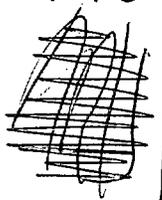


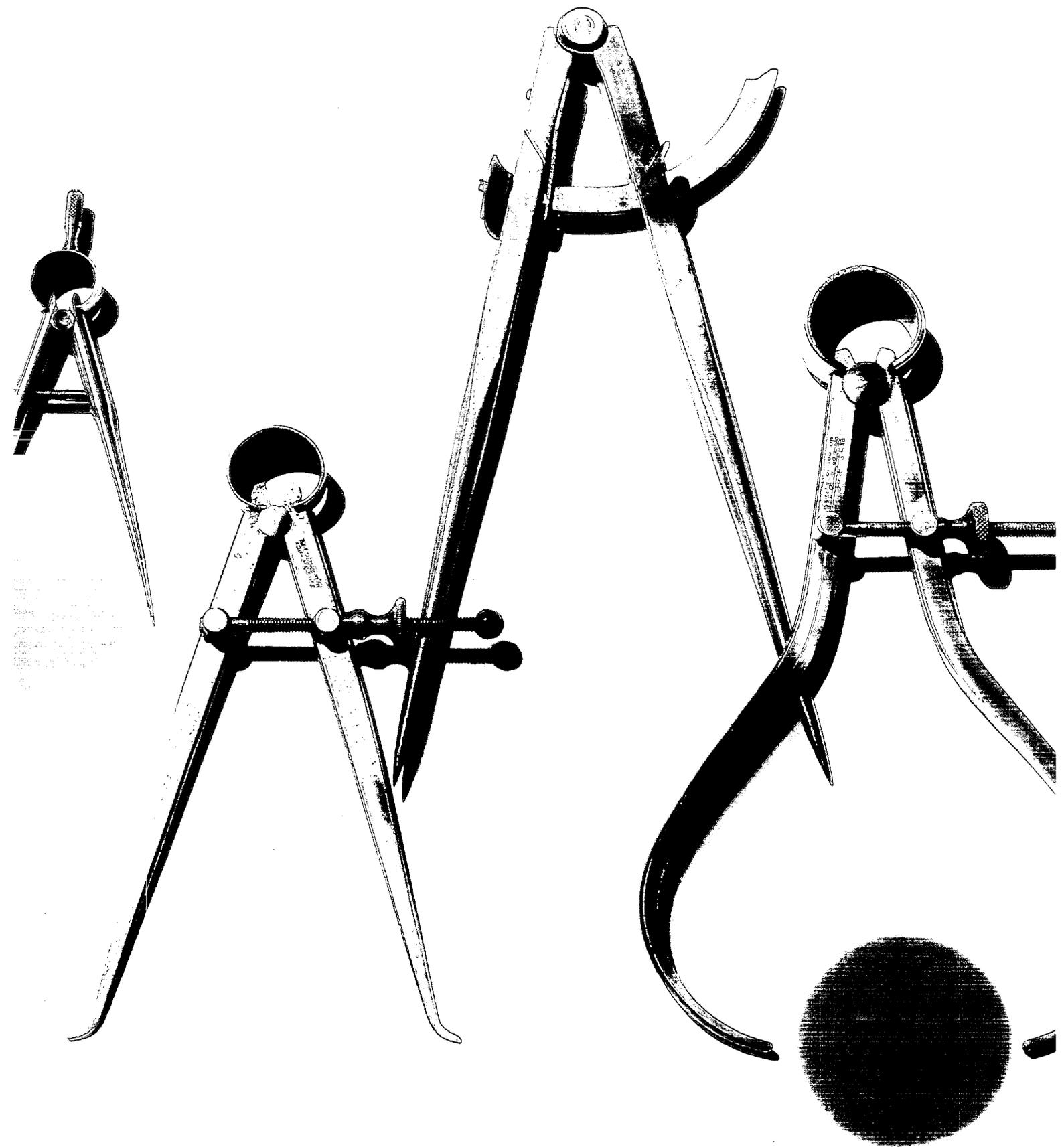


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Examine → Expand → Explore → 

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**MAY 15 2006**  
**B THOMSON FINANCIAL**





# Examine

## Dear Stockholders,

For SciClone, 2005 marked a year of advancement and transition. Sales of ZADAXIN continued to increase, with 22% revenue growth year over year, primarily due to increased demand in China, our largest market. We reported positive interim data from a large phase 2 malignant melanoma trial conducted by our European partner Sigma-Tau. We completed our proof-of-concept liver cancer trial and reported a positive trend in median survival for patients treated with ZADAXIN in combination with standard therapy. We concluded the first of our two phase 3 hepatitis C clinical trials, gathering extensive safety and efficacy data, though unfortunately the trial did not show statistical significance. We opened an Investigational New Drug (IND) application for SCV-07 and completed the initial phase 1 studies demonstrating safety and tolerability for this exciting and versatile drug candidate. And importantly, we appointed new management with extensive experience in international drug development and regulatory approvals to re-focus the company by building on our strengths to achieve clinical, commercial and financial success.

We are transitioning from being primarily a development company with international sales to becoming a biopharmaceutical company applying its competitive advantage in the rapidly growing Chinese pharmaceutical market. In the near-term, we plan to expand our product offerings in China while we advance the development of our proprietary products for selected promising opportunities in the major pharmaceutical markets.

## Expand on Our Success in China

Our successful sales and marketing operation in China distinguishes SciClone from the vast majority of biopharmaceutical and biotechnology companies. According to IMS Health, by 2010 the Chinese pharmaceutical market is expected to become the largest pharmaceutical market in the world outside of the United States and the European Union, creating a significant growth opportunity for Western pharmaceutical companies.

Since launching ZADAXIN in China in 1997, we have built a sales and marketing organization of over 100 medical representatives operating out of regional offices located in key metropolitan areas. These highly trained men and women have established valuable relationships with hospital-based physicians and pharmacists as well as medical thought leaders throughout China. We believe that today, ZADAXIN is a well-recognized, high-quality, imported, premium-priced product, largely due to our medical representatives' efforts to promote scientific knowledge about its varied clinical uses.

Building on our established reputation in China, we plan to expand our commercial portfolio by in-licensing or acquiring Chinese marketing rights to additional pharmaceutical products from Western biopharmaceutical and biotechnology companies. Our experience in this market and our ability to devote priority attention to each product provides our prospective partners with an effective and immediate pathway to introduce their products to this rapidly growing market. To maintain maximum efficiency in our existing operations, we will continue to focus on products in the areas of oncology, infectious disease and intensive care medicine. Importantly, these potential new products should be proprietary, with novel attributes that would be most effectively marketed by our highly-trained, scientifically-sophisticated and hospital-focused sales force.

Finally, in order to effectively expand our product offerings, we intend to add breadth to our Chinese operations by recruiting a few key experts familiar with the development and regulatory environment in China. These specialists will manage future Chinese clinical trials and regulatory submissions utilizing local experts and reputable Contract Research Organizations (CROs) that conduct clinical studies using Good Clinical Practices (GCP). We anticipate that this model would provide us with an extremely cost-effective means to conduct the clinical trials required for Chinese registration, while providing our partners with data useful for their product development efforts in other markets.

### **Explore Therapeutic Opportunities for ZADAXIN and SCV-07**

Our product development opportunities for the pharmaceutical markets in the United States and Europe are focused on both ZADAXIN and SCV-07. At the end of 2005, we and our European partner Sigma-Tau reported positive interim tumor response data from a large phase 2 clinical trial using ZADAXIN in combination with standard therapy to treat stage IV malignant melanoma. Data from this trial showed a distinct dose-dependent response in patients treated with increasing doses of ZADAXIN (1.6 and 3.2 mg) when used in combination with fixed doses of DTIC chemotherapy with or without low-dose interferon. Earlier in the year, Sigma-Tau added a 6.4 mg ZADAXIN arm to the trial to determine if the use of a higher dose of ZADAXIN would continue to provide a dose-dependent response in this patient population. We expect to report additional tumor response data as well as preliminary survival information from this trial later in 2006.

Also in late 2005, we reported results from a proof-of-concept study comparing the use of ZADAXIN with trans-arterial chemoembolization (TACE) to TACE alone in unresectable hepatocellular carcinoma, or primary liver cancer. For the group of patients who were randomized and received treatment, a median survival of 994 days was observed for the 14 patients who received ZADAXIN plus TACE, compared with a median survival of only 399 days for the 11 patients who received TACE alone. No difference was observed in tumor response between the treatment groups.

Based on data from these two cancer trials, we believe that developing ZADAXIN for an oncology indication is our best near-term opportunity for regulatory approval in the United States and Europe. We believe that the most expeditious pathway toward achieving this goal is in advanced stage malignant melanoma, a patient population which is in desperate need of new and more effective treatment alternatives. Following receipt of additional data from the phase 2 melanoma trial, we and Sigma-Tau expect to meet with regulatory authorities in the United States and Europe later this year to discuss our plans for initiating phase 3 clinical trials as soon as possible.

Importantly, in March 2006 we were granted Orphan Drug designation in the United States from the U.S. Food and Drug Administration (FDA), and have applied for similar Orphan Drug status with the European Agency for the Evaluation of Medical Products (EMEA). If we are successful in obtaining regulatory approval, Orphan Drug designation could provide SciClone exclusive marketing rights for thymosin alpha 1, the chemical composition of ZADAXIN, for the treatment of malignant melanoma for seven years in the United States and, if granted, up to ten years in the European Union.

We are excited about the potential opportunities for our other drug candidate, SCV-07. With evidence of clinical efficacy in multi-drug resistant tuberculosis and preclinical activity in several bacterial and viral disease models, SCV-07 has potential broad clinical applicability. To efficiently explore SCV-07's clinical prospects

and optimize our potential return from its development, we intend to initiate proof-of-concept trials with a subcutaneous formulation in a variety of disease settings. We believe our first significant opportunity is in vaccine sparing, that is, the ability to obtain effective vaccination using a lower dose of a scarce vaccine by adjunctive therapy with SCV-07. This may allow more people to be protected with a limited supply of vaccine. We expect to initiate a vaccine sparing trial with the influenza vaccine in the second half of 2006 to coincide with the flu vaccination season. As we look to expand the potential applications of SCV-07 further, we expect to initiate a phase 1 study with oral formulations of SCV-07 in the first half of this year. The availability of SCV-07 as an oral immunomodulating agent could broaden the potential of this drug significantly. In addition, using animal models, we are exploring opportunities for SCV-07 in additional indications, including certain cancers that proliferate due to a defect in the body's immune surveillance.

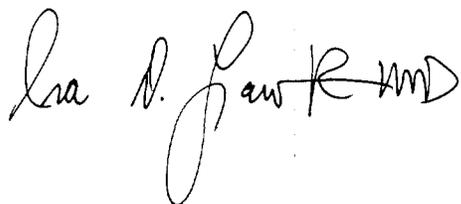
#### **Execute Our Strategy and Achieve Objectives to Deliver Value to Our Stockholders**

We believe the effective implementation of our plans for 2006 is essential to achieve our long-term objectives of building a strong pharmaceutical presence in China and efficiently developing ZADAXIN and SCV-07 for indications with promising market potential.

In 2006, we expect to in-license or acquire the rights for at least one product for our operations in China. In addition, we intend to expand our development and regulatory capabilities in China to facilitate the conduct of clinical trials and Chinese regulatory submissions for these compounds. We expect to report additional data from our phase 2 malignant melanoma clinical trials and discuss with the FDA and EMEA the appropriate regulatory pathway to obtain marketing approval for the use of ZADAXIN to treat melanoma. We expect that Sigma-Tau will continue to conduct the European clinical trial using ZADAXIN in a triple therapy combination to treat hepatitis C. And finally, we intend to initiate a vaccine sparing proof-of-concept clinical trial with SCV-07 in the United States and investigate its clinical use in an oral formulation in a phase 1 study.

I want to thank our employees for their dedication to SciClone, our investors for their continued belief in the company, and our directors and advisors for their guiding expertise as we pursue new development paths and strategic growth opportunities. It is an exciting time for SciClone, and I look forward to reporting our progress as we move forward.

Sincerely,



Ira D. Lawrence, M.D.  
March 29, 2006







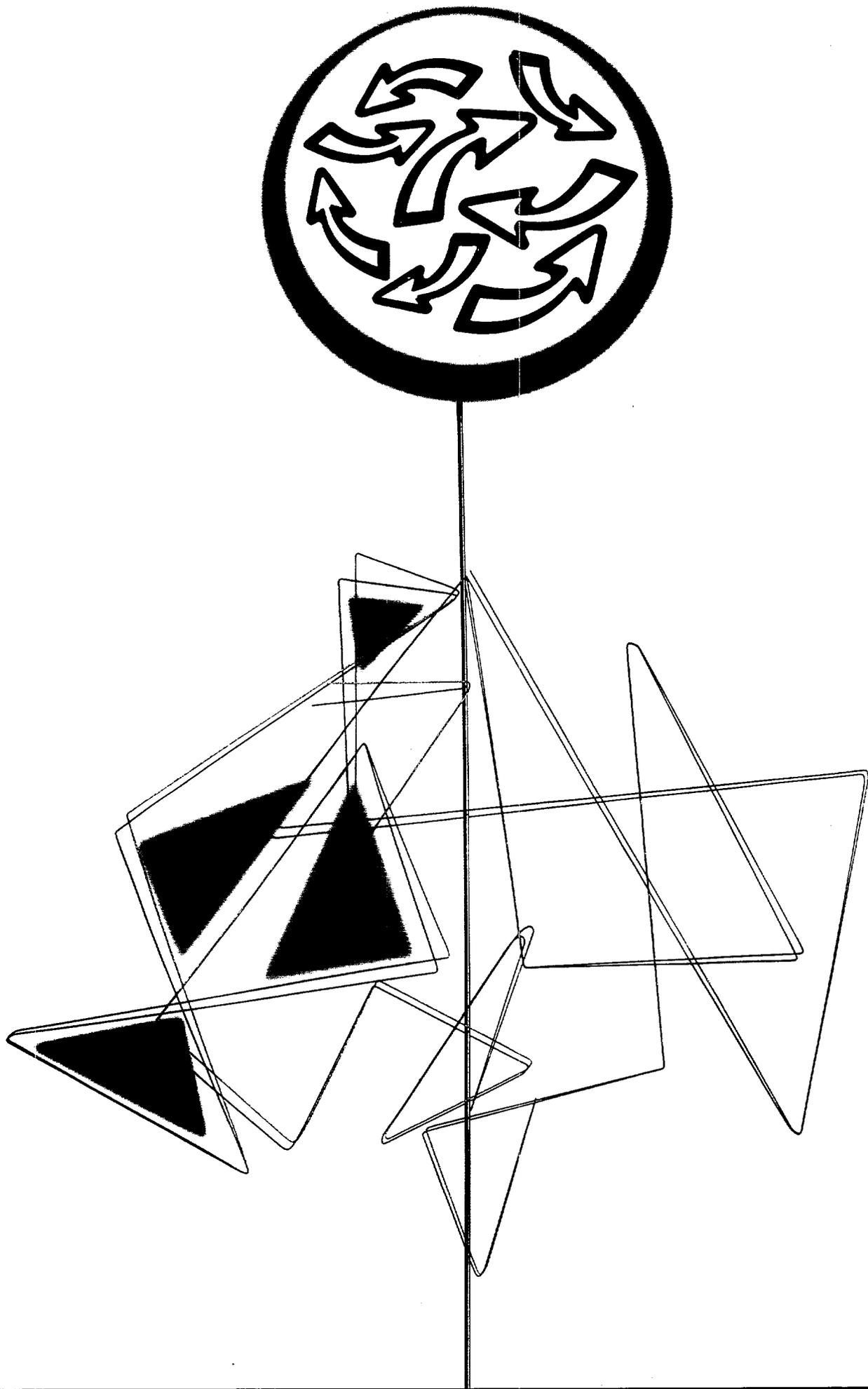
# Expand

## Poised for Growth in China

Currently estimated by IMS Health to be \$12 billion, the Chinese pharmaceutical market is growing at an average annual rate of 15 to 20%. By 2010, it is expected to surpass Japan and become the largest pharmaceutical market in the world outside of the United States and the European Union. Rapidly improving economic conditions and an aging population with increasing healthcare needs present tremendous opportunity to introduce new pharmaceutical products in this market. However, restructuring of the state healthcare system, changing regulatory environment and historical business practices pose challenges for Western biopharmaceutical companies wishing to enter this growing market today. As in any other business arena, the critical elements for success in China are knowledge, experience, relationships and resources.

In the ten years since SciClone received regulatory approval in China for ZADAXIN, we have worked hard to build it into one of the strongest brand name, imported pharmaceutical products in this market. This success is the direct result of our ever growing knowledge of, and experience in, this rapidly changing market where we have been able to focus our resources to develop strong relationships with medical thought-leaders, physicians, pharmacists, and distributors.

Because we see our presence in China as a core differentiating strength for SciClone, we plan to build on our success in this market by in-licensing or acquiring the marketing rights to late-stage or approved products. We believe our strong corporate and product reputation, in addition to our relationships with medical thought-leaders throughout China, will greatly facilitate our abilities to execute on this plan, and, importantly, would make us the partner of choice for companies interested in entering the Chinese pharmaceutical market.





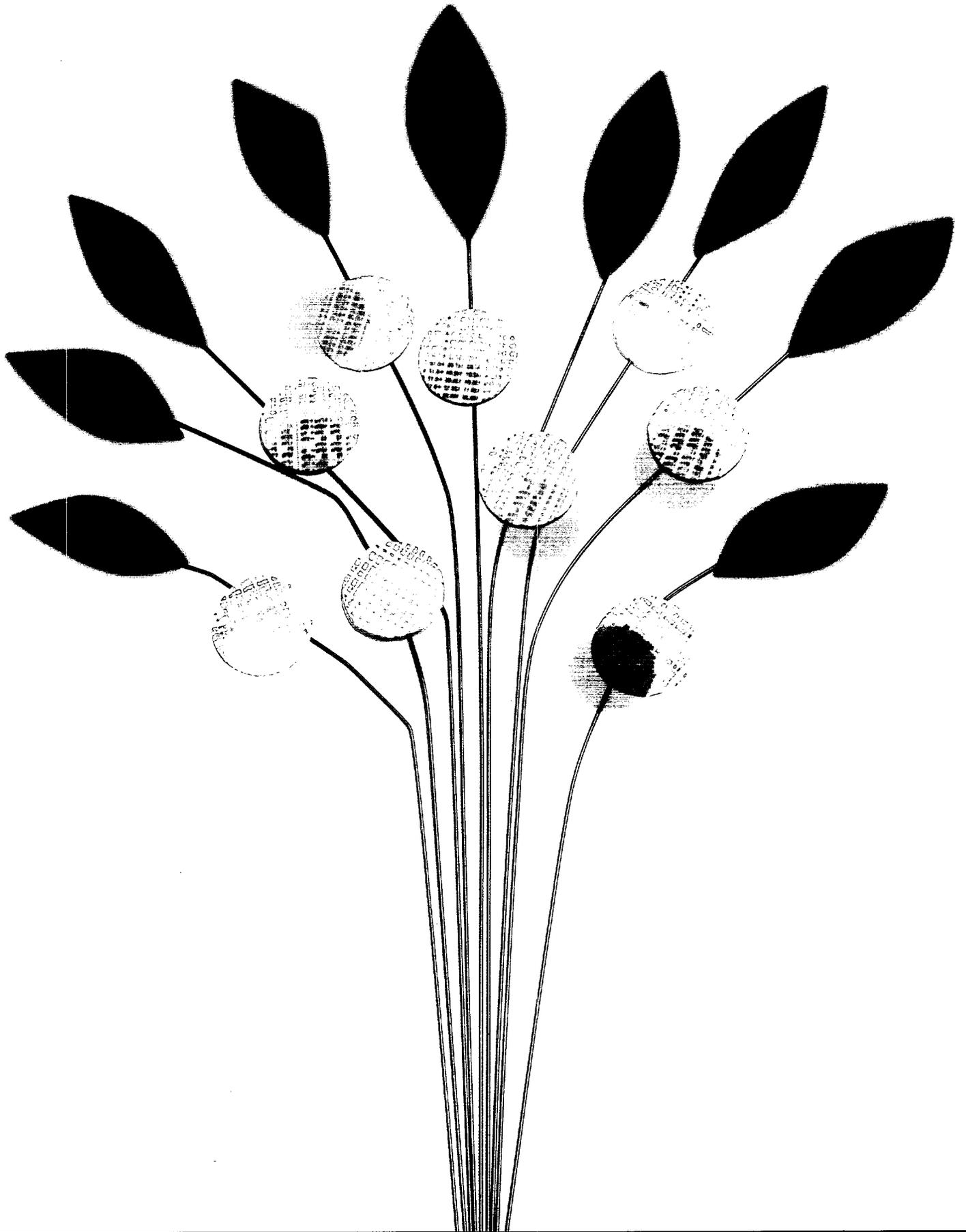
# Explore

## Compelling Therapeutic Potential for Proprietary Drug Candidates

Our primary U.S. and European clinical development objective for both ZADAXIN and SCV-07 is to secure regulatory approvals for the treatment of serious or life-threatening diseases.

We are developing ZADAXIN for the treatment of advanced stage malignant melanoma patients. The American Cancer Society estimates that in 2006 approximately 7,900 Americans will die from melanoma. Melanoma is classified as stage IV, the most advanced and imminently deadly form, once the cancer has spread beyond the skin to a distant site in the body. Unfortunately, none of the current therapies have proven to be effective at extending overall patient survival. We believe that ZADAXIN could offer a significant enhancement to the existing treatments for this patient population, which currently has few therapeutic options. Our European partner, Sigma-Tau, is conducting a large phase 2 clinical trial using ZADAXIN in combination with standard therapy to treat stage IV malignant melanoma. Interim data indicated that groups treated with ZADAXIN showed a distinct dose-dependent response in the combination therapy.

SCV-07 has shown evidence of clinical efficacy in multi-drug resistant tuberculosis, and early preclinical data suggest utility in a variety of viral and bacterial diseases. Initially, we plan to evaluate the ability of SCV-07 to reduce the dose of a vaccine necessary to provide protection, and thereby allow scarce vaccines to benefit a far larger population. In addition, we intend to conduct proof-of-concept clinical trials to determine other promising disease indications. Based on encouraging animal data, we plan to conduct a phase 1 clinical trial to determine if SCV-07 could be used orally, an attribute which would broaden the clinical applications for this compound substantially.





## Corporate Officers

**Ira D. Lawrence, M.D.**  
President and Chief Executive Officer

**Richard A. Waldron**  
Chief Financial Officer

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

**Hans P. Schmid**  
Managing Director  
SciClone Pharmaceuticals International, Ltd.

## Board of Directors

**Dean S. Woodman<sup>1</sup>**  
Chairman, SciClone Pharmaceuticals, Inc.  
Founder, Robertson Stephens  
Former Managing Director, ING Barings

**John D. Baxter, M.D.<sup>2,3</sup>**  
Professor of Medicine  
University of California, San Francisco

**Richard J. Hawkins<sup>1,2</sup>**  
Chairman and Chief Executive Officer  
LabNow, Inc.

**Rolf H. Henel<sup>2,3</sup>**  
Partner, Naimark & Associates, Inc.

**Ira D. Lawrence, M.D.**  
President and Chief Executive Officer

**Jon S. Saxe<sup>1,3</sup>**  
Former President, PDL BioPharma, Inc.  
(formerly Protein Design Labs, Inc.)  
Former Vice President, Hoffman-LaRoche Inc.

<sup>1</sup> Audit Committee Member

<sup>2</sup> Compensation Committee Member

<sup>3</sup> Nominating and Corporate Governance Committee Member

## Corporate Headquarters

SciClone Pharmaceuticals, Inc.  
901 Mariner's Island Blvd., Suite 205  
San Mateo, California 94404-1573  
Telephone: (650) 358-3456 or  
(800) SCICLONE  
Facsimile: (650) 358-3469

## Website

You can obtain recent press releases and other corporate information by visiting SciClone's website at [www.sciclone.com](http://www.sciclone.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 our investor relations department at (650) 358-3437 or send an e-mail message to [investorrelations@sciclone.com](mailto:investorrelations@sciclone.com).

## Common Stock Listing

SciClone's common stock trades on the NASDAQ National Market<sup>®</sup> under the symbol SCLN.

## 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) 522-6645  
E-mail: [shrrelations@mellon.com](mailto:shrrelations@mellon.com)  
[www.melloninvestor.com/isd](http://www.melloninvestor.com/isd)

## Independent Auditors

Ernst & Young LLP  
Palo Alto, California

## Legal Counsel

DLA Piper Rudnick Gray Cary US LLP  
San Francisco, California

## Annual Meeting

The Annual Meeting of Stockholders will be held on Tuesday, June 13, 2006 at 10:00 a.m. Pacific Time at the Marriott San Mateo/ San Francisco Airport, 1770 S. Amphlett Blvd., San Mateo, California 94402. Detailed information about the meeting is contained in the Notice of Annual Meeting of Stockholders and Proxy Statement sent with a copy of the Annual Report on Form 10-K to each stockholder of record as of April 17, 2006.

SciClone, the SciClone logo, the Swirl logo and ZADAXIN are registered trademarks of SciClone Pharmaceuticals, Inc. in the United States and numerous other countries.

## Forward-Looking Statements

The information in this annual report contains forward-looking statements including our expectations and beliefs regarding future sales and financial results for 2006, and progress and results of our clinical trials. Words such as "expects," "plans," "believe," "may," "will," "anticipate," "intended" and variations of these words or similar expressions are intended to identify forward-looking statements. In addition, any statements that refer to expectations, goals, 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 changes in demand for ZADAXIN, developments in our dispute with SPKK, the progress or failure of clinical trials, our actual experience in executing on our objectives, the performance of our partners, maintenance of the sufficiency and eligibility of the enrolled patient population, unanticipated delays or additional expenses incurred during our clinical trials, our future cash requirements, delays in analyzing and synthesizing data obtained from clinical trials, future actions of our strategic partners, unexpected delays in preparation for enrollment, future actions by the U.S. Food and Drug Administration or equivalent regulatory authorities in Europe or China and the fact that experimental data and clinical results derived from studies with a limited group of patients may not be predictive of the results of larger studies, as well as other risks and uncertainties described in SciClone's filings with the Securities and Exchange Commission.

# 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, 2005,

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)*

Delaware

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

94-3116852

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

901 Mariner's Island Boulevard

San Mateo, California

*(Address of principal executive offices)*

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, \$0.001 par value

*(Title of Class)*

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$200,082,635 as of June 30, 2005, based upon the average bid and asked 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 7, 2006, there were 45,899,107 shares of the Registrant's Common Stock outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference from the definitive proxy statement for the Company's 2006 Annual Meeting of Stockholders 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 Annual Report on Form 10-K (the "Proxy Statement").

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As used in this Annual Report, the terms “we,” “us,” “our,” the “Company” and “SciClone” mean SciClone Pharmaceuticals, Inc. and its subsidiaries (unless the context indicates a different meaning). SciClone, the SciClone logo and ZADAXIN are registered U.S. trademarks and SCV-07 is a trademark of SciClone Pharmaceuticals, Inc. All other Company names and trademarks included in this Annual Report are trademarks, registered trademarks or trade names of their respective owners.

## 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 business, industry, management's beliefs and certain assumptions made by us. Words such as "anticipate," "expect," "intend," "plan," "believe" or similar expressions are intended to identify forward-looking statements including those statements we make regarding our future financial results; the timing of events related to, and the potential outcome of clinical trials and our planned product development efforts. 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. is a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases, primarily cancer and viral and other infectious diseases. Our lead product ZADAXIN® is currently being evaluated in a large, phase 2 stage IV malignant melanoma clinical trial in Europe. In addition, a large phase 3 clinical trial is ongoing in Europe using ZADAXIN as part of a novel triple therapy combination for the treatment of hepatitis C virus (HCV). ZADAXIN is approved for sale in select markets internationally, most notably in China where we have an established sales and marketing operation. Our strategy is to leverage our advantage in China by in-licensing or acquiring the marketing rights to other products to market in this rapidly growing pharmaceutical market.

In December 2005, we reported results from the first of our two U.S. phase 3 trials evaluating the double therapy combination of ZADAXIN and pegylated interferon alpha to treat HCV patients who had failed previous therapy. The results from this trial did not demonstrate that ZADAXIN in combination with pegylated interferon alpha provides a statistically significant clinical benefit when compared with pegylated interferon alpha alone. Although not statistically significant, a positive ZADAXIN treatment-related trend was observed. Data from the second U.S. HCV trial is expected to be reported by us in June 2006.

ZADAXIN currently is approved for sale internationally, primarily in Asia, the Middle East and Latin America for the treatment of hepatitis B virus (HBV), HCV and for use as a vaccine adjuvant. ZADAXIN is marketed through our wholly-owned subsidiary SciClone Pharmaceuticals International Ltd. (SPIL). In 2005, revenues from the sale of ZADAXIN totaled \$27.8 million, of which 91% were to China, an increasingly important and rapidly growing pharmaceutical market. We have established a strong sales and marketing operation in China with over 100 medical representatives in the field who are dedicated to promoting ZADAXIN to hospital-based physicians in the major metropolitan areas. While ZADAXIN is approved for the treatment of HBV and as a vaccine adjuvant in China, Chinese physicians are also prescribing it for use in certain cancer and intensive care settings.

SCV-07, our second proprietary drug development candidate, has shown evidence of clinical efficacy in multi-drug resistant tuberculosis and early pre-clinical data suggesting utility in a variety of viral and bacterial diseases. In a recently completed phase 1 clinical trial, SCV-07 appears to be safe and well tolerated at various single and multiple doses. We plan to initially evaluate the ability of SCV-07 to reduce the dose of a vaccine necessary to provide protection, and thereby allow scarce vaccines to benefit a far larger population, by conducting a phase 2a vaccine sparing trial using a subcutaneous formulation of SCV-07 with the influenza vaccine in the second half of 2006 to coincide with the flu vaccination season. In addition, we intend to conduct phase 2a proof-of-concept clinical trials to determine other promising disease indications. Based on encouraging

animal data, we also plan to conduct a Phase 1 clinical trial to determine if SCV-07 could be used orally, an attribute which would substantially broaden the potential clinical utility of this compound.

SciClone Pharmaceuticals, Inc. was organized in 1990 as a California corporation and reincorporated in Delaware in 2003. Our corporate headquarters are located in San Mateo, California. For information about our revenues from external customers, measures of our profit and loss, our total assets and other financial matters, you should read our Consolidated Financial Statements provided in Part II, Item 8 of this Form 10-K.

## STRATEGY

Our objective is to develop and commercialize therapeutics to treat life-threatening diseases. Because we view China as an increasingly important and rapidly growing market, we intend to leverage and expand our established Chinese business by acquiring the rights to other products to market in China. To meet these objectives, our specific near-term initiatives include achieving regulatory approval for our lead product ZADAXIN in the United States and Europe; growing and expanding our Chinese sales and marketing business unit; and developing our product pipeline.

- **Secure Regulatory Approvals for ZADAXIN in the United States and Europe.** Our lead drug candidate ZADAXIN is being evaluated in combination with the standard treatment of dacarbazine chemotherapy with and without low-dose interferon alpha in a large, phase 2 stage IV malignant melanoma clinical trial. These trials are being conducted by our European marketing and development partner, Sigma-Tau S.p.A. Recently, we reported encouraging interim overall response data that showed a definite dose-dependent improvement in overall response with the addition of ZADAXIN to standard therapy. Later this year, we expect to report additional overall tumor response data as well as preliminary survival information. With these data, we, in collaboration with Sigma-Tau, intend to approach the U.S. Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMA) to share these data and to discuss our plans to initiate phase 3 registration trials. We believe that an approval in the United States or Europe would increase ZADAXIN sales in international markets where the drug is currently approved and facilitate approvals in additional international markets.
- **Grow and Expand Chinese Sales and Marketing Business Unit.** ZADAXIN is currently approved for sale in over 30 countries internationally and in 2005 generated \$27.8 million in sales revenues. Over 90% of these sales were to China, where we have established a successful sales and marketing business including an existing team of over 100 medical representatives focused on promoting ZADAXIN to hospital-based pharmacies and physicians in the major metropolitan areas. We intend to leverage our capabilities in China by licensing or acquiring the rights to other high quality and premium priced products to market through our established channels. As China is rapidly growing economically and is becoming an increasingly important pharmaceutical market, we believe that other pharmaceutical companies will be interested in partnering with us in order to gain access to this market. To support this expansion, we intend to explore enhancing our capabilities in China by adding a few key experts who are familiar with the development and regulatory environment in China. These specialists would manage future Chinese clinical trials and regulatory submissions utilizing reputable Contract Research Organizations (CROs) that conduct clinical trials using Good Clinical Practices (GCP).
- **Develop Product Pipeline with an Emphasis on Cancer and Infectious Disease.** We intend to build on our experience developing therapeutics that target life-threatening diseases. Beyond our lead drug candidate, ZADAXIN, we are expanding our product pipeline by developing SCV-07. SCV-07 is a potentially orally available compound that stimulates the body's immune system through a variety of mechanisms, and preclinical animal model studies using SCV-07 have shown its promise in combating a broad range of viral and infectious diseases. We expect to commence a phase 2a vaccine sparing trial using a subcutaneous formulation of SCV-07 with the influenza vaccine in the second half of 2006 and to initiate phase 2a studies with the SCV-07 subcutaneous formulation in varied viral and infectious disease indications. In addition, we plan to initiate a phase 1 study in healthy volunteers to investigate two oral formulations of SCV-07 in the first half of 2006.

## SCICLONE'S LEAD PRODUCT ZADAXIN

ZADAXIN, generically referred to as thymalfasin, is a pure synthetic preparation of thymosin alpha 1, which is a natural substance that circulates in the body and is instrumental in the immune response to certain cancers and viral infections. After the administration of a single, standard 1.6 mg subcutaneous dosage of ZADAXIN, the circulating levels of thymosin alpha 1 are temporarily increased 50 to 100 times its normal level in the body. Published scientific and clinical studies have shown that ZADAXIN helps stimulate and direct the body's immune response to eradicate certain cancers such as malignant melanoma as well as infectious diseases like HCV and HBV. ZADAXIN appears to be well tolerated with few reports of significant side effects or toxicities associated with its use.

ZADAXIN elicits a variety of immune system responses against cancer cells and viruses. One such response is an increase in white blood cell production and their differentiation into CD-4 helper-cells, specifically towards differentiation of T helper 1 (Th1) cells (Th1 cells secrete cytokines such as interleukin-2 (IL-2) and gamma interferon). Studies have shown that a Th1-directed immune response is fundamental to the eradication of certain cancers such as malignant melanoma as well as infectious diseases like HCV and HBV. Moreover, as ZADAXIN increases Th1 cells, it also decreases production of Th2 cytokines, such as IL-4, which are associated with persistence of viral infection.

Similarly, ZADAXIN helps increase the production of CD-8 and NK, or natural killer, cells that are able to directly attack and kill certain cancer and virally-infected cells. In addition, ZADAXIN has recently been shown to stimulate the innate immune system through effects on Toll-like receptors (TLRs), specifically TLR2 and TLR9. Both of these activities are important in mounting an effective immune response to 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. ZADAXIN also exhibits anti-tumor and anti-viral properties by enhancing the expression of surface-marker proteins (antigens) on certain cancer and virally-infected cells. The enhancement in the expression of these antigens enables the body's immune system to more effectively recognize and target cancer and virally-infected cells for eradication.

## CLINICAL DEVELOPMENT

### *ZADAXIN for Advanced-Stage Malignant Melanoma*

If diagnosed early, the cure rate for melanoma is high. However, once the melanoma has metastasized, or spread, the likelihood of patient survival drops dramatically. The American Cancer Society estimated that in 2005 approximately 7,700 Americans died from melanoma. Melanoma is classified as stage IV, the most advanced form, once the cancer has spread beyond the skin to a distant site in the body. At this stage, median survival is approximately six to nine months. Commonly used treatments for stage IV patients include chemotherapeutic agents, like dacarbazine (DTIC), and immunotherapeutics, including interferon alpha. Response to treatment can vary from patient to patient and is largely dependent on the stage of melanoma, disease site and the extent to which the cancer has spread. Unfortunately, none of the current therapies have proven to be very effective at extending overall patient survival. Accordingly, most physicians believe that the best alternative for most stage IV melanoma patients is to enroll in a clinical trial in order to receive an investigational therapeutic.

A critical factor in the progression of cancer is the failure of the body's immune system to detect the presence of cancerous cells. This is especially true for melanoma, and specific tumor-associated surface-marker proteins, or antigens have been identified that are specifically linked to melanoma. This evidence provides a strong rationale for the utility of immunotherapy, like ZADAXIN, in treating melanoma.

ZADAXIN is currently being investigated in a large, multi-center open-label phase 2 trial, conducted and funded by Sigma-Tau. In this trial, Sigma-Tau is evaluating different dose levels of ZADAXIN in combination

with DTIC chemotherapy with and without low-dose interferon alpha as a first-line treatment for malignant melanoma. All of the patients enrolled in this trial have stage IV melanoma. Most of these patients have visceral metastases and the remaining patients have lung metastases and skin or lymph node metastases. The trial was originally designed as a four arm study with DTIC in combination with low dose interferon alpha as the control arm. The other three treatment arms are described in the table below. Patients are receiving six cycles of therapy for 6 months and will be observed for a period of 12 months after the end of therapy. The trial's primary endpoint is overall tumor response. Secondary endpoints include overall survival, duration of response, time to disease progression and immunological response.

In December 2005, we reported encouraging interim overall tumor response data on patients enrolled in the first three ZADAXIN arms of this trial, compared to the control arm of DTIC plus low-dose interferon alpha, commonly used agents in the treatment of this disease. At the time of our report in December 2005, 270 out of the 320 stage IV malignant melanoma patients enrolled in four treatment arms had been evaluated according to RECIST criteria for overall tumor response, which includes partial and complete responses. In each of the three treatment arms that include ZADAXIN, a higher response rate was observed as compared to the response achieved in the control arm. Overall tumor response was achieved by 12.9% of the patients treated with 3.2 mg of ZADAXIN in combination with DTIC, compared with only 3.9% of patients in the control arm. Furthermore, the addition of ZADAXIN to DTIC and low-dose interferon alpha provided a greater overall tumor response in a dose-related fashion as shown in the table below. 7.4% of patients who were treated with 1.6 mg of ZADAXIN, DTIC and low-dose interferon alpha achieved an overall response, and 10.9% of patients who were treated with 3.2 mg of ZADAXIN, DTIC and low-dose interferon alpha achieved an overall response. The adverse events observed so far in this trial are consistent with those expected for this group of patients treated with DTIC and interferon alpha. Based on an early observation of promising ZADAXIN dose-related response in May 2005, a fifth treatment arm consisting of 6.4 mg dose of ZADAXIN, DTIC and low-dose interferon alpha was subsequently started. Consequently, tumor response data on the patients enrolled in this fifth arm were not reported in December 2005.

<u>Treatment Arms (n=270)</u>	<u>Overall Tumor Response</u>
DTIC + low-dose interferon alpha (control arm) . . . . .	3.9%
ZADAXIN (1.6 mg) + DTIC + low-dose interferon alpha . . . . .	7.4%
ZADAXIN (3.2 mg) + DTIC + low-dose interferon alpha . . . . .	10.9%
ZADAXIN (3.2 mg) + DTIC . . . . .	12.9%

Source: Sigma-Tau

Later this year, we expect to report additional data including overall tumor response from patients in all five treatment arms and preliminary survival information on the first 320-patient cohort. With these additional data, we, together with Sigma-Tau, intend to share these data with the FDA and EMEA and discuss with these regulatory agencies our plans to begin phase 3 trials. We expect these phase 3 trials to be multi-national with the majority of clinical trial sites located in the geographic areas with the highest prevalence of melanoma including the United States, Australia and Northern Europe.

**ZADAXIN for Hepatocellular Carcinoma**

In addition to malignant melanoma, ZADAXIN has been evaluated in a phase 2 proof-of-concept hepatocellular carcinoma, or liver cancer, trial in the United States. In December 2005, we reported a positive survival benefit in patients treated with ZADAXIN plus transarterial chemo-embolization (TACE) compared with patients treated with TACE alone. Specifically, a median survival of 994 days was observed for the 12 patients who received ZADAXIN plus TACE, compared with a median survival of only 399 days for the 13 patients who received TACE alone, the control arm. No difference was observed in tumor response between the treatment groups.

We are encouraged by these data, which we believe indicate that ZADAXIN may offer benefit in a cancer setting. Based on the promising interim data achieved in the large phase 2 malignant melanoma trial, our phase 3 development efforts for ZADAXIN in the United States and Europe are focused on stage IV melanoma as we believe this would be the most expeditious route toward achieving U.S. or European regulatory approval for a cancer indication.

### *ZADAXIN for Hepatitis C*

Hepatitis C is a systemic disease localized in the liver, and for the majority of patients can lead to serious complications, including cirrhosis of the liver, liver failure and hepatocellular carcinoma or liver cancer. The World Health Organization estimates that 170 million people worldwide are infected with HCV. In the United States, 2.7 million people are chronically infected with HCV, according to the Centers for Disease Control and Prevention. However, only approximately 100,000 HCV patients annually are undergoing currently approved therapy of pegylated interferon alpha and ribavirin. We believe that improvement to the efficacy or tolerability of current therapy could significantly increase the number of patients seeking care.

In the United States, we have conducted two phase 3 trials to evaluate the double therapy combination of ZADAXIN and pegylated interferon alpha to treat HCV patients who have failed previous treatment and become non-responder patients. The two trials were multi-center, double-blinded, randomized and placebo-controlled. The first trial enrolled over 500 HCV non-responder patients without cirrhosis of the liver and the second trial enrolled over 500 HCV non-responder patients with early cirrhosis. Patients in both trials received a 48-week course of therapy of either ZADAXIN (1.6 mg, twice a week) and pegylated interferon alpha (180 mcg, once a week) or placebo and pegylated interferon alpha followed by a 24-week observation period. The primary endpoints of each trial are the achievement of sustained viral response (SVR) measured at week 72 by PCR assay (24 weeks after completing 48 weeks of therapy), and an improvement in the liver histological activity index assessed by liver biopsy at week 72. The secondary endpoints are normalization of ALT (an enzyme that indicates liver damage when present in elevated levels in the liver) measured at week 72, and the end of therapy response rate (ETR) measured at week 48.

In December 2005, we reported final results from the first trial that enrolled HCV non-responder patients without cirrhosis, and in May 2006 we expect to report final results from the second trial that enrolled HCV non-responder patients with early cirrhosis. Final results from the first trial indicated that treatment with ZADAXIN and pegylated interferon alpha did not demonstrate a statistically significant benefit compared with treatment with pegylated interferon alone in sustained viral response (SVR) or histologic improvement, the trial's co-primary endpoints, although a positive ZADAXIN treatment-related trend was observed in SVR. ZADAXIN was well tolerated with no treatment-related toxicities or side effects. In addition, patients who received ZADAXIN therapy were less likely to relapse, a typical occurrence associated with HCV therapy where the virus reappears after previously being undetectable at the end of 48 weeks of treatment, although this trend also did not prove statistically significant.

In addition to the U.S. HCV trials, our partner Sigma-Tau is conducting a triple combination therapy trial evaluating ZADAXIN, pegylated interferon alpha and ribavirin in non-responder patients to a previous course of pegylated interferon alpha and ribavirin. Sigma-Tau began enrollment in December 2004 and the trial is expected to be completed in early 2008.

This triple therapy phase 3 clinical trial is multi-center, double-blinded, randomized and placebo-controlled and Sigma-Tau plans to conduct the trial in 40 sites throughout Europe. Patients are randomized to receive either ZADAXIN (1.6 mg, twice a week) or a placebo (twice a week) and all patients receive pegylated interferon alpha (180 mcg, once a week) and a standard dose of ribavirin (1,000 to 1,200 mg, daily, according to body weight). After completing 48 weeks of treatment, patients will be monitored for a 24-week observation period. The primary endpoint is SVR measured at week 72 at the end of the 24-week observation period. The secondary endpoints are normalization of ALT measured at the end of weeks 48 and 72, absence of HCV RNA measured at week 48, and an improvement in the liver biopsy.

The design of Sigma-Tau's phase 3 triple therapy clinical trial is supported by encouraging results achieved from a small, single-arm triple therapy pilot trial conducted by our licensee in Mexico. Final endpoint results from this 25-patient trial were reported at the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in October 2004 and showed that 19% of genotype 1 non-responder patients achieved an SVR. All of these patients were non-responders to previous therapy of interferon alpha with ribavirin. These data compare favorably to the 9% SVR reported from a separate, unrelated trial that treated genotype 1 non-responder patients with pegylated interferon and a low dose of ribavirin but without ZADAXIN. Although it is difficult to draw conclusions from two separate, unrelated trials, we believe the results achieved from this pilot triple therapy trial are encouraging.

### **SCV-07**

Our proprietary drug development candidate, SCV-07, is a potential orally available compound, and early pre-clinical data suggest that it has potential utility in a variety of viral and infectious diseases. We recently completed single and multi-dose ranging phase 1 clinical trials in healthy volunteers that investigated the safety and pharmacokinetics profile of a subcutaneous formulation of SCV-07. SCV-07 appeared to be safe and well tolerated at doses up to 1 mg/kg, approximately one thousand times the dose level utilized in a proof-of-concept tuberculosis trial in Russia, without any dose limiting adverse effects.

Based on positive data from recent animal model studies that suggest SCV-07 is orally bioavailable, we expect to conduct a phase 1 study evaluating two oral formulations of SCV-07 in the first half of 2006. In addition, we expect to begin phase 2a proof-of-concept trials with the subcutaneous formulation of SCV-07 in varied viral and infectious diseases starting in the second half of 2006. Initially, we plan to explore the utility of SCV-07 in an influenza vaccine sparing setting. Specifically, this study would evaluate the potential to obtain effective vaccination using a lower dose of vaccine by adjunctive therapy with SCV-07. If successful, this may allow for protection of a greater portion of a population with a limited supply of vaccine.

SCV-07 is a synthetic dipeptide that has demonstrated immunomodulatory activity by increasing T-cell differentiation and function, biological processes that are necessary for the body to fight off infection. SCV-07 specifically stimulates the immune system through its effects on T-helper 1 cells, which are essential for clearance of viral infections; and we have additional recent data that demonstrate an apparent involvement with Toll-like Receptors of the innate immune system which could also be involved in its mechanism of action. We acquired exclusive worldwide rights, outside of Russia, to SCV-07 from Verta, Ltd., a biotechnology company located in St. Petersburg, Russia.

In September 2002, we reported final results from a phase 2 clinical study conducted by Verta in Russia of SCV-07 in tuberculosis at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). After 3 months, 80% (35/44) of tuberculosis patients treated with a five-day regimen of SCV-07 therapy in combination with anti-tuberculosis chemotherapy were no longer contagious, as measured by negative sputum cultures, compared to 37% (10/27) of patients whose treatment did not include SCV-07.

## **PRE-CLINICAL DEVELOPMENT**

### ***Pegylated ZADAXIN***

In May 2004, we entered into a collaborative agreement with Nektar Therapeutics to develop a pegylated formulation of ZADAXIN. Nektar has applied its Advanced PEGylation technology to ZADAXIN with the objective of improving the therapeutic use (less frequent dosing) and potential efficacy (through a higher concentration level in the body for a longer period of time). If the formulation is successful, pegylated ZADAXIN could lead to improved patient compliance due to less frequent dosing and would allow the drug to remain in the body at a higher concentration level for a longer period of time, potentially increasing efficacy in

several indications. In addition to providing a proprietary next-generation ZADAXIN, we believe that a pegylated formulation also could broaden the potential application of ZADAXIN in cancer therapy. We have selected a pegylated version of ZADAXIN, and are proceeding with pre-clinical studies.

## **SALES AND MARKETING BUSINESS UNIT IN CHINA**

A critical component of our long-term strategy is the growth and expansion of our sales and marketing business in China, which accounts for over 90% of our total sales. SciClone has an established sales and distribution infrastructure and has been selling ZADAXIN in China since 1997. Currently, we have over 100 medical representatives operating out of regional offices in Beijing, Shanghai and Hong Kong. Our medical representatives are focused specifically on promoting knowledge and use of ZADAXIN to physicians and pharmacies at the leading 500 hospitals in China where ZADAXIN is recognized as a high-quality, imported, premium priced product. We are an active participant in regional and international liver disease related medical conferences.

IMS Health estimates indicate that the pharmaceutical market in China, the world's most populous nation, is approximately \$12 billion per year, compared with over \$200 billion per year in the United States, and is estimated to be growing at an average rate of 15 to 20% per year. At its current growth rate, in 10 years, China will surpass Japan in the amount spent per year on pharmaceutical drugs. China is expected to become the fifth largest pharmaceutical market by 2010. The current and projected pharmaceutical growth rate is being fueled by an aging population, demand for Western branded pharmaceutical products by an increasingly affluent middle class, and increasing incidence rates in cancer and infectious disease. An estimated 70% of the pharmaceutical market opportunity is concentrated in major metropolitan areas like Beijing, Shanghai, Hangzhou and Guangzhou. SciClone's sales efforts target these major metropolitan hospitals which treat middle class and wealthy patients. Importantly, market entry is challenging for companies without established networks in China because hospitals continue to favor local generic drugs and drug distribution is highly regulated.

We intend to leverage our extensive existing sales and marketing capabilities in China to grow our revenue and expand our product offerings in this rapidly growing market. We are actively evaluating opportunities to acquire or in-license the marketing rights to other products that can be effectively and efficiently marketed to physicians by our team of medical representatives. To maintain maximum efficiency in our existing operations, we will continue to focus on products in the areas of oncology, infectious disease and intensive care medicine. While the timing can be difficult to predict, we intend to in-license or acquire the marketing rights for at least one new product for China in 2006. To support our efforts to expand our product portfolio in China, we intend to explore enhancing our existing capabilities by recruiting a few key experts who are familiar with the development and regulatory environment in China. Our plan is for these specialists to manage future Chinese clinical trials and regulatory submissions utilizing local experts and Contract Research Organizations (CROs) that follow Good Clinical Practices (GCP). We expect that this model would provide us with a cost effective way to conduct clinical trials that are sufficient for regulatory approval within China, while providing our partners with potentially useful data for their product development efforts in other markets.

In China, the physicians' and their hospital pharmacies' orders for ZADAXIN are fulfilled by licensed ZADAXIN distributors who purchase their supplies from our selected importing agents. We sell ZADAXIN to these well-established, government-licensed importing agents. Our sales are made on a no-return basis, except under limited terms regarding product quality. Sales terms to the importing agents in China typically are for payment in six months to accommodate the importing agents' costs of importation including duties and quality assurance testing fees and the long collection cycle associated with sales within the country.

## **SALES AND MARKETING**

In 2005, Guang Dong South Pharmaceutical Foreign Trade Co., Ltd, Zhuhai Goldsn Medicine Co., Ltd and China National Pharmaceutical Foreign Trade Corporation accounted for 57%, 19%, and 15% of our sales,

respectively. In 2004, China National Pharmaceutical Foreign Trade Corporation, China Meheco Corporation and Guang Dong South Pharmaceutical Foreign Trade Co., Ltd accounted for 32%, 29% and 23% of our sales, respectively. In 2003, China National Pharmaceutical Foreign Trade Corporation and China Meheco Corporation accounted for 52% and 14% of sales, respectively. No other customers accounted for more than 10% of sales in those periods. Our customers in China are well-established trading companies and our sales to them represent a small part of their total business. Since we commenced our operations and through December 31, 2005 we have not had a bad debt expense associated with any of our Chinese customers.

China accounted for 91%, 91% and 88% of ZADAXIN sales for the years ended December 31, 2005, 2004 and 2003, respectively. ZADAXIN is approved in China for the treatment of HBV and for use as a vaccine adjuvant. However, physicians also have been using ZADAXIN increasingly in oncology and in intensive care cases. In addition to China, ZADAXIN is approved in over 34 countries, primarily in Asia, the Middle East and Latin America where our licensed distributors are largely responsible for the marketing and sales of the product. ZADAXIN's approvals are principally for the treatment of HBV, with additional approvals in certain countries for the treatment of HCV, as a vaccine adjuvant, or as a chemotherapy adjuvant for cancer patients with weakened immune systems. We sell ZADAXIN in various international markets through our wholly owned subsidiary, SciClone Pharmaceuticals International Ltd. (SPIL).

SPIL is registered in the Cayman Islands and has its principal offices in Hong Kong. SPIL orders ZADAXIN from our European manufacturer and contracts with a third party for the storage of our finished goods inventory at warehousing facilities in Hong Kong. SPIL then distributes our product worldwide from these warehousing facilities based on purchase orders from our customers. Under our established distribution arrangements, local importers and distributors are responsible for the importation, inventory, distribution and invoicing of ZADAXIN.

## **INTELLECTUAL PROPERTY AND PROPRIETARY RIGHTS**

### ***Patents***

We seek regulatory approval for our products in disease areas with unmet medical need, significant market potential and where we have a proprietary position through patents covering use, process, or composition of matter for our products. For our lead product ZADAXIN, we are the licensee or owner of patents relating to the use of thymosin alpha 1 for certain diseases and its process of manufacture.

We are the exclusive licensee or owner of patents relating to the use of ZADAXIN as a therapy for HCV that do not expire until 2015 in the United States and until 2012 in Japan and the major commercial markets in Europe. In addition, patents relating specifically to the use of thymosin alpha 1 in treating HCV in non-responders to interferon alpha treatment have been issued to us in the United States and various international markets. In the United States, certain European countries and Japan, the period of patent protection may be extended depending on the relevant dates of patent grant and market authorization, and we may, depending on the timing of any future approval, be eligible for such an extension.

We are the exclusive licensee or owners of patents that have been issued in the United States, Japan, China and other international markets relating to the treatment of HBV using thymosin alpha 1. We are the licensee or owner of patents relating to the use of ZADAXIN as a combination therapy for HBV that do not expire until 2019 in the United States and Europe and 2012 in Japan. We are also the exclusive licensee of patents that have been issued in the United States, a majority of European countries, Japan, and other international markets that relate to 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. We have not been issued a patent with respect to the use of ZADAXIN as a therapy for melanoma. However, thymosin alpha 1 marketing exclusivity for this indication may be available to us under orphan drug designation or first-to-market protection in the United States or Europe.

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 United States, 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 analogues and derivatives of thymosin alpha 1 which have been granted in the United States and in important international markets. Our commercialized product, and the product we are using in our clinical trials, is thymosin alpha 1 and not an analogue or derivative. However, we continue to seek additional proprietary rights relating to the use of thymosin alpha 1.

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

Under our agreement with Nektar Therapeutics, we retain all proprietary rights to pegylated ZADAXIN. In addition, we have filed a patent application for pegylated ZADAXIN in the United States and other major markets.

### ***Proprietary Rights***

In addition to our patent protection, we intend to use other means to protect our proprietary rights. We may pursue marketing exclusivity periods that are available under regulatory provisions in certain countries including the United States, Europe and Japan.

Orphan drug protection has been or may 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 in the United States and Europe. We have applied for orphan drug designation with the FDA and EMEA for ZADAXIN as a treatment for malignant melanoma, however, we can give no assurances that any such designation will be granted.

We have filed trademark applications worldwide 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 implemented anti-counterfeiting measures on commercial packaging and we are registering the packaging with customs departments in countries where such procedures exist. We 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.

### **MANUFACTURING**

ZADAXIN is manufactured for us by third parties under exclusive contract manufacturing and supply agreements. We closely monitor production runs of ZADAXIN and regularly conduct our own quality assurance audit programs. We believe the manufacturing facilities of our contract suppliers are in compliance with the FDA's current Good Manufacturing Practices, and the Japanese or European equivalents of such standards.

Contract suppliers in the United States manufacture ZADAXIN for process validation and for our clinical trials in the United States. Contract suppliers in Europe manufacture ZADAXIN for our phase 2 and 3 clinical trials in Europe and for sale in other international markets where approved.

In the event of the termination of an agreement with any single supplier, we believe that we would be able to enter into arrangements with other suppliers with similar terms. We do not intend at this time to acquire or establish our own dedicated manufacturing facilities for any of our products. We believe that our current manufacturing partners have enough manufacturing capacity to meet potential market demand should ZADAXIN be approved in the major pharmaceutical markets of the United States, Europe and Japan.

## COMPETITION

Our competitors include biopharmaceutical companies, biotechnology firms, universities and other research institutions, both in the United States and abroad, that are actively engaged in research and development or marketing of products in the therapeutic areas we are pursuing, particularly cancers such as malignant melanoma and certain infectious diseases such as HCV and HBV. Currently, competitors are marketing drugs for HCV, HBV and cancer, or have products in clinical trials. We believe that the principal competitive factors in this industry for a marketed drug include the efficacy, safety, price, therapeutic regimen, manufacturing, quality assurance and associated patents and the capabilities of its marketer.

In addition, most of our competitors, particularly large biopharmaceutical companies, have substantially greater financial, technical, regulatory, manufacturing, marketing and human resource capabilities than SciClone. Most of them also have extensive experience in undertaking the pre-clinical 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.

For the treatment of HCV, the only products approved by the FDA are interferon alpha, in both standard and pegylated forms, and ribavirin, which is useful only in combination with interferon alpha. In addition, there are several other potential therapeutic products currently in clinical trials.

For the treatment of HBV, current therapies being marketed by competitors include interferon alpha, in both standard and pegylated forms, marketed primarily by Schering-Plough and Roche, nucleoside analogues such as lamivudine, marketed by GlaxoSmithKline, and the nucleotide analogue adefovir, marketed by GlaxoSmithKline and Gilead Sciences. Other potentially competitive products currently under development include Bristol-Myers Squibb's nucleoside analogue, entecavir. In addition to these products, in our largest market China, ZADAXIN faces competition from other synthetic and generic biological extracts, which are locally manufactured and significantly lower priced.

For the treatment of cancer, many companies are researching, developing, or marketing other products for use alone or in combination with other therapies. In addition, we expect continuing advancements in and increasing awareness of the use of therapeutics which boost the immune system to fight cancer and infectious diseases. These developments may create new competitors. Future clinical trials may or may not show ZADAXIN to have advantages or clinically significant synergistic value over such existing or future competitive products.

## RESEARCH AND DEVELOPMENT

A major portion of our operating expenses to date is related to research and development (R&D). R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. A substantial portion of our development expenses are third party expenses relating to the conduct of clinical trials. R&D expenses were \$14,406,000, \$17,994,000, and \$18,949,000 for the years ended December 31, 2005, 2004, and 2003, respectively. We intend to maintain our strong commitment to R&D as an essential component of our product development effort. Licensed technology developed by outside parties is an additional source of potential products.

## EMPLOYEES

As of December 31, 2005, we had 165 employees, 31 in the United States and 134 in foreign offices. From time to time, we engage the services of 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.

## GOVERNMENT REGULATION

Regulation by governmental authorities in the United States 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 pre-clinical and clinical trials and testing related to our products. When our products are manufactured, tested or sold in the United States, 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 manufacturing establishment must be registered with the FDA. 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 (cGMP). In complying with cGMP standards, manufacturers must continue to expend time, money and effort in the area of production and quality assurance to ensure full technical compliance.

The steps required before a new drug or biological product may be distributed commercially in the United States generally include:

- conducting appropriate pre-clinical laboratory evaluations, including animal studies, in compliance with the FDA's Good Laboratory Practice (GLP) requirements, to assess the potential safety and efficacy of the product, and to characterize and document the product's chemistry, manufacturing controls, formulation and stability;
- submitting the results of these evaluations and tests to the FDA, along with manufacturing information and analytical data, in an Investigational New Drug Application (IND), and receiving approval from the FDA that the studies proposed under the IND are allowed to proceed;
- obtaining approval of Institutional Review Boards (IRBs) to introduce the drug into humans in clinical studies;
- conducting adequate and well-controlled human clinical trials in compliance with the FDA's Good Clinical Practice (GCP) requirements 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,
  - *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 pre-clinical studies, clinical studies, and adequate data on chemistry, manufacturing and control information to ensure reproducible product quality batch after batch, in an NDA or Biologics License Application (BLA); and
- obtaining FDA approval of the NDA or BLA, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements, 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.

The process of obtaining regulatory approval is lengthy, uncertain, and requires the expenditure of substantial resources. Each NDA or BLA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2006, the user fee for an application requiring clinical data, such as an NDA or BLA, is \$767,400. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$42,130), and an annual establishment fee (\$264,000) on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the drug also includes a non-orphan indication, and if a contract manufacturer is used, the contract manufacturer is responsible for the establishment fee.

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, an NDA or BLA supplement may be required to be submitted to the FDA.

Additionally, after the FDA has authorized a drug product to enter commercial distribution, numerous regulatory requirements apply. These include, among others, the cGMPs, which require manufacturers to follow extensive design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting drug products for unapproved or "off-label" uses; and adverse event reporting regulations, which require that manufacturers report to the FDA if their drug may have caused or contributed to a death or serious injury. The FDA and other regulatory agencies have broad post-market and regulatory and enforcement powers, and significant enforcement activity has occurred as to the sales and marketing practices of pharmaceutical companies. Failure to comply with the applicable U.S. drug regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, refunds, recalls or seizures of products (which would result in the cessation or reduction of production volume), total or partial suspension of production, withdrawals or suspensions of current product applications, and criminal prosecution. Adverse events related to a drug product in any existing or future markets could cause regulatory authorities to withdraw market approval for such product.

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 is required to 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 the 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 suppliers to develop and supply drugs for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the United States or, for a disease that affects more than 200,000 individuals in the United States, where the sponsor does not realistically anticipate its product becoming profitable. Under these provisions, a supplier 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. 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 hepatocellular carcinoma.

In the European Union, incentives for suppliers to develop medicinal products for the treatment of rare diseases are provided pursuant to the Orphan Medicinal Products Regulation (Regulation (EC) 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. However, it should be noted that, as in the United States, 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 suppliers 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 U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for the patent term extension.

The 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. The Pediatric Research Equity Act authorizes the FDA to require pediatric studies for drugs and biological products to ensure the drugs' or products' safety and effectiveness in children. This Act required that new NDAs, BLAs or supplements to NDAs or BLAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data, or full or partial waivers.

We may seek the benefits of additional orphan, exclusivity, patent term extension, or fast track provisions, with respect to ZADAXIN 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 pre-clinical 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 United States, 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 United States. In general, a drug that has been approved for commercial sale in the United States 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 United States 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 United States for clinical trial purposes, and will seek to obtain FDA approval, where necessary, for any future shipments from the United States to any unlisted country.

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 and could prevent or delay regulatory approval of any of our products.

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. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payors.

### **THIRD-PARTY REIMBURSEMENT**

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. In most of the markets in which we are currently approved to sell ZADAXIN, reimbursement for ZADAXIN under government or private health

insurance programs is not yet widely available, and in many of these countries government resources and per capita income may be so low that our products will be prohibitively expensive. In the United States, Europe and Japan, proposed health care reforms could limit the amount of governmental or third-party reimbursement available for our products should they be approved for sale in these markets. 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 legislative efforts and proposals to implement such government controls.

**AVAILABLE INFORMATION**

We file electronically with the Securities and Exchange Commission (the Commission or the 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 and 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 filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78m(a) or 78o(d)), 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 March 1, 2006, 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>
Ira D. Lawrence, M.D. ....	52	President, Chief Executive Officer and Director
Richard A. Waldron ....	52	Chief Financial Officer and Secretary
Alfred R. Rudolph, M.D. ....	58	Chief Operating Officer
Hans P. Schmid ....	54	Managing Director, SciClone Pharmaceuticals International Ltd.

*Ira D. Lawrence, M.D.* has served as our President, Chief Executive Officer and as a Director since April 2005. From 1995 to 2005, Dr. Lawrence was at Fujisawa Healthcare, Inc., most recently as the Senior Vice President of Research and Development. Fujisawa Healthcare Inc., was the U.S. subsidiary of Fujisawa Pharmaceutical Co. that recently merged with Yamanouchi Pharmaceutical Co. to form Astellas Pharma Inc. From 1993 to 1995, Dr. Lawrence served as Vice President of Research and Development at GenDerm Corporation. Dr. Lawrence was the Associate Director of Clinical Studies, Immunology at Fujisawa Healthcare, Inc. from 1991 to 1993. Prior to 1991, Dr. Lawrence practiced internal medicine and allergy/clinical immunology, most recently as the Assistant Chief of Staff at the Veterans Administration Lakeside Medical Center and Assistant Professor at Northwestern University Medical School. Dr. Lawrence earned his M.D. degree, from the Hahnemann Medical College (now Drexel University College of Medicine) and his B.A. from Temple University. Dr. Lawrence completed his internship and residency in internal medicine at Northwestern University and his fellowship at the Division of Allergy and Clinical Immunology at the Johns Hopkins University School of Medicine.

*Richard A. Waldron* has served as our Chief Financial Officer since 2001. In July 2004, Mr. Waldron and Dr. Rudolph were appointed jointly to the Office of the President and served in that office until the appointment of Dr. Ira Lawrence as our President and Chief Executive Officer in April 2005. Mr. Waldron has over 20 years of experience in the finance and management of biotechnology companies. Prior to joining us in March 2001, he was Vice President and Chief Financial Officer from June 1999 to August 2000 for Genelabs Technologies, Inc. and from July 1995 through March 1999, he was Vice President and Chief Financial Officer of GeneMedicine, Inc. 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.

*Alfred R. Rudolph, M.D.* has served as our Chief Operating Officer since 1998. In July 2004, Dr. Rudolph and Mr. Waldron were appointed jointly to the Office of the President and served in that office until the appointment of Dr. Ira Lawrence as our President and Chief Executive Officer in April 2005. Dr. Rudolph has over 30 years of experience in the biopharmaceutical industry. Since joining us in April 1997, Dr. Rudolph has been responsible for the clinical, research, regulatory, manufacturing, and quality assurance functions of our Company. Before joining us, 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 medical training in Hematology-Oncology at Syracuse University.

*Hans P. Schmid* has served as Managing Director for SciClone Pharmaceuticals International Ltd. since July 2004. He previously served as Vice President, Finance, Administration and Business Development since joining SciClone in May 2001. He has over 25 years of financial and pharmaceutical experience in the U.S. and international markets. Prior to joining SciClone, Mr. Schmid was Chief Financial Officer from December 1999 to April 2001 for Questcor Pharmaceuticals, Inc. and Senior Vice President, International Business Development from February 1997 to September 1999 for Oread, Inc., a contract pharmaceutical company. From 1985 to 1997 he worked at Syntex Corporation as Vice President of Finance and Administration for Pharmaceutical Operations Asia/Pacific region and at F. Hoffmann-LaRoche as Senior Vice President, Finance and Head of Administrative Services for Roche Bioscience. Previously he held financial and operational positions with Itel Corporation in Germany, Japan, England and the United States. He received his B.A. degree from the Commercial Trade School, Lucerne, Switzerland, and has studied International Business Management and Finance at San Francisco State University.

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

#### **Item 1A. 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.*

**Additional clinical trials will be required for the successful commercialization of ZADAXIN and if the results of our clinical trials are not favorable, we will be unable to obtain regulatory approval for the intended indications we are evaluating.**

Our ability to achieve and sustain operating profitability depends in large part on our ability to commence, execute and complete clinical programs and obtain additional regulatory approvals for ZADAXIN and other drug

candidates, particularly in the United States and Europe. We are also dependent on our ability to increase ZADAXIN sales in China and other markets. In particular, our ability to achieve and sustain profitability will depend in large part on our ability to commercialize ZADAXIN for the treatment of HCV or malignant melanoma in the United States and Europe.

To obtain regulatory approvals, we must, among other requirements, complete carefully controlled and well-designed clinical trials demonstrating that a particular drug is safe and effective for the applicable disease. We cannot depend on data from prior trial results to predict or demonstrate that our potential drug products are safe and efficacious under regulatory guidelines to qualify for commercial sale. We cannot assure you, nor can you rely on our previous clinical trial results to predict, that our ongoing or future clinical trials will yield favorable results. Adverse or inconclusive clinical results would prevent us from filing for regulatory approval of ZADAXIN (thymosin alpha 1) for the indications that we are evaluating, and our current programs in those areas would fail. In the past, Alpha 1 Biomedical, from which we acquired certain rights to thymosin alpha 1, conducted a phase 3 clinical trial of thymosin alpha 1 as a therapy for HBV that did not produce statistically significant results and Alpha 1 Biomedical did not submit an NDA to the FDA.

In December 2005 we announced results from the first of our two U.S. phase 3 HCV clinical trials. This clinical trial did not demonstrate that the combination of ZADAXIN and pegylated interferon alpha provides a statistically significant clinical benefit when compared to the use of pegylated interferon alpha alone in non-responder patients without cirrhosis of the liver, although a positive ZADAXIN treatment-related trend was observed. Data from the second U.S. phase 3 HCV clinical trial using ZADAXIN in combination with pegylated interferon alpha to treat non-responder HCV patients with early cirrhosis is expected to be reported in June 2006. Given the FDA general requirement of successful results from two phase 3 clinical trials to support an approvable New Drug Application, it is unlikely that an NDA based on these two clinical trials would be approved by the FDA. The current standard of care for HCV therapy is the combination of pegylated interferon alpha with ribavirin. This combination is not approved by the FDA or the EMEA for the treatment of non-responders, however, in clinical practice pegylated interferon alpha with ribavirin is widely used for the treatment of both treatment naïve and non-responder HCV patients. The European HCV phase 3 clinical trial being conducted by Sigma-Tau has been designed to compare the efficacy of the triple combination of ZADAXIN, pegylated interferon alpha and ribavirin with the current standard of care. The final results of the European trial will not be known before the end of 2007. As with the FDA, the EMEA generally requires two confirmatory phase 3 clinical trials to support their equivalent of an NDA. Therefore, results of the current triple therapy combination trial, even if positive and statistically significant, would by themselves be insufficient to support an NDA to the EMEA, and results from a second confirmatory phase 3 clinical trial would be needed. At this time, plans for such trial have not been made. We cannot assure you that we or our European partner, Sigma-Tau, will undertake such trial, that any clinical trial of the triple therapy combination will yield favorable results, that the second U.S. phase 3 HCV clinical trial will show statistical significance, that we will receive approval for ZADAXIN for the treatment of HCV in Europe or the United States or for the treatment of HCV in other countries, or that we will achieve significant levels of sales. If we are unable to do so, our business will be harmed.

In December 2005, we and Sigma-Tau announced promising interim results from a large phase 2 clinical trial in Europe evaluating ZADAXIN in combination with dacarbazine (DTIC) chemotherapy with and without low-dose interferon alpha to treat patients with stage IV, the most advanced and imminently fatal form of, malignant melanoma. These preliminary data show a distinct ZADAXIN dose-dependent response in combination with DTIC chemotherapy with and without low-dose interferon alpha. The trial's primary endpoint is overall tumor response. Preliminary survival information on the first 320-patient cohort is expected in mid-2006. We and Sigma-Tau plan to initiate phase 3 clinical trials in late 2006 to study the efficacy of ZADAXIN in combination with chemotherapy for the treatment of malignant melanoma. We cannot assure you that the final results of the phase 2 clinical trial will be favorable or support the design and initiation of phase 3 clinical trials, that we or Sigma-Tau will receive approval for the indication or that we will achieve significant levels of sales. If we are unable to do so, our business will be harmed.

**We may have difficulty in recruiting patients for our clinical trials. Higher than anticipated patient drop out rates in our clinical trials could adversely affect trial results and make it more difficult to obtain regulatory approval.**

In December 2005 we announced results from the first of our two U.S. phase 3 HCV clinical trials. This clinical trial did not demonstrate that the combination of ZADAXIN and pegylated interferon alpha provides a statistically significant clinical benefit when compared to the use of pegylated interferon alpha alone in non-responder patients without cirrhosis of the liver, although a positive ZADAXIN treatment-related trend was observed. These results may make Sigma-Tau's efforts to fully recruit patients for the currently ongoing ZADAXIN phase 3 HCV triple therapy combination trial more difficult and take longer than planned. In addition, HCV clinical trials are lengthy. The trials require patient treatment for 48 weeks and a follow-up observation period for an additional 24 weeks. Patient dropouts are expected and each of our two phase 3 HCV clinical trials in the United States enrolled more than the planned number of 500 patients, but even then dropouts were higher than anticipated. A patient who drops out at any point in the 72 weeks of the trial is considered a "failure to respond" in results of the clinical trial. In general, the fewer patients who complete each trial, the higher the positive response rate for the group of remaining ZADAXIN treated patients in such trial needs to be in order to demonstrate statistical significance. Therefore, a higher than anticipated dropout rate lowers the chances of proving statistical significance which could adversely affect our clinical trial results. Dropouts did not prevent us from completing our first U.S. phase 3 HCV clinical trial and are not expected to prevent completion of our second trial, however, the European phase 3 HCV triple therapy combination trial is still enrolling patients and dropouts may affect the ability to fully enroll the trial in a reasonable period of time and the final results of the trial.

**We cannot predict the safety profile of the use of ZADAXIN when used in combination with other drugs.**

Many of our trials involve the use of ZADAXIN in combination with other drugs. Some of these drugs, particularly pegylated interferon alpha, ribavirin and dacarbazine are known to cause adverse patient reactions. Even if ZADAXIN does not produce adverse side effects when used alone, we cannot predict how it will work with other drugs, including causing possible adverse side effects not directly attributable to the other drugs that could compromise the safety profile of ZADAXIN when used in certain combination therapies.

**If we do not obtain regulatory approval for ZADAXIN for the intended indications that we are evaluating, our revenues will be limited and we may never become profitable.**

Our ability to execute on our business strategy has been largely dependent on our ability to obtain regulatory approval for the use of ZADAXIN, particularly in the United States and Europe. The regulatory approval processes in the United States and Europe are demanding and typically require 12 months or more in the United States and 18 months or more in Europe from the date of submission of a New Drug Application (NDA). We have committed significant resources, including capital and time, to develop ZADAXIN, and intend to continue to do so, including the initiation and execution of additional clinical trials, with the goal of obtaining such approvals. If we do not obtain these approvals, we will be unable to achieve any substantial increase in our revenue from ZADAXIN and our ZADAXIN sales in other jurisdictions could decline.

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 may change from time to time and new regulations may be adopted.

Obtaining regulatory approval in developing countries also is time-consuming and expensive. In some countries where we are contemplating marketing and selling ZADAXIN, the regulatory approval process often relies on prior approvals obtained in the United States or in Europe. Without such prior approvals, our ability to

obtain regulatory approvals for ZADAXIN in these countries may be delayed or prevented. 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, and we have experienced difficulties in preparing for regulatory approval in Japan. We cannot assure you that we will ultimately obtain regulatory approvals in our targeted countries in a timely and cost-effective manner or at all. If we fail to obtain the required regulatory approvals to develop, market and sell ZADAXIN in countries where we currently do not have such rights, our revenues will be limited, and our future prospects will be dependent upon our ability to in-license or to bring earlier stage products to market, any of which will require substantial financial expenditures.

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 impose costly procedures upon our activities. Even if we obtain regulatory approval for our products, such approval may impose limitations on the indicated uses for which our products may be marketed. Unsatisfactory data resulting from clinical trials may also adversely affect our ability to market and sell ZADAXIN in markets where it is approved for sale.

**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 worldwide nature of our business. Following the departure of our Chief Executive Officer on July 14, 2004, we established an Office of the President, and believe that the Company continued to function effectively under the Office of the President. Our new President and Chief Executive Officer, Dr. Ira Lawrence, began his service to the Company on June 1, 2005. However, we may be affected adversely by any future changes in our key management personnel. 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, we assign numerous key responsibilities to a limited number of individuals, and we would experience difficulty in finding immediate replacements for any of them. 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 personnel.

**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 operating results and 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 operating results and financial condition will be harmed. In the year ended December 31, 2005, approximately 91% of our ZADAXIN sales were to customers in China. For the years ended December 31, 2004 and 2003, sales to our customers in China accounted for approximately 91% and 88%, respectively, of product sales. Sales of ZADAXIN in China may be limited due to the low average personal income, lack of patient cost reimbursement, poorly developed infrastructure and existing and potential competition from other products, including generics. In China, ZADAXIN is approved only for the treatment of HBV and as a vaccine adjuvant. We face competition from certain large, global pharmaceutical companies who are aggressively marketing competing products for the treatment of HBV and other indications where ZADAXIN is used on an off-label basis. In addition, several local companies have introduced lower priced locally manufactured generic thymosin which is a competitive product.

We expect such competition to continue and there could be a negative impact on the price and the volume of ZADAXIN sold in China, which would harm our business. Our efforts to in-license other pharmaceutical products for marketing in China and other markets may be unsuccessful or may not have a meaningful effect on our dependence on ZADAXIN sales in those markets.

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 registrations, permits, pricing approvals and reimbursement, unexpected changes in regulatory requirements and political instability. We are also subject to the laws and regulations of other countries regarding the marketing, sale and distribution of our products in those countries where approvals have been obtained. We experience other issues with managing foreign sales operations including long payment cycles, potential difficulties in accounts receivable collection and, especially from significant customers, fluctuations in the timing and amount of orders. Operations in foreign countries also expose us to risks relating to difficulties in enforcing our proprietary rights, currency fluctuations and adverse or deteriorating economic conditions. If we experience problems with obtaining registrations, complying with reimbursement rules or compliance with other laws, or if we experience difficulties in payments or intellectual property matters in foreign jurisdictions, or if significant political, economic or regulatory changes occur, our results could be adversely affected.

We do not have product sales in the United States, Europe or Japan with which to offset any decrease in our revenue from ZADAXIN sales in Asia, Latin America and the Middle East, and sales outside of China have not been substantial to date. 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. In China, individual provinces and, in some cases, individual hospitals can and have established pricing requirements for a product to be included on formulary lists. These prices may be lower than our distributors have been selling ZADAXIN in which case we have been removed from formulary lists, which consequently has reduced sales to certain hospitals.

**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 typically place large, and therefore relatively few, orders within any six month period. 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. We rely on four to six importers, in any given quarter, to supply substantially all of our product in China. Because we use a small number of importing agents in China, our receivables from any one importing agent are material, and if we were unable to collect receivables from any importer, our business and cash-flow would be adversely affected.*

**Our sales of ZADAXIN may fluctuate due to seasonality of product orders and sales in any quarter may not be indicative of future sales.**

Our sales for the quarter ended June 30, 2003 were greatly affected by the demand in China for ZADAXIN in connection with the treatment of SARS. To date, SARS has not re-emerged, like influenza, as a seasonal public health problem. However, if SARS or a similar epidemic were to emerge, it is not possible to predict what effect, if any, this would have on future sales of ZADAXIN. Although we do not market ZADAXIN for use in treating such epidemic diseases, if ZADAXIN is purchased in connection with future outbreaks of seasonal viral contagions, product sales could become more concentrated in certain quarters of the calendar year, quarterly sales levels could fluctuate and sales in any quarter may not be indicative of sales in future periods.

**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, and we have limited intellectual property protection in China.**

Our success depends significantly on our ability to obtain and maintain meaningful patent protection for our products and technologies and to preserve our trade secrets. 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 that may be issued, if any, 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, including composition of matter patents, we have rights to other patents and patent applications relating to ZADAXIN and ZADAXIN analogues, including method of use patents with respect to the use of ZADAXIN for certain indications. We do not have a patent on the use of ZADAXIN as a therapy for the treatment of melanoma. If other parties develop generic forms of ZADAXIN for other indications, including conducting clinical trials for such indications, our patents and other rights might not be sufficient to prohibit them from marketing and selling such generic forms of ZADAXIN. If other parties develop analogues or derivatives of ZADAXIN, our patents and other rights might not be sufficient to prohibit them from marketing these analogues or derivatives.

Pharmaceutical products are either not patentable or have only recently become patentable in some of the countries in which we market or may market ZADAXIN. We do not have patent protection for ZADAXIN in China, our largest market. Other companies market generic thymosin alpha 1 in China, sometimes in violation of our trademark or other rights which we defend by informing physicians and hospitals of the practice as well as through the limited legal recourse. Past enforcement of intellectual property rights in many of these countries, including China in particular, 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 are involved in intellectual property claims and litigation, the proceedings may divert our resources and subject us to significant liability for damages, substantial litigation expense and the loss of our proprietary rights.**

Our commercial success 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 a third-party patent that may relate to our products and may cover a method of action used by ZADAXIN. We cannot assure you that our mechanism of action does not infringe on their claim. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our potential products. For example, U.S. patent applications may be kept confidential for 12 or more months while pending in the Patent and Trademark Office, and patent applications filed in foreign countries are often first published six months or more after filing. 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, regardless of merit, 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. Any conflicts resulting from the patent rights of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection.

If other companies obtain patents with conflicting claims, we may be required to obtain licenses to those patents or develop or obtain alternative technology to manufacture or market the affected products and processes. We may not be able to obtain any such licenses on acceptable terms or at all. Any failure to obtain such licenses could delay or prevent us from pursuing the development or commercialization of our potential products. Our efforts to defend against any of these claims would require us to devote resources and attention that could have been directed to our operations and growth plans.

We may need to initiate litigation, which could be time-consuming and expensive, to enforce our proprietary rights or to determine the scope and validity of others' rights. If litigation results, a court may find our patents or those of our licensors invalid or may find that we have infringed on a competitor's rights. If any of our competitors have filed patent applications in the United States which claim technology we also have invented, the Patent and Trademark Office may require us to participate in expensive interference proceedings to determine who has the right to a patent for the technology. 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.

**We rely on third parties to supply our clinical trial and commercial products. Deficiencies in their work could delay or harm one or more important areas of our business including our sales, clinical trials or the regulatory approval process.**

We rely on third parties, who are subject to regulatory oversight, to supply our clinical and commercial products. We have been in the process of registering a new manufacturer of ZADAXIN and if we encounter problems with this process of validation, our sales or our clinical trials could be adversely affected. If sales of ZADAXIN were to increase dramatically, our third-party suppliers may not be able to supply ZADAXIN quickly enough, which could limit our ability to satisfy increased demand or could adversely affect the ability of these suppliers to provide products for our clinical trials. If unanticipated deficiencies in these suppliers occur, we could experience delays in our ability to fulfill regulatory requirements which may adversely affect our sales or prospects for regulatory marketing approvals. We have an exclusive supplier of pegylated interferon alpha for our U.S. phase 3 HCV and European phase 3 HCV clinical trials. Any recall of the manufacturing lots of the pegylated interferon alpha used in our clinical trials could detract from the integrity of the trial data and its potential use in future regulatory filings.

**If we are not able to establish and maintain adequate manufacturing 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 stringent regulatory requirements and at an acceptable cost. Typically we have at any time only one supplier for each phase of manufacturing of our product. Manufacturing interruptions or failure to comply with regulatory requirements could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures 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.

We are in the process of registering a new supplier for ZADAXIN with regulatory agencies in markets where ZADAXIN is approved for sale. We have received such registration in China. This process, quality assurance and other steps could cause delays or interruptions of supply in certain other markets. In some countries, a manufacturing change may require additional regulatory approvals which may delay ZADAXIN marketing approvals in new markets. 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.

**We may not be able to successfully develop or commercialize our products. We may consider strategic alliances with other companies in efforts to broaden our product development pipeline.**

While we have limited sales of ZADAXIN in certain markets, we do not yet have regulatory approval for ZADAXIN for the key markets of the United States, Europe and Japan and, in this respect, ZADAXIN is still being developed. Our only other potential product presently is SCV-07 and it is in an earlier stage of development than ZADAXIN. We may consider and undertake various strategies to expand our portfolio of potential products, including acquiring product candidate rights through licenses or other relationships, or through other strategic relationships including acquisitions of other companies that may have proprietary rights to other development candidates or the capability to discover new drug candidates. Such transactions could require a substantial amount of our financial resources, or, if equity is involved, may result in substantial dilution to current stockholders. Strategic transactions also require substantial management time and effort and are subject to various risks that could adversely affect us or our financial results.

To fully develop our products, we will need to commit substantial resources to extensive research, development, pre-clinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to the potential products being ready for sale. We cannot assure that our efforts will produce commercially viable products. 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. 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 and our sales have been primarily in a single country, China. Our future revenue growth depends to great extent on increased market acceptance and commercialization of ZADAXIN in additional countries, particularly in the United States, Europe and Japan. If we fail to successfully market ZADAXIN, or if we cannot commercialize this drug in the United States and other additional markets, our revenue and operating results will be limited. If unexpected and serious adverse events are reported, or if expected efficacy results are not achieved, it would have a material adverse effect on our business. Our future revenue will also depend in part on our ability to develop other commercially viable and accepted products. Market acceptance of our products will depend on many factors, including our ability to convince prospective customers to use our products as an alternative to other treatments and therapies and to convince prospective strategic partners to market our products effectively and to manufacture our products in sufficient quantities with acceptable quality and at an acceptable cost. In addition, doctors must opt to use treatments involving our products. If doctors elect to use a different course of treatment, demand for our drug products would be reduced. Failure to do any of the above will lead to an unfavorable outcome on the results of our operations.

**We rely on third-party clinical investigators to conduct our clinical trials and, as a result, we may encounter delays outside our control.**

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.

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

We believe our existing resources will be sufficient to fund our operations, including anticipated clinical trials, into late 2008. However, we cannot assure that such funds will be sufficient, or that we will attain

profitable operations in that period if ever. In addition to development plans for ZADAXIN, we intend to develop other products and we may need additional funds in the future to support such development and to support future growth and achieve profitability. If we need to raise additional funds in the future and such funds are not available on reasonable terms, if at all, our commercialization efforts may be impeded, our revenues may be limited and our operating results may suffer.

**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, 2005, we had an accumulated deficit of approximately \$159 million. 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, and these losses may increase if we cannot increase or sustain revenue. As a result, we may never achieve profitability.

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

Outside of our current principal market of China, we have limited sales, marketing and distribution capabilities, and we anticipate that we may be relying on third-party collaborators to sell, market and distribute our products for the foreseeable future particularly in the major pharmaceutical markets of the United States, Europe and Japan should we receive regulatory approval to market our products in those territories. 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 future operating results. Moreover, 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.

**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 or promote our drugs, and if they are not successful in their efforts or fail to do so, our business will suffer. For example, Sigma-Tau is responsible for the development and marketing of ZADAXIN in most of Europe. 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 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 with our collaborators, including disputes over ownership rights to intellectual property, know-how or technologies developed with our collaborators. We may not be able to negotiate similar additional arrangements in the future to develop and commercialize ZADAXIN or other products.

**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 will increase. Our success depends on our ability to compete in this industry, but we cannot assure you that we will be able to successfully compete with our competitors. Increased competitive pressure could lead to intensified price-based competition resulting in lower prices and margins, which would hurt our operating results.

We are focused on developing ZADAXIN as a treatment for HCV and HBV and certain cancers. Several large biopharmaceutical companies have substantial commitments to interferon alpha, an approved drug for treating HBV and HCV, and to lamivudine and adefovir, approved drugs to treat HBV. 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 HCV, HBV, cancer and other diseases that will be superior to ours.

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

Significant uncertainty exists as to the reimbursement status of new therapeutic products, such as ZADAXIN. We cannot assure you that third-party insurance coverage and reimbursement will be available for therapeutic products we might develop. We cannot assure you that we will be able to maintain or increase third-party payments for ZADAXIN in China. The failure to obtain or maintain third-party reimbursement for our products would harm our business. Further, we cannot assure you that additional limitations will not be imposed in the future in the United States or elsewhere on drug coverage and reimbursement due to proposed health care reforms. In many emerging markets where we have marketing rights to ZADAXIN, but where government resources and per capita income may be so low that our products will be prohibitively expensive, we may not be able to market our products on economically favorable terms, if at all.

Efforts by governmental and third-party payers to contain or reduce health care costs or the announcement of legislative proposals or reforms to implement government controls could cause us to reduce the prices at which we market our drugs, which would reduce our gross margins and may harm our business.

**Settlements regarding our claims relating to the Japanese clinical trials may not be favorable.**

Based on recent information received from Schering Plough KK (SPKK) and in conjunction with our own investigative efforts, we have determined that we cannot submit a Japanese new drug application (JNDA), or apply for a pre-JNDA preliminary review, for ZADAXIN as a therapy for HBV to the Ministry of Health in Japan. This conclusion is based on SPKK's failure to conduct certain audits and generate certain reports during the pre-2001 studies that it managed and our conclusion that such documentation cannot be created at this time. This conclusion is not based on the substantive results of the Japan trials, which showed ZADAXIN to have competitive efficacy and safety in the treatment of HBV. We and SPKK continue to investigate and discuss the issues involved, and how this matter should be fairly resolved. We and SPKK are in the process of mediation which we expect to conclude by the end of our first fiscal quarter of 2006. We cannot provide any assurance as to the outcome of the mediation. If mediation concludes without satisfactory results, we intend to pursue arbitration. Arbitration can be expensive and protracted and there can be no assurance that this dispute will be concluded in the near future or resolved favorably to us.

SciClone is now determining the appropriate development strategy for ZADAXIN in Japan, however, it is unlikely that SciClone will be able to submit a JNDA for ZADAXIN in Japan for some years, if at all. If this process is restarted, it could be lengthy and could incur significant management time and expense.

**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, if at all, 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.

**We depend on international sales, and global conditions could negatively affect our operating results.**

A large majority of our sales are in China. Heightened tensions resulting from the current geopolitical conditions in the Middle East, North Korea and elsewhere could worsen, causing disruptions in foreign trade,

which would harm our sales. In particular, 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 geopolitical conditions could decrease our sales and harm our operating results.

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

We are subject to various federal, state and local laws, regulations and recommendations relating to the use, manufacture, storage, handling and disposal of hazardous materials and waste products (including radioactive compounds and infectious disease agents), as well as safe working conditions, laboratory and manufacturing practices and the experimental use of animals. The extent of government regulation that might result from future legislation or administrative action in these areas cannot be accurately predicted.

We do not currently maintain hazardous materials at our facilities. 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 environmental laws and regulations. Further, in the event of an accident, we would be liable for any damages that result, and the liability could exceed our resources.

**Our stock price may be volatile, and an investment in our stock could suffer a decline in value.**

The market price of our common stock has experienced, and may continue to experience, substantial volatility due to many factors, some of which we have no control over, including:

- progress and results of clinical trials involving ZADAXIN;
- progress of ZADAXIN through the regulatory process, especially regulatory actions and the adequacy of clinical data and documentation for regulatory purposes in the United States, Europe and Japan;
- timing and achievement of milestones;
- announcements of technological innovations or new products by us or our competitors;
- announcement and completion of corporate acquisition, merger, licensing or marketing arrangements, or sales of assets;
- government regulatory action affecting our drug products or our competitors' drug products in both the United States and foreign countries;
- developments or disputes concerning patent or proprietary rights;
- changes in the composition of our management team or board of directors;
- changes in company assessments or financial estimates by securities analysts;
- actual or anticipated fluctuations in our quarterly operating results;
- changes in assessments of our internal controls over financial reporting;
- general stock market conditions and fluctuations for the emerging growth and biopharmaceutical market sectors;
- economic conditions in the United States or abroad; and
- broad financial market fluctuations in the United States, Europe or Asia.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of our attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

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

Our collaborative partner Sigma Tau and affiliates hold a substantial amount of our stock. The stock is freely tradeable and Sigma Tau is not under any obligation to SciClone which would prevent it from selling some or all of the stock it holds.

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 present stockholders will be reduced and the price of our common stock may fall.

**Sales of our common stock by officers and directors could affect our stock price.**

Our board of directors has approved an amendment to our trading policy that permits officers and directors to enter into trading plans that comply with the requirements of Rule 10b5-1 of the Securities Exchange Act of 1934, as amended. Rule 10b5-1 allows corporate officers and directors to adopt written, pre-arranged stock trading plans when they do not have material, non-public information. Using these plans, officers and directors can gradually diversify their investment portfolios, can spread stock trades out over an extended period of time to reduce any market impact and can avoid concerns about initiating stock transactions at a time when they might be in possession of material, non-public information. As of February 13, 2006, one director has adopted such a plan, and other directors or officers may do so in the future. We expect future sales by officers and directors either under 10b5-1 plans or otherwise as a result of their personal financial planning. We do not believe the volume of such sales would affect our trading price; however, the market could react negatively to sales by our officers and directors, which could affect the trading price of our stock.

**Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.**

Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our charter documents contain certain anti-takeover provisions, including provisions in our certificate of incorporation providing that stockholders may not cumulate votes, stockholders' meetings may be called by stockholders only if they hold 25% or more of our common stock and provisions in our bylaws providing that the stockholders may not take action by written consent. Additionally, our board of directors has the authority to issue 10 million shares of preferred stock and to determine the terms of those shares of stock without any further action by the stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that may be issued. The issuance of preferred stock could make it more difficult for a third-party to acquire a majority of our outstanding voting stock. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future.

**If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results. As a result, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.**

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our business and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. For example, in the quarter

ended June 30, 2005, we identified a material weakness in our internal controls over financial reporting as defined in Public Company Accounting Oversight Board (PCAOB) Standard No. 2. This material weakness related to our failure, due to our lack of familiarity with certain technical stock option accounting matters, to evaluate the correct accounting effect of a stock price performance based option granted to our Chief Executive Officer on June 1, 2005, the date he commenced his employment. Due to the terms of this option, Accounting Principles Board Opinion No. 25 (APB 25) requires the application of variable accounting and specifically requires the recognition of non-cash expense in the period that portions of the option vest or are deemed probable of vesting at the end of the reporting period. The vesting of this option is directly determined by the price level of trading activity in our stock, and the conditions required to recognize a related non-cash expense did not occur in the interim period ended June 30, 2005. However, had the conditions required the recognition of a non-cash expense related to this option under APB 25, our accounting procedures at June 30, 2005 would not have correctly applied APB 25. Because of the material weakness described above, management concluded that the Company did not maintain effective internal control over financial reporting as of June 30, 2005. The Company's management identified the steps necessary to address the material weakness described above, and executed remediation plans, as discussed in "Item 4. Controls and Procedures" of our September 30, 2005 quarterly report on Form 10-Q incorporated by reference.

Any failure to implement and maintain the improvements in the controls over our financial reporting, or difficulties encountered in the implementation of these improvements in our controls, could cause us to fail to meet our reporting obligations. Any failure to improve our internal controls to address these identified weaknesses could also cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

**New accounting pronouncements may impact our financial position or results of operations.**

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and this may lead to changes in our accounting policies in the future. One such new pronouncement issued in December 2004 by the Financial Accounting Standards Board (FASB) is FASB Statement No. 123 (revised 2004), "Share-Based Payment" (SFAS 123R). SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. We adopted SFAS 123R on January 1, 2006. The Company currently accounts for share-based payments to employees and directors using Accounting Principles Board Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options and employee stock purchase plans. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our cash or overall financial position.

**New legislation may impact our financial position or results of operations.**

Compliance with changing regulations concerning corporate governance and public disclosure has resulted in and may continue to result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ National Market rules, are creating uncertainty for companies such as ours and costs are increasing as a result of this uncertainty and other factors. 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 has and may continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

**We may be subject to currency exchange rate fluctuations, which could adversely affect our financial performance.**

Substantially all of our product sales are denominated in U.S. dollars. Fluctuation in the U.S. dollar exchange rate with local currency directly affects the customer's cost for our product. In particular, a stronger

U.S. dollar vis-à-vis the local currency would tend to have an adverse effect on sales and potentially on collection of accounts receivable. Through the periods ended December 31, 2005, this exposure to currency exchange rate fluctuations had been minimal because the Chinese currency had been pegged to the U.S. dollar. However, the Chinese currency is no longer pegged to the U.S. dollar and consequently, our foreign operations may expose us to greater risk of decreased sales due to currency exchange rate fluctuations in the future. In addition, we are subject to currency exchange rate fluctuations as a result of expenses incurred by our foreign operations. In particular, one of our supply arrangements under which we purchase finished products is denominated in euros and costs of our marketing efforts in China are paid in local currency. Consequently, changes in exchange rates could unpredictably and adversely affect our operating results and could result in exchange losses. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have a material adverse impact on our future operating results and stock price.

**Item 1B. *Unresolved Staff Comments***

None

**Item 2. *Properties***

We currently lease approximately 22,000 square feet of office space at our headquarters in San Mateo, California and limited office space in Beijing, Hong Kong, Shanghai, Singapore, Tokyo and Sao Paulo. 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, 2005.

## PART II

### Item 5. *Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

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

The following table sets forth the high and low bid 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>2005</b>		
4th quarter .....	\$5.70	\$1.94
3rd quarter .....	8.18	4.44
2nd quarter .....	5.18	2.10
1st quarter .....	3.82	2.55
<b>2004</b>		
4th quarter .....	\$4.86	\$3.54
3rd quarter .....	5.17	3.30
2nd quarter .....	5.88	4.40
1st quarter .....	8.19	5.06

#### Stockholders

As of March 1, 2006, there were approximately 382 holders of record of our common stock and 45,899,107 shares of common stock issued and outstanding.

#### Dividends

We have not paid any dividends on our common stock during the fiscal years ended December 31, 2005, 2004, and 2003 and currently intend to retain any future earnings for use in our business.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K is incorporated by reference from the section entitled "Securities Authorized for Issuance under Equity Compensation Plans" in Part III, Item 12 of this Form 10-K.

**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,				
	2005	2004	2003	2002	2001
<b>Statement of Operations data:</b>					
Product sales	\$27,842,000	\$ 22,765,000	\$31,732,000	\$ 17,101,000	\$ 13,831,000
Contract revenue	492,000	1,631,000	806,000	671,000	—
Total revenues	28,334,000	24,396,000	32,538,000	17,772,000	13,831,000
Cost of product sales	4,875,000	4,577,000	5,636,000	3,487,000	2,742,000
Gross margin	23,459,000	19,819,000	26,902,000	14,285,000	11,089,000
Operating expenses:					
Research and development	14,406,000	17,994,000	18,949,000	11,647,000	8,561,000
Sales and marketing	10,237,000	9,665,000	9,018,000	8,724,000	8,764,000
General and administrative	7,457,000	6,311,000	4,134,000	3,902,000	3,897,000
Total operating expenses	32,100,000	33,970,000	32,101,000	24,273,000	21,222,000
Loss from operations	(8,641,000)	(14,151,000)	(5,199,000)	(9,988,000)	(10,133,000)
Income from payment on note receivable from former officer	—	—	—	—	3,497,000
Interest and investment income	1,273,000	1,285,000	266,000	323,000	751,000
Interest expense	(345,000)	(361,000)	(361,000)	(361,000)	(334,000)
Other income (expense), net	—	(51,000)	19,000	(11,000)	(13,000)
Net loss	<u>\$ (7,713,000)</u>	<u>\$ (13,278,000)</u>	<u>\$ (5,275,000)</u>	<u>\$ (10,037,000)</u>	<u>\$ (6,232,000)</u>
Basic and diluted net loss per share	<u>\$ (0.17)</u>	<u>\$ (0.30)</u>	<u>\$ (0.13)</u>	<u>\$ (0.29)</u>	<u>\$ (0.19)</u>
Weighted average shares used in computing basic and diluted net loss per share	<u>45,328,714</u>	<u>44,626,337</u>	<u>39,568,199</u>	<u>35,002,003</u>	<u>32,356,287</u>

	December 31,				
	2005	2004	2003	2002	2001
<b>Balance Sheet data:</b>					
Cash, cash equivalents and Investments	\$42,256,000	\$51,299,000	\$62,975,000	\$21,150,000	\$16,468,000
Working capital	48,667,000	55,427,000	72,950,000	29,116,000	26,930,000
Total assets	59,515,000	69,709,000	83,822,000	37,111,000	32,096,000
Other long-term liabilities	—	1,044,000	900,000	—	—
Total stockholders' equity	51,063,000	55,123,000	68,250,000	23,354,000	22,774,000
Convertible notes payable	1,600,000	5,600,000	5,600,000	5,600,000	5,600,000

## **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 consolidated 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**

We are a biopharmaceutical company engaged in the development and commercialization of therapeutics to treat life-threatening diseases, primarily cancer, and viral and other infectious diseases. Our lead product ZADAXIN is approved for sale in select markets internationally, most notably in China where we have an established sales and marketing operation. Our strategy is to leverage our advantage in China by in-licensing or acquiring the marketing rights to other products to market in this rapidly growing pharmaceutical market. ZADAXIN is currently being evaluated in a large, phase 2 stage IV malignant melanoma clinical trial in Europe. In addition, a large phase 3 clinical trial is ongoing in Europe using ZADAXIN as part of a novel triple therapy combination for the treatment of HCV. In December 2005, we reported results from the first of our two U.S. phase 3 trials evaluating the double therapy combination of ZADAXIN and pegylated interferon alpha to treat HCV patients who had failed previous therapy. The results from this trial did not demonstrate that ZADAXIN in combination with pegylated interferon alpha provides a statistically significant clinical benefit when compared with pegylated interferon alpha alone. Although not statistically significant, a positive ZADAXIN treatment-related trend was observed. Data from the second U.S. HCV trial is expected to be reported in June 2006.

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. Our primary focus has been the clinical development of ZADAXIN as a part of a new combination therapy for the treatment of HCV.

We manufacture ZADAXIN for sale, and for our clinical trials, through third party contract manufacturers, and we conduct our research and development efforts principally through arrangements with clinical research sites, contract research organizations and universities.

From commencement of operations through December 31, 2005, we have an accumulated deficit of approximately \$159,000,000. At least over the next few years, we expect net losses to continue at similar levels or to increase due to increased operating expenses 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 execution and successful completion of ZADAXIN clinical trials and securing regulatory approvals for ZADAXIN in the major pharmaceutical markets of the United States, Europe, and Japan, and, if approved in those countries, the successful commercialization and marketing of ZADAXIN. In addition, other factors may also impact our ability to achieve and sustain operating profitability, including the pricing of ZADAXIN and its manufacturing and marketing costs, our ability to compete in pharmaceutical markets, the cost of long-term product development and commercialization programs, the timing and costs of acquiring rights to additional drugs, our ability to fund our operations and the entrance into and extension of agreements for product development and commercialization, where appropriate.

We expect net sales to increase in 2006 due to increase sales to China. Primarily due to the level of research and development activities and other operations, we expect a net loss and a reduction in cash, cash equivalents and short-term investments for 2006.

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.

## **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 our Consolidated Financial Statements" in Part II, 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***

We recognize revenue from product sales at the time of shipment. There are no significant customer acceptance requirements or post-shipment obligations on our part. 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, we will replace products that have expired or are deemed to be damaged or defective when delivered. We exercise judgment in estimating return reserves. 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. We exercise judgment in determining the period over which our performance obligations have been fulfilled which can have an impact on the timing and amount of revenue that is recognized in a particular reporting period. Nonrefundable contract fees for which no further performance obligations exist, and for which there is no continuing involvement by us, 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. We exercise judgment in our determination of the achievement of milestones which can have an impact on the timing and amount of revenue recognized in a particular reporting period.

Amounts invoiced relating to arrangements where revenue cannot be recognized are reflected on our balance sheet as deferred revenue and recognized as the applicable revenue recognition criteria are satisfied.

### ***Accounts Receivable***

We are required to estimate the collectibility of our trade receivables. 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. A considerable amount of judgment is required in assessing the ultimate realization of these receivables including, but not limited to, an analysis of the historical payment patterns of our customers, individual customer circumstances and their geographic region including a review of the local economic environment. 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 or the economic environment in which they operate were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required which would increase our general and administrative expenses and increase our reported net loss. Conversely, if actual credit losses are significantly less than expected, this would decrease our general and administrative expenses and decrease our reported net loss.

### ***Inventories***

Our inventories are stated 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. If our current assumptions about future production or inventory levels and demand were to change or if actual market conditions are less favorable than those projected by management, inventory write-downs may be required which could negatively impact our gross margins and results of operations.

### ***Impairment of Intangible Assets***

At December 31, 2005, we had net intangible assets of \$472,000 related to ZADAXIN product rights and have 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. 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 research and development expenses are principally incurred for our clinical trials including our phase 3 clinical trials in the United States. Research and development expenses 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 vary 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, for the phase 3 clinical trials in the United States, these expenses are higher for the initial and final months of a patient's scheduled 18 months of treatment and observation. Expenses relating to the clinical research organizations or other entities managing the trials and laboratory and other direct expenses are recognized in the period they are estimated to be incurred and the services performed. We monitor active 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, requiring the recording of additional expenses and an increase in net loss in the future.

### ***Stock Option Valuation***

The preparation of the financial statement footnotes requires us to estimate the fair value of stock options granted to employees and directors. While fair value may be readily determinable for awards of stock, market quotes are not available for long-term, nontransferable stock options because these instruments are not traded. We currently use the Black-Scholes option pricing model to estimate the fair value of employee and director

stock options. Option valuation models require the input of highly subjective assumptions, including stock price volatility. Changes to the subjective input assumptions could materially affect the estimated fair value of our stock options as disclosed in note 1 of the Notes to Consolidated Financial Statements.

In order to estimate the value of stock options, we use the Black-Scholes model, which requires the use of certain subjective assumptions. The most significant assumptions are our estimates of the expected volatility, and expected term of the award. We utilized historical information available to support our estimate of certain assumptions required to value stock options. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. We believe that it is appropriate to place greater weight on historical realized volatilities when developing an estimate of expected volatility. We believe that historical realized volatilities of options with appropriate terms are a strong indicator of future volatility. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, lengthier option terms provide more opportunity to exploit market highs. However, empirical data shows that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. Accordingly, companies are required to estimate the expected term of the option for input to an option-pricing model. When establishing an estimate of the expected term, we consider the vesting period for the award, our historical experience of employee stock option exercises, and the expected volatility. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, we are likely to change our valuation assumptions used to value stock based awards granted in future periods.

### ***Results of Operations***

Product sales were \$27,842,000, \$22,765,000 and \$31,732,000 for the years ended December 31, 2005, 2004 and 2003, respectively, and all were derived from sales of ZADAXIN. Sales to customers in China accounted for approximately 91%, 91% and 88% of this revenue for the years ended December 31, 2005, 2004 and 2003, respectively. Product prices have remained stable throughout the 2003, 2004 and 2005 periods. Approximately \$11,000,000 of the sales in 2003 were from an unanticipated temporary increase in demand for ZADAXIN from hospitals in China at the time of the SARS outbreak during the second quarter of 2003.

For the years ended December 31, 2005, 2004 and 2003, sales to between three and five importing agents in China accounted for approximately 91%, 91% and 88%, respectively of our product sales. In 2005, Guang Dong South Pharmaceutical Foreign Trade Co., Ltd, Zhuhai Goldsn Medicine Co., Ltd and China National Pharmaceutical Foreign Trade Corporation accounted for 57%, 19%, and 15% of our sales, respectively. In 2004, China National Pharmaceutical Foreign Trade Corporation, China Meheco Corporation and Guang Dong South Pharmaceutical Foreign Trade Co., Ltd accounted for 32%, 29% and 23% of our sales, respectively. In 2003, China National Pharmaceutical Foreign Trade Corporation and China Meheco Corporation accounted for 52% and 14% of sales, respectively. No other customers accounted for more than 10% of sales in those periods. As of December 31, 2005, approximately \$8,847,000 or, 90% of our accounts receivable were attributable to three customers in China. We perform on-going credit evaluations of our customers' financial condition, and generally do not require collateral from our customers.

Contract revenue was \$492,000, \$1,631,000 and \$806,000 for the years ended December 31, 2005, 2004 and 2003, respectively. The contract revenue for 2004 includes a \$1,000,000 milestone payment we received from Sigma-Tau relating to the completion of enrollment of our U.S. phase 3 HCV clinical trials. The remaining contract revenue recognized in 2003, 2004 and 2005 is in connection with the \$2,685,000 payment we received from Sigma-Tau in January 2002. This revenue is recognized as contract revenue over the course of the ZADAXIN U.S. phase 3 HCV clinical trials and the period of sharing the clinical data from these trials with Sigma-Tau in accordance with the requirements under our contract.

Gross margin was 83%, 81% and 83% in 2005, 2004 and 2003, respectively. The increase in gross margin percentage in the 2005 period was primarily the result of lower product costs for product sold in that period. The decrease in gross margin percentage in the 2004 period was primarily the result of higher product costs in connection with the transfer to a new toll manufacturer for ZADAXIN and lower product costs in the 2003 periods due to higher volume productions in response to the SARS epidemic in China. We expect cost of product sales and hence gross margin to vary from year to year, depending upon the level of ZADAXIN sales, the absorption of product-related fixed costs, and any charges associated with excess or expiring finished product inventory.

Research and development (R&D) expenses were \$14,406,000, \$17,994,000 and \$18,949,000 for the years ended December 31, 2005, 2004, and 2003, respectively. The decrease over the years from 2003 to 2005 was primarily related to the U.S. phase 3 HCV clinical trials nearing completion at the end of 2005. During 2005, we recorded approximately \$3,400,000 of expenses related to the U.S. phase 3 HCV trial. This compares to expenses in 2004 of approximately \$8,600,000 and approximately \$9,400,000 in 2003. In 2005, 2004 and 2003, R&D expenses represented approximately 45%, 53% and 59%, 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 primarily relate to clinical trials. Pharmaceutical development costs consist of product formulation and chemical analysis. During 2005, we recorded approximately \$4,300,000 of research, \$8,300,000 of clinical development, and \$1,800,000 of pharmaceutical development activities. This compares to expenses in 2004 of approximately \$4,100,000 of research, \$11,800,000 of clinical development, and \$2,100,000 of pharmaceutical development activities and expenses in 2003 of approximately \$2,100,000 of research, \$14,500,000 of clinical development, and \$2,300,000 of pharmaceutical development activities.

The initiation and continuation of our current clinical development programs has had and will continue to have a significant effect on our research and development expenses. In general, we expect research and development expenses 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. An expansion or significant extension of our clinical development programs may require us to seek additional capital resources.

Sales and marketing expenses were \$10,237,000, \$9,665,000 and \$9,018,000 for the years ended December 31, 2005, 2004 and 2003, respectively. The year-to-year increases from 2003 to 2005 were related to expenses for advertising and conferences associated with the expansion of our marketing efforts for ZADAXIN. The increase in sales and marketing expenses in 2005 was primarily due to increased expenses related to conferences of \$244,000 and increased expenses associated with the expansion of our marketing efforts of approximately \$208,000. The increase in sales and marketing expenses in 2004 was primarily due to increased expenses related to conferences of approximately \$581,000. We expect sales and marketing expenses for 2006 to be higher than those incurred in 2005 due to increased sales efforts.

General and administrative expenses were \$7,457,000, \$6,311,000 and \$4,134,000 for the years ended December 31, 2005, 2004 and 2003, respectively. The increase in 2005 was primarily related to increased legal fees of approximately \$625,000 to support increased legal and regulatory activities, increased accounting fees of approximately \$237,000 associated with increased securities regulation requirements and approximately \$472,000 related to non-cash stock-price performance based option expenses. The increase in 2004 was primarily attributable to a non-recurring expense of \$1,098,000 incurred in connection with the separation of our former Chief Executive Officer from the Company in July 2004, increased accounting fees of approximately \$755,000

associated with increased regulatory requirements and an increase in legal fees of approximately \$278,000. In the near term, we expect increased general and administrative expenses as we increase our general and administrative activities to support increased expenditures on business development, legal and regulatory activities.

Interest and investment income was approximately \$1,273,000, \$1,285,000 and \$266,000 for the years ended December 31, 2005, 2004 and 2003, respectively. Interest and investment income in 2004 included a gain from the sale of equity securities in the amount of approximately \$697,000. Excluding this gain in 2004, the increase in interest and investment income in 2005 is primarily due to cash balances earning higher interest rates in the 2005 periods. Interest and investment expense relating to \$5,600,000 of convertible notes payable was \$345,000, \$361,000 and \$361,000 for each of the years ended December 31, 2005, 2004 and 2003.

Net loss for the years ended December 31, 2005, 2004 and 2003 was \$7,713,000, \$13,278,000 and \$5,275,000, respectively. Net loss was lower in 2005 than in 2004 principally due to higher net sales and gross margin and lower operating expenses. Net loss per share for the years ended December 31, 2005, 2004 and 2003 was \$0.17, \$0.30 and \$0.13, respectively. Weighted average shares outstanding for the years ended December 31, 2005, 2004 and 2003 were 45,328,714, 44,626,337 and 39,568,199, respectively.

### ***Income Taxes***

At December 31, 2005, we had net operating loss carryforwards for federal income tax purposes of approximately \$119,000,000 which expire in the years 2006 through 2025. 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, 2005, we had federal tax credit carryforwards of approximately \$5,000,000 which expire in the years 2009 through 2025.

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.

### ***Liquidity and Capital Resources***

At December 31, 2005, 2004 and 2003, we had \$42,256,000, \$51,299,000 and \$62,975,000, respectively, in cash, cash equivalents and short-term investments. In each of these years, the principal factors affecting these balances were the net loss and cash provided by financing activities. We currently estimate cash, cash equivalents and short-term investments at December 31, 2006 will be lower than the balance at December 31, 2005. The expected decrease in this balance is primarily attributable to further expected net loss. 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, 2005, the letters of credit totaled \$692,000, one for \$633,000 under our lease agreement, the other for \$59,000 to facilitate our value added tax filings in Europe.

Net cash used in operating activities totaled \$8,091,000, \$12,335,000 and \$8,055,000 for the years ended December 31, 2005, 2004 and 2003, respectively. Net cash used in operating activities for the year ended December 31, 2005 was primarily due to the net loss of \$7,713,000. Net cash used in operating activities for the year ended December 31, 2004 was less than the net loss primarily due to a \$1,599,000 decrease in inventory levels. Net cash used in operating activities for the year ended December 31, 2003 was more than the net loss primarily due to a \$2,347,000 increase in inventory levels to provide an uninterrupted supply of ZADAXIN as we transferred production to a new contract manufacturer.

Net cash used by us in investing activities amounted to \$6,434,000 for the year ended December 31, 2005 as compared to net cash provided by investing activities in the amount of \$351,000 for the year ended December 31, 2004 and \$647,000 for the year ended December 31, 2003. The increase in 2005 is primarily due to the purchase of U.S. Treasury Securities in the amount of \$6,034,000 in 2005.

Net cash used in financing activities totaled \$834,000 for the year ended December 31, 2005 as compared to net cash provided by financing activities in the amount of \$289,000 for the year ended December 31, 2004 and \$50,074,000 for the year ended December 31, 2003. Net cash used in financing activities for the year ended December 31, 2005 consisted of the repayment of a \$4,000,000 convertible note partially offset by proceeds received of approximately \$3,003,000 related to exercises of outstanding options under our employee and director stock option plans and \$163,000 from the issuance of common stock under our employee stock purchase plan. Net cash provided by financing activities for the year ended December 31, 2004 consisted of approximately \$12,000 related to exercises of outstanding options under our employee and director stock option plans and \$277,000 from the issuance of common stock under our employee stock purchase plan. Net cash provided by financing activities for the year ended December 31, 2003 consisted of approximately \$44,426,000 from a public offering of common stock, approximately \$2,536,000 from the exercise of outstanding warrants to purchase common stock by institutional and accredited investors, approximately \$1,800,000 from the issuance of common stock to Sigma-Tau, approximately \$1,050,000 related to exercises of outstanding options under our employee and director stock option plans and \$262,000 from the issuance of common stock under our employee stock purchase plan.

The following table summarizes our contractual obligations and other commitments as of December 31, 2005.

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>
Convertible note payable(1) .....	\$ 1,648,000	\$1,648,000	\$ —	\$ —	\$—
Operating leases(2) .....	3,105,000	1,579,000	1,515,000	11,000	—
Purchase obligations(3) .....	4,749,000	2,243,000	2,506,000	—	—
Royalty obligations(4) .....	600,000	520,000	40,000	40,000	—
<u>Total .....</u>	<u>\$10,102,000</u>	<u>\$5,990,000</u>	<u>\$4,061,000</u>	<u>\$51,000</u>	<u>\$ 0</u>

- (1) The convertible note matures in March 2006. See note 11 of the Notes to Consolidated Financial Statements. Included in the amounts above is \$48,000 for interest payments.
- (2) These are future minimum rental commitments for office space and copiers leased under non-cancelable operating lease arrangements.
- (3) This includes approximately \$1,012,000 in minimum purchase requirements from a contract manufacturer, approximately \$321,000 in research and development fees payable to the contract research organization under our agreement for the U.S. phase 3 HCV clinical trials, and approximately \$3,416,000 payable to our European marketing and development partner, Sigma-Tau, to conduct and complete an HCV clinical trial in Europe.
- (4) This includes \$20,000 per year through 2010 in minimum royalty payments to the U.S. Army and \$500,000 of non-cancelable prepaid royalties to be paid to Wayne State University. Additionally upon regulatory approval of ZADAXIN and commercialization of the product in certain countries, the Company is obligated to pay the U.S. Army and Wayne State University a royalty based on a percentage of ZADAXIN sales. See note 11 of the Notes to Consolidated Financial Statements.

Our existing capital resources and funds from product sales are sufficient to finance our operations for the immediate future but are not sufficient to complete our current plans to conduct and complete clinical trials with SCV-07 and ZADAXIN, and, if we proceed with all the development efforts we are planning, we would need to raise additional financing. The unavailability or the inopportune timing of any financing could prevent or delay our long-term product development and commercialization programs, either of which would severely hurt our business. We cannot assure you that funds from financings will be sufficient to complete our current plans to conduct and complete clinical trials. The need, timing and amount of any such financing would depend upon

numerous factors, including the level of ZADAXIN 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, the timing of regulatory approvals, developments in relationships with existing or future collaborative parties, the status of competitive products, and the condition of the capital markets and the availability of financing for SciClone in particular.

There are no officers or directors that were involved in related party transactions in 2005.

#### **Off-Balance Sheet Arrangements**

There were no off-balance sheet arrangements in 2005, 2004 or 2003.

#### **Recent Accounting Pronouncement**

In December 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R") which revises SFAS 123, and supersedes APB 25, and its related implementation guidance. Generally the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the instruments issued. Compensation cost will be recognized over the period that an employee or director provides service in exchange for the award. We adopted SFAS 123R using the modified prospective basis on January 1, 2006 and anticipate compensation expense for the twelve months ended December 31, 2006 to be approximately \$2,600,000. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees and directors using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options and employee stock purchase plans. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our cash or overall financial position. However, had we adopted SFAS 123R using the Black-Scholes option pricing model in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in the Accounting for Stock-Based Compensation section of Note 1 of our Notes to Consolidated Financial Statements.

#### **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 our cash solely in U.S. Treasury or U.S. government agency notes and highly rated, highly liquid short-term municipal securities. 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 \$177,347 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, 2005. Actual results may differ materially.

Substantially all our sales and most of our manufacturing costs to date have been in U.S. dollars. However, our purchases from one of our contract manufacturers are denominated in euros and costs of our marketing efforts in China are paid in local currency. This exposes us to foreign currency exchange rate fluctuations. Losses related to foreign currency exchange rate fluctuations have been insignificant to date.

**Item 8. *Financial Statements and Supplementary Data***

**SCICLONE PHARMACEUTICALS, INC.**

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## Report of Independent Registered Public Accounting Firm

### The Board of Directors and Stockholders of SciClone Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of SciClone Pharmaceuticals, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. 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 the standards of the Public Company Accounting Oversight Board (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, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of SciClone Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006

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

	<u>December 31, 2005</u>	<u>December 31, 2004</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 25,845,000	\$ 41,204,000
Restricted short-term investments .....	692,000	700,000
Other short-term investments .....	15,719,000	9,395,000
Accounts receivable, net of allowance of \$82,000 in 2005 and \$452,000 in 2004 .....	9,701,000	10,279,000
Inventories .....	3,272,000	4,179,000
Prepaid expenses and other current assets .....	1,890,000	1,478,000
Total current assets .....	<u>57,119,000</u>	<u>67,235,000</u>
Property and equipment, net .....	380,000	398,000
Intangible assets, net .....	472,000	542,000
Other assets .....	1,544,000	1,534,000
Total assets .....	<u>\$ 59,515,000</u>	<u>\$ 69,709,000</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 626,000	\$ 1,733,000
Accrued compensation and employee benefits .....	2,028,000	2,177,000
Accrued professional fees .....	642,000	452,000
Other accrued expenses .....	1,687,000	1,409,000
Accrued clinical trials expense .....	1,658,000	1,500,000
Deferred revenue .....	211,000	537,000
Convertible note payable .....	1,600,000	4,000,000
Total current liabilities .....	<u>8,452,000</u>	<u>11,808,000</u>
Deferred revenue .....	—	134,000
Other long-term liabilities .....	—	1,044,000
Convertible note payable .....	—	1,600,000
Commitments and contingencies .....	—	—
Stockholders' equity:		
Preferred stock; \$0.001 par value; 10,000,000 shares authorized; no shares outstanding .....	—	—
Common stock; \$0.001 par value; 75,000,000 shares authorized; 45,877,420 and 44,677,845 shares issued and outstanding in 2005 and 2004, respectively .....	46,000	45,000
Additional paid-in capital .....	210,245,000	206,608,000
Accumulated other comprehensive income .....	53,000	38,000
Accumulated deficit .....	(159,281,000)	(151,568,000)
Total stockholders' equity .....	<u>51,063,000</u>	<u>55,123,000</u>
Total liabilities and stockholders' equity .....	<u>\$ 59,515,000</u>	<u>\$ 69,709,000</u>

See notes to consolidated financial statements.

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

	Year ended December 31,		
	2005	2004	2003
Revenues:			
Product sales .....	\$27,842,000	\$ 22,765,000	\$31,732,000
Contract revenue .....	492,000	1,631,000	806,000
Total revenues .....	28,334,000	24,396,000	32,538,000
Cost of product sales .....	4,875,000	4,577,000	5,636,000
Gross margin .....	23,459,000	19,819,000	26,902,000
Operating expenses:			
Research and development .....	14,406,000	17,994,000	18,949,000
Sales and marketing .....	10,237,000	9,665,000	9,018,000
General and administrative .....	7,457,000	6,311,000	4,134,000
Total operating expenses .....	32,100,000	33,970,000	32,101,000
Loss from operations .....	(8,641,000)	(14,151,000)	(5,199,000)
Interest and investment income .....	1,273,000	1,285,000	266,000
Interest and investment expense .....	(345,000)	(361,000)	(361,000)
Other income (expense), net .....	—	(51,000)	19,000
Net loss .....	\$ (7,713,000)	\$ (13,278,000)	\$ (5,275,000)
Basic and diluted net loss per share .....	\$ (0.17)	\$ (0.30)	\$ (0.13)
Weighted average shares used in computing basic and diluted net loss per share .....	45,328,714	44,626,337	39,568,199

See notes to consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2002	36,904,916	\$ 156,290,000	\$ —	\$ 79,000	\$(133,015,000)	\$ 23,354,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	847,171	3,256,000	—	—	—	3,256,000
Issuance of common stock to Sigma-Tau	504,938	1,800,000	—	—	—	1,800,000
Reincorporation in Delaware	—	(161,308,000)	161,308,000	—	—	—
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	227,119	—	592,000	—	—	592,000
Issuance of common stock in secondary offering, net of financing costs	6,000,000	6,000	44,420,000	—	—	44,426,000
Net loss	—	—	—	—	(5,275,000)	(5,275,000)
Net unrealized gain on available-for-sale securities	—	—	—	97,000	—	97,000
Total comprehensive loss	—	—	—	—	—	(5,178,000)
Balance at December 31, 2003	44,484,144	44,000	206,320,000	176,000	(138,290,000)	68,250,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	193,701	1,000	288,000	—	—	289,000
Net loss	—	—	—	—	(13,278,000)	(13,278,000)
Net unrealized loss on available-for-sale securities	—	—	—	(138,000)	—	(138,000)
Total comprehensive loss	—	—	—	—	—	(13,416,000)
Balance at December 31, 2004	44,677,845	45,000	206,608,000	38,000	(151,568,000)	55,123,000
Issuance of common stock from exercise of stock options, warrants and employee stock purchase plan	1,199,575	1,000	3,165,000	—	—	3,166,000
Compensation related to option awards	—	—	472,000	—	—	472,000
Net loss	—	—	—	—	(7,713,000)	(7,713,000)
Net unrealized gain on available-for-sale securities	—	—	—	15,000	—	15,000
Total comprehensive loss	—	—	—	—	—	(7,698,000)
Balance at December 31, 2005	45,877,420	\$ 46,000	\$210,245,000	\$ 53,000	\$(159,281,000)	\$ 51,063,000

See notes to consolidated financial statements.

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

	Year ended December 31,		
	2005	2004	2003
<b>Operating activities:</b>			
Net loss .....	\$ (7,713,000)	\$(13,278,000)	\$(5,275,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	203,000	190,000	160,000
Amortization of deferred financing costs .....	25,000	25,000	25,000
Non-cash expense related to employee stock options .....	472,000	—	—
Other non-cash (income) expense, net .....	16,000	(3,000)	(13,000)
Gain on sale of equity investment .....	—	(697,000)	—
Changes in operating assets and liabilities:			
Accounts receivable .....	578,000	(137,000)	(866,000)
Inventories .....	907,000	1,599,000	(2,347,000)
Prepaid expenses and other assets .....	(447,000)	952,000	(355,000)
Accounts payable and other accrued expenses .....	(1,328,000)	(912,000)	345,000
Accrued compensation and employee benefits .....	(693,000)	737,000	352,000
Accrued clinical trials expense .....	158,000	(389,000)	923,000
Accrued professional fees .....	191,000	(29,000)	(198,000)
Deferred revenue .....	(460,000)	(537,000)	(806,000)
Long-term liabilities .....	—	144,000	—
Net cash used in operating activities .....	(8,091,000)	(12,335,000)	(8,055,000)
<b>Investing activities:</b>			
Purchases of property and equipment .....	(119,000)	(196,000)	(303,000)
Proceeds from sales of short-term and equity investments .....	—	697,000	1,000,000
Proceeds from maturities of short-term investments .....	5,950,000	6,000,000	500,000
Payments on purchases of short-term investments .....	(12,265,000)	(6,150,000)	(550,000)
Net cash (used in) provided by investing activities .....	(6,434,000)	351,000	647,000
<b>Financing activities:</b>			
Proceeds from issuances of common stock, net .....	3,166,000	289,000	50,074,000
Repayment of convertible note .....	(4,000,000)	—	—
Net cash (used in) provided by financing activities .....	(834,000)	289,000	50,074,000
Net increase (decrease) in cash and cash equivalents .....	(15,359,000)	(11,695,000)	42,666,000
Cash and cash equivalents, beginning of year .....	41,204,000	52,899,000	10,233,000
Cash and cash equivalents, end of year .....	\$ 25,845,000	\$ 41,204,000	\$52,899,000
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for interest .....	\$ 336,000	\$ 336,000	\$ 336,000
<b>Non-cash investing activities:</b>			
Obligations incurred related to prepaid royalties .....	\$ —	\$ —	\$ 1,200,000

See notes to consolidated financial statements.

**SCICLONE PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL 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 currently being evaluated in melanoma and HCV clinical trials. ZADAXIN currently is approved for sale in certain international locations, and is sold primarily in China through the Company’s wholly-owned subsidiary SciClone Pharmaceuticals International Ltd. (“SPIL”).

***Basis of Presentation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, SPIL, SciClone Italy S.R.L., SciClone Japan K.K., SciClone do Brasil – Produtos Farmaceuticos Ltda, and SciClone Pharmaceuticals International Holding Ltd. SPIL 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. SciClone do Brasil is registered in Brazil with its principal office located in Sao Paulo. SciClone Pharmaceuticals International Holding Ltd is registered in Cayman Islands with its principal office located in Hong Kong. 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 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.

Amounts invoiced relating to arrangements where revenue cannot be recognized are reflected on our balance sheet as deferred revenue and recognized as the applicable revenue recognition criteria are satisfied.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

The Company is required by its lease agreement to have a letter of credit secured by a certificate of deposit of \$633,000 at December 31, 2005. Under its European value added tax filing arrangement, the Company has a letter of credit secured by a certificate of deposit of \$59,000 at December 31, 2005. These amounts are recorded as restricted short-term investments on the accompanying balance sheets.

The Company classifies its investment portfolio as available-for-sale and held-to-maturity. The Company records the available-for-sale 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 municipals. 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 interest and investment income along with interest earned. Realized gains or losses are determined on the basis of specific identification and included in interest and investment income. The Company also has held-to-maturity investments and records them at amortized cost. The Company does an assessment each reporting period to determine whether any investment is impaired. Management believes the credit risk associated with these investments is limited due to the nature of the investments.

For the years ended December 31, 2005, 2004 and 2003, net unrealized gains (losses) of approximately \$15,000, \$(138,000) and \$97,000, respectively, were included in accumulated other comprehensive income. For the year ended December 31, 2005, there were no realized gains. For the year ended December 31, 2004, a net realized gain of approximately \$697,000 was recognized primarily in connection with the sale of equity securities. For the year ended December 31, 2003, there were no realized gains.

### ***Fair Value of Financial Instruments***

The fair value of our cash equivalents and available-for-sale marketable securities are based on quoted market prices and the carrying amounts are equal to their respective fair values at December 31, 2005 and 2004. The amortized cost of the held-to-maturity securities approximates the fair value at December 31, 2005 and 2004.

Other financial instruments, including accounts receivable, accounts payable and accrued liabilities, are carried at cost, which the Company believes approximates fair value because of the short-term maturity of these instruments. The Company believes the reported value of its convertible debt of \$1,600,000 and \$5,600,000 at December 31, 2005 and 2004, respectively, approximates the fair value.

### ***Inventories***

Inventories consist principally of raw materials and finished-good products. Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. We periodically review the inventory in order to identify obsolete items. If obsolete items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the impairment is first recognized.

### ***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.

### ***Intangible Assets***

Intangible assets with definite lives are amortized over their estimated useful lives and are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

The Company's policy is to identify and record impairment losses, if necessary, 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 several countries, principally as a treatment for HBV. Based on the Company's anticipated financial results for future ZADAXIN sales, it has been determined that the expected 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, would be included as a separate component of other comprehensive income (loss) in the statement of stockholders' 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 the Company's 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. SciClone's 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 primarily relate to clinical trials. Pharmaceutical development costs consist of product formulation and chemical analysis.

ZADAXIN clinical trials have the largest and most significant impact on the Company's 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 vary 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 the 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 the Company's behalf are accrued based on the level of patient enrollment and activity according to the protocol. In general, for the U.S. phase 3 clinical trials, these expenses are 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 and other entities managing the trials and laboratory and other direct expenses are recognized in the period they are estimated to be incurred and the services performed. The Company monitors active patient enrollment levels and related activity to the extent possible and adjusts estimates accordingly.

#### ***Shipping and Handling Costs***

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

### **Advertising Expenses**

The Company 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, 2005, 2004 and 2003 were \$150,000, \$235,000 and \$255,000 respectively.

### **Income Taxes**

Income taxes are accounted for under the 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 includes 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 the effect of an additional 7,080,186, 8,979,653 and 7,906,758 shares in 2005, 2004 and 2003, respectively, related to convertible notes payable, outstanding options and warrants. The impact of these shares was not included in the calculation of diluted net loss per share as their effect was antidilutive.

### **Accounting for Stock-Based Compensation**

The Company accounts for its stock option and employee stock purchase plans under the provisions of Accounting Principles Board Opinion 25 ("APB 25") and related Interpretations. Accordingly, the Company does not 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. The following weighted-average assumptions used for the years ended December 31 are as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Weighted-average fair value of stock options granted	\$ 1.79	\$ 3.22	\$ 4.10
Risk-free interest rate	3.77%	2.59%	2.00%
Dividend yield	0.00%	0.00%	0.00%
Volatility factor of the expected market price of our common stock	73.39%	87.36%	93.29%
Weighted-average expected life of option (years)	3.70	4.00	4.03
Weighted-average fair value of employee stock purchase plan purchases	\$ 0.76	\$ 1.83	\$ 1.74
Risk-free interest rate	2.98%	3.32%	2.00%
Dividend yield	0.00%	0.00%	0.00%
Volatility factor of the expected market price of our common stock	62.22%	85.34%	94.31%
Weighted-average expected life (years)	0.41	0.24	0.25

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 and director 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 stock options and stock purchases.

Our CEO was granted a target stock price award (see Footnote 13, Target Stock Price Option) and, therefore, the grant date fair values related to each of the four vesting portions of this award have been calculated and the related expense included in the SFAS 123 pro forma expense disclosure over their derived service periods. For the years ended December 31, 2005, 2004 and 2003, approximately \$232,000, \$0 and \$0, respectively is included in the SFAS 123 pro forma expense below related to this award.

Had compensation expense for the Company's option and employee stock purchase plans been determined based on the fair value at the grant date for awards in 2005, 2004 and 2003 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 as indicated below:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss—as reported .....	\$ (7,713,000)	\$(13,278,000)	\$(5,275,000)
Total stock-based employee compensation expense included in reported net loss .....	472,000	—	—
Total stock-based employee compensation expense determined under the fair value based method for all awards .....	<u>(3,212,000)</u>	<u>(4,257,000)</u>	<u>(3,010,000)</u>
Net loss—pro forma .....	<u>\$(10,453,000)</u>	<u>\$(17,535,000)</u>	<u>\$(8,285,000)</u>
Basic and diluted net loss per share—as reported .....	<u>\$ (0.17)</u>	<u>\$ (0.30)</u>	<u>\$ (0.13)</u>
Basic and diluted net loss per share—proforma .....	<u>\$ (0.23)</u>	<u>\$ (0.39)</u>	<u>\$ (0.21)</u>

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.

### ***Comprehensive Income (Loss)***

The Company reports changes in unrealized gains or losses on the Company's available-for-sale securities in comprehensive income (loss). The accumulated other comprehensive income balances represent the unrealized gains or losses on these securities at the balance sheet dates.

### ***Segment Information***

The Company operates in one segment (see Note 15).

### ***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, 2005, sales to three importing agents in China accounted for 91% of the Company's product sales. Sales to four importing agents in China accounted for 91% of the Company's product sales for the year ended December 31, 2004 and sales to five importing agents in China accounted for 88% of the Company's product sales for the year ended December 31, 2003. In 2005, the three largest customers accounted for 57%, 19% and 15% of sales, respectively. No other customer accounted for more than 10% of sales in 2005. In 2004, the three largest customers accounted for 32%, 29% and 23% of sales, respectively. No other customer accounted for more than 10% of sales in 2004. In 2003, the largest customer accounted for 52% of sales and the second largest customer accounted for 14% of sales. No other customers accounted for more than 10% of sales in 2003. As of December 31, 2005, approximately \$8,847,000, or 90% of the Company's accounts receivable were attributable to three 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 contractual payment due dates and the Company's collectibility experience.

#### ***Recently Issued Accounting Pronouncements***

In December 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R") which revises SFAS 123, and supersedes APB 25, and its related implementation guidance. Generally the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires share-based payments to employees and directors, including grants of stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the instruments issued. Compensation cost will be recognized over the period that an employee or director provides service in exchange for the award. We adopted SFAS 123R using the modified prospective basis on January 1, 2006 and anticipate compensation expense for the twelve months ended December 31, 2006 to be approximately \$2,500,000. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees and directors using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee and director stock options. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. Had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in the Accounting for Stock-Based Compensation section of Note 1 to our consolidated financial statements above.

#### ***Reclassifications***

The Company has made certain classification changes to the 2004 consolidated balance sheets to ensure consistency with the current period presentation. As of December 31, 2004, \$492,000 was reclassified from accounts payable to other accrued expenses.

**Note 2 — Marketable Securities**

The following is a summary of available-for-sale and held-to maturity securities:

<b>Available-For Sale Securities</b>			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Estimated Fair Value</b>
December 31, 2005:			
Certificates of deposit . . . . .	\$ 823,000	\$ —	\$ 823,000
Short-term municipal securities . . . . .	9,450,000	—	9,450,000
Corporate equity securities . . . . .	51,000	53,000	104,000
	<u>\$10,324,000</u>	<u>\$53,000</u>	<u>\$10,377,000</u>
December 31, 2004:			
Certificates of deposit . . . . .	\$ 805,000	\$ —	\$ 805,000
U.S. government obligations . . . . .	22,843,000	—	22,843,000
Short-term municipal securities . . . . .	9,200,000	—	9,200,000
Corporate equity securities . . . . .	51,000	38,000	89,000
	<u>\$32,899,000</u>	<u>\$38,000</u>	<u>\$32,937,000</u>
<b>Held-to-Maturity Securities</b>			
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Estimated Fair Value</b>
December 31, 2005:			
U.S. Treasury securities . . . . .	\$6,034,000	\$—	\$6,034,000
	<u>\$6,034,000</u>	<u>\$—</u>	<u>\$6,034,000</u>
December 31, 2004:			
U.S. Treasury securities . . . . .	\$ —	\$—	\$ —
	<u>\$ —</u>	<u>\$—</u>	<u>\$ —</u>

As of December 31, 2005, there was \$692,000 in restricted short-term investments and \$9,685,000 in other short-term investments held in available-for sale securities. As of December 31, 2004, the available-for-sale securities are included as follows, \$22,843,000 in cash and cash equivalents; \$700,000 in restricted short-term investments and \$9,395,000 in other short-term investments. As of December 31, 2005 and 2004 all available-for sale securities excluding the short-term municipal securities had maturities of 12 months or less. The short-term municipals are auction rate securities which have long final maturities, however, because they are highly rated, highly liquid and their interest rate is reset at auction every 30 days, they are included as available-for-sale securities. The Company's interest rate risk associated with these securities is limited due to this interest rate reset mechanism.

As of December 31, 2005, there was \$6,034,000 in other short-term investments classified as held-to-maturity securities. These securities are U.S. Treasury bills which will mature in February and May 2006. The fair market value of the investments approximated their cost at December 31, 2005. As of December 31, 2004, there were no held-to-maturity securities.

**Note 3 — Prepaid Expenses and Other Current Assets**

The following is a summary of prepaid expenses and other current assets:

	December 31,	
	2005	2004
Prepaid insurance .....	\$ 702,000	\$ 694,000
Prepaid rent .....	107,000	102,000
Prepaid clinical trial expense .....	41,000	247,000
VAT receivable .....	464,000	142,000
Other prepaid expenses .....	576,000	293,000
	<u>\$1,890,000</u>	<u>\$1,478,000</u>

**Note 4 — Inventories**

Inventories consisted of the following:

	December 31,	
	2005	2004
Raw materials .....	\$ 797,000	\$1,517,000
Work in progress .....	476,000	276,000
Finished goods .....	1,999,000	2,386,000
	<u>\$3,272,000</u>	<u>\$4,179,000</u>

**Note 5 — Property and Equipment**

Property and equipment consisted of the following:

	December 31,	
	2005	2004
Office furniture and fixtures .....	\$ 342,000	\$ 290,000
Office equipment .....	828,000	788,000
Leasehold improvements .....	162,000	139,000
	1,332,000	1,217,000
Less accumulated depreciation and amortization .....	(952,000)	(819,000)
Net property and equipment .....	<u>\$ 380,000</u>	<u>\$ 398,000</u>

Depreciation expense for the years ended December 31, 2005, 2004 and 2003 was \$133,000, \$115,000 and \$90,000, respectively.

## Note 6 — Intangible Assets

Intangible assets include the following:

	December 31,	
	2005	2004
Intangible product rights . . . . .	\$ 2,456,000	\$ 2,456,000
Accumulated amortization . . . . .	(1,984,000)	(1,914,000)
	<u>\$ 472,000</u>	<u>\$ 542,000</u>

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 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 HCV in-process technology.

Acquired ZADAXIN product rights are being amortized on a straight-line basis over their estimated useful lives. Amortization expense for the years ended December 31, 2005, 2004 and 2003 was \$70,000 per year and for the years 2006 through 2012 is expected to be \$70,000 per year. Based upon the progress in the ZADAXIN clinical trials and the Company’s actual experience of product sales, the Company has assessed that the acquired product rights will be useful to the Company through 2012 when the European patent for the use of ZADAXIN in the treatment of HCV expires. The Company reassesses the useful life of these assets in accordance with current facts and circumstances.

## Note 7 — Other Accrued Expenses

The following is a summary of other accrued expenses:

	December 31,	
	2005	2004
Accrued royalties . . . . .	\$ 500,000	\$ 420,000
Accrued pre-clinical trial expenses . . . . .	93,000	133,000
Accrued interest payable . . . . .	32,000	52,000
Accrued annual report costs . . . . .	60,000	81,000
Accrued sales and marketing expenses . . . . .	501,000	492,000
Accrued manufacturing costs . . . . .	47,000	—
Other . . . . .	454,000	231,000
	<u>\$1,687,000</u>	<u>\$1,409,000</u>

## Note 8 — Collaborative Agreements

In May 2004, the Company entered into an agreement with Sigma-Tau, whereby Sigma-Tau will be conducting a multi-center phase 3 hepatitis C triple therapy clinical trial in Europe with approximately 550 patients. The objective of the European trial is to provide data on ZADAXIN’s use as part of a triple therapy in treating HCV patients. The Company is providing ZADAXIN, approximately \$2,500,000 of funding support during the course of patient enrollment of which \$584,000 has been paid as of December 31, 2005, and a \$1,500,000 milestone payment to Sigma-Tau at the completion of the study. Based on the level of activity

in this trial, the Company has recorded approximately \$1,203,000 and \$169,000 of research and development expense related to this trial in the years ended December 31, 2005 and 2004, respectively.

In October 2003, the Company and Wayne State University (“WSU”) amended a license agreement that WSU and A1B had entered into in 1994 that was subsequently assigned by A1B to SciClone. The 2003 amendment allows the Company to maintain an exclusive license to certain WSU patents regarding the use of thymosin alpha 1 in the treatment of hepatitis B and hepatitis C. In addition to certain minimum royalty payments following sales of ZADAXIN in certain territories, the Company is obligated to pay WSU a total of \$1,400,000 in pre-paid royalties over the following three years whether or not the Company receives regulatory approval for ZADAXIN or sales are made in the covered territories including the United States. The Company can offset the annual minimum royalties due on sales of ZADAXIN with these pre-paid royalties to the extent of 50% of the annual royalties in any one year. In the year ended December 31, 2005, 2004 and 2003, the Company paid \$400,000, \$300,000 and \$200,000, respectively of the pre-paid royalties. These amounts plus the unpaid balance of \$500,000 that is due in the next year have been recorded as pre-paid royalties in the long term other assets account on the accompanying balance sheets. The remaining obligation to pay \$500,000 as of December 31, 2005 has been included in other accrued expenses on the accompanying balance sheet.

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 then 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 estimated time to complete the ZADAXIN U.S. phase 3 HCV clinical trials and deliver the clinical data, the substantive performance requirements under the contract amendment. For the year ended December 31, 2005, 2004 and 2003, the Company recognized \$492,000, \$537,000 and \$806,000, respectively, as contract revenue and the remaining balance of \$211,000 is recorded as deferred revenue as of December 31, 2005. Additionally, in the second quarter of 2004, the Company recognized a \$1,000,000 milestone payment from Sigma-Tau for the full enrollment of the Company’s current phase 3 U.S. clinical trials as there are no future performance obligations associated with the milestone payment.

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 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.

**Note 9 — Other Long-term Liabilities**

The following is a summary of other long-term liabilities:

	December 31,	
	2005	2004
Accrued compensation and employee benefits .....	\$ —	\$ 544,000
Accrued royalties .....	—	500,000
	\$ —	\$1,044,000

## Note 10 — Income Taxes

As a result of net losses, the Company did not record any federal or state income tax expense for the years ended December 31, 2005, 2004 and 2003.

The domestic and foreign components of pre tax income (loss) for the years ended December 31 are as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Domestic .....	\$(14,386,000)	\$(17,433,000)	\$(15,768,000)
Foreign .....	<u>6,673,000</u>	<u>4,155,000</u>	<u>10,493,000</u>
Loss .....	<u>\$ (7,713,000)</u>	<u>\$ (13,278,000)</u>	<u>\$ (5,275,000)</u>

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

	<u>2005</u>	<u>2004</u>
Net operating loss carryforwards .....	\$ 41,409,000	\$ 36,264,000
R&D credit carryforwards .....	6,000,000	5,474,000
Other .....	<u>1,303,000</u>	<u>1,156,000</u>
Gross deferred tax assets .....	48,712,000	42,894,000
Valuation allowance .....	<u>(48,712,000)</u>	<u>(42,894,000)</u>
Total deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance increased by approximately \$5,818,000, \$6,349,000 and \$5,825,000 in the years ended December 31, 2005, 2004 and 2003, respectively. Deferred tax assets relating to net operating loss carryforwards as of December 31, 2005 include approximately \$2,973,000 associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders' equity. The Company did not have any deferred tax liabilities at December 31, 2005 or 2004.

At December 31, 2005, the Company has net operating loss carryforwards for federal income tax purposes of approximately \$119,000,000 which expire in the years 2006 through 2025. At December 31, 2005, the Company has federal tax credit carryforwards of approximately \$5,000,000 which expire in the years 2006 through 2025.

At December 31, 2005, the Company has state net operating loss carryforwards of approximately \$16,000,000 available to reduce future taxable income. The carryforwards begin to expire in 2007, if not utilized. In addition, the Company has research and development tax credit carryforwards of approximately \$800,000 for state tax purposes at December 31, 2005. The tax credit carryforwards will be carried forward indefinitely until utilized.

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.

## Note 11 — 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. Rent expense in 2005, 2004 and 2003 was \$1,458,000, \$1,393,000, and \$1,362,000, respectively. Minimum future rental payments amount to a total of \$3,040,000, which consists of \$1,561,000 in 2006, \$1,181,000 in 2007 and \$298,000 in 2008.

### ***Purchase Obligations***

For the years ended December 31, 2005, 2004 and 2003, the Company had purchase obligation requirements in the amounts of \$4,749,000, \$6,456,000 and \$5,270,000, respectively. At December 31, 2005, the purchase obligations consist of minimum purchase requirements from a contract manufacturer in the amount of \$1,012,000. In addition, there were research and development fees payable to the contract research organization under our agreement for the U.S. phase 3 HCV clinical trials in the amount of \$321,000 and \$3,416,000 to our European marketing and development partner, Sigma-Tau, to conduct and complete an HCV clinical trial in Europe.

### ***Royalties***

Under the October 2003 amendment to the Patent License Agreement with Wayne State University, the Company is obligated to pay WSU a royalty, subject to minimum amounts, on a percentage of ZADAXIN net sales revenue for the treatment of hepatitis B and hepatitis C in certain countries including the United States, the European Union and Japan, but not including China. In addition, the Company is obligated to pay WSU pre-paid royalties of \$500,000 in 2006 whether or not the Company receives regulatory approval for ZADAXIN or sales are made in the covered territories including the United States. In the year ended December 31, 2005, 2004 and 2003, the Company paid WSU \$400,000, \$300,000 and \$200,000, respectively, of pre-paid royalties. The Company can offset the annual minimum royalties due on sales of ZADAXIN with these pre-paid royalties to the extent of 50% of the annual royalties in any one year.

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 2005, 2004 and 2003 the Company paid \$20,000 per year to the U.S. Army related to the minimum annual royalty.

### ***Convertible Notes Payable***

In March 2001, the Company issued a \$1,600,000 convertible note to an investment affiliate of UBS AG. The \$1,600,000 note is convertible at the option of the holder 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 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 convertible note to an investment affiliate of UBS AG. The \$4,000,000 note was convertible into 407,610 shares of common stock at a fixed conversion price of \$9.8133 per share. In December 2005, the \$4,000,000 note was repaid.

### **Note 12 — Stockholders' Equity**

On July 18, 2003, the Company reincorporated from a California corporation to a Delaware corporation by merging the Company, then a California corporation, with and into SciClone Pharmaceuticals Inc., a Delaware corporation and wholly-owned subsidiary of the Company. Each share of outstanding stock of the California corporation was automatically exchanged for a like share of stock of the Delaware corporation.

### ***Common Stock and Warrants***

In July 2004 when the former CEO left the Company, his outstanding unvested options to purchase 253,541 shares of the Company's common stock became fully vested and all of his outstanding options to purchase 1,615,454 shares became exercisable for a one or two year period. These changes to the former CEO's options did not result in any stock-based compensation as the changes were effected in accordance with the original terms of the option grants.

In September 2003, the Company completed a public offering of 6,000,000 shares of common stock at \$8.00 per share and received proceeds of \$45,120,000 from the sale, net of \$694,000 of financing-related costs.

In January 2003, the Company completed a \$1,800,000 direct placement to affiliates of Sigma-Tau. 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 were not permitted to sell any of the shares purchased in this private placement until January 24, 2004.

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. None of these warrants were exercised and the exercise period of all these warrants expired in January 2005. In addition, the placement agent for this transaction received, as part of its fee, five-year warrants to purchase 108,000 shares of common stock at an exercise price of \$7.00 per share. In 2003, warrants to purchase 3,240 shares of common stock were exercised for proceeds of \$22,680. No additional placement agent warrants were exercised, and the exercise period for the balance of the placement agent warrants expired in January 2005.

In January 1999, the Company issued warrants to purchase a total of 150,000 shares of common stock to Cato Research Ltd. as part of a settlement agreement. Of this total, warrants to purchase 50,000 shares of common stock were exercised at a price of \$1.225 for proceeds of \$61,250 in March 2000. In January 2004, the remaining warrants to purchase 100,000 shares of common stock were exercised at a price of \$2.25 for 65,753 shares of common stock.

### ***Stock Award Plans***

In August 1991, the Board of Directors and stockholders 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 stockholders 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 stockholders 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 stockholders 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 stockholders 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 stockholders 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. Although the 1991, 1992 and 1995 Plans expired, the outstanding options relating to them are fully valid. In May 2004, the Board of Directors and the stockholders of the Company approved the 2004 Stock Option Plan (the "2004 Plan") and reserved 2,500,000 shares for issuance thereunder. The 2004 Plan permits the award of incentive stock options or nonstatutory stock options. In June 2005, the Board of Directors and stockholders of the Company approved an increase in the maximum number of shares issuable under the 2004 Plan by 2,300,000 shares to a total of 4,800,000 shares. The Board of Directors and stockholders also approved amendments to the 2004 Plan to expand the types of stock-based incentives authorized under the 2004 Plan and to restate the 2004 Plan as the 2005 Equity Incentive Plan (the "2005 Plan"). The 2005 Equity Incentive Plan permits the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, stock purchase rights, stock bonuses, restricted stock units, performance shares and performance units. The options are granted at fair market value on the date of grant and expire ten years from the date of grant.

Under the 1991, 1992, 1995 and 2005 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 stockholders of the Company approved the 1995 Nonemployee Director Stock Option Plan (the "Nonemployee Director Plan") and reserved 250,000 shares for issuance thereunder. In June 2000 and June 2002 the Board of Directors and stockholders of the Company approved an increase of 250,000 in the shares reserved for issuance under the Nonemployee Director Plan. In May 2004, the Board of Directors and stockholders of the Company approved the 2004 Outside Directors Stock Option Plan and reserved 465,000 shares for issuance thereunder and the 1995 Nonemployee Director Stock Option Plan was canceled. The 2004 Outside Directors Stock Option 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 Stockholders ("Annual Grant"). The options are granted at fair market value on the date of grant and expire ten years from the date of grant. Initial Grants will become exercisable in three equal annual installments beginning on the first anniversary of the date of grant, and Annual Grants will become exercisable in twelve equal monthly installments from the date of grant, subject in each case to the Outside Director's continuous service on our Board of Directors. In June 2005, the Board of Directors and stockholders of the Company approved an increase in the maximum number of shares issuable under the 2004 Outside Directors Stock Option Plan by 550,000 shares to a total of 1,015,000 shares.

The following table summarizes the stock option activity under the 1991, 1992, 1995 and 2005 Stock Option Plans, the Nonemployee Director Plan and the 2004 Outside Director Stock Option Plan:

	Shares Available For Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
<b>Balance at December 31, 2002</b>	2,053,806	5,097,482	4.76
Options canceled	345,168	(345,168)	7.43
Options granted	(1,162,034)	1,162,034	6.17
Options exercised	—	(380,630)	2.76
Plan shares expired	(79,697)	—	—
<b>Balance at December 31, 2003</b>	1,157,243	5,533,718	5.02
2004 Plan shares reserved	2,500,000	—	—
2004 Outside Directors Plan shares reserved	465,000	—	—
Options canceled	225,955	(225,955)	6.35
Options granted	(1,402,000)	1,402,000	5.05
Options exercised	—	(3,150)	3.79
Plan shares expired	(269,775)	—	—
<b>Balance at December 31, 2004</b>	2,676,423	6,706,613	4.99
2005 Plan shares reserved	2,300,000	—	—
2004 Outside Directors Plan shares reserved	550,000	—	—
Options cancelled	984,025	(984,025)	6.15
Options granted	(1,924,000)	1,924,000	3.24
Options exercised	—	(1,119,462)	2.68
Plan shares expired	(949,948)	—	—
<b>Balance at December 31, 2005</b>	<u>3,636,500</u>	<u>6,527,126</u>	4.69

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.22 – \$2.97 .....	1,384,729	6.83	\$ 2.51	659,959	\$ 2.02
\$3.24 – \$3.68 .....	1,098,000	9.04	3.39	154,834	3.47
\$3.69 – \$4.25 .....	1,089,070	5.84	3.91	1,003,902	3.90
\$4.50 – \$5.26 .....	1,146,455	6.58	4.97	763,957	4.99
\$5.50 – \$7.13 .....	1,117,397	6.49	5.85	759,466	5.88
\$7.63 – \$12.50 .....	691,475	4.79	10.03	691,475	10.03
	<u>6,527,126</u>	6.72	4.69	<u>4,033,593</u>	5.21

As of December 31, 2004 and 2003, options outstanding were exercisable for 4,971,804 and 3,943,906 shares, respectively.

In July 1996, the Board of Directors and stockholders of the Company approved the 1996 Employee Stock Purchase Plan (the "ESPP") and reserved 500,000 shares for issuance thereunder. In June 2003, the Board of Directors and stockholders of the Company approved an increase of 500,000 in the shares reserved for issuance under the 1996 Employee Stock Purchase Plan. 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 80,113, 124,798, and 127,920 shares to employees in 2005, 2004 and 2003, respectively. In January 2006, the Board of Directors amended the ESPP to provide that, for each Offering Period commencing after January 31, 2006, the purchase price of the stock shall be equal to 95% of the fair market value of a share of the Company's Common Stock on the Purchase Date (or such other amount as may be established by the Board).

#### Reserved Shares

As of December 31, 2005, the Company had reserved shares of common stock for future issuance as follows:

Options outstanding .....	6,527,126
Shares available for grant .....	3,636,500
Convertible notes payable .....	553,060
ESPP .....	304,973
	<u>11,021,659</u>

#### Note 13 — Target Stock Price Option

The Company entered into an employment agreement with its new CEO effective June 1, 2005. The employment agreement included the award of an option to purchase 400,000 shares of the Company's common stock at \$2.97 per share, the closing price on the NASDAQ National Market of a share of the Company's common stock on June 1, 2005. This option has a term of 10 years and 25% of such second option will vest upon the Company's common stock trading after June 1, 2005 for at least 30 consecutive calendar days at or greater than a target closing stock price, as reported on the NASDAQ National Market, of (a) \$4.50 on or before June 1, 2008, (b) \$6.00 on or before June 1, 2009, (c) \$8.00 on or before June 1, 2010, and (d) \$10.00 on or before June 1, 2011, each price as adjusted for stock dividends, stock splits or similar changes in the Company's capital structure.

Under APB 25, the Company recognizes non-cash expense related to the stock price performance based option granted to our Chief Executive Officer on June 1, 2005, the date he commenced his employment. The terms of this option require the application of variable accounting, and the related non-cash expense to be recognized is effected by the price level of trading activity in our stock. The Company recognizes non-cash expense when the vesting of a portion of the option is determined to be probable. During the three-month period ended September 30, 2005 the market price of the Company's common stock price had closed above \$4.50 for at least 30 consecutive calendar days thus triggering the vesting of 25% of the shares underlying the option. Therefore, the Company recognized a \$423,000 non-cash expense attributable to this vesting in the three-month period ended September 30, 2005. As of December 31, 2005, the vesting of any of the other portions of the option was not probable and, therefore, no other expense related to this option has been recognized.

Under SFAS 123, the option is considered a target stock price award and, therefore, the grant date fair values related to each of the four vesting portions of this award have been calculated and the related expense included in the SFAS 123 pro forma expense disclosure over the derived service periods for each of the four vesting portions of the award. The aggregate fair value of the award was estimated to be \$691,000 at the date of grant using a Monte Carlo simulation option pricing model with the following assumptions, risk-free interest rate of 4.097%; dividend yield of 0%; volatility factor of 74% and expected life of 10 years. The fair values of the four vesting portions of the awards of \$186,000, \$173,000, \$166,000 and \$166,000 are being amortized over their related derived service periods which are 13, 21, 28, and 36 months, respectively. For the years ended December 31, 2005, 2004 and 2003, approximately \$232,000, \$0 and \$0, respectively, of such expense is included in the SFAS 123 pro forma expense (see Footnote 1, Significant Accounting Policies, Accounting for Stock-Based Compensation).

#### **Note 14 — 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 \$170,000, \$161,000 and \$129,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

#### **Note 15 — 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 President and Chief Executive Officer has been identified as the Chief Operating Decision Makers ("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 engaged in sales and marketing and product distribution worldwide.

Information regarding geographic areas is as follows:

	Product Sales for the Year Ended December 31,	Contract Revenue for the Year Ended December 31,	Long Lived Assets December 31,	Net Assets December 31,
<b>2005</b>				
U.S . . . . .	\$ —	\$ —	\$1,931,000	\$14,281,000
China . . . . .	25,464,000	—	281,000	36,602,000
Other . . . . .	2,378,000	492,000	184,000	180,000
Total . . . . .	<u>\$27,842,000</u>	<u>\$ 492,000</u>	<u>\$2,396,000</u>	<u>\$51,063,000</u>
<b>2004</b>				
U.S . . . . .	\$ —	\$ —	\$1,980,000	\$26,892,000
China . . . . .	20,714,000	—	283,000	28,014,000
Other . . . . .	2,051,000	1,631,000	211,000	217,000
Total . . . . .	<u>\$22,765,000</u>	<u>\$1,631,000</u>	<u>\$2,474,000</u>	<u>\$55,123,000</u>
<b>2003</b>				
U.S . . . . .	\$ —	\$ —	\$2,043,000	\$45,093,000
China . . . . .	28,078,000	—	213,000	22,928,000
Other . . . . .	3,654,000	806,000	215,000	229,000
Total . . . . .	<u>\$31,732,000</u>	<u>\$ 806,000</u>	<u>\$2,471,000</u>	<u>\$68,250,000</u>

Three customers accounted for 10% or more of total revenues (57%, 19% and 15%) for an aggregate of 91% of total revenues for the year ended December 31, 2005. Three customers accounted for 10% or more of total revenues (32%, 29% and 23%) for an aggregate of 84% of total revenues for the year ended December 31, 2004. Two customers accounted for 10% or more of total revenues (52% and 14%) for an aggregate of 66% of total revenues for the year ended December 31, 2003. No other customer accounted for more than 10% of total revenues during these years.

**Note 16 — Selected Quarterly Financial Data (unaudited)**

	Three Months Ended			
	March 31	June 30	September 30	December 31
<b>2005</b>				
Product sales . . . . .	\$ 6,661,000	\$ 6,851,000	\$ 7,016,000	\$ 7,314,000
Contract revenue . . . . .	134,000	134,000	134,000	90,000
Cost of product sales . . . . .	997,000	1,166,000	1,337,000	1,375,000
Gross margin . . . . .	5,798,000	5,819,000	5,813,000	6,029,000
Net loss . . . . .	(1,494,000)	(1,505,000)	(3,089,000)	(1,625,000)
Basic and diluted net loss per share . . . . .	(0.03)	(0.03)	(0.07)	(0.04)
<b>2004</b>				
Product sales . . . . .	\$ 5,414,000	\$ 5,613,000	\$ 5,753,000	\$ 5,985,000
Contract revenue . . . . .	228,000	1,135,000	134,000	134,000
Cost of product sales . . . . .	1,142,000	1,178,000	1,109,000	1,148,000
Gross margin . . . . .	4,500,000	5,570,000	4,778,000	4,971,000
Net loss . . . . .	(3,133,000)	(2,877,000)	(4,913,000)	(2,355,000)
Basic and diluted net loss per share . . . . .	(0.07)	(0.06)	(0.11)	(0.05)

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

Not applicable

**Item 9A. *Controls and Procedures***

(a) Evaluation of Disclosure Controls and Procedures

**Disclosure Controls and Procedures**

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of its management, including our President and Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures in ensuring that material information required to be disclosed in the Company's reports filed or submitted under the Securities Exchange Act of 1934, as amended, has been made known to them in a timely fashion. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in reaching a reasonable level of assurance that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

**Management's Annual Report on Internal Control over Financial Reporting; Attestation Report of the Registered Public Accounting Firm**

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. All control systems have inherent limitations so that no evaluation of controls can provide absolute assurance that all control issues are detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, we assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework. Based on this assessment and those criteria, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2005.

Ernst & Young LLP, an independent registered public accounting firm, has audited and issued an attestation report on management's assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, as stated in their report which is included below.

## **Report of Independent Registered Public Accounting Firm**

### **The Board of Directors and Stockholders of SciClone Pharmaceuticals, Inc.**

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that SciClone Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). SciClone Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*In our opinion, management's assessment that SciClone Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, SciClone Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.*

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of SciClone Pharmaceuticals, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005 and our report dated March 10, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006

### **Changes in Internal Control over Financial Reporting**

There has been no change in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Act of 1934, as amended) that was identified in connection with the evaluation thereof that occurred during the fourth quarter of 2005 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

### **Item 9B. Other Information**

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 Proxy Statement under the caption "ELECTION OF DIRECTORS — Nominees," and "ELECTION OF DIRECTORS — Board Meetings and Committees — *Audit Committee*." Information relating to the executive officers of the Company is set forth in Item 1 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 — Compliance with Section 16(a) of the Exchange Act."

### **Code of Ethics**

We have adopted a code of business conduct and ethics, and a policy providing for the reporting of potential violations of the code, for directors, officers (including our principal executive officer, principal financial officer and controller) and employees, known as the Corporate Code of Conduct and Reporting ("Whistle Blowing") of Perceived or Alleged Violations (the "Code of Conduct"). The Code of Conduct is available on our website at <http://phx.corporate-ir.net/phoenix.zhtml?c=103184&p=irol-govConduct>. Additionally, stockholders may request a free copy of the Code of Conduct 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).

### **Item 11. Executive Compensation**

The information required by this Item 11 is incorporated by reference from the Proxy Statement under the captions "EXECUTIVE COMPENSATION AND OTHER MATTERS" and "ELECTION OF DIRECTORS — Compensation of Directors." Also, the information specified in Item 402 (k) and (l) of Regulation S-K and set forth in the Proxy Statement is not incorporated herein by reference.

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

**Securities Authorized for Issuance under Equity Compensation Plans**

As of December 31, 2005, the Company maintained seven compensation plans that provide for the issuance of 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 1995 Nonemployee Director Stock Option Plan, the 1996 Employee Stock Purchase Plan, the 2004 Outside Directors Stock Option Plan and the 2005 Equity Incentive Plan, which plans have all been approved by the Company's stockholders. The Company does not currently maintain any compensation plans that have not been approved by the Company's stockholders. The following table sets forth information regarding outstanding options and shares reserved for future issuance under the foregoing plans as of December 31, 2005:

<u>Plan Category</u>	<u>Number of shares to be issued upon exercise of outstanding options, warrants and rights</u> (a)	<u>Weighted-average exercise price of outstanding options, warrants and rights</u> (b)	<u>Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a))</u> (c)
Equity compensation plans approved by stockholders:			
1991 Stock Plan . . . . .	261,075	\$5.8960	—
1992 Stock Plan . . . . .	81,500	\$5.3126	—
1995 Equity Incentive Plan . . . . .	3,471,051	\$5.0576	—
1995 Nonemployee Director Stock Option Plan . .	535,000	\$6.6908	—
1996 Employee Stock Purchase Plan . . . . .	0	0	304,973 <sup>(1)</sup>
2004 Outside Directors Stock Option Plan . . . . .	365,000	\$4.4119	650,000
2005 Equity Incentive Plan . . . . .	<u>1,813,500</u>	<u>\$3.2504</u>	<u>4,719,000</u>
Total . . . . .	<u>6,527,126</u>	<u>\$4.6900</u>	<u>5,673,973</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 "SECURITY 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."

**Indebtedness of Management**

The information required by this subsection "Indebtedness of Management" of this Item 13 is incorporated by reference from the information provided under the subheading "- Indebtedness of Management" under the heading "EXECUTIVE COMPENSATION AND OTHER MATTERS" of the Proxy Statement.

**Item 14. Principal Accountant Fees and Services**

The information required by this Item 14 is incorporated by reference from the Proxy Statement under the caption "RATIFICATION OF APPOINTMENT OF INDEPENDENT AUDITORS – Principal Accountant Fees."

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

Item 15 (a). The following documents are filed as part of this Annual Report on Form 10-K:

(1) *Financial Statements.* The following financial statements of the Company are contained in Item 8, Part II on pages 43 - 64 of this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets at December 31, 2005 and 2004.

Consolidated Statements of Operations for each of the three years in the period ended December 31, 2005.

Consolidated Statement of Stockholders' Equity for the three years ended December 31, 2005.

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2005.

Notes to Consolidated Financial Statements.

(2) *Financial Statement Schedules*

The following schedule required to be filed by Item 8 of this form and Item 15(d) is contained on page 70 of this Report:

Schedule II — Valuation and Qualifying Accounts for each of the three years in the period ended December 31, 2005.

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 thereto.

(3) *Exhibits.*

Refer to Item 15(b) below.

Item 15 (b). **Exhibits.**

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

<u>Exhibit Number</u>	<u>Description</u>
3(i).1(1)	Amended and Restated Certificate of Incorporation.
3(ii).1(1)	Bylaws.
4.1(9)	Rights Agreement dated as of July 25, 1997 between the Registrant and Chase Mellon Shareholder Services, LLC
4.2(1)	First Amendment to Rights Agreement dated as of July 17, 2003 between the Registrant and Mellon Investor Services LLC.
4.3(13)*	6% Convertible Note dated as of December 7, 2000 by the Registrant in favor of UBS AG, London Branch.
4.4(13)*	Option Agreement dated as of October 26, 2000 by and between the Registrant and UBS AG, London Branch.
4.5(13)*	Amendment No. 1 to Option Agreement dated as of December 19, 2000 by and between the Registrant and UBS AG, London Branch.
4.6(14)*	6% Convertible Note dated as of March 21, 2001 by the Company in favor of UBS AG, London Branch.

<u>Exhibit Number</u>	<u>Description</u>
4.7(14)*	Option Agreement dated as of February 16, 2001 by and between the Company and UBS AG, London Branch.
4.8(14)*	Amendment No. 1 to Option Agreement dated as of March 21, 2001 by and between the Company and UBS AG, London Branch.
10.1(3)**	Registrant's 1991 Stock Plan, together with forms of agreements thereunder.
10.2(2)**	Registrant's 1992 Stock Plan, together with forms of agreements thereunder.
10.3(5)**	Registrant's 1995 Equity Incentive Plan, together with forms of agreement thereunder.
10.4(5)**	Registrant's 1995 Nonemployee Director Stock Option Plan, together with forms of agreement thereunder.
10.5(17)**	Registrant's 1996 Employee Stock Purchase Plan, as amended.
10.6(26)**	Registrant's 2005 Equity Incentive Plan, as amended.
10.7(26)**	Registrant's 2004 Outside Directors Stock Option Plan, as amended.
10.8(2)	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").
10.9(4)	Amendment No. 4 to Spieker Lease, dated October 4, 1994.
10.10(6)	Amendment No. 7 to Spieker Lease, dated November 14, 1995.
10.11(8)	Amendment No. 8 to Spieker Lease, dated August 26, 1996.
10.12(13)	Amendment No. 14 to Spieker Lease dated November 21, 2000.
10.13(19) **	Employment Agreement, effective as of February 1, 1996, between the Registrant and Donald R. Sellers.
10.14(19) **	Fifth Amendment of Employment Agreement, effective as of November 30, 2003, between the Registrant and Donald R. Sellers.
10.15(13) **	Change in Control Agreement between the Company and Alfred Rudolph dated as of November 19, 1999.
10.16(13) **	Change in Control Agreement between the Company and Donald R. Sellers dated as of November 19, 1999.
10.17(15) **	Change in Control Agreement between the Company and Richard A. Waldron dated as of April 30, 2001.
10.18(17) **	Change in Control Agreement between the Company and Hans P. Schmid dated as of April 22, 2003.
10.19(18) **	Form of Indemnity Agreement by and between the Registrant and each director and executive officer of SciClone Pharmaceuticals, Inc.
10.20(21)*/**	Agreement Regarding Consulting, Resignation and General Release of Claims between Registrant and Donald R. Sellers, dated July 14, 2004.
10.21(7)*	License Agreement effective April 19, 1996 between the Registrant and the National Institute of Health Office of Technology Transfer.
10.22(10)	Alpha Rights Acquisition Agreement by and between the Registrant and Alpha 1 Biomedicals, Inc., dated December 17, 1997.

<u>Exhibit Number</u>	<u>Description</u>
10.23(11)*	Expanded and Amended Thymosin Alpha 1 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.
10.24(16)*	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.
10.25(20)*	Amendment No. 2 to the Expanded and Amended Thymosin Alpha 1 License, Distributorship and Supply Agreement between the Registrant and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., dated May 20, 2004.
10.26(20)*	Amendment No. 3 to the Expanded and Amended Thymosin Alpha 1 License, Distributorship and Supply Agreement between the Registrant and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., dated May 21, 2004.
10.27(12)	Acquisition Agreement between the Company and Sclavo S.p.A. dated April 20, 1998.
10.28(12)	First Amendment to Acquisition Agreement between the Company and Sclavo S.p.A., dated April 20, 1998.
10.29(14)*	Registration Rights Agreement by and between the Company and UBS AG, London Branch dated as of February 16, 2001.
10.30(16)*	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.
10.31(19)*	Manufacturing and Supply Agreement between SciClone Pharmaceuticals International Ltd. and Patheon Italia S.p.A. dated as of November 1, 2002.
10.32(22)**	Agreement between the Company and Alfred R. Rudolph, dated September 10, 2004.
10.33(22)**	Agreement between the Company and Richard A. Waldron, dated September 10, 2004.
10.34(24)**	Employment Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.
10.35(24)**	Change in Control Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.
10.36(24)**	Indemnity Agreement between SciClone Pharmaceuticals, Inc. and Ira D. Lawrence, M.D. dated as of April 25, 2005.
10.37(25)	Amendment of Stock Option Agreement between SciClone Pharmaceuticals, Inc. and Jere E. Goyan, Ph.D. dated as of May 29, 2005.
10.38(25)	Amendment of Stock Option Agreement between SciClone Pharmaceuticals, Inc. and Edwin C. Cadman, M.D. dated as of May 29, 2005.
10.38(27)**	Amendment to Offer Letter dated as of February 24, 2006 by and between SciClone Pharmaceuticals International, Ltd. and Hans P. Schmid including offer letter dated May 21, 2001 between SciClone Pharmaceuticals International, Ltd. and Hans P. Schmid as Exhibit A thereto.
14	See "Code of Ethics" in Item 10: Executive Officers and Directors, of this Annual Report on Form 10-K.
21.1(28)	Subsidiaries of Registrant.

<u>Exhibit Number</u>	<u>Description</u>
23.1(28)	Consent of Independent Registered Public Accounting Firm.
24.1(28)	Powers of Attorney. See page 74.
31.1(28)	Rule 13a-14(a) Certification of Principal Executive Officer.
31.2(28)	Rule 13a-14(a) Certification of Principal Financial Officer.
32.1(28)	Section 1350 Certification of Principal Executive Officer.
32.2(28)	Section 1350 Certification of Principal 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 Current Report on 8-K filed on July 28, 2003.
- (2) 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.
- (3) Incorporated by reference from the Company's Registration Statement on Form S-8 (No. 33-66832) filed with the Commission on August 3, 1993.
- (4) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1994.
- (5) Incorporated by reference from the Company's Registration Statement on Form S-8 (No. 33-80911) filed with the Commission on December 28, 1995.
- (6) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 1995.
- (7) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1996.
- (8) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 1996.
- (9) Incorporated by reference from the Company's Current Report on Form 8-K filed on October 14, 1997.
- (10) Incorporated by reference from the Company's Current Report on Form 8-K filed on January 26, 1998.
- (11) Incorporated by reference from the Company's Current Report on Form 8-K filed on April 20, 2000.
- (12) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 1998.
- (13) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
- (14) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2001.
- (15) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2001.
- (16) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2002.

- (17) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2003.
- (18) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2003.
- (19) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2003.
- (20) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004.
- (21) Incorporated by reference from the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2004.
- (22) Incorporated by reference from the Company's Current Report on Form 8-K filed on September 15, 2004.
- (23) Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2004.
- (24) Incorporated by reference from the Company's Current Report on Form 8-K filed on April 29, 2005.
- (25) Incorporated by reference from the Company's Current Report on Form 8-K filed on June 1, 2005.
- (26) Incorporated by reference from the Company's Current Report on Form 8-K filed on June 20, 2005.
- (27) Incorporated by reference from the Company's Current Report on Form 8-K filed on February 28, 2006.
- (28) Filed herewith.

Item 15 (c). See Item 15(a) above.



**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, 2005</b>				
Reserves and allowances deducted from asset accounts:				
Allowance for uncollectible accounts .....	\$452,000	\$ —	\$370,000	\$ 82,000
<b>Year Ended December 31, 2004</b>				
Reserves and allowances deducted from asset accounts:				
Allowance for uncollectible accounts .....	\$638,000	\$ —	\$186,000	\$452,000
<b>Year Ended December 31, 2003</b>				
Reserves and allowances deducted from asset accounts:				
Allowance for uncollectible accounts .....	\$638,000	\$ —	\$ —	\$638,000

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