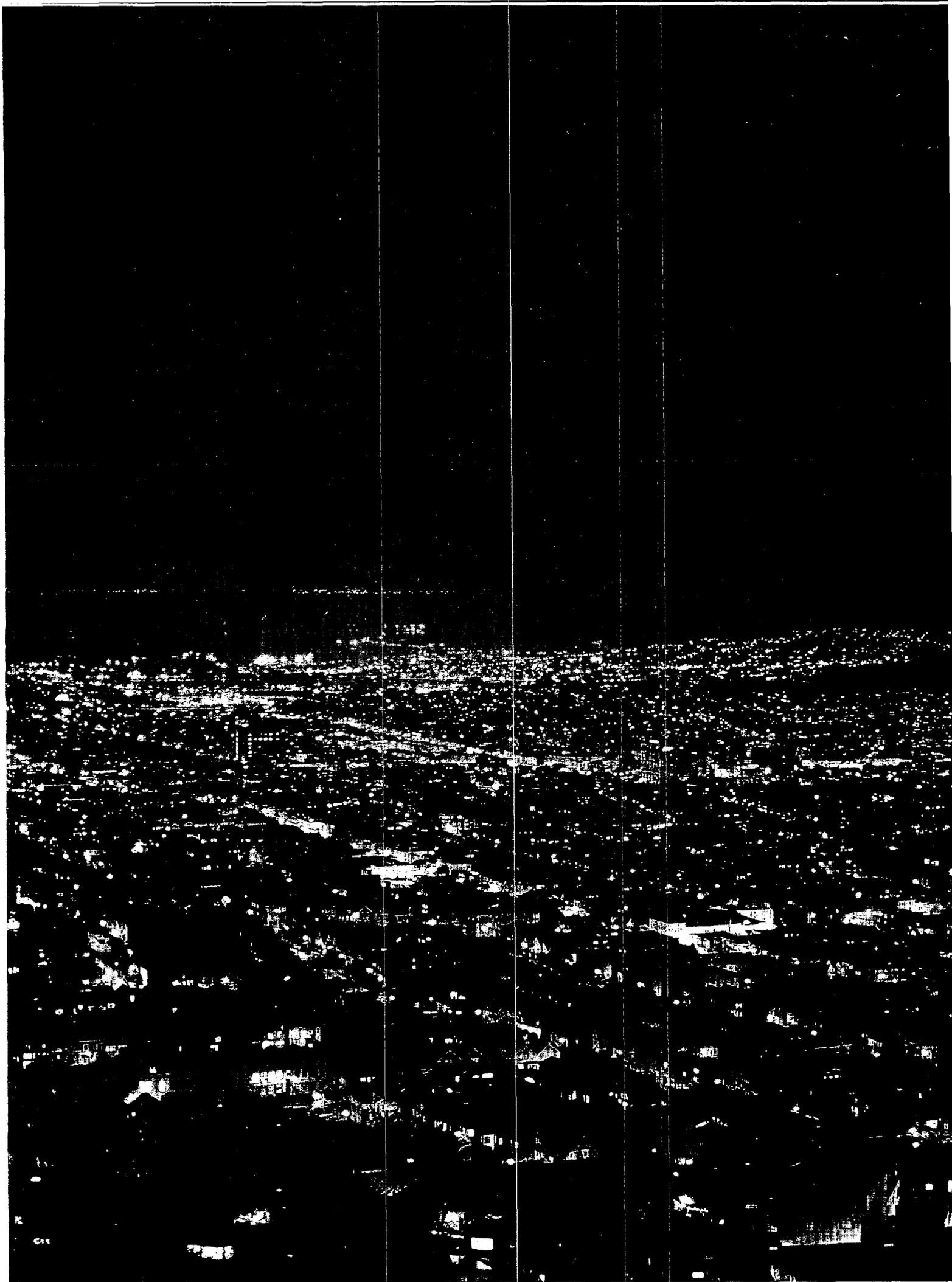
Have I said enough good things? I think not, but only because it is not possible to adequately express my appreciation. As Helen Keller said, "The best and most beautiful things cannot be described, seen, or even touched, they must be felt with the heart." Suffice to say, my heart overflows. Thank you.

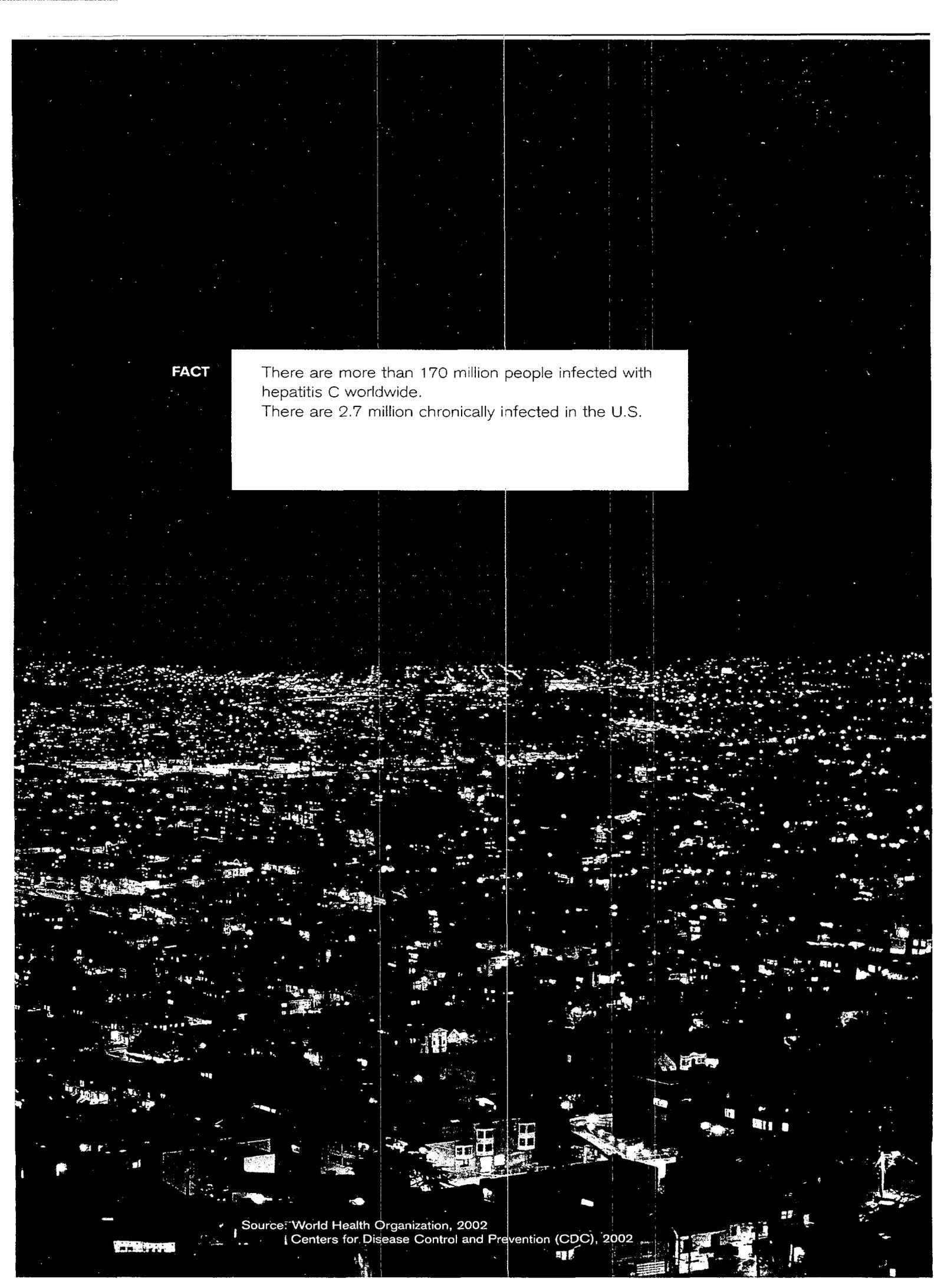
Most sincerely,



Carol L. Spence





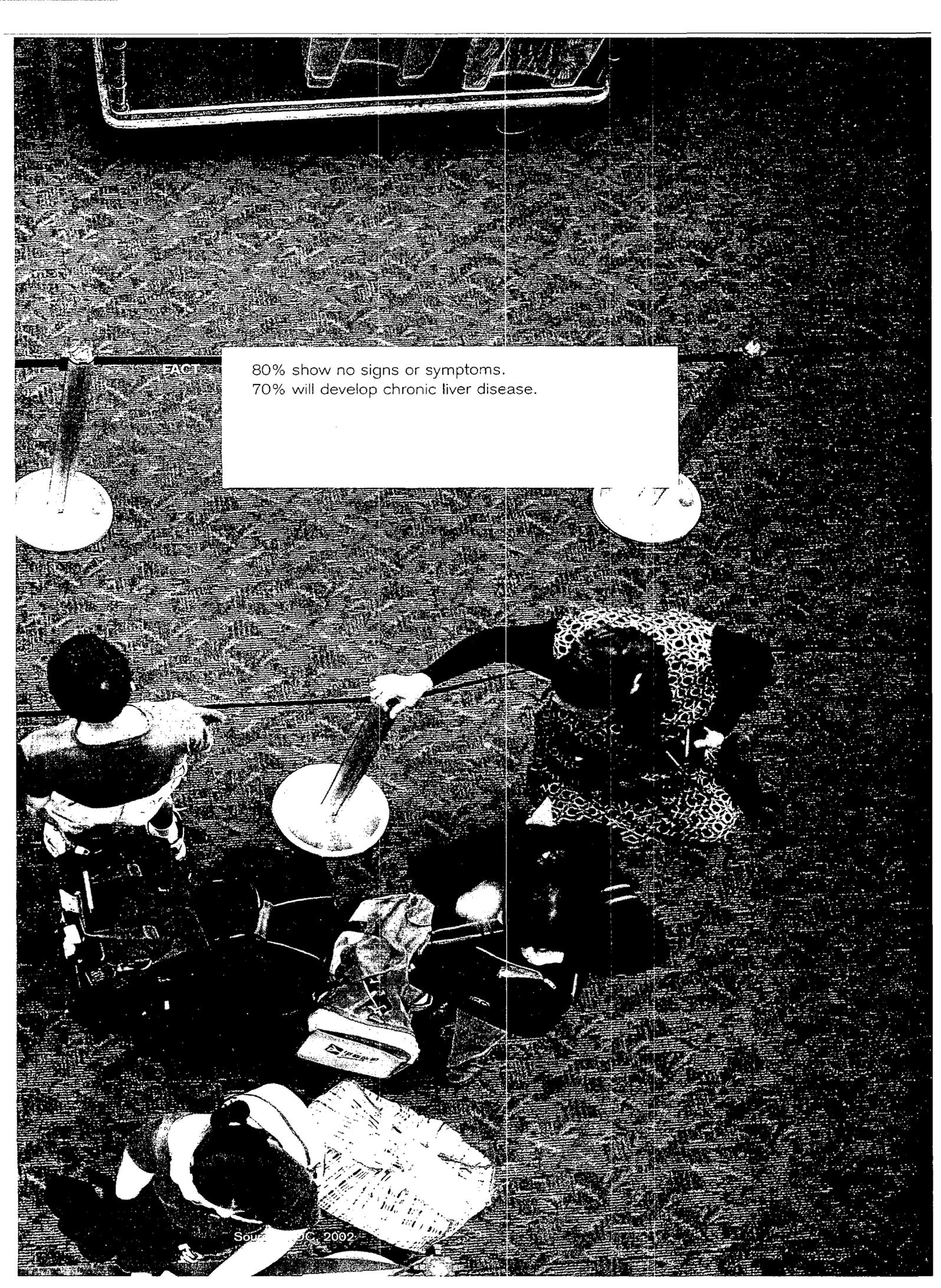
An aerial night photograph of a city, likely San Francisco, showing a dense grid of lights from buildings and streets. The lights are reflected on a body of water in the foreground, creating a shimmering effect. The overall scene is dark, with the city lights providing the primary illumination.

**FACT**

There are more than 170 million people infected with hepatitis C worldwide.  
There are 2.7 million chronically infected in the U.S.

Source: World Health Organization, 2002  
Centers for Disease Control and Prevention (CDC), 2002





FACT

80% show no signs or symptoms.  
70% will develop chronic liver disease.



**FACT**

Hepatitis C is the leading cause of liver transplant.  
Hepatitis C causes 10,000 deaths annually in  
the U.S.



91

After a decade of progress,  
today hepatitis C therapies are only  
effective in half of all patients.

1991

**INTERFERON (SIX MONTHS)**  
6% of patients  
respond <sup>(1)</sup>

1994

**INTERFERON (12 MONTHS)**  
13% of patients  
respond <sup>(1)</sup>

1998

**INTERFERON + RIBAVIRIN**  
38% of patients  
respond <sup>(1)</sup>

2000

**PEGYLATED INTERFERON +  
RIBAVIRIN**  
52% of patients  
respond <sup>(2)</sup>

"Just over 50% of hepatitis C patients in the U.S. respond to treatment with the current standard of care, pegylated interferon and ribavirin. This leaves 50% of patients without a cure. The number of people acutely in need of new therapeutic options is growing every year."

Adrian Di Bisceglie, M.D.  
Professor of Internal Medicine  
Saint Louis University School of Medicine

(1) McHutchison et al., New England Journal of Medicine 339: 1485-1492 (1998)

(2) Package insert information, pegylated interferon and ribavirin.

Genotype 1 is the most difficult to treat strain of the hepatitis C virus.

The majority of patients who fail therapy have genotype 1.

Half of all patients in the U.S. have a high viral load of genotype 1.

70% of these patients fail current therapies.

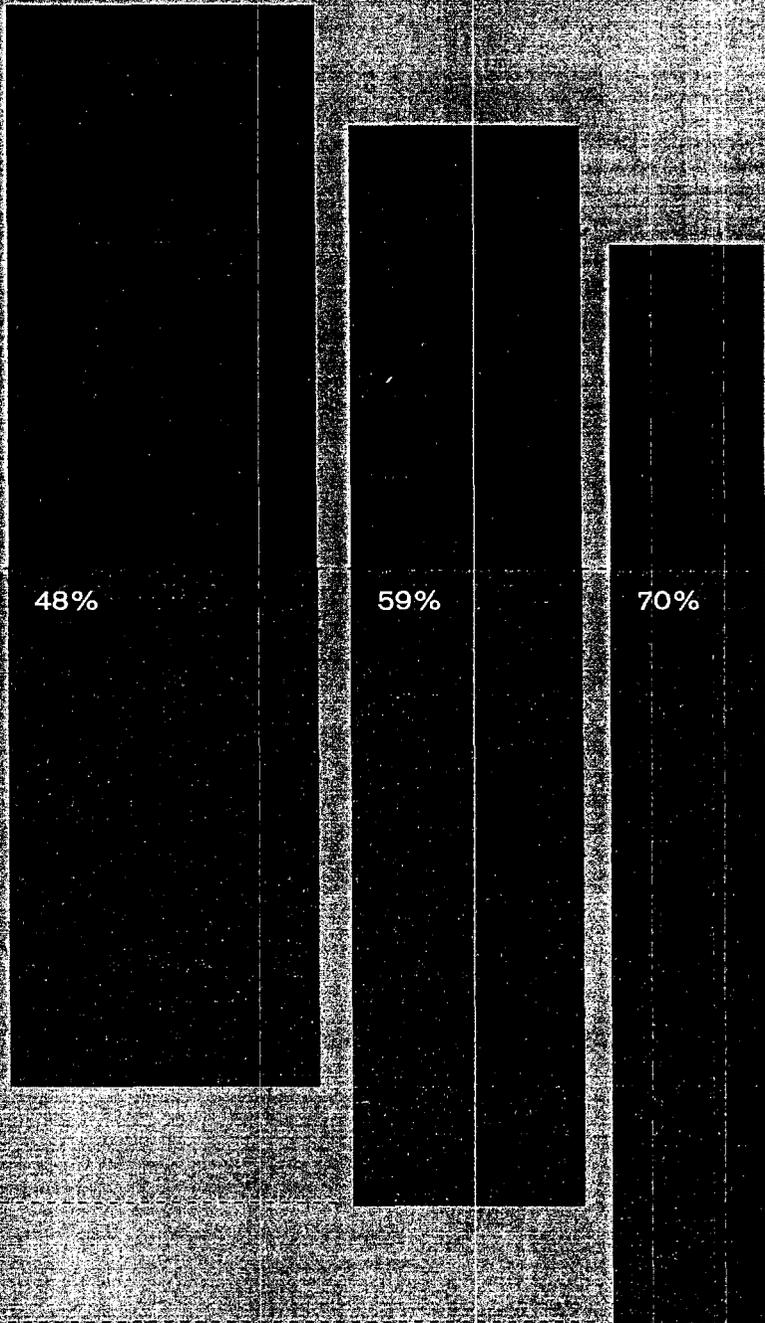
% of patients responding to therapy

% of patients failing therapy

All patients

Genotype 1  
(3/4 of all patients)

Genotype 1 and high viral load  
(1/2 of all patients)



Source: National Institutes of Health, 2002

Package insert information, pegylated interferon and ribavirin

Treating hepatitis C requires a difficult and costly one year of therapy. Left untreated, hepatitis C can cause cirrhosis and liver cancer, which is fatal.

**FACT**  
Up to one year of therapy

- Weekly injections of pegylated interferon
- Twice daily doses of ribavirin
- Frequent dose adjustment

**FACT**  
Severely affects daily life

Common side effects include fatigue, headache, muscle aches, fever, nausea, insomnia, and depression

**FACT**  
May cause serious complications

Rare side effects include heart failure, suicidal thoughts, liver damage

**FACT**  
Not suitable for many patients

Other medical conditions make therapy inappropriate

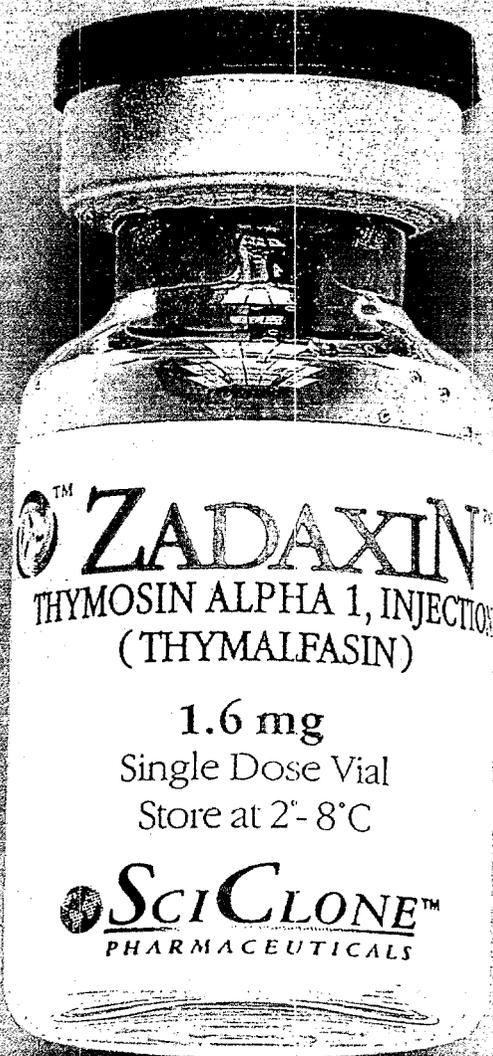
Many patients continue to experience adverse effects up to six months after ending therapy.

**FACT**  
Failure is common

Half of patients fail  
current therapy and  
re-treatment is rarely  
effective

“Chronic hepatitis C infection affects many patients. While our current therapies are effective in approximately 50% of patients, therapy is costly, prolonged, associated with significant side effects and is not suitable for many groups of patients.”

John G. McHutchison, M.D.  
Director, GI/Hepatology Research  
Duke University Medical Center



**ZADAXIN™**  
THYMOSIN ALPHA 1, INJECTOR  
(THYMALFASIN)

**1.6 mg**  
Single Dose Vial  
Store at 2°-8°C

**SCICLONE™**  
PHARMACEUTICALS

## ZADAXIN

ZADAXIN is a pure synthetic preparation of thymosin alpha 1, a substance which circulates naturally and is instrumental in the body's immune response to fight viral infections and certain cancers. ZADAXIN is easily and safely administered just under the skin twice a week. After administration, thymosin alpha 1 circulates at 50 to 100 times its normal level in the body.

Currently in phase 3 clinical trials for viral infections hepatitis B and C and phase 2 clinical trials for cancers of the skin and liver, ZADAXIN has the potential to improve the treatment regimen for a variety of life-threatening diseases.

### **Commercial Use**

ZADAXIN has been administered to more than 10,000 patients in both clinical and commercial use, alone and in combination with antiviral and anticancer drugs, without producing any ZADAXIN related significant side effects or toxicities.

ZADAXIN is manufactured in the U.S. and Europe in compliance with U.S. FDA, European, and Japanese equivalent current Good Manufacturing Practices (cGMP) by third party contract manufacturers.

Supporting SciClone's regulatory strategy, ZADAXIN is patent protected as a hepatitis C therapy through 2015 in the U.S. and 2012 in the European Union and Japan. ZADAXIN is patent protected as a hepatitis B therapy into 2012 in Japan.

## Hepatitis C

There are 170 million people infected with the hepatitis C virus worldwide, with 2.7 million chronically infected in the U.S. In the major pharmaceutical markets of the U.S., Europe, and Japan, sales of hepatitis C therapies totaled \$1.7 billion in 2001 and are projected to reach \$6.6 billion in 2011.<sup>(1)</sup>

SciClone is conducting two phase 3 clinical trials in the U.S. for ZADAXIN in combination with pegylated interferon as a re-treatment for hepatitis C non-responders. SciClone's goal is for ZADAXIN to be part of the first U.S. FDA approved hepatitis C therapy for non-responders.

SciClone is currently enrolling hepatitis C non-responders in two phase 3 multicenter, randomized, and double-blinded clinical trials. Patients are receiving 12 months of treatment and six months of follow-up observation. The 1,000 patient size and rigorous trial design is preferred by the U.S. FDA and is intended to produce statistically significant results to support regulatory approvals in the U.S., Europe, and Japan.

### Clinical Data

A 12-week study reported that up to 36% of non-responders re-treated with ZADAXIN in combination with pegylated interferon showed a dramatic reduction or elimination of hepatitis C viral RNA. A 12-week early virologic response is often considered a predictor of possible successful treatment.

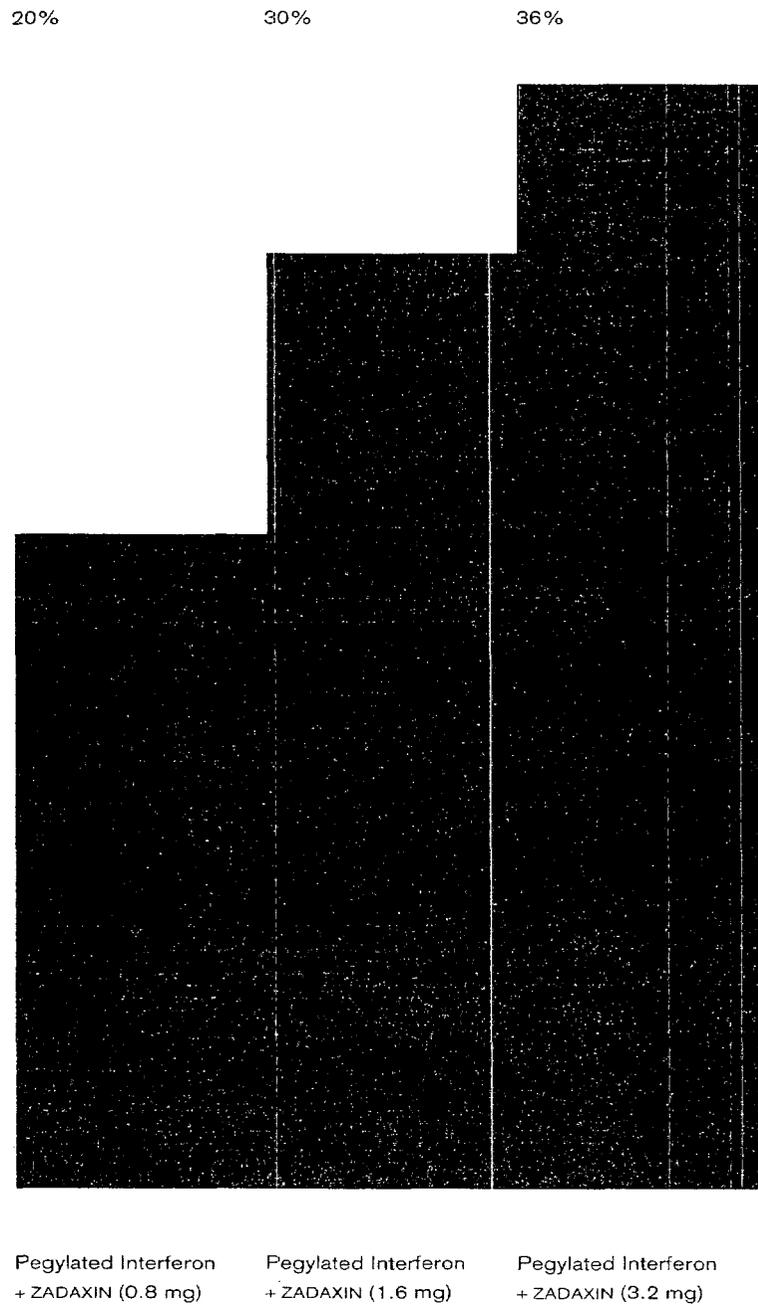
In this study, increasing doses of ZADAXIN resulted in higher patient response rates. This demonstrates that ZADAXIN may add benefits to pegylated interferon in re-treating non-responders.

Current therapies are rarely effective in re-treating non-responders.

(1) Decision Resources, 2002

# ZADAXIN Adds Benefits to Pegylated Interferon in Re-treating Hepatitis C Non-responders

## 12-Week Early Virologic Response Rates



Source: Iftikar, R., Di Bisceglie, A., Pockros, P., Rustgi, V., Schulman, M., Martins, E. (2002) Hepatology 36: 36CA

## Hepatitis B

There are 350 million chronically infected hepatitis B carriers, with 90% in Asia and the Mediterranean region. There are 3.8 million chronic hepatitis B carriers in Japan.

Worldwide sales of hepatitis B therapies totaled \$325 million in 2001.<sup>(1)</sup>

SciClone has completed its phase 3 hepatitis B clinical trial in Japan treating over 300 patients with ZADAXIN as a monotherapy. The preliminary data from the first one-third of patients showed that after six months of therapy and 12 months of follow up observation, 24% of patients had a sustained response and viral replication stopped — the most important goal of hepatitis B therapy. This result is a 50% improvement over the sustained response rate of lamivudine, the largest selling drug currently approved for treating hepatitis B.

SciClone is compiling and analyzing the complete trial data which, if positive, will serve as the basis for a regulatory filing to submit to the Japanese Ministry of Health and Welfare.

## Clinical Data

ZADAXIN has shown the ability to cure hepatitis B. In several studies, ZADAXIN has produced sustained response rates of up to 40% when used as a monotherapy and up to 70% when used in combination with interferon or lamivudine. ZADAXIN has not produced significant side effects.

By comparison, interferon also produces sustained response rates of about 40% when used as a hepatitis B therapy. However, interferon causes significant adverse side effects and is not tolerated by many patients. Other hepatitis B therapies such as lamivudine and adefovir slow the progression of liver disease but are not very effective in successfully eliminating the hepatitis B virus.

(1) Datamonitor, 2002

## Cancer

SciClone is conducting phase 2 cancer trials for ZADAXIN in both the U.S. and Europe.

SciClone's phase 2 cancer trials in the U.S. are designed to show that ZADAXIN produces survival benefits for liver cancer patients. These trials are treating patients with ZADAXIN in combination with either transarterial chemoembolization (TACE) or radio frequency ablation (RFA).

SciClone's European Union marketing and development partner, Sigma-Tau, is conducting and funding a phase 2 malignant melanoma clinical trial involving over 300 patients in Europe. The trial is currently enrolling patients who will receive the chemotherapy drug dacarbazine (DTIC) in combination with either ZADAXIN, interferon, or ZADAXIN plus interferon. The best performing arm of this phase 2 trial will become the basis of a phase 3 trial targeting a cancer approval for ZADAXIN in Europe.

### Clinical Data

The data from a previous liver cancer trial indicate that ZADAXIN in combination with TACE resulted in survival rates of 80% after 12 months of therapy, versus less than 50% for TACE alone. The median survival for advanced liver cancer patients is typically only 8 months.

The data from a previous malignant melanoma trial indicate that ZADAXIN in combination with interferon and DTIC resulted in an increase in tumor response and survival rates with median survival of 12.5 months. The median survival for late-stage malignant melanoma patients is typically only 5 months.



SciClone Pharmaceuticals, Inc. is a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases. Its lead product ZADAXIN is in several late-stage clinical trials, including two phase 3 hepatitis C clinical trials in the U.S., a recently completed phase 3 hepatitis B clinical trial in Japan, a phase 2 malignant melanoma clinical trial in Europe, and two phase 2 liver cancer trials in the U.S. In addition to ZADAXIN, SciClone's other drug development opportunities include SCV-07, a potentially orally available therapeutic to treat viral and infectious diseases, and products to address the protein-based disorder that causes cystic fibrosis.

# Late-Stage Clinical Trials in Major Markets

ZADAXIN

INDICATION

Hepatitis C / United States  
Hepatitis B / Japan

Liver Cancer / United States  
Malignant Melanoma / Europe (with Sigma-Tau)

SCV-07

Tuberculosis / Russia (with Verta)

CPX

Cystic Fibrosis / United States

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ZADAXIN adds benefits to hepatitis C  
non-responders in a 12-week dose  
ranging study

Phase 3 ZADAXIN hepatitis C trial  
dosed first patients

Phase 3 ZADAXIN hepatitis B trial  
shows positive preliminary data

Phase 2 ZADAXIN cancer trial initiated  
by Sigma-Tau

Phase 2 SCV-07 tuberculosis trial  
yields positive results

24% increase in sales during 2002



Donald R. Sellers  
President and  
Chief Executive Officer

Richard A. Waldron  
Chief Financial Officer

Letter from the President and  
Chief Executive Officer

Dear Stockholders,

2002 was a defining year for SciClone. Over the course of the year our clinical progress was unparalleled in the history of the company. We began enrollment and treatment of patients in two ZADAXIN phase 3 hepatitis C clinical trials in the United States. We completed treatment and follow-up for over 300 patients in our ZADAXIN phase 3 hepatitis B clinical trial in Japan. Our European partner, Sigma-Tau S.p.A., began treating patients in a 300 patient phase 2 clinical trial studying ZADAXIN in malignant melanoma. We reported positive phase 2 data on SCV-07, a patented compound which stimulates the immune system. In addition, we announced significant scientific milestones in many new indications for ZADAXIN, contributing to our pipeline for the future. At the same time, we continued to expand our international business, reporting record sales which provided valuable cash flow to support our late-stage clinical trials.

#### U.S. – Phase 3 Hepatitis C Clinical Trials

During the second quarter of 2002, the first of the 1,000 patients we plan to enroll were enrolled and treated in two U.S. phase 3 hepatitis C trials, bringing to fulfillment years of relentless planning, preparation, prioritization and commitment. These trials represent the future of the company and everyone associated with SciClone is excited to be a part of this pivotal event in the Company's history.

If approved, ZADAXIN would be a major component of the first hepatitis C therapy for non-responders like Carol Spence, the most difficult to treat segment of the hepatitis C population. If our clinical trials demonstrate increased efficacy and safety in treating the most difficult patients, we can logically extend the benefit of using ZADAXIN to almost every patient.

In the multi-billion dollar hepatitis C market, we have chosen to focus on the largest and most difficult to treat patient group for several reasons. First, there is a large and growing market need. Virtually half of all hepatitis C patients fail initial therapy with the only two currently approved drugs, interferon alpha (in normal and pegylated forms) and ribavirin, used to augment the interferon. Once a patient fails therapy they rarely respond to re-treatment with the same drugs. Second, our preparatory clinical and scientific research has consistently shown that ZADAXIN safely adds benefit to interferon for hepatitis C non-responders. Third, ZADAXIN's patent protection for use in the treatment of hepatitis C extends into 2015 in the U.S.

#### Japan – Phase 3 Hepatitis B Results

In March 2002, we reported preliminary data on the first one-third of the patients in our ZADAXIN phase 3 hepatitis B clinical trial in Japan. 24% of the reported patients demonstrated a successful sustained interruption of viral replication, indicating these patients were on their way to eliminating the hepatitis B virus. Published data from lamivudine's approval trials shows lamivudine, the most widely used drug for the treatment of hepatitis B worldwide, only produces a 16% response rate.

Late in 2002, the last of over 300 patients completed treatment and follow-up in this phase 3 clinical trial. The data are currently being collected and analyzed and we expect to report results during the second quarter of 2003. If positive safety and efficacy results from this clinical trial are reported, it would be instrumental, not only in preparing a regulatory filing in Japan, but also could benefit SciClone's marketing efforts in countries where ZADAXIN is approved and regulatory efforts in markets where ZADAXIN is pending approval.

#### Europe – Phase 2 Cancer Clinical Trial

Sigma-Tau S.p.A., our European partner, is funding and conducting a clinical development program pursuing a cancer approval for ZADAXIN in Europe. In September, Sigma-Tau began enrolling patients in a trial

involving over 300 patients. This phase 2 multicenter clinical trial is using ZADAXIN in combination with chemotherapy to treat metastatic malignant melanoma. In exchange, Sigma-Tau will have access to our U.S. hepatitis C and Japanese hepatitis B data for intended regulatory filings in Europe.

#### Scientific Advancements

In addition to the continued progress in our late-stage clinical trials, 2002 was a year of significant scientific achievement as measured by the numerous presentations and abstracts published. Over the course of the year, we reported positive preclinical results for ZADAXIN in a variety of diseases, including hepatitis, colorectal cancer, breast cancer, and HIV, as well as scientific presentations reinforcing ZADAXIN's mechanism of action in enhancing the body's immune system.

#### Pipeline

New indications for ZADAXIN, together with the patented molecules SCV-07 and CPX, provide important opportunities to expand our product line and clinical programs. Last September, we reported that adding SCV-07, a novel immune system enhancing drug, to existing tuberculosis therapy demonstrated a significant reduction in the ability of tuberculosis patients to infect others. These phase 2 data indicate that SCV-07 is safe and effective in humans. We plan to continue testing SCV-07 in other diseases and, if appropriate, open a U.S. Investigational New Drug application for this drug.

#### International Sales Growth

While we remain focused on the successful completion of our late-stage clinical trials in the U.S., Europe, and Japan, we continue to benefit from increasing demand and sales growth for ZADAXIN in international markets, particularly China. This sales growth provides an important source of positive cash flow in these highly turbulent and unpredictable financial markets and has been achieved against a backdrop of global economic slowdown and geopolitical instability. We enter 2003 with growing momentum and

confidence in our clinical, scientific, and marketing progress. We are prepared for the advancement and completion of key trials, regulatory approvals, and further international sales growth. I thank our employees for their hard work and sustained contributions to the company, our shareholders for their continued support, and Carol Spence and the thousands of patients who have been treated with ZADAXIN for their belief in the value of our products.

Sincerely,



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

## Letter from the Chief Financial Officer

In 2002, SciClone made significant progress in achieving our primary near-term financial objective of securing the funding required for our U.S. phase 3 hepatitis C trials. We did this through increasing cash flow from our international operations, completing a direct equity placement, and controlling our burn rate.

**Targeting Resource Allocation to ZADAXIN**  
Our business strategy focuses on a few products in the late-stage of development. Specifically, we have allocated the majority of our resources to the completion of ZADAXIN's late-stage clinical trials. Our U.S. phase 3 hepatitis C trials are of the utmost importance, and represent an opportunity to maximize the benefit from our investment in ZADAXIN. Current hepatitis C therapy of pegylated interferon and ribavirin generates annual sales of over \$2 billion in the U.S. alone, yet about half of all patients fail this combination therapy. We believe that ZADAXIN represents the next potential blockbuster drug in combination therapy for this disease. Importantly, SciClone has retained full marketing rights for ZADAXIN in the U.S. and enjoys patent protection for its use in hepatitis C therapy into 2015.

### Minimizing Clinical Trial Risk

As we plan to maximize the potential returns of our ZADAXIN investment, we seek to minimize the risks of the clinical trials. Our phase 3 hepatitis C trials were designed with input from world-leading hepatologists. These 500-patient clinical trials are two of the largest hepatitis C clinical studies ever conducted in the U.S. and among the largest in the world conducted solely with non-responders to previous therapy. Our endpoints are well defined and widely accepted as the determinants of successful treatment for hepatitis C. We are utilizing ZADAXIN in combination with the most recently FDA-approved pegylated interferon, supplied by Roche at no cost to us.

### Funding Clinical Development

ZADAXIN sales in international markets, primarily in China, are an important source of funding for our U.S. clinical trials. In 2002, we increased cash flow from international sales of ZADAXIN by growing sales, holding marketing expenses flat, improving accounts receivable and managing inventory levels. As a company with product revenue and large potential upside, SciClone was able to raise \$10.6 million in 2002 in an extremely difficult equity market for publicly held biopharmaceutical companies. With these cash inflows and through our controlled management of the burn rate, we increased our cash position to finish the year at over \$21 million.

Our financial plan focuses on carrying us through the end of our phase 3 hepatitis C clinical trials. In 2003, we expect and have planned for our research and development expenditures to increase in conjunction with the patient enrollment in these trials.

Although ZADAXIN is our primary current focus, we have two additional drug candidates in our pipeline, CPX and SCV-07, which are in earlier stages of clinical development.

As we advance our pipeline, the prospects for value creation at SciClone have never been more defined. We have endeavored to reduce the risk from clinical design, regulatory, and financial standpoints, and we believe that this attentiveness will result in maximum return from our efforts.

We are confident about our progress and the long-term prospects of our program.

Sincerely,



Richard A. Waldron  
Chief Financial Officer  
SciClone Pharmaceuticals, Inc.





**Senior Management**

Donald R. Sellers <sup>(1)</sup>  
President and Chief Executive Officer  
SciClone Pharmaceuticals, Inc. and  
Managing Director  
SciClone Pharmaceuticals International Ltd.

Alfred R. Rudolph, M.D. <sup>(1)</sup>  
Chief Operating Officer

Richard A. Waldron <sup>(1)</sup>  
Chief Financial Officer

Eduardo B. Martins, M.D., Ph.D.  
Vice President, Medical Affairs

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

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

Randy J. McBeath  
Vice President, Marketing

Hans P. Schmid  
Vice President, Finance, Administration and  
Business Development  
SciClone Pharmaceuticals International Ltd.

Chung-Ying Tam  
Vice President and Regional  
Managing Director, Greater China  
SciClone Pharmaceuticals International Ltd.

Kenneth R. Cowan  
Regional Managing Director, Middle East,  
Africa and Eastern Europe  
SciClone Pharmaceuticals International Ltd.

Craig B. Varden  
Regional Managing Director, Pacific Rim  
SciClone Pharmaceuticals International Ltd.

(1) Corporate Officer

**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. and  
Managing Director  
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, Cyanamid  
International – Lederle Division

Jon S. Saxe  
Former President, Protein Design Labs, Inc.  
Former President and  
Chief Executive Officer, Synergen, Inc.  
Former Vice President, Hoffman-LaRoche, Inc.

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

### Corporate 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, Grand Cayman, 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-K or 10-Q reports filed with the Securities and Exchange Commission, please contact Amy Figueroa, CFA, Director of Investor Relations of SciClone Pharmaceuticals at (650) 358-3437 or send an e-mail message to [investorrelations@sciclone.com](mailto: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 14, 2003, the last reported sales price of SciClone's common stock, as reported by the Nasdaq National Market was \$5.20 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](http://www.melloninvestor.com)

### Independent Auditors

Ernst & Young LLP  
Palo Alto, California

### Legal Counsel

Gray Cary Ware & Freidenrich LLP  
San Francisco, California

### Annual Meeting

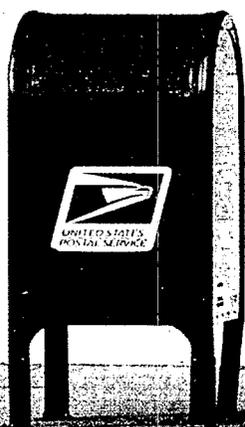
The Annual Meeting of Shareholders will be held on Thursday, May 29th at 10:00 a.m. Pacific Time at the Hilton Garden Inn, 2000 Bridgepointe Circle, San Mateo, California 94404. Detailed information about the meeting is contained in the Notice of Annual Meeting of Shareholders and Proxy Statement sent with a copy of the Annual Report to each shareholder of record as of April 9, 2003.

SCICLONE, the SCICLONE logo, the Swirl logo and ZADAXIN are registered trademarks of SciClone Pharmaceuticals, Inc. in the U.S. Patent and Trademark Office.

### Forward-looking Statements

The information in this annual report contains forward-looking statements including our expectations and beliefs regarding prospects for ZADAXIN, future demand for ZADAXIN and other drugs in our pipeline and its impact on SciClone's sales and earnings, results, potential regulatory approvals of ZADAXIN and other drugs in our pipeline, the advancement of our clinical trials, the production of statistically significant results from our clinical trials, our ability to submit regulatory filings and initiate new clinical trials, our research and development expenses levels, 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. and the reporting of results for our phase 3 hepatitis B trials in Japan. 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 fact that one person's experience with ZADAXIN may not be predictive of the results of studies or clinical trials; results from studies with a limited group of patients may not be predictive of the results of larger studies and clinical trials; positive results received from clinical trials for one indication may not be predictive of the results of studies or clinical trials for another indication; 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 unresponsive to 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.

Design: Howry Design Associates, SF/CA  
Writing: Angela Bitting  
Photography: Dwight Eschlieman  
Printing: Anderson Lithograph



 **SCICLONE**<sup>®</sup>  
PHARMACEUTICALS

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, 2002,

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

*(State or other jurisdiction of  
Incorporation or organization)*

901 Mariner's Island Boulevard  
San Mateo, California

*(Address of principal executive offices)*

94-3116852

*(I.R.S. Employer  
Identification No.)*

94404

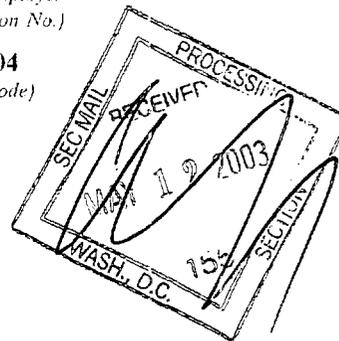
*(Zip Code)*

(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 \$180,927,000 as of March 4, 2003, 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.

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$72,081,000 as of June 28, 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 4, 2003, there were 37,465,064 shares of the Registrant's Common Stock outstanding.

Part III incorporates by reference from the definitive proxy statement for the Registrant's 2003 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.

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## 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 including those statements we make regarding anticipated product sales; the timing and outcome of clinical trials; the timing of reporting of clinical trial results; partnering prospects for ZADAXIN; our expectations and ability to seek additional capital resources, initiate marketing collaborations and initiate new product development; ZADAXIN's ability to enhance the immune system; research and development and other expense levels; level of gross margin and the allocation of financial resources to certain trials and programs. 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. 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") is a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases. Our lead product ZADAXIN is in several late-stage clinical trials, including two phase 3 hepatitis C clinical trials in the U.S., a recently completed phase 3 hepatitis B clinical trial in Japan, a phase 2 malignant melanoma clinical trial in Europe, and two phase 2 liver cancer trials in the U.S. In addition to ZADAXIN, our other drug development opportunities include SCV-07, a potentially orally available therapeutic to treat viral and infectious diseases, and products to address the protein-based disorder that causes cystic fibrosis.

ZADAXIN has been approved for sale by the ministries of health in over 30 countries and is marketed in China and selected other countries outside the U.S. The cash flow generated by these operations contributes significant support to our ZADAXIN late-stage clinical trials. ZADAXIN has been administered to over 10,000 patients to date in both clinical and commercial use, alone and in combination with antiviral and anticancer drugs, without producing any known ZADAXIN related significant side effects or toxicities. ZADAXIN is manufactured by third party manufacturers in the U.S. and Europe in compliance with U.S. Food and Drug Administration (FDA) current Good Manufacturing Practices (cGMP), or the foreign equivalent of such standards.

Our business strategy focuses on developing late-stage products to treat life-threatening diseases that offer significant market opportunities. ZADAXIN is currently in multiple phase 3 and phase 2 clinical trials for the treatment of viral diseases and cancer. These therapeutic categories currently represent multi-billion dollar markets in the U.S., Europe, and Japan. We design our clinical trials with the input of leading physicians and selected major pharmaceutical companies, and we structure trials to support regulatory approval for ZADAXIN in the U.S., Europe, and Japan.

ZADAXIN is the only non-interferon based new drug that we know of in phase 3 hepatitis C clinical trials in the U.S. today. We are currently enrolling patients in our hepatitis C trials and all of the planned 1,000 patients must have previously failed hepatitis C therapies currently approved by the U.S. FDA. Half of all hepatitis C patients treated in the U.S. fail to respond to current therapy and become "non-responders." Re-treatment of non-responders with the same drugs is rarely effective. Our trials are designed to prove that

ZADAXIN in combination with pegylated interferon alpha should be the first U.S. FDA approved therapy for non-responders.

In Japan, our over 300 patient phase 3 clinical trial using ZADAXIN as a therapy for hepatitis B is complete. We are compiling and analyzing the final data and expect to report the results in the second quarter of 2003. If the results are positive, we intend to submit a hepatitis B regulatory filing in Japan.

Our European partner Sigma-Tau is targeting a European oncology approval for ZADAXIN. Sigma-Tau is currently enrolling patients in a phase 2 malignant melanoma clinical trial that is planned to enroll over 300 patients in Europe. In addition, Sigma-Tau intends to use data from our U.S. phase 3 hepatitis C clinical trials, if they are positive, to pursue regulatory approval for ZADAXIN for this indication in Europe.

In the major pharmaceutical markets, we have maintained significant marketing rights and strong intellectual property protection for ZADAXIN. We anticipate that ZADAXIN should have enhanced partnering value at the conclusion of its U.S. phase 3 clinical trials, if they are successful, although there is no assurance such a partnering arrangement will be pursued or can be achieved. We have strong intellectual property protection for ZADAXIN as a therapy for hepatitis C with patent protection into 2015 in the U.S. and 2012 in the European Union and Japan. ZADAXIN as a therapy for hepatitis B is patent protected into 2012 in Japan.

## ZADAXIN

ZADAXIN is a pure synthetic preparation of thymosin alpha 1, a substance that circulates naturally and is instrumental in the body's immune response to fight viral infections and certain cancers. ZADAXIN is easily and safely administered just under the skin twice a week. After administration, thymosin alpha 1 circulates at 50 to 100 times its normal level in the body. In over 10,000 patients to date, ZADAXIN has been administered in both clinical and commercial use, alone and in combination with antiviral and anticancer drugs, without producing any ZADAXIN related significant side effects or toxicities. ZADAXIN is also referred to as thymalfasin, the generic name for thymosin alpha 1.

Published scientific and clinical studies have shown that ZADAXIN helps stimulate, maintain and direct the body's antiviral and anticancer immune response. ZADAXIN helps the immune system target and eradicate virally infected or cancer cells.

When the immune system recognizes virally infected or cancer cells, it responds by increasing white blood cells called CD4 helper T-cells. These cells can be directed towards one of two pathways, referred to as T-helper 1 (Th1) or T-helper 2 (Th2). Studies have shown that a Th1-directed immune response is fundamental to the eradication of certain viral disease, such as hepatitis C or hepatitis B, and certain cancers.

ZADAXIN helps activate a Th1-directed immune response by promoting stem cell differentiation into CD4 T-cells and subsequent differentiation of those cells into the Th1 subset. At the same time, ZADAXIN helps increase the production of CD8 T-cells and NK or natural killer cells, a population of cells able to directly attack and kill virally-infected and certain cancer cells. As ZADAXIN increases Th1 cytokines such as interleukin-2 (IL-2) and gamma interferon, it also decreases production of Th2 cytokines such as IL-4. Both of these activities are important in an effective cellular response to a hepatitis C viral infection. Moreover, ZADAXIN reduces T-cell apoptosis, or programmed cell death, which allows these beneficial cells to circulate for a longer period of time.

In addition to its positive effects on the immune system, ZADAXIN also exhibits direct antiviral effects. ZADAXIN enhances the expression of surface-marker proteins on virally-infected and certain cancer cells. These surface markers help the body's immune system recognize and target virally infected and cancer cells for eradication by the immune response.

### *Clinical Development Strategy*

Our U.S. clinical development strategy for ZADAXIN has been to select an indication that offers a large patient population representing a significant market potential, the opportunity for improvement to current

therapy, the likelihood of an expedited regulatory review due to lack of approved treatment options, and where we have a strong intellectual property position. Our primary focus is on our phase 3 hepatitis C clinical trials in the U.S. These trials were designed to generate data to support a New Drug Application in the U.S. and similar regulatory filings in Europe and Japan.

### *Hepatitis C*

In the U.S., we have selected hepatitis C as the first targeted U.S. FDA approved indication for ZADAXIN. We believe this indication offers a large patient population representing a significant market opportunity, the opportunity for improvement to current therapy, and the potential for an expedited review by the U.S. FDA.

The hepatitis C virus (HCV) is one of the world's most prevalent blood borne chronic infectious diseases. Complications from HCV include cirrhosis of the liver, liver failure and liver cancer. The World Health Organization estimates that more than 170 million people are infected with hepatitis C worldwide, including an estimated 10 million people in the U.S., Europe and Japan. The Centers for Disease Control estimate that four million people in the U.S. are infected with HCV. HCV related deaths among this group are expected to triple by 2010 to 30,000 annually. There is no vaccine to prevent HCV infection.

The total market for HCV therapies in the U.S., Europe and Japan was \$1.7 billion in 2001 and is expected to grow to \$6.6 billion by 2011, according to Decision Resources' estimates.

The current standard of care for HCV patients is the new longer-acting pegylated form of interferon alpha, most typically used in combination therapy with the antiviral drug ribavirin. Pegylated interferon alpha can induce severe toxicities and ribavirin introduces additional toxicities of its own. Many patients cannot, or will not, tolerate a complete 12 month course of interferon alpha and ribavirin at approved optimal doses, and dose reduction of one or both drugs is commonly prescribed. Consequently, efficacy may be reduced.

Current HCV therapy of pegylated interferon alpha and ribavirin is effective in just over half of all treated patients and the side effect profile is severe. For the estimated 2 million HCV carriers in the U.S. with a high viral load of a particularly difficult to treat HCV strain (genotype 1), current therapy is even less effective and works in only 30 percent of patients. Patients who fail current therapy (non-responders) seldom respond to re-treatment with the same therapy. The large majority of non-responders have a high viral load of HCV genotype 1.

Published data indicate ZADAXIN in combination with pegylated interferon alpha has the potential to benefit HCV non-responders. Complete data from a twelve week study in 31 patients show that groups of HCV non-responders, all with a high viral load of genotype 1, treated with ZADAXIN in combination with pegylated interferon alpha reported ZADAXIN dose-related early virologic response rates ranging from 20 to 36 percent. These data, which showed increasing dose-related response rates, suggest ZADAXIN's potential to add to the antiviral effects of pegylated interferon alpha. Early virologic response is suggested to be an early indicator of sustained response. A sustained response is evidence of complete clearance of the virus from the body six months after completion of 12 months of therapy. A sustained responder is considered effectively cured of hepatitis C.

We are conducting two phase 3 clinical trials in the U.S. using ZADAXIN in combination with pegylated interferon alpha as a therapy for non-responders to previous hepatitis C therapy. Our goal is for ZADAXIN in combination with pegylated interferon alpha to be the first U.S. FDA approved hepatitis C therapy for non-responders, the most difficult group of HCV patients to treat. If this combination therapy is approved for non-responders, we believe that ZADAXIN could be beneficial in combination with current therapy (pegylated interferon alpha with or without ribavirin) as a first course of therapy for all HCV patients. Currently, ZADAXIN is the only non-interferon based new drug that we know of in phase 3 hepatitis C clinical trials in the U.S. ZADAXIN used alone or in combination with other drugs to treat hepatitis C is patent protected into 2015 in the U.S. and into 2012 in Europe and Japan.

Our two ZADAXIN phase 3 hepatitis C clinical trials are designed to provide statistically significant results and demonstrate a clinical benefit from using ZADAXIN in combination with pegylated interferon

alpha in treating hepatitis C non-responders. These trials are multicenter, randomized, and double-blinded and plan to enroll a total of 1,000 hepatitis C non-responder patients. One trial is treating patients with mild cirrhosis of the liver and the other trial is treating patients with no liver damage. These trials are two of the largest hepatitis C clinical studies ever conducted exclusively in the U.S. and among a few in the world to treat solely non-responders.

In these clinical trials, patients in equal numbers are being assigned to a 12 month course of ZADAXIN plus pegylated interferon alpha or placebo plus pegylated interferon alpha. After completing treatment, all patients will be followed for a six month observation period. These treatment and follow up periods are consistent with the U.S. FDA standard for demonstrating sustained response to hepatitis C therapy. Primary endpoints are a sustained virological response (clearance of the HCV virus) and an improvement in the liver histological activity index measured at the end of the six month follow up observation period. Secondary endpoints are the same as the primary endpoints but are measured at the end of the 12 months of therapy.

The PEGASYS brand of pegylated interferon alpha 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. These trials are also supported by our European partner Sigma-Tau, which has European marketing and development rights for ZADAXIN. In early 2002, Sigma-Tau contributed \$2,685,000 to SciClone for funding of these trials, and is obligated to make an additional \$1,000,000 milestone payment when the targeted 1,000 patients are enrolled in these trials. Sigma-Tau and affiliates currently own close to 10% of SciClone's common stock outstanding.

#### *Hepatitis B*

The hepatitis B virus (HBV) is one of the world's most prevalent blood borne chronic infectious diseases. The disease often leads to cirrhotic complications and progression to liver cancer. The World Health Organization estimates that more than 350 million people worldwide are chronically infected with HBV. There are effective hepatitis B vaccines that account for the relatively low incidence of the virus in certain markets, such as the U.S. with only 1.3 million chronically infected. However, in many areas of the world, particularly in Asia, the virus is highly prevalent.

The worldwide market for HBV therapeutics was \$325 million in 2001. Significant pharmaceutical markets for hepatitis B therapy exist in Japan, China, Southern Europe, and the Middle East. In Japan, there are 3.8 million chronically infected HBV carriers. We have regulatory approval and are marketing ZADAXIN as a hepatitis B therapy in certain countries, most notably in China. We recently completed a phase 3 clinical trial in Japan, encompassing over 300 patients using ZADAXIN as a monotherapy, and we expect to report the results in the second quarter of 2003.

The goal of hepatitis B therapy is to induce a durable interruption of viral replication which will lead to a sustained response. Current HBV therapies in the U.S., Europe, and Japan are inadequate in achieving this goal of a sustained response. In Japan, these therapies include interferon alpha and the nucleoside analogue lamivudine.

Interferon alpha, an injected drug, is effective in stopping HBV viral replication in approximately 40 percent of patients. However, many patients are unable to tolerate the manufacturers' recommended four months of therapy administered at doses three to four times that of interferon alpha's recommended HCV therapy dose. The severe side effects frequently require dose reduction and even termination of therapy. Lamivudine, an oral drug, is effective in achieving a sustained response in approximately 16 percent of patients after one year of therapy. Lamivudine's primary benefit, while it is taken, is suppressing of the virus and slowing the progression of liver disease. However, after therapy is stopped the virus typically rebounds, sometimes so strongly it can be fatal. Another concern is that prolonged use of lamivudine causes the hepatitis B virus to mutate, sometimes to a form resistant to the drug, making therapy even more problematic. Viral mutations are common after just one year of therapy. Adefovir, recently approved in the U.S. and Europe but presently not in Japan, is a nucleotide reverse transcriptase inhibitor that, like lamivudine, suppresses hepatitis B viral replication while the drug is taken. Adefovir, also an oral drug, is effective in achieving a sustained response in approximately 12 percent of patients after one year of therapy. It is uncertain yet whether prolonged use of adefovir will lead to resistant viral mutations.

We have publicly reported positive preliminary data from our ZADAXIN phase 3 hepatitis B clinical trial in Japan. Preliminary data on the first evaluated one-third of patients in this over 300 patient study showed ZADAXIN produced a sustained response in 24 percent of patients after six months of therapy and 12 months of follow up. In separate smaller studies, ZADAXIN has produced sustained response rates of up to 40% when used as a monotherapy and up to 70% in pilot studies when used in combination with interferon alpha or lamivudine. ZADAXIN has not produced any significant reported adverse effects.

Our ZADAXIN phase 3 hepatitis B clinical trial in Japan is designed to demonstrate a clinical benefit from using ZADAXIN in treating hepatitis B. The trial patients were assigned to either one of two different doses of ZADAXIN monotherapy for six months and then were observed for 12 months of follow up. At the end of treatment and follow up observation, the primary endpoint is global improvement, as measured by a virological, chemical, and biological response.

We have completed the treatment and follow up observation in this clinical trial and are compiling and analyzing the complete data. We expect to report results from this trial during the second quarter of 2003. If the final data are positive and demonstrate an efficacy and safety benefit to using ZADAXIN in treating hepatitis B, we will prepare a regulatory filing document to submit to the Japanese Ministry of Health and Welfare. ZADAXIN as a therapy for hepatitis B is patent protected into 2012 in Japan.

#### *Oncology*

We believe that 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. We believe that oncology will be a major market opportunity for ZADAXIN.

We are conducting two phase 2 liver cancer clinical trials in the U.S. Our European partner Sigma-Tau is targeting a European oncology approval for ZADAXIN. Sigma-Tau is currently enrolling patients in a phase 2 malignant melanoma clinical trial and intends to use the data from this trial, if positive, to determine the optimal design for a pivotal phase 3 oncology trial. Sigma-Tau intends to use data from our U.S. phase 3 hepatitis C clinical trials, if positive, to pursue regulatory approval for ZADAXIN for this indication in Europe.

Liver cancer (hepatocellular carcinoma or HCC) is a common result of untreated or progressive hepatitis C or hepatitis B and is one of the most prevalent fatal malignancies in the world with approximately one million new cases annually. The median survival for advanced HCC patients is only eight months.

Current liver cancer therapies include transarterial chemoembolization (TACE) and radio frequency ablation (RFA). In the U.S., our ZADAXIN phase 2 liver cancer clinical trials are designed to demonstrate a clinical benefit from using ZADAXIN in combination with TACE or RFA. Patients are receiving either ZADAXIN in combination with TACE or ZADAXIN in combination with RFA, the two most common procedures for liver cancer patients whose tumors cannot be treated either by surgery or by liver transplantation. Patients are receiving six months of therapy and are being observed for a period of 12 months after the end of therapy. The endpoints are survival and tumor response. ZADAXIN for the treatment of liver cancer is protected by Orphan Drug status in both the U.S. and Europe.

Malignant melanoma is one of the deadliest forms of cancer. There are 80,000 new melanoma cases diagnosed annually in the U.S. and Europe and the median survival for late-stage malignant melanoma patients is only five months.

Current malignant melanoma therapies include interferon alpha and the chemotherapy drug dacarbazine (DTIC). Data from a previous European pilot study indicate that ZADAXIN in combination therapy with interferon alpha and DTIC chemotherapy increases tumor response rates and survival rates in malignant melanoma patients. In these studies, 23 of the 46 late-stage patients using ZADAXIN plus interferon alpha and DTIC showed a complete or partial response. Moreover, the median survival for participating patients was 12.5 months, more than double the historical average.

The ZADAXIN phase 2 malignant melanoma clinical trial in Europe is designed to demonstrate a clinical benefit from using ZADAXIN in combination with standard chemotherapy. This clinical trial is being funded and conducted by Sigma-Tau, which has exclusive marketing rights for ZADAXIN in most Western European countries. Sigma-Tau is currently enrolling stage 4 (metastatic) malignant melanoma patients and plans to enroll over 300 patients in this trial. All patients in this four-arm study are receiving DTIC chemotherapy. In addition to receiving DTIC, each patient is randomly assigned to receive either ZADAXIN (in varying doses), interferon alpha, or ZADAXIN plus interferon alpha. Patients are receiving six months of therapy and will be observed for a period of 12 months after the end of therapy. The endpoints are tumor response and survival. The results of this clinical trial, if positive, are expected to be used in the design of a ZADAXIN combination therapy phase 3 clinical trial for malignant melanoma.

#### *Additional Product Development Opportunities*

Although most of our resources and efforts are concentrated on developing ZADAXIN, our additional product development opportunities include a potentially orally administered therapeutic to treat viral and infectious diseases and products to address the protein-based disorder that causes cystic fibrosis.

#### *SCV-07*

SciClone has acquired the rights to a new class of immunomodulators that stimulate the immune system in a manner similar to ZADAXIN. One of these is SCV-07, which also has the potential to be administered orally. In 1999, we acquired the exclusive worldwide rights outside of Russia to SCV-07 and other compounds of a new class of immunomodulators from Verta Ltd., a biotechnology company in St. Petersburg, Russia. SCV-07 and its related class of compounds are covered by a U.S. composition of matter patent as well as for their use as immunomodulators.

The World Health Organization estimates that tuberculosis (TB) kills 2 million people each year, and is the most common infectious disease in the world today. TB is a highly infectious disease and getting a patient to a non-contagious state is a primary goal of treatment and is critical to efforts to contain the spread of the disease.

Data from phase 2 clinical trials conducted by Verta in Russia demonstrated that SCV-07 has the capability to significantly increase the rate at which tuberculosis patients become non-contagious. In phase 2 clinical trials, 80 percent of TB patients undergoing standard anti-TB chemotherapy plus a five-day regimen of parenteral SCV-07 therapy were no longer contagious (as measured by negative sputum cultures) after three months compared to 37 percent of patients whose anti-TB therapy did not include SCV-07. In addition, all of the patients receiving SCV-07 reported an improvement in symptoms, including fever and cough, and there was a significant decrease in the number of patients with lung damage. SCV-07 did not lead to additional adverse events in any of the patients.

We are pursuing grant funding to conduct additional clinical trials to test the optimal dosing and oral administration of SCV-07 in the treatment of infectious diseases with the intention of opening a U.S. Investigational New Drug application (IND) to study SCV-07 in the U.S.

#### *CPX for Cystic Fibrosis*

CPX is a novel small molecule protein-repair therapy that can be orally administered. CPX is targeted for the treatment of cystic fibrosis (CF), a common fatal genetic disorder among Caucasians. We licensed CPX and a related class of compounds from the National Institutes of Health (NIH). CPX has been granted Orphan Drug status in both the U.S. and Europe.

In preclinical studies conducted at the NIH, CPX demonstrated the ability to repair the two principal protein defects underlying the cause of CF. CPX appears to enable the defective protein to travel through the cell and reach the epithelial cell membrane ("trafficking") and to improve an originally impaired transport of chloride ions across the cell membrane. This mechanism of action is intended to prevent the build-up of viscous mucus in the first place, and thus lessen the danger of fatal infection common in CF patients.

Our first CPX phase 2 clinical trial in the U.S. was designed to demonstrate CPX's protein repair activity in CF patients. Due to the erratic digestive absorption patterns of CF patients, the sustained circulatory drug levels required to assess efficacy were not achieved. We worked with the Cystic Fibrosis Foundation's Therapeutic Development Network and reformulated CPX to prepare for additional toxicology and early human studies. We currently are conducting development activities with a reformulated CPX.

### **Marketing and Sales**

SciClone initially had marketing rights to ZADAXIN only outside of the U.S. and Europe. We began and developed our marketing and sales capabilities in the international markets available to us and to date we have received ZADAXIN approvals by the ministries of health in over 30 countries outside of the U.S., most of Europe, and Japan. ZADAXIN's approvals are principally for the treatment of hepatitis B and hepatitis C, and also in certain countries as a vaccine or chemotherapy adjuvant for patients with weakened immune systems. Our international sales provide significant cash flow to help fund ZADAXIN's phase 3 hepatitis C clinical trials in the U.S.

After consolidating worldwide rights to ZADAXIN in 1998, we were able to begin implementing our plans to develop ZADAXIN for regulatory approval in the U.S. and Europe.

In the U.S., we have retained full commercial rights to ZADAXIN. We currently are conducting phase 3 clinical trials in the U.S. and we anticipate that ZADAXIN should have enhanced partnering value after the conclusion of these trials, if they are successful. However, there is no assurance that we will pursue or achieve a partnering arrangement.

In the European Union (EU), Sigma-Tau is our exclusive marketing and development partner for ZADAXIN. As part of our collaborative agreement, we will provide our U.S. hepatitis C phase 3 clinical trial data to assist Sigma-Tau's efforts to obtain regulatory approval in the EU for ZADAXIN in hepatitis C therapy. In addition, Sigma-Tau intends to seek EU regulatory approval for ZADAXIN for other indications and is currently conducting and funding a large phase 2 clinical trial using ZADAXIN in combination therapy for malignant melanoma. We received from Sigma-Tau a \$2,685,000 payment in January 2002 that is being recognized evenly as contract revenue over the period of our U.S. hepatitis C clinical development activities, estimated at three years beginning in the second quarter of 2002. This payment is part of the \$3,685,000 Sigma-Tau has agreed to pay us to help fund the U.S. hepatitis C clinical trials. The remaining \$1,000,000 will be paid upon completion of patient enrollment in our U.S. clinical trials.

In Japan, we have recently completed a phase 3 clinical trial for ZADAXIN as a monotherapy for hepatitis B. Schering-Plough is our exclusive marketing partner for ZADAXIN in Japan.

In the markets where ZADAXIN is approved and actively marketed, our marketing activities include providing ZADAXIN related medical education, clinical experience programs and participation in regional and international liver disease related medical conferences. Where appropriate, these programs will extend into other markets when ZADAXIN has regulatory approval.

ZADAXIN sales are made in U.S. dollars and are managed by our wholly owned international subsidiary, SciClone Pharmaceuticals International Ltd. (SPIL). SPIL is registered in the Cayman Islands, headquartered in Hong Kong, and has international offices in Beijing, Hong Kong, Shanghai, and Singapore. SPIL manages a distribution center in Hong Kong that receives shipments of ZADAXIN manufactured in Europe under contract agreements and distributes from there to international markets. Under our established distribution arrangements, local importers and distributors are responsible for the importation, inventory, distribution, and invoicing of ZADAXIN.

Our largest single market for ZADAXIN is currently the People's Republic of China, which accounted for 88%, 89%, and 86% of ZADAXIN sales for the years ended December 31, 2002, 2001, and 2000, respectively. China is the world's most populous nation and also has the largest population of hepatitis B, hepatitis C, and liver cancer patients. Although China and other developing countries generally do not reimburse patients for relatively expensive therapies such as ZADAXIN, SPIL has successfully established and expanded the use of ZADAXIN in China in recent years.

In China, SPIL sells ZADAXIN to well-established, government licensed importing agents. Sales are made on a no returns basis, except under limited terms regarding product quality. These importing agents in turn sell ZADAXIN to four licensed distributors who then distribute ZADAXIN to hospital pharmacies and physicians throughout the country. In addition to its Hong Kong office, SPIL also operates representative offices in Beijing and Shanghai, and employs a medical education team of approximately 60 full time employees in China to promote physicians' knowledge and use of ZADAXIN.

## **Manufacturing**

ZADAXIN is manufactured in accordance with U.S. FDA current Good Manufacturing Practices (cGMP), and the Japanese or European equivalents of such standards. Products are manufactured by third parties under exclusive contract manufacturing and supply agreements. We closely monitor production runs of our products and regularly conduct our own quality assurance audit programs.

For our phase 3 clinical trials in the U.S. and Japan, ZADAXIN is manufactured to U.S. FDA and Japanese cGMP standards by contract manufacturers in the U.S. For our phase 2 clinical trial in Europe and for sale in other international markets where approved, ZADAXIN is manufactured to European cGMP standards by contract manufacturers in Europe.

In the event of the termination of an agreement with any single supplier or manufacturer, we believe that we would be able to enter into arrangements with similar terms with other suppliers or manufacturers. We do not intend to acquire or establish our own dedicated manufacturing facilities for any of our products at this time.

## **Patents and Proprietary Rights**

### *Patents*

An important element of our product development strategy is to seek regulatory approval for our products for indications with significant market potential and where we have a strong proprietary position through patents covering use, process, or composition of matter of our products. For our lead product ZADAXIN, we have significant patent protection regarding the use of thymosin alpha 1, or thymalfasin, and its process of manufacture.

We have patents covering the use of thymosin alpha 1 for treatment of hepatitis C that have been issued in the U.S., a majority of European countries and numerous international markets and extend into 2015 in the U.S. and 2012 in the European Union and Japan. In addition, patents for the specific use of thymosin alpha 1 in treating hepatitis C in non-responders to interferon alpha treatment have been issued to us in the U.S. and various international markets.

We are the exclusive licensee or owners of patents that have been issued in the U.S., Japan, China and other international markets covering the treatment of hepatitis B using thymosin alpha 1. We are also the exclusive licensee of patents that have been issued in the U.S., a majority of European countries, Japan, and other international markets that 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.

For process patents, we are either a patentee or exclusive licensee of use and process patents related to the method of making and therapeutic uses of thymosin alpha 1. Our process patents are directed to methods of making thymosin alpha 1 and have been issued in the U.S., a majority of European countries, Japan, Canada, Hong Kong, Taiwan, and South Korea. Although the composition of matter patents related to thymosin alpha 1 have expired in the major pharmaceutical markets, we have several composition of matter patents and applications directed to analogs and derivatives of thymosin alpha 1 which have been granted in the U.S. and in important international markets. We continue to seek additional proprietary rights for thymosin alpha 1.

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 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.

### *Proprietary Rights*

In addition to our patent protection, we intend to use other means to protect our proprietary rights. We are pursuing marketing exclusivity periods that are available under regulatory provisions in certain countries including the U.S., Europe, and Japan. These marketing exclusivity periods benefit the holder of the first marketing approval for new chemical entities or their equivalents for a given indication.

Orphan Drug protection has been or will be sought where available if such protection also grants 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. and for hepatocellular carcinoma in Europe. We hold an Orphan Drug product designation for CPX to treat cystic fibrosis in the U.S. and Europe and are pursuing other types of protection where applicable.

We have filed applications worldwide to recognize and protect trademarks for ZADAXIN and other trademarks that appear on our commercial packaging and promotional literature. Copyrights for the commercial packaging may prevent 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 plan to register the packaging with customs departments in countries where such procedures exist. 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.

### **Competition**

There are few drugs currently approved by the U.S. FDA for the treatment of hepatitis C or hepatitis B. For the treatment of hepatitis C in the U.S., there are currently two versions of pegylated interferon alpha being marketed, one by Schering-Plough under the trade name "Peg-Intron<sup>TM</sup>", the other by F. Hoffmann La-Roche under the trade name "PEGASYS<sup>TM</sup>". Schering-Plough markets ribavirin under the trade name "Rebetol<sup>TM</sup>", and F. Hoffmann La-Roche sells a separate brand of ribavirin under the trade name "COPEGUS<sup>TM</sup>". In previous clinical studies, ZADAXIN has demonstrated the ability to add to the antiviral effects of pegylated interferon alpha without adding to the side effects caused by pegylated interferon alpha. Of the many future potential hepatitis C therapies being developed, ZADAXIN is the only non-interferon new therapy currently in phase 3 clinical trials in the U.S. and we believe that other new therapies are years behind ZADAXIN's late-stage of development.

For the treatment of hepatitis B, current therapies marketed include interferon alpha, nucleoside analogues such as lamivudine, and the nucleotide reverse transcriptase inhibitor adefovir. In previous clinical studies, ZADAXIN as a monotherapy has demonstrated up to the same efficacy as interferon alpha without producing adverse side effects. Moreover, in small studies ZADAXIN in combination with interferon alpha or lamivudine has demonstrated significantly higher efficacy rates without producing additional side effects.

There are numerous methods to treat other viral diseases and cancer and new therapeutic options continue to be developed. ZADAXIN, as a pure synthetic preparation of thymosin alpha 1, a substance that circulates naturally and is instrumental in the body's immune response to fight viral infections and certain cancers, may be useful in combination therapy for these other indications. ZADAXIN is currently being studied in human clinical trials in combination with the chemotherapeutic agents DTIC and interferon alpha for the treatment of malignant melanoma. In over 10,000 patients to date, ZADAXIN has been administered in both clinical and commercial use, alone and in combination with antiviral and anticancer drugs, without producing any ZADAXIN related significant adverse side effects or toxicities. We believe that as newer and better directed antiviral and anticancer therapies are developed, ZADAXIN may increase these therapies'

efficacy without adding to the side effect profile, although there can be no assurance that ZADAXIN or other products we may develop will prove effective or safe in such uses.

### Government Regulation

Regulation by governmental authorities in the U.S. and foreign countries is a significant factor in the manufacturing and 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. 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. In complying with cGMP standards, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance.

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 Investigational New Drug Application, or IND, and receiving FDA approval of the IND;
- 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;
  - *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; and
  - *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 to the FDA the results of preclinical studies, clinical studies, and adequate data on chemistry, manufacturing and control information to ensure reproducible product quality batch after batch in a New Drug Application, or NDA, or Biologics License Application, or BLA; and
- obtaining FDA approval of the NDA or BLA prior to any commercial sale or shipment of the pharmaceutical agent.

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.

After FDA approval has been obtained, the FDA will require post-marketing reporting to monitor the side effects of the drug. Further 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. 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 the manufacturing process or manufacturing facility, a NDA or BLA supplement may be required to be submitted to the FDA.

The FD&C Act includes provisions intended 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 set forth a procedure for designation of a drug as a "fast track product." Concurrent with or after an IND is filed, the sponsor may request designation as a fast track product, and the FDA will respond within 60 days.

An 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 FDA approves a schedule for submission of the completed application. 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, and the sponsor may be required to conduct post-approval studies to validate and/or confirm the endpoint. 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.

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. 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 drug for the same indication without a showing of clinical superiority, 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 treatment of chronic active hepatitis B, DiGeorge Anomaly, and hepatocellular carcinoma, and for CPX for treatment of cystic fibrosis.

In the European Union, incentives for manufacturers to develop medicinal products for the treatment of rare diseases are provided pursuant to the Orphan Medicinal Products Regulation (141/2000). 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 incentives 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.

We have been granted orphan designation throughout the EU for ZADAXIN for treatment of hepatocellular carcinoma, and for CPX for 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. The recently enacted Best Pharmaceuticals for Children Act provides an additional six months of marketing exclusivity for new or marketed drugs for certain pediatric testing conducted at the written request of the FDA.

We may seek the benefits of additional orphan, DPCPTRA, or fast track provisions, but we cannot assure 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 certain preclinical studies and clinical trials 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.

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. An unapproved drug may be exported to a "listed country" (Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and countries in the European Union and the European Economic Area) for investigational purposes without FDA authorization if exported in accordance with laws of the foreign country, and in accordance with the export requirements. Export of drugs to an unlisted country for clinical trial purposes continues to require FDA approval. 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. 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.

Failure to comply with applicable U.S. or foreign regulatory requirements 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. Further, additional government regulation may be established or imposed by legislation or otherwise, which could prevent or delay regulatory approval of ZADAXIN, CPX or any of our 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.

The level of revenues and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce the costs of health care through various means, including the extent and availability of reimbursement. We are unable to predict when any proposed health care reforms will be implemented, if ever, or the effect of the implemented reforms on our business.

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, SCV-07 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 EU marketing and development partner Sigma-Tau.

### **Third Party Reimbursement**

ZADAXIN is a relatively expensive therapeutic product. The amount of product utilized by the patient depends on the disease, the dose, and length of treatment. The cost will typically be several thousands of U.S. dollars for a course of therapy. Currently, ZADAXIN is sold principally in countries without broad government provided health care reimbursement programs or adequate and widely distributed private health insurers or other third party payor organizations. This lack of third party reimbursement impedes the availability of ZADAXIN to the broad affected patient populations in markets where it is approved. 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, 2002, we had 97 employees, 23 in the U.S., and 74 in foreign offices. We consider our relations with our employees to be satisfactory.

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**

In January 2003, Sigma-Tau and its affiliates increased their aggregate ownership to close to 10% of SciClone's common stock outstanding by purchasing approximately 504,938 unregistered shares of common stock directly from the company for \$1.8 million. Prior to this transaction, all warrants held by Sigma-Tau to purchase a total of 400,000 shares of SciClone's common stock were cancelled, and no new warrants were issued.

### **Available Information**

We file electronically with the Securities and Exchange Commission (or SEC) our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may

obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is <http://www.sec.gov>.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at <http://www.sciclone.com>, by contacting the Investor Relations Department at our corporate offices by calling 800-724-2566 or by sending an e-mail message to [investorrelations@sciclone.com](mailto:investorrelations@sciclone.com).

### Executive Officers of the Registrant

As of February 28, 2003, the executive officers of the Company, who are elected by and serve at the discretion of the Board of Directors, were as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Donald R. Sellers .....	58	President, Chief Executive Officer, and Director, SciClone Pharmaceuticals, Inc.; Managing Director, SciClone Pharmaceuticals International Ltd.
Alfred R. Rudolph, M.D. ....	55	Chief Operating Officer
Richard A. Waldron .....	49	Chief Financial Officer

*Donald R. Sellers* has served as SciClone's President, Chief Executive Officer and Director since 1996. From 1993 to present, he has also served as Managing Director of SciClone Pharmaceuticals International Ltd. At SciClone, Mr. Sellers has helped to acquire global rights to ZADAXIN®, the Company's leading immune system enhancing drug, to bring ZADAXIN into phase 3 clinical trials in the U.S. and Japan and into 30 countries where it is sold worldwide generating revenues of \$17 million in 2002. Mr. Sellers has nearly 30 years of experience in the global pharmaceutical industry, working with SciClone, Pfizer, Revlon Healthcare Group and Sterling Drug International. Mr. Sellers spent five years in Military Intelligence serving with Special Forces and as a Counter-Intelligence Special Agent. He has an A.B. degree from Lafayette College and a Master of International Management degree with honors from the American Graduate School of International Management. Mr. Sellers speaks five languages.

*Alfred R. Rudolph, M.D.*, Chief Operating Officer of SciClone Pharmaceuticals, Inc., has over 30 years of experience in the biopharmaceutical industry. Since joining SciClone in April 1997, Dr. Rudolph has been responsible for the clinical, research, regulatory, manufacturing, and quality assurance functions of the Company. Before joining SciClone, Dr. Rudolph was President and Chief Operating Officer of Neptune Pharmaceuticals, Inc., a marine-based natural product screening company. Previously, Dr. Rudolph was Senior Vice President of T Cell Sciences, Inc., Director of Clinical Operations at Cetus Corporation, and Clinical Assistant Professor of Medicine at University of California, San Francisco. He began his pharmaceutical career with Bristol Myers, where he worked in cancer drug development. Dr. Rudolph earned a B.S. in Electrical Engineering from the University of Rochester, and completed his fellowship training in Hematology-Oncology at Syracuse University.

*Richard A. Waldron*, Chief Financial Officer of SciClone Pharmaceuticals, Inc., has over twenty years experience in the financing and management of biotechnology companies. Prior to joining SciClone in March 2001, 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, 2002.

**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
<b>2002</b>		
4th quarter .....	\$4.35	\$2.50
3rd quarter .....	3.27	1.98
2nd quarter .....	4.98	1.97
1st quarter .....	4.85	2.13
<b>2001</b>		
4th quarter .....	\$3.45	\$2.50
3rd quarter .....	5.13	2.50
2nd quarter .....	5.83	3.77
1st quarter .....	7.75	3.69

**Recent Sales of Securities**

In January 2003, the Company completed a direct placement to affiliates of Sigma-Tau, in reliance upon Regulation D of the Securities Act of 1933, as amended. The affiliates purchased 504,938 shares of SciClone's common stock at \$3.5648 per share. The shares issued were restricted securities, and Sigma Tau and its affiliates are not permitted to sell any of the shares purchased in this private placement until January 24, 2004. Prior to this transaction, 400,000 warrants held by Sigma-Tau to purchase shares of SciClone's common stock were cancelled.

In June 2002, we completed a \$10,600,000 direct offering of common stock to institutional investors. The direct offering consisted of 4,088,460 registered shares of common stock at \$2.60 per share.

**Shareholders**

As of March 4, 2003, there were approximately 393 holders of record and approximately 17,910 beneficial holders of our common stock and 37,465,064 shares of common stock issued and outstanding.

As of December 31, 2002, 36,904,916 shares of common stock were outstanding. If all options, warrants, and convertible securities outstanding were exercised or converted into shares of Common Stock, 8,436,262 shares would be issued and would result in total shares of common stock outstanding of 45,341,178.

**Dividends**

We have not paid any dividends on our common stock during the fiscal years ended December 31, 2000, 2001, and 2002 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.

	Year Ended December 31,				
	2002	2001	2000	1999	1998
<b>Statements of Operations data:</b>					
Product sales . . . . .	\$ 17,101,000	\$ 13,831,000	\$15,357,000	\$ 9,091,000	\$ 3,625,000
Contract/grant revenue . . . . .	671,000	—	—	307,000	100,000
Total revenues . . . . .	17,772,000	13,831,000	15,357,000	9,398,000	3,725,000
Cost of product sales . . . . .	3,487,000	2,742,000	3,113,000	1,761,000	1,036,000
Gross margin . . . . .	14,285,000	11,089,000	12,244,000	7,637,000	2,689,000
Operating expenses:					
Research and development . . . . .	11,647,000	8,561,000	4,182,000	4,604,000	9,293,000
Sales and marketing . . . . .	8,724,000	8,764,000	7,720,000	5,503,000	5,123,000
General and administrative . . . . .	3,902,000	3,897,000	3,538,000	3,386,000	3,982,000
Total operating expenses . . . . .	24,273,000	21,222,000	15,440,000	13,493,000	18,398,000
Loss from operations . . . . .	(9,988,000)	(10,133,000)	(3,196,000)	(5,856,000)	(15,709,000)
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 . . . . .	323,000	751,000	1,066,000	157,000	514,000
Interest and investment expense . . . . .	(361,000)	(334,000)	(36,000)	—	(21,000)
Other income (expense), net . . . . .	(11,000)	(13,000)	49,000	212,000	89,000
Net loss . . . . .	(10,037,000)	(6,232,000)	(1,717,000)	(5,467,000)	(21,071,000)
Deemed dividend on issuance of preferred stock . . . . .	—	—	—	—	(3,143,000)
Net loss attributable to common shareholders . . . . .	<u>\$(10,037,000)</u>	<u>\$(6,232,000)</u>	<u>\$(1,717,000)</u>	<u>\$(5,467,000)</u>	<u>\$(24,214,000)</u>
Basic and diluted net loss attributable to common shareholders per share . . . . .	<u>\$ (0.29)</u>	<u>\$ (0.19)</u>	<u>\$ (0.06)</u>	<u>\$ (0.26)</u>	<u>\$ (1.48)</u>
Weighted average shares used in computing basic and diluted net loss per share . . . . .	<u>35,002,003</u>	<u>32,356,287</u>	<u>29,904,924</u>	<u>21,162,936</u>	<u>16,335,096</u>

	December 31,				
	2002	2001	2000	1999	1998
<b>Balance Sheet data:</b>					
Cash, cash equivalents and investments .....	\$21,150,000	\$16,468,000	\$22,497,000	\$ 3,621,000	\$ 5,410,000
Working capital .....	29,116,000	26,930,000	30,281,000	7,091,000	3,845,000
Total assets .....	37,111,000	32,096,000	36,167,000	13,124,000	11,727,000
Redeemable preferred stock .....	—	—	—	—	848,000
Total shareholders' equity .....	23,354,000	22,774,000	28,077,000	9,301,000	6,428,000
Convertible notes payable .....	5,600,000	5,600,000	4,000,000	—	—

**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" contained in this Annual Report on Form 10-K.

**Overview**

During the periods encompassed by this Annual Report on Form 10-K, we have devoted substantially all of our resources to our ZADAXIN clinical trials and our ZADAXIN commercialization activities. We conduct our research and 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 is conducted by our executive officers and other staff from our headquarters located in San Mateo, California.

From commencement of operations through December 31, 2002, we have an accumulated deficit of approximately \$133,000,000. We expect our sales, gross margin and operating expenses to increase over the next several years as we expand our research and development, clinical testing and sales and marketing capabilities. Our ability to achieve and sustain operating profitability is primarily dependent on the initiation, execution and completion of 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 orders for ZADAXIN from international markets, particularly China, 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 or delays 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 States, which 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. 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 the Company, 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 on the achievement of the milestones, as defined in the respective agreements and provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there are no future performance obligations associated with the milestone payment.

To date we have not recorded estimated reductions to revenue for expected sales returns as we have not experienced any 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, 2002, sales to six importing agents in China accounted for 88% of the Company's product sales and sales to four importing agents accounted for 89% and 86% of our product sales for the years ended December 31, 2001 and 2000, respectively. In 2002, the largest customer accounted for 41% of sales and the second largest customer accounted for 27% of sales. No other

customers accounted for more than 10% of sales in 2002. In 2001, the largest customer accounted for 47% of sales and the second largest customer accounted for 30% of sales. No other customers accounted for more than 10% of sales in 2001. In 2000, the largest customer accounted for 63% of sales and the second largest customer accounted for 14% of sales. No other customers accounted for more than 10% of sales in 2000. As of December 31, 2002, approximately \$8,627,000 or 87% of our accounts receivable were attributable to four customers in China. We perform on-going credit evaluations of our customers' financial condition, and generally do not require collateral from our 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% of past due accounts receivable based on the length of time the receivables are past due and our collectibility experience.

#### *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 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, 2002, we had net intangible assets of \$682,000 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.

#### *Research and Development Expenses*

Our phase 3 clinical trials in the U.S. will increase our research and development expenditures significantly over the next year. Research and development expenditures are charged to operations as incurred. Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous institutions that conduct the clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. Expenses related to grants to the institutions are accrued based on the level of patient enrollment and activity according to the protocol. In general, these expenses will be higher for the initial and final months of a patient's scheduled 18 months of treatment and observation. Expenses relating to the clinical research organization managing the trials and laboratory and other direct expenses are recognized in the period they are incurred and the services performed. 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 \$17,101,000, \$13,831,000 and \$15,357,000 for the years ended December 31, 2002, 2001 and 2000, respectively. The increase in sales from 2001 to 2002 was primarily due to increased sales volume to our importing agents in China, whereas the greater sales in 2000 compared to 2001 was primarily due to a large sale of ZADAXIN to a new importer in China during the third quarter of 2000. For the year ended December 31, 2002, importing agents in China accounted for 88% of our product sales and accounted for 89% and 86% for the years ended December 31, 2001 and 2000, 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 actively marketed. 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. However, our primary corporate focus is the execution and funding of our phase 3 clinical trials in the U.S. Because we are concentrating our resources on these efforts, we are focusing our international sales and marketing efforts on maintaining and developing sales in existing active markets rather than investing in the development of new markets. Although we remain optimistic regarding the prospects of ZADAXIN, we cannot assure that we will achieve sales increases, maintain existing sales levels, or that we will receive additional marketing indication approvals for ZADAXIN. 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 additional future operating losses.

As part of our collaborative agreement with Sigma-Tau, we received a \$2,685,000 payment from Sigma-Tau in January 2002 which is being recognized evenly as contract revenue over the period of our U.S. hepatitis C clinical development activities, estimated to be three years beginning in the second quarter of 2002.

Cost of product sales was \$3,487,000, \$2,742,000 and \$3,113,000 for the years ended December 31, 2002, 2001 and 2000, 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 \$14,285,000, \$11,089,000 and \$12,244,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Gross profit margin was 80% in 2002, 2001 and 2000. We expect slight decreases in gross margin going forward in international markets including China, our largest and most mature market, should we maintain our product pricing and absorb any increases in product costs.

Research and development expenses were \$11,647,000, \$8,561,000 and \$4,182,000 for the years ended December 31, 2002, 2001, and 2000, respectively. The increase in each year was primarily to support our ZADAXIN phase 3 clinical trials in the U.S. and Japan. In 2002, 2001 and 2000, research and development (R&D) expenses represented approximately 48%, 40% and 27%, respectively, of our total costs and expenses. The major components of R&D expenses consist of clinical studies performed by clinical trial institutions and contract research organizations, related materials and supplies, preclinical work, pharmaceutical development, personnel costs, including salaries and benefits, third party research funding, 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 clinical access programs. Pharmaceutical development costs consist of product formulation and chemical analysis. During 2002, we recorded approximately \$2,300,000 on research, \$8,300,000 on clinical development, and \$1,100,000 on pharmaceutical development activities. This compares to expenses in 2001 of approximately \$2,800,000 on research, \$5,000,000 on clinical development, and \$800,000 on pharmaceutical development activities and expenses in 2000 of approximately \$2,400,000 on research, \$500,000 on clinical development, and \$1,300,000 on pharmaceutical development activities.

The initiation and continuation of our 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. Due to the uncertain nature of the clinical trial process, and enrollment rates in particular, it is not possible to determine the timing of completion or total cost expected to be incurred for each trial. In general, we expect 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 \$8,724,000, \$8,764,000 and \$7,720,000 for the years ended December 31, 2002, 2001 and 2000, respectively. The decrease from 2001 to 2002 was related to slightly lower promotional and advertising expenses. The increase from 2000 to 2001 was 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.

General and administrative expenses were \$3,902,000, \$3,897,000 and \$3,538,000 for the years ended December 31, 2002, 2001 and 2000, respectively. The increase from 2000 to 2001 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 increase 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 and \$400,000 for the years ended December 31, 2001 and 2000, 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 was fully repaid in the third quarter of 2001.

Interest and investment income was approximately \$323,000, \$751,000 and \$1,066,000 for the years ended December 31, 2002, 2001 and 2000, respectively. The decrease over the years was due to lower average invested cash balances and lower interest rates.

Interest and investment expense was approximately \$361,000, \$334,000 and \$36,000 for the years ended December 31, 2002, 2001 and 2000, respectively. The increase over the years was from the interest accrued on senior unsecured convertible notes.

### **Liquidity and Capital Resources**

At December 31, 2002, 2001 and 2000, we had \$21,151,000, \$16,468,000 and \$22,497,000, respectively, in cash, cash equivalents and short-term investments. The short-term investments consist primarily of highly liquid marketable securities. We have two letters of credit each secured by a certificate of deposit. At December 31, 2002, the letters of credit total \$685,000, one for \$633,000 under our lease agreement, the other for \$52,000 to facilitate our value added tax filings in Europe.

Net cash used in operating activities totaled \$5,869,000, \$12,008,000 and \$5,917,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Net cash used in operating activities for the year ended December 31, 2002 was less than the net loss primarily due to the receipt of a payment from Sigma-Tau of \$2,685,000 for a clinical trial collaboration which increased deferred revenue balances, increases in accounts payable, increases in accrued clinical trials expense and, decreases in inventories, partially offset by increases in prepaid expenses and accounts receivable. 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, an increase in inventories 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 inventories. These increases in 2000 were partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable.

Net cash provided by investing activities of \$7,000 for the year ended December 31, 2002 related to the net sale of \$73,000 in short term investments and purchases of \$66,000 in property and equipment. Net cash used in investing activities of \$450,000 for the year ended December 31, 2001 related to the net purchases of \$351,000 in short term investments and \$99,000 in property and equipment. Net cash used in investing

activities of \$430,000 for the year ended December 31, 2000 related to the net purchases of \$331,000 in short term investments partially offset by the purchases of \$99,000 in property and equipment.

Net cash provided by financing activities totaled \$10,577,000, \$5,995,000 and \$24,886,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Net cash provided by financing activities for the year ended December 31, 2002 consisted of approximately \$9,914,000 from a direct offering of common stock to institutional investors, approximately \$514,000 related to exercises of outstanding options under our employee stock option plans and \$149,000 for the issuance of common stock under our employee stock purchase plan. 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, 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, \$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.

The following tables summarize our contractual cash obligations and other commitments as of December 31, 2002.

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
Convertible notes payable	\$ 5,600,000	—	\$4,000,000	\$1,600,000	—
Operating leases	\$ 6,262,000	\$1,302,000	\$2,750,000	\$2,210,000	—
Minimum annual royalty obligations	\$ 390,000	\$ 65,000	\$ 195,000	\$ 130,000	—
Total contractual cash obligations	\$12,252,000	\$1,367,000	\$6,945,000	\$3,940,000	—
		<u>Amount of Commitment Expiration Per Period</u>			
<u>Other Commercial Commitments</u>	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>After 5 years</u>
Letters of credit	\$ 685,000	\$ 685,000	—	—	—

There are no officers or directors that were involved in related party transactions in 2002.

We believe 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 through equity or debt financing or from a collaborative partner. 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 our expectations, or a combination thereof, we believe our existing capital resources and interest on funds available are adequate to maintain our current and planned operations into 2004. We are actively reviewing alternatives for equity or debt financings and potential partnering activities.

## Income Taxes

At December 31, 2002, we had net operating loss carryforwards for federal income tax purposes of approximately \$71,400,000 which expire in the years 2006 through 2022. 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, 2002, we had federal tax credit carryforwards of approximately \$4,100,000 which expire in the years 2009 through 2022.

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 Statement of Financial Accounting Standards No. 148 "Accounting for Stock-Based Compensation — Transition and Disclosure" ("SFAS 148") in December 2002. SFAS 148 amends Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation" ("SFAS 123") to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of SFAS 148 are effective for fiscal years ending after December 15, 2002 and have been included in the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The Company has elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," to account for employee stock options.

## Risk Factors

*You should carefully consider the risks described below, in addition to the other information 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 clinical trials in the U.S. for the approval of ZADAXIN in combination with pegylated interferon alpha for the treatment of hepatitis C may fail, which will harm our business.**

Currently, there is no U.S. FDA approved therapy for hepatitis C patients who have failed to respond to prior therapy with interferon alpha plus ribavirin or with interferon alpha alone. We designed our phase 3 clinical trials based on the use of ZADAXIN in combination with pegylated interferon alpha to address this medical need. There can be no assurances that the results from our previous hepatitis C studies with ZADAXIN and non-pegylated interferon alpha which enabled us to produce this design will carryover to the trials involving a combination of ZADAXIN and pegylated interferon alpha and any resulting data may be insufficient or inadequate to demonstrate appropriate efficacy under FDA guidelines. In addition, insufficient data resulting from the clinical trials would also adversely affect our ability to market and sell ZADAXIN in markets where it is approved for sale. In 2002 we began enrolling patients in both of the phase 3 trials in our hepatitis C clinical program in the U.S.; however, there are trials being conducted by competitors seeking to enroll similar patients and competition for appropriate patients for these clinical trials is significant. We may not be able to enroll patients quickly enough to meet our timing expectations for completing the trial which would delay the preparation of a new drug application (NDA); or we may not be able to fully enroll the studies or patient drop out rates could be higher than anticipated, either of which could weaken the quality of an NDA. Our hepatitis C clinical trials have been designed to show that the combination of ZADAXIN and pegylated interferon alpha adds a significant clinical benefit when compared to the use of pegylated interferon alpha alone in the re-treatment of hepatitis C patients who have not responded to prior therapy. However, the

independent use of the pegylated form of interferon alpha may perform better than anticipated which could weaken the quality of an NDA. ZADAXIN has been used both clinically and commercially in thousands of patients without producing any reported ZADAXIN related significant side effects or toxicities, and the pegylated interferon alpha used in the clinical trials has been approved by the FDA and has documented adverse side effects. Should the combination therapy of ZADAXIN and pegylated interferon alpha cause significant new or to a greater degree the same adverse side effects, our clinical trials could be delayed, patients may drop out at a greater than anticipated rate, we may be forced to halt the trials, or the FDA may reject an NDA due to safety issues. If any of the foregoing occurs, our efforts to market and sell ZADAXIN will be impaired, our business will suffer and the price of our stock may decline.

**Our phase 3 clinical trials in Japan for the approval of ZADAXIN for the treatment of hepatitis B may fail, which will harm our business.**

There is a need for better hepatitis B therapies that improve efficacy and do not cause side effects. Our phase 3 clinical trial was designed based on the use of ZADAXIN to address this medical need. There can be no assurances that the results from our previous hepatitis B studies that enabled this design will carryover to the trials involving ZADAXIN and any resulting data may be insufficient or inadequate to demonstrate appropriate efficacy under Japanese Ministry of Health guidelines. In addition, insufficient data resulting from the clinical trial would also adversely affect our ability to market and sell ZADAXIN in markets where it is approved for sale. We may not be able to compile and analyze trial data quickly enough to meet our timing expectations, which would delay the preparation of a Japanese new drug application (JNDA). Our hepatitis B clinical trial was designed to show that ZADAXIN adds a significant clinical benefit in the treatment of hepatitis B patients. Although ZADAXIN has been used safely by over 10,000 patients to date, should ZADAXIN cause significant adverse side effects, our JNDA could be delayed or the Japanese Ministry of Health may reject our JNDA on safety issues. If any of the foregoing occurs, our efforts to market and sell ZADAXIN will be impaired, and our business will suffer and the price of our stock may decline.

**We rely on third parties to manufacture our clinical trial product. Deficiencies in their work could delay or harm our trials or the approval process and harm our business.**

We manufacture the ZADAXIN used in our phase 3 trials under cGMP guidelines and under our direct manufacturing and quality control using third party cGMP manufacturers and suppliers. If unanticipated deficiencies in these manufacturers or suppliers occur, this could create a delay in the assembling of a timely and acceptable NDA. Not all of the ZADAXIN planned to be used in our hepatitis C clinical trials has been manufactured and received. Pegylated interferon alpha is being supplied to us by Roche on an as needed basis. Any delay in receiving or recall of pegylated interferon alpha or ZADAXIN could delay the clinical trials or detract from the integrity of the trial data. If any of the foregoing occurs, our efforts to market and sell ZADAXIN in combination with pegylated interferon alpha will be impaired, our business will suffer and the price of our stock may decline.

**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 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 fulfill 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. We have experienced difficulties with the formulation of CPX which has delayed its further development. 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; however, until we obtain additional resources, substantially all of our resources are focused on the development of ZADAXIN. 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. Failure to do so will hurt our operations.

**If we fail to satisfy and comply with governmental regulations or if government regulations change, our business may 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 indications or 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.

**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 or prevent 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. 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 approval in these countries. 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 will limit our revenues.

In addition, adverse results that occur in our clinical trials could result in restrictions on the use of ZADAXIN, which may also hurt our business.

**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 that we will ever achieve more 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, any of which may harm our business and cause our stock price to fall.

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; whether any or all of our outstanding convertible notes are converted to common stock; 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, 2002, we had an accumulated deficit of approximately \$133,000,000. 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.

**Our revenue is 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 product revenue 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 China. Sales of ZADAXIN in China may be limited due to its low average personal income, lack of patient cost reimbursement, poorly developed infrastructure, and existing and potential competition from other products, including generics. We are currently in the process of renewing our importation permit to allow us to continue to sell our product to the importers in China. Our business would be severely harmed if we were unable to renew the permit or if the renewal process were prolonged and we were not granted an exemption to make periodic shipments into China. In China ZADAXIN is sold as an imported finished product. The attractiveness of the ZADAXIN market has encouraged local companies to introduce lower priced locally manufactured generic competitive products. As this occurs, there could be a negative impact on the price and the volume of ZADAXIN sold to this country and this would harm our business.

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.

**Because of China's tiered method of importing and distributing finished pharmaceutical products, our quarterly results may vary substantially from one period to the next.**

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 a small number of 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.

**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 and we anticipate changes will be needed if our volume requirements increase. 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 would 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.**

The clinical development of ZADAXIN is our primary product development objective; however, if we do not devote additional resources to CPX or 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 hurt our business and cause 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, market or 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 may be 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, market or sell our products or maintain our competitive position with respect to our products. Although many of our patents relating to ZADAXIN have expired, 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 operations 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 amortization or impairment of goodwill or 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, and

cancer. 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 outside of the U.S. as a treatment for hepatitis C and hepatitis B and certain cancers as our primary source of product revenue. Several large biopharmaceutical companies have substantial commitments to interferon alpha, an approved drug for treating hepatitis B and hepatitis C, and to lamivudine and adefovir, approved drugs 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, cancer, and other diseases that will be superior to ours.

In the U.S., our product ZADAXIN is being evaluated in combination with pegylated interferon alpha for the treatment of hepatitis C patients who have failed to respond to prior therapy with interferon alpha plus ribavirin or with interferon alpha alone. Other companies are researching, developing, or marketing other products for use alone or in combination with interferon alphas or pegylated interferon alphas for clinical indications including HCV and HBV. Such competitive products include ribavirin, allegedly improved ribavirin molecules and other products not yet in late stage clinical trials such as therapeutic vaccines and reverse transcriptase inhibitors. Our clinical trials may not show ZADAXIN to have advantages over such existing or future competitive products nor to have clinically significant synergistic value.

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 development may create new competitors. We cannot assure you that we will be able to successfully compete with any such competitors.

**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 essentially 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.

**The current geopolitical situation in the Middle East and other countries may cause our business to suffer.**

If the current geopolitical conditions in the Middle East and North Korea continue or worsen resulting global developments 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 the current war on terrorism causes economic slowdowns in the economies of or business disruptions in 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 essentially all of our product revenue, then our sales could decrease. In addition, our commercial product is manufactured in Europe and distributed by us from our operations in Hong Kong. Any disruption of our supply and distribution activities due to war or acts of terrorism could decrease our sales. Any decrease in sales 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 were 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 be adversely 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.

**Future changes in financial accounting standards may cause adverse unexpected revenue or expense fluctuations, affect our reported or future results of operations or impact our reported or future financial position.**

A change in accounting policies can have a significant effect on our reported results and may affect our reporting of transactions completed before the change is effective. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or financial position or the way we conduct our business. Specifically, legislative and other proposals could result in changes to accounting rules requiring us to account for employee stock options issued at market value as an expense. These and other potential changes could materially increase the expenses we report under generally accepted accounting principles, and adversely affect our operating results.

**Compliance with legislative actions and changing regulations related to corporate governance and public disclosure may result in additional expenses including higher insurance costs.**

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq Stock Market rules, are creating increased requirements for companies such as ours and there may be additional regulatory rulings and changes. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, insurers have increased rates as a result of higher claims rates over the past year and may increase rates in future years. Our rates for our various insurance policies have increased significantly and may increase further in future years.

**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.**

U.S. and global economies have weakened due to the effects and uncertainties caused by the events of September 2001 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. We cannot assure you that the price of our common stock will remain at or exceed current levels.

**Our indebtedness may result in future liquidity problems.**

As of December 31, 2002, we had \$5,600,000 in convertible notes payable, \$4,000,000 of which were issued in the quarter ended December 31, 2000 and \$1,600,000 in the quarter ended March 31, 2001. This indebtedness, or additional debt we may incur to fund our operations, may make it more difficult for us to obtain additional financing. The outstanding 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, 2002 we had cash, cash equivalents and short-term investments of \$21,100,000.

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

As of December 31, 2002, stock options for 5,097,482 shares of common stock were outstanding, of which options for 3,677,142 shares were exercisable. Also outstanding as of the same date were warrants exercisable for 1,970,500 shares of common stock at prices ranging from \$2.25 to \$31.33 per share, 400,000 of which were cancelled in January 2003, and two issues of notes convertible into a total of 684,140 shares of common stock. In addition, the note holder has 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 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 solely in U.S. Treasury or U.S. government agency notes. Our investments in these notes are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short-term notes and maintain an average maturity of less than one year. A hypothetical 60 basis point increase in interest rates would result in an approximate \$90,355 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, 2002. Actual results may differ materially.

Substantially all our sales and manufacturing costs to date have been in U.S. dollars. Accordingly, we currently have no material exposure to foreign currency rate fluctuations.

Item 8. *Financial Statements and Supplementary Data*

**SCICLONE PHARMACEUTICALS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

**Consolidated Financial Statements at December 31, 2002 and 2001 and for  
Each of the Three Years in the Period Ended December 31, 2002**

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## 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, 2002 and 2001, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. Our audits also included the financial statement schedule listed at Item 15(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, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, 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 30, 2003

**SCICLONE PHARMACEUTICALS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	<u>December 31, 2002</u>	<u>December 31, 2001</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 20,233,000	\$ 15,518,000
Restricted short-term investments .....	685,000	633,000
Other short-term investments .....	232,000	317,000
Accounts receivable, net of allowances of \$638,000 in 2002 and 2001 .....	9,276,000	8,792,000
Inventories .....	3,431,000	4,059,000
Prepaid expenses and other current assets .....	<u>2,297,000</u>	<u>1,333,000</u>
Total current assets .....	36,154,000	30,652,000
Property and equipment, net .....	111,000	167,000
Intangible assets, net .....	682,000	1,091,000
Other assets .....	<u>164,000</u>	<u>186,000</u>
Total assets .....	<u>\$ 37,111,000</u>	<u>\$ 32,096,000</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 3,150,000	\$ 1,575,000
Accrued compensation and employee benefits .....	1,089,000	960,000
Accrued clinical trials expense .....	966,000	296,000
Accrued professional fees .....	679,000	633,000
Deferred revenue .....	895,000	—
Other accrued expenses .....	<u>259,000</u>	<u>258,000</u>
Total current liabilities .....	7,038,000	3,722,000
Deferred revenue .....	1,119,000	—
Convertible notes payable .....	5,600,000	5,600,000
Commitments and contingencies		
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; 36,904,916 shares in 2002 and 32,474,150 shares in 2001 issued and outstanding .....	156,290,000	145,713,000
Accumulated other comprehensive income .....	79,000	39,000
Accumulated deficit .....	<u>(133,015,000)</u>	<u>(122,978,000)</u>
Total shareholders' equity .....	<u>23,354,000</u>	<u>22,774,000</u>
Total liabilities and shareholders' equity .....	<u>\$ 37,111,000</u>	<u>\$ 32,096,000</u>

See notes to consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2002	2001	2000
Revenues:			
Product sales .....	\$ 17,101,000	\$13,831,000	\$15,357,000
Contract revenue .....	671,000	—	—
Total revenues .....	17,772,000	13,831,000	15,357,000
Cost of product sales .....	3,487,000	2,742,000	3,113,000
Gross margin .....	14,285,000	11,089,000	12,244,000
Operating expenses:			
Research and development .....	11,647,000	8,561,000	4,182,000
Sales and marketing .....	8,724,000	8,764,000	7,720,000
General and administrative .....	3,902,000	3,897,000	3,538,000
Total operating expenses .....	24,273,000	21,222,000	15,440,000
Loss from operations .....	(9,988,000)	(10,133,000)	(3,196,000)
Interest and investment income .....	323,000	751,000	1,066,000
Interest and investment expense .....	(361,000)	(334,000)	(36,000)
Other income (expense), net .....	(11,000)	(13,000)	49,000
Income from payment on note receivable from former officer .....	—	3,497,000	400,000
Net loss .....	\$(10,037,000)	\$(6,232,000)	\$(1,717,000)
Basic and diluted net loss per share .....	\$ (0.29)	\$ (0.19)	\$ (0.06)
Weighted average shares used in computing basic and diluted net loss per share .....	35,002,003	32,356,287	29,904,924

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, 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
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	342,306	663,000	—	—	663,000
Issuance of common stock from private placements	4,088,460	9,914,000	—	—	9,914,000
Net loss	—	—	—	(10,037,000)	(10,037,000)
Net unrealized gain on available-for-sale securities	—	—	40,000	—	40,000
Total comprehensive loss					(9,997,000)
Balance at December 31, 2002	<u>36,904,916</u>	<u>\$156,290,000</u>	<u>\$79,000</u>	<u>\$(133,015,000)</u>	<u>\$ 23,354,000</u>

See notes to consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31.		
	2002	2001	2000
<b>Operating activities:</b>			
Net loss .....	\$(10,037,000)	\$ (6,232,000)	\$(1,717,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	556,000	556,000	529,000
Non-cash gain on equity securities .....	—	(52,000)	—
Gain from payment on note receivable from former officer .....	—	(3,497,000)	(400,000)
Changes in operating assets and liabilities:			
Accounts receivable .....	(484,000)	(171,000)	(4,278,000)
Inventories .....	628,000	(2,039,000)	(939,000)
Prepaid expenses and other assets .....	(967,000)	(205,000)	621,000
Accounts payable and other accrued expenses .....	1,576,000	(603,000)	466,000
Accrued clinical trials expense .....	670,000	94,000	(57,000)
Accrued professional fees .....	46,000	(32,000)	(199,000)
Accrued compensation and employee benefits .....	129,000	173,000	57,000
Deferred revenue .....	2,014,000	—	—
Net cash used in operating activities .....	<u>(5,869,000)</u>	<u>(12,008,000)</u>	<u>(5,917,000)</u>
<b>Investing activities:</b>			
Purchase of property and equipment .....	(66,000)	(99,000)	(99,000)
Proceeds from sale of short-term investments .....	73,000	—	—
Payment on purchase of short-term investments .....	—	(351,000)	(331,000)
Net cash provided by (used in) investing activities ..	<u>7,000</u>	<u>(450,000)</u>	<u>(430,000)</u>
<b>Financing activities:</b>			
Proceeds from issuance of common stock, net .....	10,577,000	898,000	20,486,000
Payment on notes receivable from former and current officers .....	—	3,497,000	400,000
Proceeds from issuance of convertible note .....	—	1,600,000	4,000,000
Net cash provided by financing activities .....	<u>10,577,000</u>	<u>5,995,000</u>	<u>24,886,000</u>
Net increase (decrease) in cash and cash equivalents .....	4,715,000	(6,463,000)	18,539,000
Cash and cash equivalents, beginning of year .....	15,518,000	21,981,000	3,442,000
Cash and cash equivalents, end of year .....	<u>\$ 20,233,000</u>	<u>\$ 15,518,000</u>	<u>\$21,981,000</u>
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for interest .....	\$ 336,000	\$ 308,000	\$ —

See notes to consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIALS STATEMENTS**

**Note 1 — The Company and Summary of Significant Accounting Policies**

*The Company*

SciClone Pharmaceuticals, Inc. (“SciClone” or the “Company”) is a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases. The Company’s lead product ZADAXIN is in several late-stage clinical trials, including two phase 3 hepatitis C clinical trials in the U.S., a recently completed phase 3 hepatitis B clinical trial in Japan, a phase 2 malignant melanoma clinical trial in Europe, and two phase 2 liver cancer trials in the U.S. ZADAXIN has been approved for sale by the ministries of health in over 30 countries and is marketed in China and selected other countries outside the U.S. primarily for the treatment of hepatitis B and hepatitis C.

*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.

*Revenue Recognition*

The Company recognizes revenue from product sales at the time of shipment. 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 on the achievement of the milestones, as defined in the respective agreements and provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there are no future performance obligations associated with the milestone payment.

*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.

**SCICLONE PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)**

We are required by our lease agreement to have a letter of credit secured by a certificate of deposit of \$633,000 at December 31, 2002. Under our European value added tax filing arrangement, we have a letter of credit secured by a certificate of deposit of \$52,000 at December 31, 2002.

The Company classifies its 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 debt instruments. Unrealized gains or losses are included in accumulated other comprehensive income on the consolidated balance sheet. 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 are determined on the basis of specific identification. Management believes the credit risk associated with these investments is limited due to the nature of the investments.

For the years ended December 31, 2002, 2001 and 2000, net unrealized gains of approximately \$40,000, \$31,000 and \$6,000, respectively, were included in accumulated other comprehensive income. For the years ended December 31, 2002, 2001 and 2000, net realized gains were less than \$1,000 for all years.

*Inventories*

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

*Property and Equipment*

Property and equipment is stated at cost, less accumulated depreciation. Depreciation is recorded over the estimated useful lives of the respective assets (three to five years) on the straight-line basis. Leasehold improvements are amortized over the shorter of the estimated useful life or lease term on the straight-line basis. Depreciation expense for the years ended December 31, 2002, 2001 and 2000 was \$122,000, \$146,000 and \$120,000, respectively.

*Intangible Assets*

Intangible assets include the following:

	December 31,	
	2002	2001
Intangible product rights .....	\$ 2,456,000	\$ 2,456,000
Accumulated amortization .....	(1,774,000)	(1,365,000)
	\$ 682,000	\$ 1,091,000

In December 1997 the Company entered into an agreement with Alpha 1 Biomedicals, Inc. ("A1B") to acquire the worldwide rights, except in Italy, Spain and Portugal, where Sclavo S.p.A. ("Sclavo"), an international pharmaceutical entity, owned exclusive marketing rights, to ZADAXIN, which rights A1B had licensed from Hoffmann-LaRoche, Inc. and F. Hoffmann-LaRoche AG, for approximately \$1,800,000. The transaction closed in July 1998 and eliminated the Company's royalty obligation to A1B with respect to all sales of ZADAXIN after the acquisition date. In April 1998, the Company entered into an agreement with Sclavo to acquire 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 expensed \$700,000 related to Hepatitis C in-process technology.

Acquired ZADAXIN product rights are being amortized on a straight-line basis beginning in September 1998. Amortization expense for the years ended December 31, 2002, 2001 and 2000 was \$409,000 per year

## SCICLONE PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

based on an estimated useful life of six years. Amortization expense for the years 2003 through 2012 is expected to be \$70,000 per year as the Company has reassessed the estimated useful life of the assets to be an additional eight years as of December 31, 2002 given that its European patent for the use of ZADAXIN in the treatment of hepatitis C expires in 2012. The Company reassesses the useful life of these assets in accordance with current facts and circumstances.

The Company's policy is to identify and record impairment losses 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. The Company to date has not identified any impairment losses on these assets. 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 has been approved for sale in over 30 countries, 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 future cash flows exceed the carrying amount of the assets.

#### *Foreign Currency Translation*

The Company translates the assets and liabilities of its foreign subsidiaries stated in local functional currencies to U.S. dollars at the rates of exchange in effect at the end of the period. Revenues and expenses are translated using rates of exchange in effect during the period. Gains and losses from the translation of financial statements denominated in foreign currencies, if material, are included as a separate component of other comprehensive income (loss) in the statement of shareholders' equity. There have been no accumulated currency translation gains or losses included in any period presented.

The Company records foreign currency transactions at the exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currency are retranslated at the exchange rates in effect at the balance sheet date. All translation differences arising from foreign currency transactions are included in results of operations and have not been significant.

#### *Research and Development Expenses*

Research and development expenditures are charged to operations as incurred. Major components of research and development expenses consist of clinical development performed on our behalf by institutions and contract research organizations, personnel costs, including salaries and benefits, 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.

The continuation of ZADAXIN clinical trials have had, and are expected to continue to have, the largest and most significant effect on our research and development expenses. Cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous institutions that conduct the clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses to the actual services received and efforts expended. Expenses related to grants to institutions that conduct the clinical trials on our behalf are accrued based on the level of patient enrollment and activity according to the protocol. In general, these expenses will be higher for the initial and final months of a patient's scheduled 18 months of treatment and observation. Expenses relating to the clinical research organization (CRO) managing the trials and laboratory and other direct expenses are

## SCICLONE PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

recognized in the period they are incurred and the services performed. The Company monitors patient enrollment levels and related activity to the extent possible and adjusts estimates accordingly.

Our phase 3 clinical trials in the U.S. will increase our research and development expenditures significantly over the next year. Research and development expenditures are charged to operations as incurred. Our cost accruals for clinical trials are based on estimates of the services received and efforts expended. Expenses related to grants to the institutions are accrued based on the level of patient enrollment and activity according to the protocol. In general, these expenses will be higher for the initial and final months of a patient's scheduled 18 months of treatment and observation. Expenses relating to the clinical research organization managing the trials and laboratory and other direct expenses are recognized in the period they are incurred and the services performed. 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.

#### *Shipping and Handling Costs*

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

#### *Advertising Expenses*

The Company expenses advertising costs as incurred and these costs are included in sales and marketing expenses for all periods presented. Advertising expenses for the years ended December 31, 2002, 2001 and 2000 were \$108,000, \$233,000 and \$204,000, respectively.

#### *Income Taxes*

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some or all of the deferred tax assets may not be realized.

#### *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. 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 8,436,262, 8,265,637 and 7,211,797 shares in 2002, 2001 and 2000, respectively, related to convertible notes payable, outstanding options and warrants regardless of conversion or exercise prices, 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

**SCICLONE PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)**

does not generally recognize compensation expense in accounting for its stock option and employee stock purchase plans for awards to employees and directors.

Pro forma information regarding net loss and net loss per share is required by Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation" ("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 2002, 2001 and 2000: risk-free interest rates of 2.00%, 4.00% and 6.00%, respectively; dividend yield of 0%; volatility factors of the expected market price of the Company's common stock of 0.96, 0.96 and 0.97, respectively, and a weighted average expected life of the option of 3.88 years, 3.94 years and 3.90 years, respectively. The weighted average estimated fair value of options granted was \$2.75 for 2002, \$2.72 for 2001 and \$7.31 for 2000. The fair value for the employee stock purchases was also estimated using the Black-Scholes model with the following assumptions for 2002, 2001 and 2000: risk-free interest rate of 2.00%, 4.00% and 6.00%, respectively; dividend yield of 0%; expected volatility of 0.96, 0.96 and 0.97, respectively, and expected life of 0.25 years. The weighted average estimated fair value of the employee stock purchase plan shares purchased was \$0.99 for 2002, \$1.86 for 2001 and \$1.96 for 2000.

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 2002, 2001 and 2000 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:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net loss — as reported .....	\$(10,037,000)	\$(6,232,000)	\$(1,717,000)
Total stock-based employee compensation expense determined under the fair value based method for all awards .....	<u>(2,283,000)</u>	<u>(2,756,000)</u>	<u>(1,962,000)</u>
Net loss — pro forma .....	<u>\$(12,320,000)</u>	<u>\$(8,988,000)</u>	<u>\$(3,679,000)</u>
Basic and diluted net loss per share — as reported	<u>\$ (0.29)</u>	<u>\$ (0.19)</u>	<u>\$ (0.06)</u>
Basic and diluted net loss per share — pro forma ..	<u>\$ (0.35)</u>	<u>\$ (0.28)</u>	<u>\$ (0.12)</u>

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 due to the different number of options granted each year.

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 separately included in the financial statements 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.

SCICLONE PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

*Comprehensive Income (Loss)*

The Company reports changes in unrealized gains or losses on the Company's available-for-sale securities in comprehensive income (loss). For the years ended December 31, 2002, 2001 and 2000, total comprehensive loss amounted to \$9,997,000, \$6,201,000 and \$1,711,000, 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. For the year ended December 31, 2002, sales to six importing agents in China accounted for 88% of the Company's product sales and sales to four importing agents accounted for 89% and 86% of our product sales for the years ended December 31, 2001 and 2000, respectively. In 2002, the largest customer accounted for 41% of sales and the second largest customer accounted for 27% of sales. No other customers accounted for more than 10% of sales in 2002. In 2001, the largest customer accounted for 47% of sales and the second largest customer accounted for 30% of sales. No other customers accounted for more than 10% of sales in 2001. In 2000, the largest customer accounted for 63% of sales and the second largest customer accounted for 14% of sales. No other customers accounted for more than 10% of sales in 2000. As of December 31, 2002, approximately \$8,627,000, or 87% of the Company's accounts receivable were attributable to four importing agents 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 and the Company's collectibility experience.

*Recent Accounting Pronouncements*

The Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148 "Accounting for Stock-Based Compensation-Transition and Disclosure" ("SFAS 148") in December 2002. SFAS 148 amends SFAS 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of SFAS 148 are effective for fiscal years ending after December 15, 2002 and have been included in these financial statements. The Company has elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," to account for employee stock options.

*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.

SCICLONE PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

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	Estimated Fair Value
<b>December 31, 2002:</b>			
Certificate of deposit .....	\$ 787,000	\$ —	\$ 787,000
U.S. government obligations .....	13,723,000	—	13,723,000
Corporate equity securities .....	51,000	79,000	130,000
	<u>\$14,561,000</u>	<u>\$79,000</u>	<u>\$14,640,000</u>
<b>December 31, 2001:</b>			
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
	<u>\$11,774,000</u>	<u>\$39,000</u>	<u>\$11,813,000</u>

As of December 31, 2002, the total available-for-sale securities are included as follows, \$13,723,000 in cash and cash equivalents, \$685,000 in restricted short-term investments and \$232,000 in other short-term investments. 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 \$317,000 in other short-term investments. As of December 31, 2002 and 2001 all available-for-sale securities had maturities of 12 months or less.

Note 3 — Inventories

Inventories consisted of the following:

	December 31,	
	2002	2001
Raw materials .....	\$2,190,000	\$2,759,000
Work in progress .....	159,000	869,000
Finished goods .....	1,082,000	431,000
	<u>\$3,431,000</u>	<u>\$4,059,000</u>

SCICLONE PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

**Note 4 — Property and Equipment**

Property and equipment consisted of the following:

	December 31,	
	2002	2001
Office furniture and fixtures .....	\$ 134,000	\$ 120,000
Office equipment .....	504,000	465,000
Leasehold improvements .....	<u>121,000</u>	<u>108,000</u>
	759,000	693,000
Less accumulated depreciation and amortization .....	<u>(648,000)</u>	<u>(526,000)</u>
Net property and equipment .....	<u>\$ 111,000</u>	<u>\$ 167,000</u>

**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 December 2001, this license was further amended to define the scope of clinical development for ZADAXIN that Sigma-Tau would undertake in Europe. Under the terms of the December 2001 amendment, the Company received \$2,685,000 in the first quarter of 2002. This contract revenue is being recognized over the three years commencing April 2002, the estimated time to complete the ZADAXIN hepatitis C U.S. clinical program and anticipated FDA regulatory filings, the substantive performance requirements under the contract amendment. For the year ended December 31, 2002, the Company recognized \$671,000 as contract revenue and the remaining \$2,014,000 is recorded as deferred revenue as of December 31, 2002.

In April 1998, the Company entered into an agreement to acquire 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 related to hepatitis C in-process technology.

In August 1997 the Company entered into a ZADAXIN Patent License Agreement with The Fitzsimons Army Medical Center of the U.S. Army (the "U.S. Army"). The Company is obligated to pay the U.S. Army

**SCICLONE PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)**

a minimum annual royalty and a royalty based on a percentage of ZADAXIN net sales revenue upon commercialization of ZADAXIN for treatment of chronic hepatitis C in certain countries, including the U.S., the European Union and Japan, but not including China.

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. Initially, 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 domestic and foreign components of loss before income tax and net loss at December 31 are as follows:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Domestic .....	\$ (9,510,000)	\$(4,445,000)	\$(3,287,000)
Foreign .....	<u>(527,000)</u>	<u>(1,787,000)</u>	<u>1,570,000</u>
Loss before income tax expense .....	<u>\$ (10,037,000)</u>	<u>\$ (6,232,000)</u>	<u>\$ (1,717,000)</u>

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

	<u>2002</u>	<u>2001</u>
<b>Assets</b>		
Net operating loss carryforwards .....	\$ 25,133,000	\$ 21,158,000
R&D credit carryforwards .....	4,466,000	3,462,000
Note receivable written off for financial reporting .....	—	1,275,000
Other .....	<u>1,121,000</u>	<u>1,553,000</u>
Gross deferred tax assets .....	30,720,000	27,448,000
Valuation allowance .....	<u>(30,720,000)</u>	<u>(27,448,000)</u>
Total deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance increased by approximately \$3,272,000, \$1,734,000 and \$3,774,000 in the years ended December 31, 2002, 2001 and 2000, respectively. Deferred tax assets relating to carryforwards as of December 31, 2002 include approximately \$6,401,000 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, 2002 or 2001.

At December 31, 2002, the Company has net operating loss carryforwards for federal income tax purposes of approximately \$71,400,000 which expire in the years 2006 through 2022. The difference between the cumulative losses for financial reporting purposes and federal income tax purposes is primarily attributable

SCICLONE PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

to losses incurred by the Company's foreign subsidiaries. At December 31, 2002, the Company has federal tax credit carryforwards of approximately \$4,100,000, which expire in the years 2009 through 2022.

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, 2002, 2001 and 2000.

**Note 7 — Commitments and Contingencies**

*Leases*

The Company leases its main office facility under a non-cancelable operating lease agreement which expires in August 2007. The lease is for a period of seven 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 2003 and 2005. Rental expense in 2002, 2001 and 2000 was \$1,376,000, \$1,296,000 and \$498,000, respectively. Minimum future rental payments amount to \$1,302,000 in 2003, \$1,323,000 in 2004, \$1,427,000 in 2005, \$1,280,000 in 2006 and \$930,000 in 2007.

*Royalties*

Under the August 1997 ZADAXIN Patent License Agreement with the U.S. Army, the Company is obligated to pay the U.S. Army a minimum annual royalty and a royalty based on a percentage of ZADAXIN net sales revenue upon commercialization of ZADAXIN for treatment of chronic hepatitis C in certain countries including the U.S., the European Union and Japan, but not including China. During 2002, 2001 and 2000 the Company paid \$20,000 per year related to the minimum annual royalty.

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 2002, 2001 and 2000 the Company paid \$45,000, \$45,000, and \$30,000, respectively, related to the minimum annual royalty.

*Convertible Notes Payable*

In March 2001, the Company issued a \$1,600,000 senior unsecured convertible note with an investment affiliate of UBS AG. The \$1,600,000 note is convertible into 276,530 shares of common stock at a fixed conversion price of \$5.7860 per share. The note accrues interest at a rate of 6% per year payable semi-annually and will mature in March 2006. The Company also received \$354,000 for granting the investor the right to purchase, at any time up to the note's maturity date, approximately \$2,400,000 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 \$4,000,000 senior unsecured convertible note with an investment affiliate of UBS AG. The \$4,000,000 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 payable semi-annually 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 note's maturity date, approximately \$5,900,000 of senior unsecured convertible notes due December 2005. If issued, the notes will bear no interest (zero coupon) and will be

## SCICLONE PHARMACEUTICALS, INC.

### NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

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 and Warrants*

In June 2002, the Company completed a direct offering of common stock to institutional investors. The Company raised net proceeds of \$9,914,000 from the offering of 4,088,460 shares of common stock at \$2.60 per share.

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. In January 2003, all of Sigma-Tau's warrants were cancelled (see Note 11 — Subsequent Events).

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 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, 2002, none of these warrants had been exercised.

In June 1998, the Company entered into an agreement with an institutional investor for an equity line that was cancelled in November 1999. 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. As of December 31, 2002, none of the foregoing warrants had been exercised.

In connection with other equity offerings, the Company has granted additional five-year warrants to investors to purchase 100,000 shares of common stock at an exercise price of \$5.67 per share. Of this amount, warrants to purchase 37,500 shares have been exercised for aggregate proceeds to the Company of approximately \$213,000. As of December 31, 2002, the remaining warrants to purchase 62,500 shares were outstanding.

##### *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, June 2000 and June 2002 the Board of Directors and shareholders of the Company approved increases of 1,500,000, 1,250,000 and 1,350,000, respectively, in the shares reserved under the 1995 Plan.

**SCICLONE PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)**

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 and June 2002 the Board of Directors and shareholders of the Company approved 250,000 increases in the shares reserved for issuance under the Nonemployee Director Plan. In May 2002, the shareholders of the Company approved to increase the Annual Grant from 10,000 shares to 20,000 shares.

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 and last trading day of each quarterly participation period. Under the ESPP, the Company sold 67,160, 33,009 and 144,505 shares to employees in 2002, 2001 and 2000, 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	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
<b>Balance at December 31, 1999</b> .....	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
<b>Balance at December 31, 2000</b> .....	1,878,972	4,426,077	5.00
Options canceled .....	214,415	(214,415)	7.27
Options granted .....	(946,800)	946,800	3.98
Options exercised .....	—	(231,605)	1.83
Plan shares expired .....	(120,718)	—	—

SCICLONE PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)

	Shares Available For Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
<b>Balance at December 31, 2001</b> .....	1,025,869	4,926,857	4.86
1995 Plan shares reserved .....	1,350,000	—	—
Nonemployee Director Plan shares reserved .....	250,000	—	—
Options canceled .....	349,979	(349,979)	6.67
Options granted .....	(795,500)	795,500	4.13
Options exercised .....	—	(274,896)	1.87
Plan shares expired .....	(126,542)	—	—
<b>Balance at December 31, 2002</b> .....	<u>2,053,806</u>	<u>5,097,482</u>	\$ 4.76

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2002:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 1.22 – \$ 1.59 .....	968,082	6.35	\$ 1.38	962,344	\$ 1.38
\$ 1.75 – \$ 3.68 .....	1,236,720	7.14	3.13	813,141	2.87
\$ 3.69 – \$ 4.50 .....	916,021	8.35	4.21	268,523	4.20
\$ 4.60 – \$ 5.50 .....	874,834	4.27	5.27	806,417	5.32
\$ 5.88 – \$10.75 .....	1,020,825	6.20	9.40	745,717	8.99
\$12.50 .....	<u>81,000</u>	.87	12.50	<u>81,000</u>	12.50
	<u>5,097,482</u>	6.43	4.76	<u>3,677,142</u>	4.57

**401k Plan**

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 an employee's salary. Company contributions, which can be terminated at the Company's discretion, were approximately \$83,000, \$73,000 and \$58,000 for the years ended December 31, 2002, 2001 and 2000, respectively.

**Reserved Shares**

As of December 31, 2002, the Company had reserved shares of common stock for future issuance as follows, excluding warrants to purchase 400,000 shares held by Sigma-Tau that were cancelled in January 2003 (see Note 11 — Subsequent Events):

Options outstanding .....	5,097,482
Warrants outstanding .....	1,970,500
Convertible notes payable .....	1,368,280
ESPP .....	<u>135,443</u>
	<u>8,571,705</u>

**SCICLONE PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)**

**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, the only product that the Company sells.

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 of the business segment.

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:

	<u>Product Sales for the Year Ended December 31,</u>	<u>Contract Revenue for the Year Ended December 31,</u>	<u>Long Lived Assets December 31,</u>	<u>Net Assets December 31.</u>
<b>2002:</b>				
U.S. ....	\$ —	\$ —	\$ 624,000	\$ 9,417,000
China .....	15,073,000	—	99,000	13,728,000
Other .....	<u>2,028,000</u>	<u>671,000</u>	<u>234,000</u>	<u>209,000</u>
Total .....	<u>\$17,101,000</u>	<u>\$671,000</u>	<u>\$ 957,000</u>	<u>\$23,354,000</u>
<b>2001:</b>				
U.S. ....	\$ —	\$ —	\$ 945,000	\$ 8,407,000
China .....	12,325,000	—	137,000	13,968,000
Other .....	<u>1,506,000</u>	<u>—</u>	<u>362,000</u>	<u>399,000</u>
Total .....	<u>\$13,831,000</u>	<u>\$ —</u>	<u>\$1,444,000</u>	<u>\$22,774,000</u>
<b>2000:</b>				
U.S. ....	\$ —	\$ —	\$1,157,000	\$17,063,000
China .....	13,174,000	—	144,000	10,973,000
Other .....	<u>2,183,000</u>	<u>—</u>	<u>495,000</u>	<u>41,000</u>
Total .....	<u>\$15,357,000</u>	<u>\$ —</u>	<u>\$1,796,000</u>	<u>\$28,077,000</u>

Two customers accounted for 10% or more of total revenues (41% and 27%) for the year ended December 31, 2002. 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. No other customer accounted for more than 10% of revenues during these years.

**SCICLONE PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIALS STATEMENTS — (Continued)**

**Note 10 — Selected Quarterly Financial Data (unaudited)**

	Three Months Ended			
	March 31	June 30	September 30	December 31
<b>2002:</b>				
Product sales .....	\$ 3,948,000	\$ 4,048,000	\$ 4,298,000	\$ 4,807,000
Contract revenue .....	—	223,000	224,000	224,000
Cost of product sales .....	792,000	815,000	918,000	962,000
Gross margin .....	3,156,000	3,457,000	3,604,000	4,068,000
Net loss .....	(2,403,000)	(3,345,000)	(1,672,000)	(2,617,000)
Basic and diluted net loss per share	(0.07)	(0.10)	(0.05)	(0.07)
<b>2001:</b>				
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
Income from payment on notes receivable from former officer...	—	—	3,497,000	—
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)

**Note 11 — Subsequent Events**

In January 2003, SciClone completed a direct placement to affiliates of Sigma-Tau, in reliance upon Regulation D of the Securities Act of 1933, as amended. The affiliates purchased 504,938 shares of the Company's common stock at \$3.5648 per share. The shares issued were restricted securities, and Sigma Tau and its affiliates are not permitted to sell any of the shares purchased in this private placement until January 24, 2004. Prior to this transaction, warrants held by Sigma-Tau to purchase 400,000 shares of SciClone's common stock were cancelled.



TABEND



TABEND



TABEND

**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 2003 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 and Related Shareholder Matters**

**Equity Compensation Plan Information**

We currently maintain five compensation plans that provide for the issuance of our common stock to officers and other employees, directors and consultants. These consist of the 1991 Stock Plan, the 1992 Stock Plan, the 1995 Equity Incentive Plan, the Nonemployee Director Stock Option Plan and the 1996 Employee Stock Purchase Plan, which plans have all been approved by the Company's shareholders. The Company does not currently maintain any compensation plans that have not been approved by the Company's shareholders. The following table sets forth information regarding outstanding options and shares reserved for future issuance under the foregoing plans as of December 31, 2002:

<u>Plan Category</u>	<u>Number of Shares to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)</u>	<u>Number of Shares Remaining Available for Future Issuance Under Equity Compensation Plans (excluding shares reflected in column (a)) (c)</u>
Equity compensation plans approved by shareholders:			
1991 Stock Plan .....	1,484,662	\$5.1831	0
1992 Stock Plan .....	102,667	\$4.9801	0
1995 Equity Incentive Plan .....	3,052,653	\$4.3635	1,768,806
1995 Nonemployee Director Stock Option Plan .....	457,500	\$6,0269	285,000
1996 Employee Stock Purchase Plan .....			<u>137,804 (1)</u>
Total .....	<u>5,097,482</u>	<u>\$5.1384</u>	<u>2,191,610</u>

(1) 1996 Employee Stock Purchase Plan is a voluntary plan open to all employees. This plan allows employees to elect payroll deductions which are used to purchase SciClone's common stock directly from the Company.

The information required by Item 403 of Regulation S-K 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. Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our filings under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our Chief Executive Officer and the Chief Financial Officer, with the assistance of other members of our management, have evaluated our disclosure controls and procedures as defined in Rule 13a-14(c) under the Securities Exchange Act of 1934, within 90 days of the filing date of this report, and have concluded based on that evaluation that those disclosure controls and procedures are effective. Since the date of that evaluation, there have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls or in other factors that could significantly affect those controls.

**Item 15. 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 36-55 of this Report on Form 10-K:

Report of Ernst & Young LLP, Independent Auditors.

Consolidated Balance Sheets at December 31, 2002 and 2001.

Consolidated Statements of Operations for each of the three years in the period ended December 31, 2002.

Consolidated Statement of Shareholders' Equity for each of the three years in the period ended December 31, 2002.

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2002.

Notes to Consolidated Financial Statements.

(2) *Financial Statement Schedules*

The following schedule is contained on page 66 of this Report:

Schedule II — Valuation and Qualifying Accounts for each of the three years in the period ended December 31, 2002.

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 15(c) below.

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

None

(c) **Exhibits.**

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

<u>Exhibit Number</u>	<u>Description</u>
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.
4.1(14)	Rights Agreement dated as of July 25, 1997 between the Registrant and Chase Mellon Shareholder Services, L.L.C.

<u>Exhibit Number</u>	<u>Description</u>
4.2(21)*	6% Convertible Note dated as of December 7, 2000 by the Registrant in favor of UBS AG, London Branch.
4.3(21)*	Option Agreement dated as of October 26, 2000 by and between the Registrant and UBS AG, London Branch.
4.4(21)*	Amendment No. 1 to Option Agreement dated as of December 19, 2000 by and between the Registrant and UBS AG, London Branch.
4.5(22)*	6% Convertible Note dated as of March 21, 2001 by the Company in favor of UBS AG, London Branch.
4.6(22)*	Option Agreement dated as of February 16, 2001 by and between the Company and UBS AG, London Branch.
4.7(22)*	Amendment No. 1 to Option Agreement dated as of March 21, 2001 by and between the Company and UBS AG, London Branch.
10.1(2)**	Registrant's 1991 Stock Plan, together with forms of agreements thereunder.
10.2(1)**	Registrant's 1992 Stock Plan, together with forms of agreements thereunder.
10.3(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").
10.4(7)	Amendment No. 4 to Spieker Lease, dated October 4, 1994.
10.5(9)	Amendment No. 7 to Spieker Lease, dated November 14, 1995.
10.6(8)**	Registrant's 1995 Equity Incentive Plan, together with forms of agreement thereunder.
10.7(8)**	Registrant's 1995 Nonemployee Director Stock Option Plan, together with forms of agreement thereunder.
10.8(24)**	Registrant's 1996 Employee Stock Purchase Plan, together with forms of agreement thereunder.
10.9(21)	Second Amendment of Employment Agreement dated December, 2000 between the Registrant and Donald R. Sellers.
10.10(10)	License Agreement effective April 19, 1996 between the Registrant and the National Institute of Health Office of Technology Transfer.
10.11(11)	Amendment No. 8 to Spieker Lease, dated August 26, 1996.
10.12(21)	Amendment No. 14 to Spieker Lease dated November 21, 2000.
10.13(15)	Alpha Rights Acquisition Agreement by and between the Registrant and Alpha I Biomedicals, Inc., dated December 17, 1997.
10.14(16)*	Expanded and Amended Thymosin Alpha I License, Distributorship and Supply Agreement by and between the Company and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. dated as of March 3, 2000.
10.15(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.
10.16(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.
10.17(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.
10.18(18)	Registration Rights Agreement by and between the Company and Cheyenne LLC dated as of June 30, 1998.
10.19(19)	Acquisition Agreement between the Company and Sclavo S.p.A. dated April 20, 1998.

<u>Exhibit Number</u>	<u>Description</u>
10.20(19)	First Amendment to Acquisition Agreement between the Company and Sclavo S.p.A., dated April 20, 1998.
10.21(22)*	Registration Rights Agreement by and between the Company and UBS AG, London Branch dated as of February 16, 2001.
10.22(21)	Change in Control Agreement between the Company and Alfred Rudolph dated as of November 19, 1999.
10.23(21)	Change in Control Agreement between the Company and Donald R. Sellers dated as of November 19, 1999.
10.24(23)	Change in Control Agreement between the Company and Richard A. Waldron dated as of April 30, 2001.
10.25(24)*	Amendment No. 1 to the Expanded and Amended Thymosin Alpha 1 License, Distributorship and Supply Agreement by and between the Company and Sigma-Tau Farmaceutiche Riunite S.p.A. dated as of December 19, 2001.
10.26(24)*	Common Stock Purchase Agreement between the Company and each of Defiante Farmaceutica Ld.A. and Aptafin S.p.A. dated as of January 21, 2003.
21.1(23)	Subsidiaries of Registrant.
23.1(24)	Consent of Ernst & Young LLP, Independent Auditors.
24.1(24)	Powers of Attorney. See page 62.
99.1(24)	Certification of Chief Executive Officer.
99.2(24)	Certification of Chief Financial Officer.

\* 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.
- (23) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2001.
- (24) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2002 filed with the Securities and Exchange Commission and included in the EDGAR database filings.

## 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 26, 2003

## 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 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 to 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 on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ DONALD R. SELLERS (Donald R. Sellers)	President and Chief Executive Officer, Director Principal Executive Officer	March 26, 2003
/s/ RICHARD A. WALDRON (Richard A. Waldron)	Chief Financial Officer Principal Financial Officer	March 26, 2003
/s/ IVAN B. HUI (Ivan B. Hui)	Corporate Controller Principal Accounting Officer	March 26, 2003
/s/ JOHN D. BAXTER, M.D. (John D. Baxter, M.D.)	Director	March 26, 2003
/s/ EDWIN C. CADMAN, M.D. (Edwin C. Cadman, M.D.)	Director	March 26, 2003
/s/ JERE E. GOYAN, PH.D (Jere E. Goyan, Ph.D.)	Chairman of Board of Directors	March 26, 2003
/s/ ROLF H. HENEL (Rolf H. Henel)	Director	March 26, 2003
/s/ JON S. SAXE (Jon S. Saxe)	Director	March 26, 2003
/s/ DEAN S. WOODMAN (Dean S. Woodman)	Director	March 26, 2003

## CERTIFICATIONS

I, Donald R. Sellers, certify that:

1. I have reviewed this Annual Report on Form 10-K of SciClone Pharmaceuticals, Inc. (the registrant);

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/

DONALD R. SELLERS

Donald R. Sellers  
Chief Executive Officer

Date: March 26, 2003

## CERTIFICATIONS

I, Richard A. Waldron, certify that:

1. I have reviewed this Annual Report on Form 10-K of SciClone Pharmaceuticals, Inc. (the registrant);

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ RICHARD A. WALDRON

Richard A. Waldron  
*Chief Financial Officer*  
*(Principal Financial & Accounting Officer)*

Date: March 26, 2003

**SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS**

**SCICLONE PHARMACEUTICALS INC.**

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Charged to Costs and Expenses</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
<b>Year Ended December 31, 2002</b>				
Reserves and allowances deducted from asset accounts:				
Allowance for uncollectable accounts .....	\$638,000	\$ —	\$ —	\$638,000
Inventory reserve .....	\$400,000	\$ —	\$210,000	\$190,000
<b>Year Ended December 31, 2001</b>				
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
<b>Year Ended December 31, 2000</b>				
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