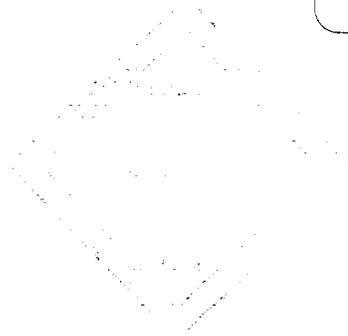


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SUPERGEN⁰¹

in which clinicians tell how
SuperGen is changing the lives *of patients*

A SERIES OF FIVE INTERVIEWS

PROCESSED
MAY 01 2002
Ⓟ THOMSON
FINANCIAL

a message from
Dr. Joseph Rubinfeld *Chairman and Chief Executive Officer*
SUPERGEN, INC.



DEAR SHAREHOLDER,

Since SuperGen's inception in 1991, our goal has been to fashion the world's preeminent oncology-focused company. Over the years, we have made steady progress, carefully building a product pipeline that now consists of ten products and three franchise compounds – that is, drugs that can be used for a variety of different indications. Perhaps in no other year has more progress been made than in 2001. Specifically, over the past twelve months, the Company completed patient enrollment in each of the three Phase III clinical studies of rubitecan as a treatment for pancreatic cancer, a tremendous undertaking; began a Phase III clinical study of decitabine as a treatment for myelodysplastic syndromes (MDS); accelerated *continues >*

from page 1 > the clinical development of Nipent® for a number of additional indications; received FDA approval for one drug; and reinforced the depth of our highly experienced oncology team.

A BROADENING VISION: These accomplishments during 2001 are particularly noteworthy in light of the fact that, in the not-too-distant past, our Company was singularly focused on generating hope for patients with pancreatic cancer – a virtual death sentence to the 30,000 Americans who are diagnosed with this disease each year. Today, we are proud to note that our vision has broadened to helping those afflicted with a variety of solid tumors and blood cancers, including MDS, graft-versus-host disease, chronic lymphocytic leukemia and chordoma. While these conditions may not be as well known as pancreatic cancer, they are, unfortunately, just as lethal. However, in only one year's time, positive data from clinical studies of Nipent and decitabine have renewed our optimism that real help for patients with these terrible afflictions may be on the way.

OUR BRIGHT FUTURE: Remembering for a moment that only one in 10,000 compounds ultimately becomes an approved drug, our three franchise compounds – rubitecan, Nipent and decitabine – represent the cornerstone of our bright future. In addition, there are several other important products in our pipeline, including the cancer vaccine, Avicine™; Partaject™-delivered busulfan; and inhaled versions of rubitecan and paclitaxel. Moreover, our company has recently received FDA approval to market the anticancer compound daunorubicin, which is used as a treatment for a variety of acute leukemias.

To ensure the most statistically significant results possible for our studies of rubitecan, we have completed enrollment

in the largest clinical study ever conducted for pancreatic cancer – over 1,800 patients. Our scientific team is now in the process of analyzing literally thousands of pages of data, and, if favorable, will file a New Drug Application (NDA).

RUBITECAN'S* UNIQUE POTENTIAL: Beyond pancreatic cancer, promising clinical data presented during 2001 have shed light on rubitecan's unique potential to fight a number of other cancers, including melanoma, prostate, lung, stomach, MDS and chronic myelomonocytic leukemia (CML) and chordoma. In addition, results from a preclinical study announced last year have revealed that rubitecan may be useful as an adjunct therapy for HIV infection and AIDS. Clearly, these data add to the increasing evidence in support of rubitecan as a franchise compound, with the potential to benefit countless numbers of patients around the world.

Earlier this year, 2002, SuperGen and Abbott Laboratories decided to mutually conclude our alliance for rubitecan. As a result, SuperGen has regained 100 percent of the worldwide marketing rights to rubitecan. It is important to note that this settlement creates a unique opportunity for us to control our own destiny in that we now solely govern our growing product pipeline, both domestically and internationally. We now can proceed, unencumbered, to pursue other business relationships worldwide for rubitecan and many other drugs in our pipeline that we believe will maximize shareholder value.

Under the now mutually-terminated agreement, Abbott had exclusive rights of first-look at all of our products. Abbott could have taken up to 180 days to look at everything we have or will have in our pipeline. This stipulation has impeded our

business activities with other potential partners. Now we have the freedom to exploit business opportunities as we see fit.

THE FUTURE OF DECITABINE: As one Phase III clinical study concludes (rubitecan), another is marching ahead. In 2001, clinicians nationwide began enrolling patients in an open-label, randomized Phase III clinical study of decitabine as a treatment for advanced MDS, a disorder in which the bone marrow fails to produce sufficient numbers of healthy blood cells. The study has targeted 35 medical centers around the country and will enroll a total of 160 patients. 80 of these patients will receive decitabine and 80 will receive the current "standard-of-care" therapy. Positive results from this study, combined with data from two previous studies (showing response rates of 49 and 50 percent, respectively), could serve as the basis for an NDA filing in 2003.

Like rubitecan, the future of decitabine lies in its potential to develop into a multiplatform franchise compound. Data from *preclinical studies, conducted by Professor Robert Brown at Beatson Laboratories at Glasgow University, were presented at the Genomic Regulation and Cancer Conference in Glasgow in July 2001. The data demonstrated that chemotherapy-resistant ovarian and colon cancer cells that were treated with decitabine became more sensitive to chemotherapy treatment. Certainly, the scientific community has been clamoring for announcements such as this.*

In addition, data from previously published clinical studies (detailed in last year's annual report) suggest that decitabine may become an effective treatment for two especially troubling diseases – sickle cell anemia and stage IV non-small cell lung

cancer, the most common type of lung cancer. With the potential to help so many people across a broad spectrum of terrible afflictions, we will continue to devote the resources necessary to accelerate the clinical development of this important compound.

NIPENT, A FRANCHISE COMPOUND: A great deal of internal optimism is being focused on Nipent, which is currently being marketed for hairy cell leukemia. A number of favorable reports in 2001, as well as continued increases in year-to-year sales, have further contributed to our belief that Nipent is worthy of franchise compound status. At last June's Pan-Pacific Lymphoma Conference, where more than 200 prominent researchers and practitioners in the areas of lymphoma and hematological malignancies gathered to evaluate current treatment regimens, discuss future treatment options and evaluate results from clinical studies, a number of opinion leaders favorably commented on Nipent's effectiveness for chronic lymphocytic leukemia (CLL), graft-versus-host disease (GvHD), non-Hodgkin's lymphoma, bone marrow transplantation and hairy cell leukemia.

Studies by Dr. Jeffrey Margolis, Director of Hematology/Oncology at William Beaumont Hospital in Royal Oak, Michigan, have indicated that Nipent is the only agent that interrupts the pathogenesis of GvHD at multiple steps.

In November and December 2001, results from numerous studies involving Nipent were presented at two important medical meetings – the 43rd Annual Meeting of the American Society of Hematology and the "Innovative Cancer Therapy for Tomorrow" symposium, sponsored by New York's Mount Sinai School of Medicine and The Chemotherapy Foundation. At

these gatherings, several distinguished researchers presented papers demonstrating Nipent's ability to become a bona-fide treatment option for CLL, bone marrow transplants, GvHD and a preparative regimen for kidney transplantation.

Of particular interest is Nipent's apparent effectiveness in GvHD, a syndrome in which immune cells from the transplant donor reject the recipient's normal tissue following an allogeneic (from a donor rather than from one's self) bone marrow transplant. Currently, 50 percent of bone marrow transplants are allogeneic, with 85 percent of these patients developing GvHD, one-third of whom ultimately will develop a high-grade form of the disease. GvHD is fatal and is currently treated unsuccessfully with various immunosuppressive therapies. We intend to initiate a Phase III clinical trial of Nipent for GvHD in the latter half of 2002.

A YEAR OF FORWARD PROGRESS: From a corporate standpoint, 2001 was another year of forward progress for SuperGen. Increasing demand for Nipent pushed sales over the \$10 million mark for the first time. Coupled with the approval of daunorubicin, we anticipate this upward curve in revenue will continue for the foreseeable future. In addition, we bolstered the depth of our management team when Edward Jacobs rejoined the Company as Chief Business Officer and Chief Financial Officer. With over \$103 million in cash and marketable securities and equities, SuperGen is fundamentally strong, enabling us to aggressively continue the development of our product pipeline.

While 2001 was a successful year for SuperGen, much work remains to be done before we are established as the premier

oncology-focused company. Toward that end, our objectives for 2002 are:

- > File a New Drug Application for rubitecan as a treatment for patients with pancreatic cancer.
- > Complete patient enrollment in the Phase III clinical trial of decitabine as a treatment for advanced MDS.
- > Initiate a pivotal Phase III clinical study of Nipent as a treatment for GvHD.
- > Continue to expand our generic and supergeneric line of cancer drugs.

These objectives are challenging, but we are closer than ever to realizing the potential that our compounds offer for cancer patients around the world. We must not and will not be deterred from accomplishing our collective mission.

Sincerely,



Joseph Rubinfeld, Ph.D.
Chairman and Chief Executive Officer

*As you move forward through these pages you will see the name OrathecinaTM.
This is the commercially branded name for rubitecan and will be used from this point on.

Five World-Class Clinicians on what SuperGen's treatments mean to them
now and in the future.

05 INTERVIEWS

The following five clinicians represent only a small sampling of the many researchers who recognize the potential of SuperGen's compounds to prolong and improve the quality of their patients' lives. They are just a few of the hundreds of clinicians, many from distinguished medical centers around the country, whose expertise, dedication and compassion are helping their patients with new weapons in the ongoing war on cancer.

01

Interview No.

in a series of five.

Dr. Laurence Baker *Director of Clinical Research, Comprehensive Cancer Center*

UNIVERSITY OF MICHIGAN



“The two partial responses were the most spectacular remissions we have ever seen...”

➤ Chordomas are tumors that begin in bone, usually in the spine at the very base of the skull or at the bottom of the spine in a bone called the sacrum. They strike only a few hundred people per year. It is uncommon for them to metastasize, but when they do they most often go to the lungs and brain. Treatment involves surgery and radiation, but chordomas are resistant to most forms of traditional chemotherapy.

“This can be a particularly devastating and painful affliction, because of where and the slow rate at which these tumors grow. In some instances, severe disability and paralysis are possible,” said Laurence Baker, D.O., Director of Clinical Research at the University of Michigan Comprehensive Cancer Center, recently ranked among the top 12 of the nation’s best cancer centers by *U.S. News & World Report*. “While some people are cured, many others do not respond to treatment or suffer a recurrence.”

In January 2000, Dr. Baker initiated a clinical trial of Orathecina as a treatment for chordoma, and the results so far have been impressive. To date, nine patients have enrolled in the clinical trial; partial responses were observed in two patients and disease stabilization was noted in four others.

“The two partial responses were the most spectacular remissions that we have ever seen in chordoma patients,” stated Dr. Baker. “In one man, within two months of starting treatment, 95 percent of the tumor had vanished and many of his symptoms had disappeared. Sadly, he decided to stop taking the medication after a year, quickly relapsed and ultimately died.

“Typically, people will progress with this disease in three or four months, but we have patients who are stable at nine or ten months and still counting,” he added. “The drug has been well tolerated and side effects have been minimal.”

Given the many positive responses to date, Dr. Baker is looking to broaden the clinical trial at other medical centers around the country.

“There is no question that further study is needed before we are able to make any conclusions, but the results thus far are dramatic,” said Dr. Baker. “This may represent a significant advance in the treatment of chordoma.”

02

Interview No.

in a series of five.

Dr. Daniel DeAngelo Dana Farber Cancer Institute

AN AFFILIATE OF HARVARD MEDICAL SCHOOL



“There is no doubt that decitabine is an effective and safe drug.”

➤ Boston’s Dana Farber Cancer Institute is among the most respected oncology centers in the world. An affiliate of Harvard Medical School and designated a Comprehensive Cancer Center by the National Cancer Institute, the Institute is also home to the “Jimmy Fund.” The famous charity has raised more than \$200 million since 1948 and has funded decades of research resulting in increased survival rates for cancer patients around the world.

Dr. Daniel DeAngelo, an Instructor of Medicine in the Leukemia Program at the Dana Farber Cancer Institute’s Department of Hematologic Malignancies, is researching new treatments for patients afflicted with advanced myelodysplastic syndromes (MDS), a disorder in which the bone marrow does not function normally and fails to produce sufficient numbers of healthy blood cells. Dr. DeAngelo is one of several clinicians around the country involved in a Phase III study of decitabine as a treatment for advanced MDS.

“Myelodysplasia is a preleukemia condition, and patients with an advanced form of MDS typically progress to acute leukemia within a short period of time, usually one or two years,” said Dr. DeAngelo. “Sadly, the typical life expectancy is anywhere from six months to three or four years. Unfortunately, there are no proven effective treatments for decreasing this progression or improving overall survival other than bone marrow transplants, but most patients are of advanced age and cannot adequately tolerate this procedure.

“Previous Phase II studies have demonstrated that decitabine is efficacious in terms of reducing the number of precancerous cells,” added Dr. DeAngelo. “Unknown is whether that reduction will delay the progression to acute leukemia or prolong life. The answers to those questions can be found only in these types of clinical trials.

“If decitabine can demonstrate the ability to decrease the risk of leukemia transformation, improve survival and improve the patient’s quality of life, it could become the standard-of-care for MDS,” stated Dr. DeAngelo. “While that remains to be seen, there is no doubt that decitabine is an effective and safe drug. Given the limited number of treatment options, the fact that we have a compound that is demonstrating any activity in MDS is very encouraging.”

03

Interview No.

in a series of five.

Dr. Michael Grever *Chairman, Department of Internal Medicine*

OHIO STATE UNIVERSITY



"We have known for years that Nipent is an excellent treatment for patients with hairy cell leukemia. The drug has generated some extraordinarily long-term good results."

➤ In 1979, Dr. Michael Grever, then an Assistant Professor of Medicine in the Division of Hematology and Oncology at The Ohio State University, participated in the first United States-based clinical studies of Nipent in patients with lymphoid malignancies. In the ensuing few years, Dr. Grever and colleagues at Ohio State demonstrated that the drug was highly effective in treating hairy cell leukemia (HCL).

More than two decades later, his career accomplishments include serving as the Associate Director of the Developmental Therapeutics Program, Division of Cancer Treatment at the National Cancer Institute and the Director of the Division of Hematologic Malignancies at Johns Hopkins University. Today, Dr. Grever is back at Ohio State, as Chairman of the Department of Internal Medicine. Though many years have passed since his early work with Nipent, his opinion of the drug hasn't changed.

"We have known for years that Nipent is an excellent treatment for patients with hairy cell leukemia," said Dr. Grever. "The drug has generated some extraordinarily long-term good results."

Although Nipent is marketed as a treatment for HCL, Dr. Grever suspects that the capabilities of the drug may reach beyond a single indication.

"Years ago, we tested Nipent in patients who were suffering from lymphatic malignancies, such as chronic lymphocytic leukemia and cutaneous T-cell lymphoma, and the results were very encouraging," he added. "Approximately fifteen percent of the patients experienced some type of response, but because

these patients had been heavily pretreated prior to Nipent, that number was considered very good."

"Promising data is being reported pertaining to graft-versus-host disease and bone marrow transplantation, and people are starting to reexamine Nipent," said Dr. Grever. "Clearly, a great deal of exploration will take place in the next several years."

In addition to his enthusiasm for Nipent, Dr. Grever is taking a closer look at another of SuperGen's franchise compounds.

"Physicians treating patients with acute leukemia have become interested in decitabine," Dr. Grever stated. "Although I have never participated in studies to date, the drug appears to have promise. Decitabine may have activity as a stand-alone agent, but we are also eager to study this compound as part of a combination therapy."

04

Interview No.

in a series of five.

Dr. Peter Jones *Director, Norris Comprehensive Cancer Center*

UNIVERSITY OF SOUTHERN CALIFORNIA



“In the next several years, I believe that decitabine could become a front-line therapy for the treatment of several hematologic malignancies.”

➤ There may not be another person in the world with more knowledge of decitabine than Dr. Peter Jones. Dr. Jones, the Director of the Norris Comprehensive Cancer Center at the University of Southern California, has been studying the drug’s unique mechanism of action – the inhibition of hypermethylation of DNA – for 25 years.

In cancer cells, a normal cellular process called DNA methylation goes awry and causes a normal cell to turn abnormal, such that the genes needed to repair the cell and suppress tumors are summarily turned off. Decitabine crosses through the cell membrane and gets absorbed into the DNA. Once that happens, it interferes with and oftentimes inhibits methylation. The drug literally manipulates the DNA and, in a sense, can make a malignant cell behave in a more normal fashion.

“For decades, we have understood how decitabine works, but the correlation between methylation and cancer has only recently been embraced by the scientific community,” said Dr. Jones. “As a result, there are significantly more clinicians and scientists who are interested in how these methylation changes occur. Decitabine is recognized as the drug of choice to reverse these changes.

“One very exciting development is taking place in the laboratory, where studies have demonstrated that a low-dose of decitabine renders the malignant cells in certain cancers more susceptible to traditional chemotherapy,” added Dr. Jones. “The methylation of DNA can cause the gene that makes a cancer cell respond to chemotherapy to literally turn off. In certain cancers, decitabine

can reactivate that gene, thus substantially increasing the effectiveness of the chemotherapeutic agent. I believe that such combination therapy could become commonplace if further studies validate our early findings.

“In the next several years, I believe that decitabine could become a front-line therapy for the treatment of several hematologic malignancies,” said Dr. Jones. “Further down the line, the drug could be proven to help increase the efficacy of other treatments, or maybe even as a preventive agent for certain types of cancer.”

05

Interview No.

in a series of five.

Dr. Kenneth Miller *Director of the Bone Marrow Transplantation Unit*

TUFTS UNIVERSITY SCHOOL OF MEDICINE



“Nipent could soon become the standard-of-care in the medical community.”

➤ According to the Leukemia and Lymphoma Society, approximately 9,000 people in North America undergo allogeneic bone marrow transplantations each year for the treatment of lymphoma, leukemia or myeloma. As Director of the Bone Marrow Transplantation Unit at Boston’s New England Medical Center, an affiliate of the Tufts University School of Medicine and one of the world’s leading medical institutions, Dr. Kenneth Miller is well aware of both the risks and rewards of this life-saving procedure.

“Allogeneic [from a donor, rather than from one’s self] bone marrow transplants are often the only effective weapon in the fight against a broad number of leukemias, lymphomas and other blood disorders,” said Dr. Miller. “Traditionally, very high levels of chemotherapy are administered prior to the transplant. While this treatment regimen suppresses the immune system, allowing the graft to grow, the excessive levels of chemotherapy often make the patient very sick. Physicians are now looking for ways to perform ‘reduced-intensity’ transplants, which would involve administering smaller doses of drug.”

Nipent (already marketed by SuperGen for the treatment of hairy cell leukemia) has demonstrated that it may become an effective part of the treatment regimen prior to reduced-intensity allogeneic bone marrow transplants. In a two-year clinical trial conducted by Dr. Miller, 50 patients received a treatment regimen of photopheresis, reduced-dose total body irradiation and a continuous infusion of Nipent before undergoing the transplant. The overall response rate was 68 percent; the overall

engraftment rate was over 90 percent; and the overall mortality rate was less than 10 percent. Side effects were minimal, with no major adverse reactions reported.

“The ability to conduct reduced-intensity allogeneic bone marrow transplants could literally revolutionize this field. Our study has proven that such a procedure can be performed on high-risk patients with low posttransplant mortality,” stated Dr. Miller. “Nipent is a very effective, well-tolerated drug to use in this capacity, and if similar results are generated in additional studies, reduced-intensity transplants, along with Nipent, could soon become the standard-of-care in the medical community.”

SuperGen: The key to life

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended December 31, 2001

OR

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

For the transition period from _____ to _____

Commission file number 0-27628

SUPERGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

91-1841574
(IRS Employer
Identification Number)

4140 Dublin Blvd., Suite 200, Dublin, CA
(Address of principal executive offices)

94568
(Zip Code)

Registrant's telephone number, including area code: **(925) 560-0100**

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 per share
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes 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 the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

The aggregate market value of the voting stock held by non-affiliates of the Registrant (based on the closing sale price of the Common Stock as reported on the Nasdaq Stock Market on March 15, 2002) was approximately \$184,979,096. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of the close of business on March 15, 2002 was 32,699,396.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, and 13 of Part III incorporate information by reference from the definitive proxy statement for the Registrant's Annual Meeting of Stockholders to be held on May 29, 2002.

SUPERGEN, INC.
2001 ANNUAL REPORT ON FORM 10-K
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PART I

ITEM 1. BUSINESS

Our disclosure and analysis in this report contain forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. When we use the words “anticipate,” “estimate,” “project,” “intend,” “expect,” “plan,” “believe,” “should,” “likely” and similar expressions, we are making forward-looking statements. In particular, these include statements relating to future actions, such as the future performance or results of current and anticipated clinical trials for Orathecin, Nipent, decitabine, and our other products in development; the timing of filing of a new drug application for Orathecin; the anticipated launch of generic daunorubicin; the timing of and anticipated approval of our generic paclitaxel; the timing and expectation of FDA approval of our new Nipent manufacturing facility; the sufficiency of our levels of Nipent inventory; the potential applications for our compounds and products; and our estimates of potential market sizes. From time to time, we also may provide oral or written forward-looking statements in other materials we release to the public. Any or all of our forward-looking statements in this report and in any other public statements we make may turn out to be wrong. For example, our clinical data in all of our clinical trials may not support filing of an NDA or the FDA may not approve our products; the analysis of our clinical trial data may be more complex than we anticipate causing delays; we may be unable to launch our generic products as planned due to manufacturing or marketing difficulties; our manufacturing source for Nipent may not be approved by the FDA or the approval may be delayed; we may have inaccurately estimated demand for Nipent and may not have sufficient inventory levels to satisfy demand; our products may not prove to be suitable for the additional indications that we currently believe based on preliminary studies; and our estimates of market sizes may prove to be inaccurate. Inaccurate assumptions we might make and known or unknown risks and uncertainties can affect our forward-looking statements. Consequently, no forward-looking statement can be guaranteed and our actual results may differ materially.

We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and Annual Reports on Form 10-K. Also note that we provide a cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our business under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors Affecting Future Operating Results” in this report. These are risks that we think could cause our actual results to differ materially from expected and historical results. Other risks besides those listed in this report could also adversely affect us.

We incorporated in March 1991 as a California corporation and changed our state of incorporation to Delaware in May 1997. Our executive offices are located at 4140 Dublin Blvd., Suite 200, Dublin, CA, 94568 and our telephone number at that address is (925) 560-0100.

Overview

We are an emerging pharmaceutical company dedicated to the acquisition, rapid development, and commercialization of oncology therapies for solid tumors and hematological malignancies. We seek to minimize the time, expense and technical risk associated with drug commercialization by identifying and acquiring pharmaceutical compounds in the later stages of development, rather than committing significant resources to the research phase of drug discovery.

During 2001 we expended significant resources furthering our ongoing clinical trial and development activities and expanding our sales and marketing infrastructure and activities. Our most significant activities surrounded our clinical efforts related to Orathecin™, generically known as rubitecan, for treatment of pancreatic cancer and to a lesser extent furthering our other clinical trial activities. During 2001, we completed enrollment in each of our three ongoing Phase III Orathecin

pancreatic cancer trials. We are still in the process of compiling and analyzing data from each of the three clinical trials. Assuming favorable results from any one or a combination of our Phase III studies, we anticipate filing a New Drug Application (“NDA”), with the United States Food and Drug Administration (“FDA”), in 2002. During 2001 we initiated a Phase III clinical program with decitabine for treatment of myelodysplastic syndrome (“MDS”). During the year we also increased our revenues to \$11.5 million, principally through increased sales of Nipent® for treatment of hairy cell leukemia, which represented 87% of our revenues.

In March 2002 we entered into a termination agreement with Abbott Laboratories (“Abbott”) to terminate two 1999 agreements under which Abbott had undertaken to market and distribute Orathecin and make investments in our common stock. We were to co-promote Orathecin with Abbott in the United States and Abbott had retained exclusive rights to market Orathecin outside of the United States. In the U.S. market, we would have shared profits from product sales equally with Abbott. Outside the U.S. market, Abbott would have paid us royalties and transfer fees based on product sales. As a result of the termination of these agreements, Abbott no longer holds any marketing, promotion, or royalty rights relating to Orathecin and is not required to pay us milestone or other payments related to Orathecin. We continue to be responsible for pursuing and funding the clinical development of Orathecin and obtaining regulatory approval for the product in the United States, Canada, member states of the European Union, and other countries.

As a result of the termination, Abbott no longer holds a right to acquire up to 49% of our common stock, no longer has a right of first refusal to acquire us, nor are we obligated to first offer rights related to our product candidates to Abbott before discussing opportunities with other potential partners. Finally, Abbott is no longer obligated to purchase shares of our common stock upon the satisfaction of Orathecin developmental and marketing milestones. Due to the termination of the agreements with Abbott, we now have the flexibility to pursue opportunities with Orathecin and other compounds on our own or with a new strategic partner. We are currently evaluating our options as we work toward completion of the ongoing Orathecin trials and evaluate the trial results.

For additional information about the possible risks to our business as a result of the termination of our relationship with Abbott, please see the section of this report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors Affecting Future Operating Results.”

Strategy

Our primary objective is to be a leading supplier of oncology therapies for solid tumors and hematological malignancies. Key elements of our strategy include:

- *Licensing or buying rights to lead compounds rather than engaging in pure discovery research.* We identify and seek to license or buy rights to products or compounds that are typically in human clinical development or already marketed. We then seek to enhance and complete the product development. We believe that our approach minimizes the significant financial investment required by pure discovery research and reduces the risk of failure in developing a commercially viable product.
- *Capitalizing on our existing clinical expertise to maximize the commercial value of our products.* We intend to retain significant participation in the commercialization of our proprietary products by funding and undertaking human clinical development ourselves. We believe this will allow us to maximize the commercial value of our products by either directly marketing our products or licensing the products on more favorable terms than would be available earlier in the development cycle. Our management and clinical staff have significant experience in developing oncology therapies, bringing products to market, and maximizing market share.

- *Utilizing technologies to develop products for improved delivery and administration of existing compounds.* We are focused on the application of our technologies to the development of improved formulations of existing anticancer agents, which will be marketed as brand name pharmaceuticals. We believe that incorporating our technologies with these compounds will result in products with improved delivery and/or administration. The development of these products is subject to the New Drug Application (“NDA”) approval process.
- *Expanding our sales and marketing expertise from hematology to the treatment of solid tumors.* We have established a leadership position in the niche market development of hematological products. We are preparing to commercialize oncology products in a number of solid tumor therapies, such as immunotherapies and vaccines, gene modulators, biotechnology-based drugs, and other areas, such as diagnostic agents and prophylaxis that will leverage our current management and market expertise.

Summary of Products and Products in Development

The following table outlines our cancer products and cancer products in development, their indication or intended use, their therapeutic category, and their regulatory status. (Non-oncological products are summarized in text below):

Product Category	Compound	Indication or Intended Use	Therapeutic Category	Regulatory Status
Cytotoxic Agent/ Immunosuppressant	Nipent	Hairy cell leukemia	Cancer	<i>Approved</i>
		Chronic lymphocytic leukemia	Cancer	Phase IV
		Low grade non-Hodgkin's lymphoma	Cancer	Phase IV
		Cutaneous T-cell lymphoma/ Peripheral T-cell lymphoma	Cancer	Phase IV
		Graft-versus-host disease	Immunological	Phase II/III
		Transplantation Therapy	Immunological	Phase I/II
		Autoimmune Disorders	Immunological	Phase I
Cytotoxic Agent (Oral)	Orathecin (Generic name rubitecan)	Pancreatic cancer	Cancer	Phase III
		Myelodysplastic syndromes/ Acute myeloid leukemia/ Chronic myeloid leukemia	Cancer	Phase II
		Various other solid tumors	Cancer	Phase I/II
		Myelodysplastic syndromes	Cancer	Phase III
Hypomethylating Agent	Decitabine	Acute myeloid leukemia/ Chronic myeloid leukemia	Cancer	Phase II
		Sickle cell anemia	Hematological	Phase II
		Non-small cell lung cancer	Cancer	Phase I/II
		Breast cancer	Cancer	Phase I/II
		Colorectal cancer	Cancer	Phase II/III
Vaccine	Avicine™	Pancreatic cancer	Cancer	Phase II/III
			Cancer	Phase II/III
Generic Anticancer Agents	Mitomycin Daunorubicin Paclitaxel	Solid tumors	Cancer	<i>Approved</i>
		Solid tumors	Cancer	<i>Approved</i>
		Solid tumors	Cancer	ANDA filed
Radio-sensitizers	Lucanthone	Brain tumors	Cancer	Phase I
Formulation Technologies	Mito Extra Partaject™ (formerly Spartaject) busulfan Partaject Orathecin Cremophor-free paclitaxel Inhaled Orathecin Inhaled paclitaxel	Solid tumors	Cancer	NDA filed
		Neoplastic meningitis/ Bone marrow transplant	Cancer	Phase I/II
		Solid tumors	Cancer	Pre-clinical
		Solid tumors	Cancer	Pre-clinical
		Solid tumors	Cancer	Phase II
		Solid tumors	Cancer	Pre-clinical
Prodrugs	CZ 112	Solid tumors	Cancer	Phase I
Anti-angiogenesis	VEGF	Solid tumors	Cancer	Pre-clinical

Oncology Products and Products in Development

1. *Nipent*

Nipent, generically known as pentostatin or deoxycoformycin, inhibits a key enzyme in the DNA synthesis process and results in cytotoxicity, primarily in lymphocytes. The specific mechanism differs from other chemotherapy agents. Nipent's most unique feature is its selectivity for lymphocytes, with little effect on bone marrow or normal tissues, which creates an interest in this product for the treatment of cancers of the lymphoid system and other hematologic malignancies. Nipent has been our principal source of revenue during 2001, 2000 and 1999, representing 87%, 82% and 91% of our revenues in each of those years, respectively.

Hairy Cell Leukemia

We acquired Nipent from the Parke-Davis division of the Warner-Lambert Company (now Pfizer) in 1996, and we are selling this drug in the United States for the treatment of hairy cell leukemia, a type of B-lymphocytic leukemia. Warner-Lambert retained a worldwide, royalty-free license to sell Nipent but has agreed not to sell Nipent in North America through September 2006. In 1997, Warner-Lambert further agreed to buy Nipent from us for all of its sales outside the United States through at least October 2004. We are permitted to sell Nipent outside of North America for diseases other than cancer until September 2006, at which time we may sell the drug worldwide for any disease.

Other Indications

We believe that Nipent has a unique mechanism of action and Phase IV trials indicate that it may have activity in a variety of other hematologic cancers. In oncology, we are pursuing treatments for lymphatic malignancies and disorders, such as chronic lymphocytic leukemia, low-grade non-Hodgkin's lymphoma, cutaneous T-cell lymphoma, and peripheral T-cell lymphoma. Nipent has received orphan drug designation by the FDA for use against chronic lymphocytic leukemia and cutaneous T-cell lymphoma. We are pursuing trials that will lead to peer reviewed articles indicating efficacy of Nipent in various leukemias.

In addition, Nipent has shown activity in various autoimmune diseases, including graft-versus-host disease that is not responsive to standard therapies, bone marrow transplantation, rheumatoid arthritis, and multiple sclerosis. We estimate the United States markets for both graft-versus-host disease and rheumatoid arthritis are larger than the market for Nipent's current applications. We are conducting Phase I clinical trials in both of these indications and have targeted graft-versus-host disease for a registration seeking Phase II/III program currently in progress. We are also developing an oral formulation of Nipent, suitable for rheumatoid arthritis and other chronic immune disorders.

2. *Orathecine*

Orathecine, generic name rubitecan, formerly known as RFS2000 or 9-NC, is an oral chemotherapy compound in the camptothecin class, which we licensed from the Stehlin Foundation for Cancer Research in 1997. Orathecine is a second-generation topoisomerase I inhibitor that causes single-strand breaks in the DNA of rapidly dividing tumor cells. We believe that Orathecine may have significant advantages over many existing anticancer drugs, including efficacy, a superior side effect profile, and oral dosing. In particular, we believe that the compound causes significantly less inhibition of bone marrow function, due in part to its dosing schedule, which provides for a cycle of five days of administration followed by two days of recovery. In clinical trials, the observed side effects are mild to moderate hematological toxicities, low-grade cystitis, infrequent and mild hair loss and gastrointestinal disorders. Finally, as an oral drug that can be taken at home, Orathecine may provide patients with additional convenience and improved quality of life, and may reduce overall healthcare costs. We believe that Orathecine is a franchise drug for leadership in the treatment of a broad array of solid

tumors and hematological malignancies. We are seeking rapid development of Orathecine and anticipate priority review by the FDA of the drug for pancreatic cancer, for which there are limited treatment options. In addition to patent protection, we have orphan drug designation for this disease, which may provide us with seven years of marketing exclusivity in the United States after FDA approval.

Pancreatic Cancer

Pancreatic cancer is associated with high patient mortality, causing more than 75,000 deaths annually in the United States and Europe. It is the fourth leading cause of death by cancer in the United States with an average survival time of four to five months following diagnosis. The current therapeutic treatment options most commonly used to treat pancreatic cancer include 5-fluorouracil (“5-FU”) and Gemzar.

In May 2000, we presented data from a Phase II study of Orathecine at a meeting of the American Society of Clinical Oncology (“ASCO”). These data demonstrated Orathecine’s efficacy in pancreatic cancer patients who had failed previous chemotherapy. Of the 45 patients with measurable disease, twenty two percent either experienced a reduction in the size of their tumor or disease stabilization, meaning that the tumor did not continue to grow. After starting Orathecine treatment, median survival for these ten patients was approximately ten months, while forty percent of these patients survived more than twelve months and twenty percent survived more than twenty four months.

In 1998 we commenced three separate stand-alone pivotal Phase III clinical trials with Orathecine for treatment of pancreatic cancer. The trials are randomized, unblinded studies being conducted in approximately 200 centers. The primary endpoint of these trials is survival. The three studies are outlined as follows:

<u>Protocol Description</u>	<u>Enrollment Completed</u>	<u>Patients Enrolled</u>
Orathecine or 5-FU in patients who have failed Gemzar	February 2001	448
Orathecine or other therapies in patients who have failed other prior therapies	June 2001	409
Orathecine or Gemzar in patients who have not undergone chemotherapy	October 2001	994

We are still in the process of compiling and analyzing data from each of the three clinical trials. Assuming favorable results from any one, two, or combination of all three of these trials, we anticipate filing an NDA with the FDA in 2002. The trial design for each of the three studies allows patients who initially were being treated with Gemzar or other therapies to “cross over,” or elect to be treated with Orathecine. At the time the trials were designed, based on results of cancer studies conducted by others, we believed that the percentage of patients that would cross over for treatment with Orathecine would be in the range of 10% to 20% of the enrolled patients. Based on a preliminary review of the clinical trial information, we believe that the number of patients in the first two studies that have actually crossed over to Orathecine has exceeded the number anticipated. This could affect the timing and statistical analysis of the studies. In early April 2002, we will be convening a panel of experts to discuss strategies for filing an NDA for Orathecine.

Myelodysplastic Syndromes

Myelodysplastic syndromes are a group of conditions that have in common abnormalities in the blood-producing cells of the bone marrow. The conditions are fatal, although patients can live for several years after diagnosis. Treatment of patients with MDS has generally proven disappointing. The current standard of care is management by supportive measures, such as blood transfusion, or the administration of antibiotics to fight infections. Hematopoietic growth factors also have been used to treat MDS.

We are conducting a Phase II Orathecin study at the M.D. Anderson Cancer Center enrolling patients with a diagnosis of MDS, as well as related conditions such as chronic myeloid leukemia and acute myeloid leukemia. Based on preliminary positive results from this study, we have initiated a confirmatory Phase II multi-center study as part of our registration seeking strategy.

Other Potential Indications

Studies have shown Orathecin to be active in more than 30 human and animal tumor models in indications such as breast, lung, colorectal, ovarian, gastric, and prostate cancers as well as sarcomas. We are aggressively pursuing more than 35 additional Phase I/II trials using Orathecin both as a single therapeutic agent and in combination with other anticancer agents in solid tumors and hematological malignancies. We intend to make available to physicians copies of peer-reviewed medical journal articles and other validated scientific information related to these trials. We believe this will provide physicians with more up-to-date product information and will better enable them to meet their patients' medical needs.

In addition, we are currently conducting pilot studies using Orathecin in combination with other chemotherapeutic agents. In studies to date, Orathecin has not exhibited the cardiac, pulmonary, hepatic or renal toxicities that limit the acute and/or chronic dosages of several chemotherapeutics. In addition, some early studies suggest Orathecin could be used to treat cancer on a chronic rather than acute basis.

3. *Decitabine*

Decitabine is a potent hypomethylating agent that we acquired from Pharmachemie B.V., a subsidiary of Teva Pharmaceuticals, in September 1999. Decitabine is a pyrimidine analog that has a mechanism of action which is different from other chemically related compounds, such as gemcitabine and cytosine arabinoside. Decitabine's mechanism is related to DNA hypomethylation. Methylation of DNA is a major mechanism regulating gene expression. Researchers have determined that an increase in methylation of DNA results in blocking the activity of several genes that regulate cell division and differentiation, known as "suppressor genes." With suppressor genes blocked, cell division becomes unregulated, causing cancer. In studies researchers have demonstrated that decitabine reduces the methylation of DNA, leading to reexpression of suppressor genes and a resulting redifferentiation and maturation of the cancer cells back to normal. Researchers have also shown that decitabine treatment restores sensitivity of tumors to treatment by drugs such as cisplatin by reversing drug resistance.

Myelodysplastic Syndromes

In multiple Phase II studies in Europe, researchers have shown decitabine to be effective for treating MDS. Based on positive results from these studies, we have initiated two randomized Phase III studies at sixty leading hospitals in the United States and Europe with 160 and 220 patients, respectively, comparing decitabine to best supportive care for MDS. The principal endpoints are time to acute myeloid leukemia or death in the United States study, and survival time in the European study. These Phase III trials, if successful, are designed to secure approval for this indication. Decitabine has received orphan drug designation from the FDA for MDS, which designation may provide us with seven years of marketing exclusivity in the United States after FDA approval.

Other Indications

In addition to MDS, Phase I/II studies have shown that decitabine is effective in a variety of other hematological malignancies such as acute myeloid leukemia and chronic myeloid leukemia. Preliminary results also suggest activity in solid tumors such as non-small cell lung cancer. Phase II clinical trials with decitabine are ongoing for this indication. Phase I results also suggest that decitabine may be

applicable for treatment of non-malignant diseases such as sickle cell anemia. A Phase II clinical program has been initiated for treatment of sickle cell anemia using decitabine.

4. *Avicine*

In July 2000, we acquired the sales and marketing rights in the United States to Avicine from AVI BioPharma, Inc. ("AVI"). Avicine is a therapeutic cancer vaccine in late-stage clinical development, and has completed five clinical studies in more than 200 patients.

Colorectal Cancer

Results from a Phase II human study using Avicine as a treatment for advanced colorectal cancer showed that patients who responded to the peptides in the vaccine, in the words of the study author, "exhibited significant survival benefits" compared to patients treated with chemotherapy alone. With the assistance of leading oncologists and the FDA, AVI has developed a Phase III protocol for Avicine as a first-line treatment for metastatic colorectal cancer.

Pancreatic Cancer

A Phase II study has been completed using Avicine in the treatment of pancreatic cancer and has demonstrated promising results. A Phase III clinical program is currently being prepared.

5. *Generic Anticancer Drugs*

We have pursued development of generic versions of existing anticancer agents as part of our Extra product development efforts. We believe that the total estimated United States sales for generic anticancer products have decreased over the last few years due to increased competition. We also believe sales for these generics may continue to decrease as a result of competitive factors. These factors may include reductions in the per unit sales price, the introduction of additional generics as well as other cancer drugs, new formulations for these drugs and the use of different therapies. Therefore, we currently intend to limit our development of generic products to those that we feel either require minimal effort to submit an Abbreviated New Drug Application ("ANDA") and obtain marketing clearance, or that offer significant market opportunities.

Mitomycin

We have received ANDA approval for our generic mitomycin, which we are selling in the United States.

Daunorubicin

We received approval of an ANDA for generic daunorubicin from the FDA in November 2001. We expect to launch this product in early 2002.

Paclitaxel

We filed an ANDA for generic paclitaxel with the FDA in August 1998 and have filed a number of responses to letters from the FDA concerning our application. We anticipate an approval in 2002.

6. *Lucanthone*

Lucanthone is a topoisomerase II inhibitor that we licensed in May 2000 from Dr. Robert Bases of the Albert Einstein College of Medicine. Researchers are currently evaluating lucanthone as a radiosensitizer in a Phase I study of patients with brain tumors.

Formulation Technology, Prodrugs, and Other Products

We are focused on the application of our technologies to the development of improved formulations of existing anticancer agents, which will be marketed as brand name pharmaceuticals. We believe that incorporating our technologies with these compounds will result in products with improved delivery and/or administration. The development of these products is subject to the NDA approval process.

1. Extra Technology

We have developed several applications for our proprietary Extra technology. We believe this technology significantly improves the safety profile and handling characteristics of several anticancer drugs currently on the market. In March 1994, we acquired exclusive worldwide rights to the patented cyclodextrin technology used in our Extra technology from Janssen Biotech, N.V. and others.

Many generic anticancer drugs are available only in a powder form that must be mixed into a solution before injection into a vein. If successful, our Extra technology will produce a ready-to-inject, stable solution that will ease administration and save time by eliminating the potentially dangerous mixing procedure. It could also provide safety benefits for those administering the dose by reducing their risk of exposure to the drug. Moreover, we believe that our ready-to-inject stable solutions may have a significantly longer shelf life at room temperature than the mixed solutions. In addition, many existing anticancer pharmaceuticals, including those under development by us, are potent toxins that can cause serious irreversible damage to a patient's muscle or skin should the drug accidentally leak during injection. We believe that our Extra technology may increase the safety of these existing anticancer drugs by shielding the tissue from the drug at the injection site. The drug is released upon circulation within the bloodstream. We believe that each of these features will result in our Extra products having a significant competitive advantage over their counterparts currently on the market.

Extra products under development

We filed an NDA for Mito Extra, our Extra formulation of mitomycin, in December 1997, which was accepted by the FDA in February 1998. In March 2002, we responded to an FDA request for additional formulation, manufacturing and clinical information. This response included a report from a recently completed multi-center study of 116 patients with advanced cancers treated with Mito Extra. In addition, we are evaluating our Extra technology for additional applications of other generic anticancer agents as well as Nipent.

2. Partaject Drug Delivery Technology

Partaject drug delivery technology is a drug delivery system that accommodates poorly water-soluble and water-insoluble compounds by encapsulating them with a fatty layer, known as a phospholipid. The Partaject technology involves coating particles of a drug that are of submicron or near micron size with a membrane-forming phospholipid layer, thereby permitting the creation of a suspension of the drug rather than a solution, and its intravenous injection without the use of potentially toxic solubilizing agents. As a result, the Partaject technology may reduce toxicity created by other injectable forms of delivery and potentially increase efficacy by facilitating delivery of compounds whose prior intravenous delivery was impractical because of solubility-related formulation difficulties.

Partaject products under development

Busulfan is currently marketed in an oral dosage form by Glaxo Wellcome Inc. It is frequently used "off-label" as a bone marrow ablating agent prior to bone marrow transplants. In 1998, we completed a Phase I clinical trial of Partaject busulfan at both Johns Hopkins Oncology Center and

Duke University Medical Center. A Phase I clinical trial in pediatric bone marrow ablation has been completed in 35 patients at St. Jude's Children's Hospital in Memphis.

Partaject busulfan is currently also being developed for intrathecal treatment of neoplastic meningitis with a Phase I/II study at Duke University Medical Center and a Phase I study is being completed by the Pediatric Brain Tumor Consortium.

We are also developing Partaject Orathecin, an intravenous formulation, which is suitable for patients who cannot swallow an oral medication. This is currently in pre-clinical development.

3. *Cremophor-Free Paclitaxel*

In January and October 2000 we were issued two United States patents for a Cremophor-free formulation of paclitaxel. We were issued a third patent for an oral formulation in November 2001. We believe that these patents have important clinical and strategic implications as such a formulation obviates the need of pre-medication, which is currently required with the use of paclitaxel. We believe that the lack of pre-medication and an oral formulation will prove to be major competitive advantages in the paclitaxel market, which industry reports estimated to be \$1.6 billion in 2000.

4. *Inhaled Cancer Drugs*

In December 1999, we entered into license and research agreements with the Clayton Foundation for Research and its technology transfer organization, Research Development Foundation. Under the terms of the agreements, we acquired worldwide rights to inhaled versions of formulations of paclitaxel and camptothecins, including Orathecin. Phase I clinical studies with inhaled Orathecin for the treatment of lung cancer and pulmonary metastatic disease have been completed at the M.D. Anderson Cancer Center and the Baylor College of Medicine and a Phase II study is under way.

5. *Oral Prodrug Delivery Technology—CZ 112*

Oral prodrug delivery technology involves administering an inactive compound, known as a prodrug, which is absorbed in the digestive tract and is converted to an active agent in the liver by an enzyme located there. Oral prodrug delivery technology could potentially enable the oral delivery of drugs that are otherwise only used in an intravenous formulation. The resulting active compounds may pass through the systemic circulation and act at peripheral sites. We are applying the oral prodrug delivery technology to compounds selected for their potential either to serve as oral delivery agents for systemically active chemotherapeutic or radio sensitizing drugs previously available only in intravenous form.

CZ 112 is an oral prodrug for Orathecin we licensed from the Stehlin Foundation in November 1999 after initial Phase I testing. We are currently completing additional pre-clinical tumor model studies prior to deciding to undertake further clinical development.

6. *Surface Safe®*

In July 1999, we acquired the Surface Safe product line from Aldorr, Inc., a medical technology development company. Surface Safe is a two-step towelette disposable cleaning system used to decontaminate any work surface where chemotherapeutic preparation is conducted. The first towelette contains chemicals recommended by the Centers for Disease Control and the Occupational Safety Health Administration to clean work surfaces. The second towelette is used to deactivate the chemicals used in the first towelette, in order to prevent damage to work surfaces through its potent oxidizing process. We launched Surface Safe in the United States in March 2001 and intend to launch the product in other countries in the near future.

Strategic and Collaborative Relationships

We identify and license or buy rights to products or compounds that are typically in human clinical development. We then seek to enhance and complete the product development and bring the product to market internally or through collaborations with others. We have entered into a variety of strategic relationships and licensing agreements in pursuing our business. Some of our more significant relationships are as follows:

1. *Orathecine*

Stehlin Foundation for Cancer Research

In September 1997, we licensed the exclusive worldwide royalty-bearing rights to Orathecine from the Stehlin Foundation for Cancer Research, a Houston, Texas-based cancer research clinic. The Stehlin Foundation was established in 1969 by Dr. John S. Stehlin, Jr. M.D., a surgical oncologist, for the express purpose of conducting basic research that can be applied directly to improving the treatment of patients with cancer. All research is clinically oriented and conducted at the Stehlin Foundation's facility in Houston, Texas. In November 1999, we amended our agreement with the Stehlin Foundation to broaden the definition of licensed compounds to include certain analogues of Orathecine. Under these agreements, we are required to seek commercial applications for Orathecine. We are required to pay the Stehlin Foundation approximately \$10 million for research and must make cash royalty payments and cash or stock milestone payments to the Stehlin Foundation as we develop and commercialize Orathecine.

Abbott Laboratories

In December 1999, we entered into two agreements with Abbott Laboratories, a Common Stock and Option Purchase Agreement and a Worldwide Sales, Distribution and Development Agreement relating to Orathecine. Under these agreements, Abbott was to invest in shares of our common stock and would participate with us in the marketing and distribution of Orathecine. We would have co-promoted Orathecine with Abbott in the United States and Abbott had exclusive rights to market Orathecine outside of the United States. In the United States market, we would have shared profits from product sales equally with Abbott, while outside of the United States market, Abbott would have paid us royalties and transfers fees based on product sales. Abbott was obligated to purchase up to \$81.5 million in shares of our common stock over a period of time. In addition, Abbott had an option to purchase up to 49% of the shares of our common stock outstanding at the time of exercise at \$85 per share. Abbott also had a right of first discussion with respect to our product portfolio and a right of first refusal to acquire us. In connection with these agreements, Abbott made a \$26.5 million equity investment in January 2000 and a \$2.5 million equity milestone payment in July 2001.

On March 4, 2002, SuperGen and Abbott mutually terminated the Common Stock and Option Purchase Agreement and the Worldwide Sales, Distribution and Development Agreement. We regained all marketing rights to Orathecine worldwide and are no longer obligated to share profits from product sales of Orathecine. Abbott no longer has the right or obligation to purchase the remaining aggregate amount equal to \$52.5 million in shares of our common stock, no longer has the option to purchase up to 49% of our outstanding shares, no longer has the right of first discussion with respect to our product portfolio, and no longer has a right of first refusal to acquire us. Accordingly, we will not receive any further milestone payments from Abbott. In connection with termination we also agreed to reimburse Abbott for \$1.6 million in development fees.

In December 1999, we entered into a Nipent distribution agreement with Abbott, which is still in effect. Beginning March 1, 2000, Abbott became the exclusive United States distributor of Nipent for a period of five years. We retain United States marketing rights for Nipent. Under this agreement, in January 2000, Abbott made a \$5 million cash payment to us in connection with the granting of the

exclusive distribution rights. This amount is being recognized in revenue ratably over the term of the distribution agreement.

2. *AVI BioPharma, Inc.—Avicine*

In July 2000, we finalized an agreement with AVI BioPharma, Inc. to obtain the United States marketing rights for Avicine, AVI's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors. Avicine is a non-toxic immunotherapy that neutralizes the effect of a tumor-associated antigen on cancer cells, while stimulating the body's immune system to react against the foreign tumor. Avicine has completed five clinical studies in more than 200 patients.

Under the terms of the agreement, we will be responsible for United States marketing and sales of Avicine, and AVI will be responsible for product manufacturing. In addition, we obtained the right of first discussion with respect to all of AVI's oncology compounds. Both companies will share clinical development and regulatory costs for the FDA approval process, and profits will be split equally. SuperGen and AVI will jointly determine the optimum development strategy for the international marketplace and will share all profits received.

We made equity investments totaling \$22 million in AVI in the form of cash and SuperGen common stock. As part of the agreement, we have an option to acquire an additional 10% of AVI's common stock. This option is exercisable for a three-year period commencing on the earlier of the date the FDA accepts the NDA submitted for Avicine, or the date on which the closing price of AVI's common stock exceeds the option exercise price. Neither event has occurred as of December 31, 2001.

3. *Peregrine Pharmaceuticals—VEGF (Anti-Angiogenesis)*

In February 2001, we completed a transaction to license a platform drug-targeting technology known as Vascular Targeting Agent ("VTA") from Peregrine Pharmaceuticals, formerly known as Techniclone Corp. The licensed technology is specially related to Vascular Endothelial Growth Factor ("VEGF"). Terms of the agreement include an up-front equity investment in Peregrine of \$600,000 and subsequent milestone payments, that ultimately could total \$8 million. In addition, we will pay royalties to Peregrine based on the net revenues of any drugs commercialized using the VEGF technology.

The VTA technology is a proprietary platform designed to specifically target a tumor's blood supply and subsequently destroy the tumor with various attached therapeutic agents.

Dr. Phillip Thorpe, Professor of Pharmacology at the University of Texas, Southwestern Medical Center, and the inventor of the VTA technology, has demonstrated proof of principle with this technology in several animal models. The results of Dr. Thorpe's studies have been published in several peer-reviewed scientific journals. The next step in the development process is filing an investigational new drug application ("IND") based on Dr. Thorpe's study data.

4. *Non-Oncology Proprietary Products*

We are currently seeking strategic alliances and licensing agreements for further development of certain non-oncology products, including RF 1010, RF 1051, pyrazinoylguanidine ("PZG"), and AM 454.

RF 1010 is an analog of a naturally occurring human non-androgenic hormone. We have conducted Phase II trials using RF 1010 to treat various forms of anemia and neutropenia. These diseases destroy red and white blood cells and thereby weaken the immune system, leaving patients susceptible to infections that could result in serious illness or death.

RF 1051, which is a naturally occurring substance in humans, has applications for treatment of diabetes and obesity. Our Phase II trials have indicated that this proprietary oral drug may cause the

body to store less fat or use more fat to produce energy. We have received orphan drug designation for RF 1051 in the treatment of Prader-Willi Syndrome, a type of genetic obesity.

PZG is a product for treatment of Type II, or adult-onset, diabetes. Animal studies and early clinical studies of PZG suggest that it may help to control the blood sugar and lipid abnormalities of diabetes, and may have utility in treating a lipid disorder unrelated to diabetes called hypertriglyceridemia, obesity, hypertension and the uremia of renal failure. We recently initiated a small, well-defined and controlled Phase II study to characterize the hypoglycemic and lipid-lowering effects of PZG in Type II diabetes.

In 2000 we acquired the intellectual property of AMUR Pharmaceuticals, Inc. ("Amur"), a company with the proprietary rights to AM 454, which can potentially prevent the onset of Type II diabetes according to pre-clinical animal studies, and rights to a 20K growth hormone, with potential for treatment of Type II diabetes. Amur's technology is based on a new water-soluble class of hormones.

Research and Development Costs

Because of the stage of our development and the nature of our business we expend significant resources on research and development activities. We expended \$47.8 million, \$31.4 million, and \$17.3 in 2001, 2000 and 1999, respectively, on research and development.

New Drug Development and Approval Process

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases state statutes and regulations also govern or impact upon the manufacturing, safety, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations, require the expenditure of substantial resources. Regulatory approval, when and if obtained, may be limited in scope which may significantly limit the indicated uses for which a product may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products, which may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

The process for new drug approval has many steps, including:

Drug discovery. In the initial stages of drug discovery before a compound reaches the laboratory, tens of thousands of potential compounds are randomly screened for activity against an assay assumed to be predictive for particular disease targets. This drug discovery process can take several years. Once a company locates a "screening lead", or starting point for drug development, isolation and structural determination may begin. The development process results in numerous chemical modifications to the screening lead in an attempt to improve the drug properties of the lead. After a compound emerges from this process, the next steps are to conduct further preliminary studies on the mechanism of action, further in vitro, or test tube, screening against particular disease targets and finally, some in vivo, or animal, screening. If the compound passes these barriers, the toxic effects of the compound are analyzed by performing preliminary exploratory animal toxicology. If the results demonstrate acceptable levels of toxicity, the compound emerges from the basic research mode and moves into the pre-clinical phase.

Pre-clinical testing. During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests typically take approximately three and one-half years to complete, and must be conducted in compliance with Good Laboratory Practice ("GLP"), regulations.

Investigational new drug application. During the pre-clinical testing, an IND is filed with the FDA to begin human testing of the drug. The IND becomes effective if not rejected by the FDA within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. All clinical trials must be conducted in accordance with Good Clinical Practice ("GCP") regulations. In addition, an Institutional Review Board ("IRB"), comprised of physicians at the hospital or clinic where the proposed studies will be conducted, must review and approve the IND. The IRB also continues to monitor the study. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, the FDA may, at any time during the 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Some limited human clinical testing may be done under a Physician's IND in support of an IND application and prior to receiving an IND. A Physician's IND is an IND application that allows a single individual to conduct a clinical trial. A Physician's IND does not replace the more formal IND process, but can provide a preliminary indication as to whether further clinical trials are warranted, and can, on occasion, facilitate the more formal IND process.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

Phase I clinical trials. After an IND becomes effective, Phase I human clinical trials can begin. These tests, involving usually between 20 and 80 healthy volunteers or patients, typically take approximately one year to complete. The tests study a drug's safety profile, and may include the safe dosage range. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. Phase I/II trials are normally conducted for anticancer product candidates.

Phase II clinical trials. In Phase II clinical trials, controlled studies are conducted on approximately 100 to 300 volunteer patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine if there are any side effects. These studies generally take approximately two years, and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety.

Phase III clinical trials. This phase typically lasts about three years and usually involves 1,000 to 3,000 patients. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any reactions that may result from long-term use of the drug.

New drug application. After the completion of all three clinical trial phases, if there is substantial evidence that the drug is safe and effective, an NDA is filed with the FDA. The NDA must contain all of the information on the drug gathered to that date, including data from the clinical trials. NDAs are often over 100,000 pages in length.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. In such an event, the NDA must be resubmitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Federal Food, Drug and Cosmetic Act, the FDA has 180 days in which to review the NDA and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter.

Marketing approval. If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional studies (Phase IV) to evaluate long-term effects.

Phase IV clinical trials and post marketing studies. In addition to studies requested by the FDA after approval, these trials and studies are conducted to explore new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community.

Orphan drug designation. The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orathecin has received orphan drug designation from the FDA for treatment of pancreatic cancer. Decitabine has also received orphan drug designation from the FDA for MDS, chronic myeloid leukemia, and acute leukemia.

Approvals outside of the United States. Steps similar to those in the United States must be undertaken in virtually every other country comprising the market for our products before any such product can be commercialized in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. There can be no assurance that approvals will be granted on a timely basis or at all. In addition, regulatory approval of prices is required in most countries other than the United States. There can be no assurance that the resulting prices would be sufficient to generate an acceptable return to us.

FDA Modernization Act of 1997

The Food and Drug Administration Modernization Act of 1997 ("FDAMA") was enacted, in part, to ensure the timely availability of safe and effective drugs, biologics and medical devices by expediting the FDA review process for new products. FDAMA establishes a statutory program for the approval of "fast track products." The fast track provisions essentially codifies the FDA's Accelerated Approval

regulations for drugs and biologics. A "fast track product" is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for such a condition. Under the new fast track program, the sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a "fast track product" at any time during the clinical development of the product. FDAMA specifies that the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. Approval of an NDA for a fast track product can be based on an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit. Approval of a fast track product may be subject to post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint, and prior review of copies of all promotional materials. If a preliminary review of the clinical data suggests efficacy, the FDA may initiate review of sections of an application for a "fast track product" before the application is complete. This "rolling review" is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees. However, the Prescription Drug User Fees Act time period does not begin until the complete application is submitted.

We intend to seek fast track designation to secure priority review of Orathecin or other appropriate products. It is uncertain if fast track designation will be obtained. We cannot predict the ultimate impact, if any, of the new fast track process on the timing or likelihood of FDA approval of any of our potential products.

Physicians may prescribe drugs for uses that are not described in the product's labeling for uses that differ from those tested by us and approved by the FDA. Such "off-label" uses are common across medical specialties and may constitute the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use. Companies cannot actively promote FDA-approved drugs for off-label uses, but a recent court decision now allows them to disseminate to physicians articles published in peer-reviewed journals, like *The New England Journal of Medicine*, that discuss off-label uses of approved products. To the extent allowed by law, we intend to disseminate peer-reviewed articles on our products to our physician customers.

Extra drug development

Each Extra product candidate contains an active drug substance which has already been approved by the FDA and may already also have generic versions approved by the FDA. The excipient for the Extra technology has also been approved by the FDA in a non-oncology application. To gain approval to market, we must provide data to the FDA to support the safety, efficacy and quality of each Extra product, but these data may be more limited in scope and content than would be required for a new chemical entity. While extensive clinical trials may not be required, we will be required to provide clinical data that demonstrate that the administration of our Extra formulation results in the same presence of the drug in the body as that of the generic version, within clinically acceptable statistical guidelines. Overall, the data packages we will submit to the FDA for Extra product candidates may be smaller than a typical NDA and may take less time to review.

We also expect that, after the safety and quality of the Extra technology have been adequately demonstrated to the FDA, future Extra submissions will be able to cross-refer to these data, further streamlining our submissions.

Generic drug development

For certain drugs that are generic versions of previously approved products, there is an abbreviated FDA approval process. A sponsor may submit an Abbreviated Application for:

- a drug product that is the “same” as the drug product listed in the approved drug product list published by the FDA (the “listed drug”) with respect to active ingredient(s), route of administration, dosage form, strength and conditions of use recommended in the labeling;
- a drug product that differs with regard to certain changes from a listed drug if the FDA has approved a petition from a prospective applicant permitting the submission of an Abbreviated Application for the changed product; and
- a drug that is a duplicate of, or meets the monograph for, an approved antibiotic drug.

An Abbreviated Application need not contain the clinical and pre-clinical data supporting the safety and effectiveness of the product. The applicant must instead demonstrate that the product is bioequivalent to the listed drug. FDA regulations define bioequivalence as the absence of a significant difference in the rate and the extent to which the active ingredient moiety becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. If the approved generic drug is both bioequivalent and pharmaceutically equivalent to the listed drug, the agency may assign a code to the product in an FDA publication that will represent a determination by the agency that the product is therapeutically equivalent to the listed drug. This designation will be considered by third parties in determining whether the generic drug will be utilized as an alternative to the listed drug.

Patents and Proprietary Technology

We actively pursue a policy of seeking patent protection for our proprietary products and technologies, whether developed in-house or from outside acquisition. We have acquired licenses to or assignments of numerous United States patents covering certain of our proprietary drugs and have received or licensed patents related to our Extra, Partaject, and Oral Prodrug technologies.

In addition to pursuing patent protection in appropriate cases, we rely on trade secret protection for our unpatented proprietary technology. We also pursue a policy of having our employees and consultants execute proprietary information agreements upon commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the relationship is confidential except in specified circumstances.

Competition

There are many companies, both public and private, including well-known pharmaceutical companies that are engaged in the development and sale of pharmaceutical products for some of the applications that we are pursuing. Our competitors and probable competitors include Eli Lilly, Ortho Biotech, Novartis, Aventis, Berlex, Bristol-Myers Squibb, Immunex, and others. These companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. These companies may succeed in developing pharmaceutical products that are more effective or less costly than any we may develop or market.

Factors affecting competition in the pharmaceutical industry vary depending on the extent to which the competitor is able to achieve a competitive advantage based on proprietary technology. If we are able to establish and maintain a significant proprietary position with respect to our proprietary products, competition will likely depend primarily on the effectiveness of the product and the number,

gravity and severity of its unwanted side effects as compared to alternative products. Companies compete with respect to generic products primarily on price and, to a lesser extent, on name recognition and the reputation of the manufacturer in its target markets. Moreover, the number of competitors offering a particular generic product could dramatically affect price and gross margin for that product or an Extra product based on that generic product. We may be at a disadvantage in competing with more established companies based on price or market reputation. In addition, increased competition in a particular generic market would likely lead to significant price erosion for our generic products and Extra products based on such generic products. This would have a negative effect on our sales and potential gross profit margins. For example, we believe that the total estimated United States sales for our proposed generic products, and generic products upon which we propose to base our Extra products, have decreased in recent years due to increased competition. We believe that sales volumes and unit prices of these generics may continue to decrease as a result of competitive factors. These factors include the introduction of additional generics and other cancer drugs, the desire of some companies to increase their market share, new formulations for those drugs and the use of different therapies.

Extensive research and development efforts and rapid technological progress characterize the industry in which we compete. Although we believe that our proprietary position may give us a competitive advantage with respect to our proposed nongeneric drugs, we expect development of new products to continue. Discoveries by others may render our current and potential products noncompetitive. Our competitive position also depends on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, implement development and marketing plans, obtain patent protection and secure adequate capital resources.

Sales and Marketing

We currently have 37 employees focused on sales, marketing, and sales support of our products to cancer hospitals and clinics in the United States. The large majority of these hospitals are members of hospital buying groups. We have focused our efforts on selling to these groups since they control a significant majority of the business in the oncology and blood disorder pharmaceutical market. We also market our products, including Nipent, to private practice oncology clinics, oncology distributors and drug wholesalers. Oncologists/hematologists, oncology nurses and oncology pharmacists are included in each of these classes of customers.

Since acceptance of our products from each buying group can be time consuming, there may be significant delays before we can win bids and generate sales revenue. However, we have taken significant steps toward product acceptance. A large number of these buying groups, including Premier Purchasing Partners, Novation, Kaiser Permanente, and the Department of Veteran Affairs, have given us approved vendor status. In addition, we have gained recognition as an approved vendor in each state that requires registration or licensing before bidding for those customers.

There are approximately 5,000 private practice oncologists/hematologists in the United States. These physicians usually purchase oncology products through distributors, with whom we have developed relationships. The four major oncology distributors in the United States are Oncology Therapeutic Network Joint Venture, L.P., Florida Infusion Services, Inc., National Specialty Services, Inc. and Priority Healthcare Corporation. These distributors control approximately 60% of the private practice oncology clinics, which in turn represent approximately 30% of the oncology-related pharmaceutical market. We have taken significant steps in building relationships with these distributors, all of which distribute Nipent. Our sales force will also continue to target the important private practice oncology clinics within their assigned territories. We also sell to large drug wholesalers that supply hospitals and hospital buying groups.

Our sales group is divided into three regions. Each region is headed by a manager with extensive industry experience who supervises specialty oncology sales representatives. We plan to expand our sales force upon receipt of additional approvals of our products under development. Our sales and marketing group conducts direct sales, sponsors speakers' programs, works with distributors, performs market research analysis, develops marketing strategies, creates and implements educational and promotional programs, establishes pricing and product advertising and maintains compliance with hospital and other buying groups.

Manufacturing

We currently outsource manufacturing for all of our products to United States and foreign suppliers. We expect to continue to outsource manufacturing in the near term. We believe our current suppliers will be able to efficiently manufacture our proprietary and generic compounds in sufficient quantities and on a timely basis, while maintaining product quality. We maintain quality control over manufacturing through ongoing inspections, rigorous review, control over documented operating procedures, and thorough analytical testing by outside laboratories. We believe that our current strategy of outsourcing manufacturing is cost-effective since we avoid the high fixed costs of plant, equipment, and large manufacturing staffs.

The FDA must issue marketing clearance and deem a manufacturer acceptable under current Good Manufacturing Practices ("GMP's") before production of active pharmaceutical ingredients, finished pharmaceuticals, or proprietary and generic drugs for commercial sale may begin. Once a proprietary or generic compound is manufactured on our behalf, it is sent to one or more domestic manufacturers that process it into the finished proprietary, Extra or generic dosage forms. We currently follow these procedures for our marketed products, Nipent and mitomycin. We then ship our finished proprietary and generic products to outside vendors for distribution to our customers.

We have entered agreements with a domestic entity for the future production of our generic compounds required for both our Extra and generic dosage forms. We have licensed from this manufacturer, on an exclusive basis, proprietary fermentation technology for anticancer antibiotic agents. In the future, we may adapt this proprietary fermentation technology to produce other bulk generics.

In December 1997, we received approval from the FDA to commercially manufacture Nipent at one of our designated vendors' manufacturing site using our proprietary manufacturing process. This vendor declared bankruptcy in July 2001 and closed its manufacturing facility. We transferred the manufacturing of Nipent to a new vendor in 2001. We are currently working with the FDA to have this new manufacturing site approved and expect approval early in the second quarter of 2002. However, if this approval is not received prior to the depletion of our inventory levels, we may experience an interruption in sales of Nipent. We believe we own sufficient bulk inventory for the manufacture of Nipent to meet our clinical and commercial needs for the near future. In April 1998, the FDA approved our application for the production and commercial distribution of mitomycin for injection. In November 2001, the FDA approved our application for the production and commercial distribution of daunorubicin hydrochloride injection. For additional information about the possible risks to our business as a result of manufacturing issues, please see the risk factor beginning "We depend on third parties for manufacturing..." in the section of this report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors Affecting Future Operating Results."

We intend to continue evaluating our manufacturing requirements and may establish or acquire our own facilities to manufacture our products for commercial distribution if we feel doing so would reduce costs or improve control and flexibility of product supply.

Employees

As of December 31, 2001, we had 115 full-time employees. We use consultants and temporary employees to complement our staffing. Our employees are not subject to any collective bargaining agreements, and we regard our relations with employees to be good.

Executive Officers and Management Team

Our current executive officers and their ages are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Joseph Rubinfeld, Ph.D.	69	Chief Executive Officer, President and Director
Edward L. Jacobs	55	Chief Business Officer/Chief Financial Officer
Karl L. Mettinger, M.D., Ph.D.	58	Senior Vice President, Chief Medical Officer

Joseph Rubinfeld, Ph.D. co-founded the Company in 1991. He has served as Chief Executive Officer, President, and a director of the Company since our inception and was Chief Scientific Officer from inception until September 1997. Dr. Rubinfeld was one of the four initial founders of Amgen in 1980 and served as Vice President and Chief of Operations until 1983. From 1987 to 1990, he was a Senior Director at Cetus Corporation. From 1968 to 1980, Dr. Rubinfeld was employed at Bristol-Myers Company International Division in a variety of positions, most recently as Vice President and Director of Research and Development. While at Bristol-Myers, Dr. Rubinfeld was instrumental in licensing the original anticancer line of products for Bristol-Myers, including Mitomycin and Bleomycin. Before that time, Dr. Rubinfeld was a research scientist with several pharmaceutical and consumer product companies including Schering-Plough Corporation and Colgate-Palmolive Co. He received his B.S. in chemistry from C.C.N.Y., and his M.A. and Ph.D. in chemistry from Columbia University. Dr. Rubinfeld has numerous patents and/or publications on a wide range of inventions and developments, including the 10-second developer for Polaroid film, manufacture of cephalosporins and the first commercial synthetic biodegradable detergent. In 1984, Dr. Rubinfeld received the Common Wealth Award for Invention.

Edward L. Jacobs rejoined SuperGen in October 2001 as Chief Business Officer and Chief Financial Officer. From February 2001 through September 2001, he served as President and Chief Executive Officer of ETEX Corporation. He originally came to SuperGen as Executive Vice President, Commercial Operations in March 1999 and served in that position until January 2001. Prior to joining us in 1999 Mr. Jacobs served as Senior Vice President, Commercial Operations at Sequus Pharmaceuticals, Inc. from November 1997 to March 1999. Between January 1995 and November 1997, Mr. Jacobs served as President and Chief Executive Officer of Trilex Pharmaceuticals Inc., now Titan Pharmaceuticals. Prior to his association with Trilex, Mr. Jacobs served in a variety of senior management positions with pharmaceutical companies, including Chief Executive at Transplant Therapeutics Inc., Vice President and General Manager of Syncor International Inc., Vice President at NEORX Corporation, Business Director of Pharmacia and Upjohn (Adria Labs, Inc.), and Johnson & Johnson (McNeil). Mr. Jacobs received a B.A. in Political Science/Journalism from California State University at Northridge.

Karl Mettinger, M.D., Ph.D., joined SuperGen in August 2000 as Senior Vice President and Chief Medical Officer. Prior to coming to SuperGen, Dr. Mettinger was at IVAX Corporation/Baker Norton Pharmaceuticals for 11 years, where he served in a number of senior management positions, including Executive Director, Clinical Research; Senior Director, Clinical Research; and Medical Director. Prior to IVAX, Dr. Mettinger was Deputy General Manager and Medical Director at KABI (currently Pharmacia). He was also an associate professor at the Karolinska Institute and a physician at the Karolinska Hospital in Stockholm for fifteen years. Dr. Mettinger obtained his medical training at the University of Lund, and his Ph.D. in the field of Hematology at the Karolinska Institute.

In addition, our management team includes the following individuals, with their relevant experience and years of industry service:

<u>Name</u>	<u>Title</u>	<u>Experience</u>
Frank Brenner	V.P., National Accounts	Adria Laboratories, Lederle International, Cetus Corporation—27 years
L. Robert Cohen	V.P., Investor Relations and Finance	Pfizer, Johnson & Johnson, Prudential-Bache Securities—33 years
Timothy L. Enns	V.P., Marketing	Upjohn, Adria, MGI Pharma, Syncor, Sequus—21 years
Frederick Grab, Ph.D.	V.P., Compliance and CMC	Bristol-Myers Squibb, Adria Laboratories, Wyeth Laboratories—33 years
Audrey Jakubowski, Ph.D.	V.P., Regulatory Affairs	Bristol-Myers Squibb, DuPont—23 years
R. David Lauper, Pharm.D	V.P., Professional Services	Bristol-Myers Squibb, Cetus-Chiron—27 years
Robert Marshall	V.P., Sales	OTN, IVEDCO, Syncor, Adria Laboratories, NeoRx—31 years
Lawrence Romel	V.P., Clinical Operations	Onyx, Sequus, Neurex, Kendall—21 years
Howard Sands, Ph.D.	V.P., Pre-Clinical Research	Sparta Pharmaceuticals, DuPont—26 years
Simeon Wrenn, Ph.D.	V.P., Biotechnology	American Home Products, American Cyanamid, Purdue Frederick, Centocor—23 years

ITEM 2. PROPERTIES.

Our principal administrative facility is currently located in leased general office space, containing approximately 50,000 square feet, in Dublin, California, under a lease that expires in November 2010. Our laboratory operations are located in an industrial building in Pleasanton, California. We also possess a five year lease to a 10,000 square foot office/warehouse space, adjacent to our laboratory facility, that is currently being subleased. We believe the above properties are suitable for our operations in the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

We are currently not subject to any material pending legal proceedings.

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

No matters were submitted to a vote of our stockholders during the fiscal quarter ended December 31, 2001.

PART II

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

Market for Common Stock

Our common stock trades on the Nasdaq National Market under the symbol "SUPG." The following table sets forth the high and low bid information for our common stock for each quarterly period in the two most recent fiscal years as reported on the Nasdaq National Market:

	High	Low
2001		
Quarter ended March 31, 2001	\$15.25	\$ 8.03
Quarter ended June 30, 2001	15.50	9.50
Quarter ended September 30, 2001	13.76	6.47
Quarter ended December 31, 2001	14.99	6.69
2000		
Quarter ended March 31, 2000	\$77.31	\$27.50
Quarter ended June 30, 2000	49.00	19.13
Quarter ended September 30, 2000	39.00	17.38
Quarter ended December 31, 2000	23.69	10.63

Holders of Record

As of March 15, 2002, there were 540 holders of record of the common stock and approximately 25,000 beneficial stockholders.

Dividends

We have never paid cash dividends on our capital stock and do not expect to pay any dividends in the foreseeable future. We intend to retain future earnings, if any, for use in our business.

Recent Sales of Unregistered Securities

None

ITEM 6. SELECTED FINANCIAL DATA.

The information set forth below is not necessarily indicative of results of future operations and should be read in conjunction with the financial statements and notes thereto appearing in Item 14 of Part IV of this Report.

	Year ended December 31,				
	2001	2000	1999	1998	1997
	(Amounts in thousands, except per share data)				
Total revenue	\$ 11,451	\$ 7,089	\$ 4,744	\$ 3,004	\$ 1,802
Net loss	(55,566)	(35,283)	(36,985)	(15,577)	(15,996)
Basic and diluted net loss per share	(1.69)	(1.04)	(1.58)	(0.77)	(0.85)
Total assets	122,717	163,333	53,478	19,793	30,772
Total stockholders' equity	107,798	149,945	44,768	16,818	28,567
Long-term obligations	—	—	—	—	—
Cash dividends per share	—	—	—	—	—

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

Our disclosure and analysis in this section of the report also contains forward-looking statements. When we use the words "anticipate," "estimate," "project," "intend," "expect," "plan," "believe," "should," "likely" and similar expressions, we are making forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. In particular, these statements include statements such as: the timing of filing of a new drug application for Orathecin; our estimates about becoming profitable; our forecasts regarding our research and development expenses; and our statements regarding the sufficiency of our cash to meet our operating needs through December 2003. Any or all of these forward-looking statements may turn out to be wrong. For example, our clinical data in our Orathecin clinical trials may not support filing of an NDA or the FDA may not approve our application if filed; the analysis of our clinical trial data may be more complex than we anticipate causing delays; we may not be successful in commercializing our products and may not become profitable when planned or at all; our research and development expenses may be larger than we currently anticipate; and our cash and capital resources may be insufficient to meet our needs. Inaccurate assumptions we might make and known or unknown risks and uncertainties can affect our forward-looking statements. Consequently, no forward-looking statement can be guaranteed and our actual results may differ materially. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

Since our incorporation in 1991 we have devoted substantially all of our resources to our product development efforts. Our product revenues to date have been limited and have been principally from sales of Nipent, which we are marketing in the United States for the treatment of hairy cell leukemia. As a result of our substantial research and development expenditures and minimal product revenues, we have incurred cumulative losses of \$183.7 million for the period from inception through December 31, 2001. These losses included non-cash charges of \$20.0 million for the acquisition of in-process research and development.

We have completed patient enrollment in each of the three separate stand-alone pivotal Phase III clinical trials with Orathecin for treatment of pancreatic cancer. The three studies—"Gemzar refractory," where patients who failed treatment with Gemzar were randomized to either Orathecin or 5-FU; "Chemotherapy refractory," where patients who have failed multiple types of chemotherapy are randomized to either Orathecin or the next best therapy; and "Chemotherapy naïve," where patients who have had no prior chemotherapy are randomized to Orathecin or Gemzar—have enrolled a combined total of over 1,800 patients. We are still in the process of compiling and analyzing data from each of the three clinical trials. Assuming favorable results from any one or a combination of our Phase III studies, we anticipate filing an NDA with the FDA in 2002. The trial design for each of the three studies allows patients who initially were being treated with Gemzar or other therapies to "cross over," or elect to be treated with Orathecin. At the time the trials were designed, based on results of cancer studies conducted by others, we believed that the percentage of patients that would cross over for treatment with Orathecin would be in the range of 10% to 20% of the enrolled patients. Based on a preliminary review of the clinical trial information, we believe that the number of patients in the first two studies that have actually crossed over to Orathecin has exceeded the number anticipated. This could affect the timing and statistical analysis of the studies. In early April 2002, we will be convening a panel of experts to discuss strategies for filing an NDA for Orathecin.

We have initiated a Phase III clinical program with decitabine for treatment of MDS, and are continuing to pursue Phase I and II clinical trials with Orathecin and a number of other drug candidates for treatment of other cancers and hematological malignancies. We are also conducting trials

with Nipent, currently approved for hairy cell leukemia, for use in other indications such as chronic lymphocytic leukemia, graft-versus-host disease, and non-Hodgkin's lymphoma. To support these additional trials, we are also continuing to increase our clinical development staff.

We expect to continue to incur operating losses at least through 2003. This is due primarily to projected spending for the development of our product candidates. The level of our expenditures related to ongoing clinical trials has increased significantly throughout the current year as we expand the number of clinical trials and increase the patient accrual into these trials. Our ability to become profitable will depend upon a variety of factors, including regulatory approvals of our products, the timing of the introduction and market acceptance of our products and competing products, increases in sales and marketing expenses related to the launch of Orathecin and other drug candidates, if approved, and our ability to control our costs. If Orathecin is not approved or commercially accepted we may remain unprofitable for longer than we currently anticipate.

In late 1999, we entered into two agreements related to Orathecin with Abbott Laboratories under which Abbott would undertake to market and distribute Orathecin and under which Abbott was obligated to make investments in the Company based on achievements of milestone events. We were to co-promote Orathecin with Abbott in the United States and Abbott had exclusive rights to market Orathecin outside of the United States. In the U.S. market, we would have shared profits from product sales equally with Abbott. Outside the U.S. market, Abbott would have paid us royalties and transfer fees based on product sales. On March 4, 2002, we mutually terminated these agreements with Abbott and they no longer have any marketing, promotion, or royalty rights relating to Orathecin. We agreed to pay Abbott \$1.6 million for development activities undertaken by Abbott and we relieved Abbott of any obligation to pay us further milestone payments. We continue to be responsible for pursuing and funding the clinical development of Orathecin and obtaining regulatory approval for the product in the United States, Canada and the member states of the European Union.

Due to the termination of the agreements with Abbott we now have the flexibility to pursue opportunities with Orathecin and other compounds on our own or with a new strategic partner. We are currently evaluating our options as we work toward completion of the ongoing Orathecin trials and evaluate the trial results. Assuming we receive regulatory approval, if we elect to pursue marketing of Orathecin on our own we will be required to significantly increase our sales and marketing departments to a greater extent than currently planned.

As part of our strategy, we intend either to market our products ourselves or co-promote these products with partners. In 2000, we entered into agreements with AVI related to the development and marketing rights to Avicine, AVI's therapeutic vaccine for colorectal cancer, which is now entering Phase III clinical trials. Under these agreements, we will share U.S. developmental and regulatory approval costs for Avicine and upon commercialization in the U.S., we will split all U.S. profits. AVI and SuperGen will jointly determine the optimum development strategy for the international marketplace and will share all profits received. In addition to an up front equity investment, we are obligated to make additional payments to AVI based on successful achievement of developmental, regulatory approval, and commercialization milestones over the next several years. As part of this agreement, we obtained the right of first discussion to all of AVI's oncology compounds and an option to acquire an additional 10% of AVI's common stock. Avicine will require significant additional expenditures to complete the clinical development necessary to gain marketing approval from the FDA and equivalent foreign regulatory agencies.

Critical Accounting Policies

Our significant accounting policies are more fully disclosed in Note 2 to our consolidated financial statements. However, some of our accounting policies are particularly important to the portrayal of our financial position and results of operations and require the application of significant judgement by our

management. We believe the following critical accounting policies, among others, affect our more significant judgements and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our net sales relate principally to two pharmaceutical products. We recognize sales revenue upon shipment and related transfer of title to customers, with allowances provided for estimated returns and exchanges. Cash advance payments received in connection with distribution agreements or research grants are deferred and recognized ratably over the period of the respective agreements.

Our principal customers are clinics, hospitals and hospital buying groups in the United States and drug distributors and wholesalers in the United States and Europe. We do not require collateral from our customers.

Intangible Assets

Intangible assets, including trademarks, covenants not to compete, acquired workforce and customer lists, are stated at cost and amortized on a straight-line basis over their estimated useful lives of six months to five years. Goodwill, which represents the excess of acquisition cost over the net assets acquired, is being amortized on a straight-line basis over five years.

Use of Estimates

In preparing our financial statements to conform with accounting policies generally accepted in the United States, we make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. These estimates include useful lives for allowances for returns and exchanges, fixed assets for depreciation calculations, and assumptions for valuing options and warrants.

Results of Operations

Year ended December 31, 2001 compared with year ended December 31, 2000

Revenues were \$11.5 million in 2001 compared to \$7.1 million in 2000. Revenues in 2001 included \$9.7 million in Nipent sales in the U.S. and \$338,000 in sales to the European distributor for Nipent. Revenues in 2000 included \$5.8 million in sales of Nipent exclusively in the U.S. marketplace. We did not record any European sales in 2000. Unlike our Nipent sales efforts in the U.S. market where we call on clinicians directly, our role in Europe is currently limited to that of a supplier. As such, we do not have a direct influence on Nipent sales at the clinical level, making their timing and magnitude difficult to predict and dependent on the efforts of our European distributor. We expect our domestic sales of Nipent to increase in 2002 and beyond as we pursue additional clinical research and publish data on the effectiveness of Nipent for other forms of leukemia and immunological disorders.

Cost of sales as a percentage of net sales revenues was 26% in 2001 compared to 27% in 2000. The decline in cost of sales percentage was due primarily to 2001 sales to the European distributor for Nipent that were made at a lower unit selling price under a supply agreement for sale outside North America. There were no European sales in 2000. To the extent that European sales comprise a more significant portion of our total Nipent sales in 2002 we would expect our margins to decrease. Current margins may not be indicative of future margins due to possible variations in average selling prices and manufacturing costs. We are in the process of qualifying a new party to manufacture Nipent and this new relationship could increase our costs or result in delays of shipments.

Research and development expenses were \$47.8 million in 2001 compared to \$31.4 million in 2000. Approximately \$20.2 million of the total in 2001 related to direct expenditures for Phase I, II, and III trials for Nipent, Orathecin, decitabine, and our other drug candidates, compared to approximately \$9.9 million in 2000. The increased expense was due primarily to the completion of enrollment of over

1,800 patients into our Phase III clinical trial of Orathecin for pancreatic cancer, enrollment of approximately 800 patients into Phase I/II clinical trials of Orathecin in various other indications, and initiation of our Phase III clinical trials of decitabine in advanced MDS. We do not expect that the Phase III trials for decitabine will be as costly as those for Orathecin, and since the Orathecin trials completed enrollment in 2001, we believe that research and development expenditures will be lower in 2002 than in 2001. However, conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product candidate. Our clinical trials may be suspended at any time if we or the FDA believe the patients participating in our studies are exposed to unacceptable health risks. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Because of these uncertainties, we cannot predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost.

Selling, general and administrative expenses were \$22.1 million in 2001 compared to \$16.0 million in 2000. This increase was due primarily to costs associated with the expansion of the sales, marketing, and professional service staffs, as well as increased costs associated with trade shows and conferences and symposiums. In addition 2001 reflects additional rent, depreciation, and facility expenses related to our relocation to a 50,000 square foot facility in December 2000.

Acquisition of in-process research and development totaled \$1.6 million in 2000 and resulted from the acquisition of the intellectual property of AMUR Pharmaceuticals, Inc. We had no such acquisitions in 2001.

Interest income was \$5.6 million in 2001 compared to \$8.2 million in 2000. The decrease was due to lower available cash balances for investment and a decline in interest rates.

Year ended December 31, 2000 compared with year ended December 31, 1999

Revenues were \$7.1 million in 2000 compared to \$4.7 million in 1999. Revenues in 2000 included \$5.8 million in sales of Nipent exclusively in the U.S. marketplace. Worldwide Nipent revenues of \$4.3 million in 1999 included \$3.0 million in U.S. sales and \$1.3 million in sales to the European distributor for Nipent. We have recorded no European sales in 2000. Unlike our Nipent sales efforts in the U.S. market where we call on clinicians directly, our role in Europe is currently limited to that of a supplier. As such, we do not have a direct influence on Nipent sales at the clinical level, making their timing and magnitude difficult to predict and dependent on the efforts of our European distributor. Revenues in 2000 also included recognition of \$833,000 in revenues related to the Nipent distribution arrangement with Abbott Laboratories, recognition of \$50,000 in revenue associated with the completion of a clinical trial for busulfan in Europe, and recognition of \$103,000 in grant revenues from the National Institutes of Health/National Cancer Institute relating to the development of IPdR.

Cost of sales as a percentage of net sales revenues was 27% in 2000 compared to 43% in 1999. The improvement in cost of sales percentage was due primarily to the absence in 2000 of sales to the European distributor for Nipent, as such sales were made at a lower unit selling price under a supply agreement for sale outside North America. Current margins may not be indicative of future margins due to possible variations in average selling prices and manufacturing costs.

Research and development expenses were \$31.4 million in 2000 compared to \$17.3 million in 1999. The increased expense was due primarily to a broader clinical development program along with its associated costs, expansion of the research and development staff, and a significant increase in the accrual rates of patients into our ongoing clinical trials.

Selling, general and administrative expenses were \$16.0 million in 2000 compared to \$10.5 million in 1999. This increase was due primarily to costs associated with the expansion of the sales, professional

services, information technology and general and administrative staffs together with increased costs associated with trade shows, speakers' programs and symposiums, investor relations, business development consulting and legal fees.

Acquisition of in-process research and development totaled \$1.6 million in 2000 and resulted from the acquisition of the intellectual property of AMUR Pharmaceuticals, Inc. In 1999, acquisition of in-process research and development totaled \$10.9 million, which included \$7.5 million relating to the acquisition of the drug candidates of Sparta Pharmaceuticals, Inc. and \$3.4 million relating to the license of decitabine from Pharmachemie.

Interest income was \$8.2 million in 2000 compared to \$1.0 million in 1999. The increase was due to the greater cash balances available for investment as a result of our Abbott corporate partnership, our March 2000 follow-on offering of common stock, and the exercise of our SUPGW warrants and related underwriters' unit purchase warrants that we issued in connection with our initial public offering in 1996.

Amortization of loan commitment fees totaled \$2.0 million in 1999. This charge was related to a credit arrangement that existed during 1999. We had no such credit arrangement in 2000 and consequently incurred no such charges during the period.

Liquidity and Capital Resources

Our cash, cash equivalents and both short and long term marketable securities totaled \$74.0 million at December 31, 2001, compared to approximately \$130.6 million at December 31, 2000. In addition, at December 31, 2001 we held approximately 2.7 million shares of registered stock of AVI BioPharma, Inc., with a market value of \$29.3 million. Our ability to resell the shares of AVI stock may be impacted partially by the fact that Dr. Rubinfeld, our Chief Executive Officer, is a director of AVI, which may require us to trade the shares during times when AVI insiders are not subject to any material undisclosed information. In addition, the registration statement covering our resale of shares may be suspended or otherwise become unavailable requiring us to sell the shares subject to volume limitations.

The net cash used in operating activities of \$49.8 million in 2001 primarily reflected the net loss for the period of \$55.6 million, offset by decreases in other receivables, prepaid expenses, and other assets totaling \$2.4 million, and an increase in accounts payable and other liabilities of \$2.5 million.

In September 2000, our Board authorized a stock repurchase plan to acquire, in the open market, an aggregate of up to one million shares of our common stock at prices not to exceed \$22 per share or \$20 million in total. In March 2001, our Board authorized the repurchase of up to two million shares under this plan, provided that the total amount of such repurchases does not exceed \$20 million. During the year ended December 31, 2001, we repurchased 963,000 shares of common stock at a cost of approximately \$9.1 million. During the year ended December 31, 2000, we repurchased 184,500 shares of common stock at a cost of approximately \$2.4 million.

We believe that our current cash, cash equivalents and marketable securities will satisfy our cash requirements at least through December 2003. Our primary planned uses of cash during that period are:

- for research and development activities, including expansion of clinical trials;
- to enhance sales and marketing efforts in advance of the potential launch of Orathecin;
- to potentially enhance manufacturing capabilities;
- to make equity investments in emerging companies that are coupled with licensing rights or options to acquire compounds or technology; and

- to finance possible acquisitions of complimentary products, technologies and businesses:

Our contractual obligations for the next five years and thereafter are as follows:

	Payments Due by Period				
	Total	< 1 year	1-3 years	4-5 years	After 5 years
Operating Leases, net	\$19,009,046	\$1,897,486	\$6,283,402	\$4,052,856	\$6,775,302
Long term obligations—contractually obligated research funding	5,180,000	1,685,000	2,275,000	760,000	460,000
Total contractual cash obligations . . .	<u>\$24,189,046</u>	<u>\$3,582,486</u>	<u>\$8,558,402</u>	<u>\$4,812,856</u>	<u>\$7,235,302</u>

The contractually obligated research funding noted above consists primarily of required payments to the Stehlin Foundation and Peregrine. We are also obligated to potentially expend up to a total of \$88 million in milestone and development related payments to AVI and Peregrine for development of Avicine and VEGF technologies. We are unable to determine precisely when and if our payment obligations under our agreements with AVI and Peregrine will become due as these obligations are based on a significant number of risks and uncertainties. Because certain of our payment obligations are based on milestone events that would not be triggered absent our receipt of revenues from the relationship, we may be able to use funds generated from these relationships to make the milestone payments.

We believe that our need for additional funding will increase in the future and that our continued ability to raise additional funds from external sources will be critical to our success. We continue to actively consider future contractual arrangements that would require significant financial commitments. If we experience currently unanticipated cash requirements, we could require additional capital much sooner than presently anticipated. We may seek such additional funding through public or private financings or collaborative or other arrangements with third parties. We may not be able to obtain additional funds on acceptable terms, if at all.

Acquisition of In-Process Research and Development and Related Assets

Factors considered when evaluating IPR&D

Acquired in-process research and development (“IPR&D”) represents the value assigned to research and development projects that were commenced but not yet completed at the date of acquisition and which, if unsuccessful, have no alternative future use in research and development activities or otherwise. In accordance with Statement of Financial Accounting Standards No. 2 “Accounting for Research and Development Costs,” as interpreted by FASB Interpretation No. 4, amounts assigned to acquired IPR&D meeting the above criteria must be expensed at the date of consummation of the transaction. Accordingly, we record a non-recurring charge for this acquired IPR&D at the date of acquisition.

The development of any of the acquired IPR&D into technologically feasible and commercially viable products depends principally on the successful performance of additional clinical trials. Though we currently expect that the acquired IPR&D will be successfully developed, the proposed products may never be commercially viable.

Year ended December 31, 2000

In September 2000, we acquired all of the intellectual property of Amur in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at \$40.00 per share. Amur’s proprietary technology is based on a new water-soluble class of hormones. Investigation of these hormones determined that a specific portion, phosphocholine, confers water

solubility to the hormones. Amur's previously conducted research and development has shown that phosphocholine may be attached to other compatible molecules representing a novel patented drug delivery technology. We recorded a charge of \$1,585,000 in connection with this acquisition.

Year ended December 31, 1999

Sparta drug candidates

In August 1999, we completed our acquisition of Sparta, a biopharmaceutical company engaged in developing technologies and drugs for the treatment of a number of life-threatening diseases, including cancer, cardiovascular disorders, chronic metabolic diseases and inflammation.

The total cost of the acquisition was approximately \$9.6 million, and consisted of the issuance of 429,082 shares of our common stock and 220,945 common stock warrants to the former Sparta stockholders. Approximately \$7.5 million of the purchase price was allocated to acquired IPR&D. The Sparta research and development programs were valued as follows:

Oral anticancer drug for the treatment of breast, colorectal and other cancers (5-FP, a prodrug of 5-FU)	\$3,430,000
Chronic metabolic disease drug (PZG)	1,380,000
Partaject method for the delivery of certain anti-cancer compounds	<u>2,640,000</u>
	<u>\$7,450,000</u>

- 5-FP, or 5-fluoro pyrimidinone, is a pyrimidinone-based prodrug that is converted to 5-FU, or 5-fluorouracil by the liver. This drug candidate was in Phase I clinical trials at the date of the acquisition.
- Animal studies and early clinical studies of PZG suggest that it may help to control the blood sugar and lipid abnormalities of diabetes.
- Partaject drug delivery technology is a drug delivery system that accommodates poorly water-soluble and water-insoluble compounds by encapsulating them with a fatty (phospholipid) layer. Currently, there are ongoing Phase I clinical trials applying the Partaject drug delivery technology to busulfan for use in bone marrow ablation and for the treatment of neoplastic meningitis.

We identified and valued the purchased research and development through extensive interviews and discussions with appropriate management and scientific personnel. We also analyzed the data provided by Sparta concerning Sparta's development projects, their respective stage of development, the time and resources needed to complete them, their expected income generating ability, target markets, and associated risks. Using an income approach that reflects the present value of the projected free cash flows generated by each individual IPR&D project identified, we focused on the income producing capabilities of the acquired technologies and quantified the present value of the future economic benefits expected to be derived from each. In the aggregate, we estimate that the total remaining development costs necessary to advance the three drug candidates through the regulatory process will be approximately \$45 million. We expect this regulatory development process to occur over several years with potential product introductions through 2005. The effective tax rate utilized for the analysis was 40%. The discount rate used to value Sparta's IPR&D was 31%. The discount rate considers an assumed weighted average cost of capital of 22% at the date of acquisition and a risk premium to reflect the risk associated with the stage of development of each of the Sparta projects. Additional amounts of the purchase consideration were recorded as intangible assets related to existing licensing rights, acquired workforce and goodwill.

Decitabine

In September 1999, we acquired worldwide rights to decitabine, a chemotherapeutic agent owned by Pharmachemie. Decitabine has been successful in multiple Phase II trials in the United States and Europe for treating myelodysplastic syndromes, or MDS, chronic myeloid leukemia and acute myeloid leukemia. The FDA has not granted marketing approval to use decitabine for the treatment of any disease.

In the decitabine acquisition we issued 171,123 shares of unregistered common stock valued at \$3.4 million, which we charged to IPR&D. In assigning the purchase price to IPR&D, we considered, among other factors, our intentions for the future use of the acquired project, its stage of completion, the lack of alternative future uses of the technology, and that no other tangible or intangible assets were acquired. We believe decitabine has a unique mechanism of action that may demonstrate its effectiveness in acute leukemias and other hematological malignancies. We currently estimate that the completion of the clinical trials and submission to the FDA of an NDA could occur in 2003 and the research and development costs to complete those processes will be approximately \$6.0 to \$8.0 million. Revenues could begin with the introduction of a product in 2004.

Related Party Transactions

EuroGen Pharmaceuticals Ltd.

In September 2001, we entered into a Supply and Distribution Agreement with EuroGen Pharmaceuticals Ltd. ("EuroGen"), a company incorporated and registered in England and Wales. The purpose of the agreement is to provide a means of furthering our access to European markets. Under the agreement, we granted EuroGen the exclusive European and South African rights to promote and sell certain of our existing generic and other products or compounds. The agreement also establishes a process for granting EuroGen rights to sell additional products in Europe and South Africa, subject to our compliance with our other existing licensing and distribution arrangements. After complying with these existing obligations, we will be required to offer EuroGen the option to obtain European and South African rights to our future products. EuroGen will seek and pay for all necessary regulatory approvals and authorizations necessary for the commercial sale of the products in the territories where they market and sell the products.

EuroGen is not yet an operating company, but we intend to hold an equity interest in the company once it raises additional capital and is operational. At December 31, 2001 we had loaned EuroGen \$260,000 under a line of credit arrangement designed to cover start-up expenses. This amount is included in Due from related parties. If EuroGen is unable to adequately fund its operations, we may not recover amounts owed to us or realize any income or benefit from the relationship.

KineMed, Inc.

In November 2001, we made an equity investment of \$150,000 to acquire 100,000 shares of Series A Convertible Preferred stock of KineMed, Inc., a start-up biotech company. The president and chief executive officer of KineMed is a former director of SuperGen. The president and chief executive officer of SuperGen is a member of the Board of Directors of KineMed. We have accounted for this investment under the cost method as our ownership is less than 20% of KineMed's outstanding shares. This investment is included on the balance sheet in Investment in stock of related parties.

AVI BioPharma, Inc.

In December 1999, we entered into an agreement with AVI BioPharma, Inc. ("AVI"). The chief executive officer of AVI is Dennis Burger, a member of our Board of Directors. The president and chief executive officer of SuperGen is a member of the Board of Directors of AVI. The transaction was

approved by members of our Board who had no interest in the transaction and evaluated the transaction with input from members of our financial and scientific staffs. Under the terms of the agreement, we acquired one million shares of AVI common stock, which amounted to approximately seven and one half percent (7.5%) of AVI's outstanding common stock, for \$2.5 million cash and 100,000 shares of our common stock at \$28.25 per share. We also acquired exclusive negotiating rights for the United States market for Avicine, AVI's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors. Avicine is a non-toxic immunotherapy that neutralizes the effect of a tumor-associated antigen on cancer cells, while stimulating the body's immune system to react against the foreign tumor.

In July 2000, we finalized an agreement with AVI to obtain the U.S. marketing rights for Avicine. We issued 347,826 shares of our common stock along with \$5 million in cash to AVI as payment for our investment, in exchange for 1,684,211 shares of AVI common stock. As part of this agreement, we obtained the right of first discussion to all of AVI's oncology compounds and an option to acquire an additional 10% of AVI's common stock for \$35.625 per share. This option is exercisable for a three-year period commencing on the earlier of the date the FDA accepts the NDA submitted for Avicine or the date on which the closing price of AVI's common stock exceeds the option exercise price. We have accounted for the investment in AVI under the cost method as our ownership is less than 20% of AVI's outstanding shares. No value has been ascribed to the option as neither of the measurements have been achieved as of December 31, 2001.

Avicine will require significant additional expenditures to complete the clinical development necessary to gain marketing approval from the FDA and equivalent foreign regulatory agencies. As part of this agreement, we are obligated to make additional payments to AVI based on successful achievement of developmental, regulatory approval, and commercialization milestones over the next several years that could total \$80 million. At December 31, 2001, we owed AVI approximately \$1.2 million relating to our share of the development costs for Avicine. This amount is included in Accounts Payable. More detail on the timing of the potential milestone payments to AVI is set forth in our discussion of liquidity and capital resources.

AMUR Pharmaceuticals, Inc.

Two of our former directors were formerly directors of AMUR Pharmaceuticals, Inc., a privately-held company conducting research and development work that we partially funded. The president of Amur performed consulting services for SuperGen and was paid \$180,000 in 2001, \$152,000 in 2000 and \$68,000 in 1999 for these consulting services. In addition, in September 1999 this individual was granted an option to purchase 5,000 shares of SuperGen stock. Using the Black Scholes option valuation model, this option was valued at \$44,000 and amortized to expense over one year. In September 2000, we acquired all of the intellectual property of Amur in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at \$40.00 per share. The transaction was evaluated by our internal scientific staff and the financial arrangements were approved by our entire Board of Directors.

Family Relationships

The Company employs a number of individuals who are immediate family members of Dr. Joseph Rubinfeld, President, Chief Executive Officer, and director of the Company. None of these family members are officers or directors of the Company.

Recently Issued Accounting Standards

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 141, "Business Combinations" ("SFAS 141"), and No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142").

SFAS 141 requires that all business combinations be accounted for by the purchase method of accounting and changes the criteria for recognition of intangible assets acquired in a business combination. The provisions of SFAS 141 apply to all business combinations initiated after June 30, 2001. We do not expect that the adoption of SFAS 141 will have a material effect on our financial position or results of operations. SFAS 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized; however, these assets must be reviewed at least annually for impairment. Intangible assets with finite useful lives will continue to be amortized over their respective useful lives. The standard also establishes specific guidance for testing for impairment of goodwill and intangible assets with indefinite useful lives. We will adopt SFAS 142 effective January 1, 2002, and accordingly, we will cease amortizing goodwill and certain intangibles. At December 31, 2001, we had approximately \$730,000 in goodwill.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"). SFAS 144 amends existing accounting guidance on asset impairment and provides a single accounting model for long-lived assets to be disposed of. Among other provisions, the new rules change the criteria for classifying an asset as held-for-sale. The standard also broadens the scope of businesses to be disposed of that qualify for reporting as discontinued operations, and changes the timing of recognizing losses on such operations. The provisions of SFAS 144 will be effective for our fiscal year 2002. We do not expect that the adoption of SFAS 144 will have a material effect on our financial statements.

Factors Affecting Future Operating Results

You should carefully consider the risks described below before making an investment decision. The risks and uncertainties described below are not the only ones facing our company. Our business operations may be impaired by additional risks and uncertainties that we do not know of or that we currently consider immaterial.

This report also contains and incorporates by reference forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of certain factors, including the risks described below and elsewhere in this report.

If the results of further clinical testing indicate that our proposed products are not safe and effective for human use, our business will suffer.

Most of our products are in the development stage and prior to their sale will require the commitment of substantial resources. All of the potential proprietary products that we are currently developing will require extensive pre-clinical and clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our products, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective in humans. Conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product candidate. Our clinical trials may be suspended at any time if we or the FDA believe the patients participating in our studies are exposed to unacceptable health risks. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Our commencement and rate of completion of clinical trials for all of our drug development programs may be delayed by many factors, including:

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the FDA to approve our clinical trial protocols;

- failure of our contract research organization to devote sufficient time and resources to our studies or to comply with strictly enforced GCP standards or otherwise satisfy their contractual obligations;
- slower than expected rate of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues;
- lack of efficacy during the clinical trials; or
- government or regulatory delays.

The clinical results we have obtained to date do not necessarily predict that the results of further testing, including later-stage controlled human clinical testing, will be successful or result in regulatory approval. If our trials are not successful, or are perceived as not successful by the FDA or physicians, our business, financial condition and results of operations will be harmed.

If we fail to obtain regulatory marketing approvals in a timely manner, our business will suffer.

Even if we believe our trials are successful, the FDA may require substantial additional clinical testing and, therefore, we would have to commit additional unanticipated resources. The FDA has substantial discretion in the drug approval process. We cannot assure you that we will submit for or obtain the necessary regulatory approvals to market our products. The FDA and comparable agencies in foreign countries impose substantial requirements for the introduction of both new pharmaceutical products and generic products through lengthy and detailed clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. We have not yet applied for nor received marketing approval for any of our internally developed proprietary products. Our proprietary drugs and products will require lengthy clinical trials along with FDA and comparable foreign agency review as new drugs. Our generic drugs will also require regulatory review and approval.

We cannot predict with certainty if or when we might submit for regulatory review those products currently under development. Once we submit our potential products for review, we cannot assure you that the FDA or other regulatory agencies will grant approvals for any of our pharmaceutical products on a timely basis or at all. Sales of our products outside the United States will be subject to regulatory requirements governing clinical trials and marketing approval. These requirements vary widely from country to country and could delay the introduction of our products in those countries.

If regulatory approval for Orathecin is not supported by our clinical data or if filing or approval of a New Drug Application with the FDA is delayed our business will be harmed.

We have expended significant resources on developing Orathecin and preparing an infrastructure to support its sales and marketing if approved for sale by regulatory authorities. While we believe we have a portfolio of product candidates with promise, we have focused much of our attention and resources on developing Orathecin. Our ongoing Phase III Orathecin clinical trials are large and complex and are requiring a significant amount of time and statistical analysis. For example, the trial design of these studies allows patients who initially were being treated with Gemzar or other therapies to elect to be treated with Orathecin. At the time the trials were designed, based on results of cancer studies conducted by others, we believed that the percentage of patients that would cross over for treatment with Orathecin would be in the range of 10% to 20% of the enrolled patients. Based on a preliminary review of the clinical trial information, we believe that the number of patients in two of the studies that have actually crossed over to treatment with Orathecin has exceeded the number anticipated. This cross over could affect the statistical analysis of the study. There is no assurance that the data or statistical analysis from these trials will support an NDA or that we will not be required to

perform additional studies. If we are able to file an NDA, the approval process may take a significant amount of time and we may not be approved. If our Orathecin development activities are unsuccessful for these or other reasons our business will be harmed.

The termination of our Orathecin related agreements with Abbott may negatively impact our business.

While we believe that the termination of our agreements with Abbott are advantageous to us in a number of respects, the termination also creates some challenges and uncertainties. By terminating our Orathecin related agreements we have eliminated restraints on our business activities and expanded some of our strategic alternatives which we deem very beneficial. At the same time we have foregone the opportunity to receive future milestone payments and other potential revenue and benefits from a well established and respected pharmaceutical company. In this respect the termination of the Abbott agreements may negatively impact our liquidity as we can not offset our development expenses with milestone payments. In addition, the termination of the agreements may be perceived negatively by other potential partners and may make it difficult for us to pursue opportunities with Orathecin or any other of our proprietary compounds. Because strategic relationships are critical to our business strategy and success, such a perception may negatively impact our business.

Expanding indications for Nipent is important to our future revenues. If we are unable to receive regulatory approval for use of Nipent to treat additional diseases our revenues will not expand as hoped.

Part of our strategy involves expanding the market opportunities for our approved drugs by seeking approval of their use for treatment of additional diseases. Nipent, which has provided over 80% of our revenues in the past three years, is a product that we believe has promise for treatment of a variety of diseases. We are conducting a series of clinical trials with Nipent that are important to the expansion of our business. These trials include Phase IV trials for chronic lymphocytic leukemia, low grade non-Hodgkin's lymphoma, cutaneous and peripheral T-cell lymphomas, and Phase II/III studies for graft-versus-host disease. If these and our other Nipent clinical trials are not successful our business may not develop as planned.

We have a history of operating losses and an accumulated deficit, we may not achieve or maintain profitability in the future, and we may need to obtain additional funding.

We incurred cumulative losses of \$183.7 million for the period from inception through December 31, 2001. Currently we are not profitable and we expect to continue to incur substantial operating losses at least through 2003. Our ability to achieve profitability will depend primarily on our ability to obtain regulatory approval for and successfully commercialize Orathecin. If Orathecin is not approved or not commercially successful we will not become profitable for a much longer period, if at all. Our success will also depend, to a lesser extent, on our ability to develop and obtain regulatory approval of Nipent for indications other than hairy cell leukemia and to bring our proprietary products to market. Our ability to become profitable will also depend upon a variety of other factors, including the following:

- increases in the level of our research and development, including the timing and costs to complete or expand our clinical trials;
- regulatory approvals of competing products, or expanded labeling approvals of existing products;
- increases in sales and marketing expenses related to the commercial launch of Orathecin if approved;
- delays in or inadequate commercial sales of Orathecin, once regulatory approvals have been received; and

- expenditures associated with acquiring products, technologies or companies and further developing these assets.

We cannot predict the outcome of these factors and we cannot assure you that we will ever become profitable.

Even if we do become profitable, we may need substantial additional funding. We expect that our rate of spending will accelerate as a result of increased clinical trial costs and expenses associated with regulatory approval and commercialization of our products now in development. We anticipate that our capital resources will be adequate to fund operations and capital expenditures at least through 2003. However, if we experience unanticipated cash requirements during this period, we could require additional funds much sooner. Our business, results of operations and cash flows will be adversely affected if we fail to obtain adequate funding in a timely manner, or at all. We may receive funds from the sale of equity securities, or the exercise of outstanding warrants and stock options. However, we cannot assure you that any of those fundings will occur, or if they occur, that they will be on terms favorable to us. Also, the dilutive effect of those fundings could adversely affect our results per share.

We depend on third parties for manufacturing and storage of our products and our business may be harmed if the manufacture of our products is interrupted or discontinued.

We have no manufacturing facilities and we currently rely on third parties for manufacturing activities related to all of our products. As we develop new products and increase sales of our existing products, we must establish and maintain relationships with manufacturers to produce and package sufficient supplies of our finished pharmaceutical products, including Nipent and Orathecin.

Our manufacturing strategy presents the following risks:

- delays in scale-up to quantities needed for multiple clinical trials could delay clinical trials, regulatory submissions and commercialization of our products in development;
- our current and future manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies for compliance with strictly enforced GMP regulations and similar foreign standards, and we do not have control over our third-party manufacturers' compliance with these regulations and standards;
- if we need to change to other commercial manufacturing contractors, the FDA and comparable foreign regulators must approve these contractors prior to our use. This would require new testing and compliance inspections. The new manufacturers would have to be educated in, or themselves develop substantially equivalent processes necessary for, the production of our products;
- if market demand for our products increases suddenly, our current manufacturers might not be able to fulfill our commercial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand; and
- we may not have intellectual property rights, or may have to share intellectual rights, to any improvements in the manufacturing processes or new manufacturing processes for our products.

Any of these factors could delay clinical trials or commercialization of our products under development, interfere with current sales, entail higher costs, and result in our being unable to effectively sell our products. In addition, we may be unable to locate replacement supply sources, or the sources that we may locate may not be approved by regulatory authorities or provide us with similar reliability or pricing and our business could suffer. For example, the company that had been purifying our Nipent finished product filed for bankruptcy. We anticipate that our current inventory levels will meet our domestic sales needs through the first quarter of 2002, and we have contracted with a new manufacturer for the purification of Nipent. However, this manufacturer must still be approved

by the FDA. If this approval is not received prior to the depletion of our inventory levels, we may experience an interruption in sales of Nipent. Any such delays may result in cancellation of orders and reduce our revenues and may also be harmful to our reputation as a reliable supplier.

In addition, we store the majority of the unpurified, bulk form of Nipent at a single location. Improper storage, fire, natural disaster, theft or other conditions at this location that may lead to the loss or destruction of the bulk concentrate could adversely affect our business, results of operations and cash flows.

We do not currently intend to manufacture any pharmaceutical products, although we may choose to do so in the future. If we decide to manufacture products, we would be subject to the regulatory risks and requirements described above. We will also be subject to similar risks regarding delays or difficulties encountered in manufacturing these pharmaceutical products and we will require additional facilities and substantial additional capital. In addition, we have only limited experience in manufacturing pharmaceutical products. We cannot assure you that we would be able to manufacture any of these products successfully in accordance with regulatory requirements and in a cost-effective manner.

We have limited sales and marketing capabilities and no distribution capabilities and may not be able to successfully commercialize our products.

We currently have limited sales and marketing resources and no distribution capability. Although we have 27 sales and marketing personnel focusing on the sale of our products to hospitals and hospital buying groups, we anticipate relying on third parties to sell and market some of our primary products. For example, before the termination of our Orathecin agreements with Abbott we anticipated relying on Abbott to assist in the distribution and sale of Orathecin. Our current sales and marketing resources are inadequate to effectively market and sell Orathecin and we may not be able to enter into additional sales and marketing arrangements with others on acceptable terms, if at all. If our arrangements with third parties are not successful, or if we are unable to enter into third-party arrangements, then we may need to substantially expand our sales and marketing force. We may not succeed in enhancing our sales and marketing capabilities or have sufficient resources to do so. If we do develop such capabilities, we will compete with other companies that have experienced and well-funded sales and marketing operations. We currently rely on third parties to distribute our products and expect to continue to do so in the future. If we fail to establish successful sales and marketing capabilities or fail to enter into successful marketing arrangements with third parties, or if our third party distributors fail to perform their obligations, our business, financial condition and results of operations will be materially and adversely affected.

Our strategic relationships with AVI and Peregrine could cause us to expend significant money on development costs with no assurance of financial return.

Under our strategic relationships with AVI and Peregrine, in exchange for marketing and other rights, we have agreed to make equity investments, fund clinical development activities, and pay license fees. The compounds underlying these strategic relationships may prove to be ineffective, may fail to receive regulatory approvals, may be unprotectable by patents or other intellectual property rights, or may otherwise not be commercially viable. If these strategic relationships are not successful our business will be materially and adversely affected.

If we fail to comply with the governmental regulations, our business will suffer.

All new drugs, including our products 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, advertising, promotion, sale and distribution of our products. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. The effect of government regulation may be to delay or to prevent marketing of our potential products for a considerable period of time and to impose costly procedures upon our activities. If regulatory approval of our products is granted, such approval may impose limitations on the indicated uses for which our products may be marketed. Further, even if regulatory approval is obtained for a product, later discovery of previously unknown problems may result in restrictions of the product, including withdrawal of the product from the market.

Among the conditions for FDA approval of all of our products in development is the requirement that the manufacturer's (at either our facilities or those of a third party manufacturer) quality control and manufacturing procedures conform to current Good Manufacturing Practices, which must be followed at all times. The FDA and foreign regulatory authorities strictly enforce GMP requirements through periodic unannounced inspections. We cannot assure you that the FDA will determine that our facilities and manufacturing procedures or any third party manufacturer of our products will conform to GMP requirements. Additionally, we, or our third party manufacturer, must pass a pre-approval inspection before we can obtain marketing approval for any of our products in development. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products including warning letters, product recalls or seizures, injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant pre-market approval or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications, civil fines and criminal prosecutions.

We and our contract research organizations are also required to comply with current GCP regulations and guidelines enforced by the FDA for all of our products in clinical development. FDA enforced GCPs through periodic inspections of study sponsors, principal investigators, and study sites. If we or our contract research organizations fail to comply with applicable GCPs, the clinical data generated in our studies may be deemed unreliable and FDA may require us to perform additional studies before approving our marketing applications. We cannot assure you that FDA will determine that any of our studies for products in clinical development comply with GCPs.

The FDA's policies may change and additional government regulations may be promulgated which could prevent or delay regulatory approval of our products. We cannot predict the likelihood of adverse governmental regulation which may arise from future legislative or administrative action, either in the United States or abroad.

If we fail to compete effectively, particularly against larger, more established pharmaceutical companies with greater resources, our business will suffer.

Factors affecting competition in the pharmaceutical industry vary depending on the extent to which the competitor is able to achieve a competitive advantage based on proprietary technology. These factors include financial resources, research and development capabilities, and manufacturing and marketing experience and resources. If we are able to establish and maintain a significant proprietary position with respect to our proprietary products, competition will likely depend primarily on the effectiveness of our products, their acceptance in the marketplace and their pricing and the number, gravity and severity of their unwanted side effects as compared to alternative products.

Our competitors have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. These competitors and probable competitors include established companies such as Eli Lilly & Co., Ortho Biotech, Berlex, Bristol-Myers Squibb Company, Immunex Corp and others. If these companies

succeed in developing pharmaceutical products that are more effective or less costly than any that we may develop or market, our business will suffer.

The patents on the compounds for which we are developing generic and Extra products are held by third parties. If these patents are expanded in scope or do not expire when anticipated, our business could suffer.

We plan to develop and market several generic and Extra drugs based on existing compounds, some of which are currently protected by one or more patents held by others. If the existing patent protection for these drugs is maintained or expanded, it is unlikely that we will be able to market our own generic and Extra versions of those drugs without obtaining a license from the patent owner, which may not be available on commercially acceptable terms, or at all.

Asserting, defending and maintaining intellectual property rights could be difficult and costly and failure to do so will harm our ability to compete and the results of our operations.

If competitors develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, if our trade secrets are disclosed or if we cannot effectively protect our rights to unpatented trade secrets, our business will be harmed.

The pharmaceutical fields are characterized by a large number of patent filings. A substantial number of patents have already been issued to other pharmaceutical companies, research or academic institutions or others. Competitors may have filed applications for or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others.

We actively seek patent protection for our proprietary products and technologies. We have a number of United States patents and also have licenses to, or assignments of, numerous patents issued both in the United States and elsewhere. We may also license our patents outside the United States. Limitations on patent protection outside the United States, and differences in what constitutes patentable subject matter in countries outside the United States, may limit the protection we have on patents or licenses of patents outside the United States.

Litigation may be necessary to protect our patent position, and we cannot be certain that we will have the required resources to pursue the necessary litigation or otherwise to protect our patent rights. Our efforts to protect our patents may fail. In addition to pursuing patent protection in appropriate cases, we also rely on trade secret protection for unpatented proprietary technology. However, trade secrets are difficult to protect. Our trade secrets or those of our collaborators may become known or may be independently discovered by others.

Our proprietary products are dependent upon compliance with numerous licenses and agreements. These licenses and agreements require us to make royalty and other payments, reasonably exploit the underlying technology of the applicable patents, and comply with regulatory filings. If we fail to comply with these licenses and agreements, we could lose the underlying rights to one or more of these potential products, which would adversely affect our business, results of operations and cash flows.

From time to time we receive correspondence inviting us to license patents from third parties. Although we know of no pending patent infringement suits, discussions regarding possible patent infringements or threats of patent infringement litigation either related to patents held by us or our licensors or our products or proposed products, there has been, and we believe that there will continue to be, significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights. Claims may be brought against us in the future based on patents held by others. These persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing,

manufacturing and marketing of the affected product. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product. We cannot assure you whether we would prevail in any of these actions or that we could obtain any licenses required under any of these patents on acceptable terms, if at all.

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.

Our success is dependent on key personnel, including Dr. Rubinfeld, our President and Chief Executive Officer, and members of our senior management and scientific staff. To successfully expand our operations, we will need to attract and retain additional, highly skilled individuals, particularly in the areas of sales, marketing, clinical administration, manufacturing and finance. We compete with other companies for the services of existing and potential employees. We believe our compensation and benefits packages are competitive for our geographical region and our industry group. However, we may be at a disadvantage to the extent that potential employees may favor larger, more established employers.

The continuing efforts of government and third-party payers to contain or reduce the costs of healthcare may adversely affect our revenues and profitability.

Our revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of health care. We cannot predict the effect that these health care reforms may have on our business, and it is possible that any of these reforms will adversely affect our business. In addition, in both the United States and elsewhere, sales of prescription pharmaceuticals are dependent in part on the availability of reimbursement to the consumer from third-party payers, like government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. If our current and proposed products are not considered cost-effective, reimbursement to the consumer may not be available or be sufficient to allow us to sell products on a competitive basis.

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

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

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

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

Business interruptions could adversely affect our business.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure and other events beyond our control. We do not have a detailed disaster recovery plan. Our facilities in the state of California have been subject to electrical blackouts as a consequence of a shortage of available electrical power. In the event these blackouts resume or increase in severity, they could disrupt the operations of our affected facilities. In addition, we do not carry sufficient business interruption insurance to compensate us for losses that may occur and any losses or damages incurred by us could have a material adverse effect on our business.

Anti-takeover provisions may prevent you from realizing a premium return.

Anti-takeover provisions of our certificate of incorporation and bylaws make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

- authorization of the issuance of up to 2,000,000 shares of our preferred stock;
- elimination of cumulative voting; and
- elimination of stockholder action by written consent.

Our bylaws establish procedures, including notice procedures, with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors or for stockholder proposals to be submitted at stockholder meetings.

We are also subject to Section 203 of the Delaware General Corporation Law, an anti-takeover provision. In general, Section 203 of the Delaware General Corporation Law prevents a stockholder owning 15% or more of a corporation's outstanding voting stock from engaging in business combinations with a Delaware corporation for three years following the date the stockholder acquired 15% or more of a corporation's outstanding voting stock. This restriction is subject to exceptions, including the approval of the board of directors and of the holders of at least two-thirds of the outstanding shares of voting stock not owned by the interested stockholder.

These provisions are expected to discourage different types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with us.

We believe that the benefits of increased protection of our potential ability to negotiate with the proponents of unfriendly or unsolicited proposals to acquire or restructure us outweigh the disadvantages of discouraging those proposals because, among other things, negotiation of those proposals could result in an improvement of their terms.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Due to the short-term nature of our interest bearing assets, which consist primarily of certificates of deposit, U.S. corporate obligations, and U.S. government obligations, we believe that our exposure to interest rate market risk would not significantly affect our operations.

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio. Our marketable securities portfolio is primarily invested in corporate debt securities with an average maturity of under one year and a minimum investment grade rating of A or A-1 or better to minimize credit risk. Although changes in interest rates may affect the fair value of the marketable securities portfolio and cause unrealized gains or losses, such gains or losses would not be realized unless the investments were to be sold prior to maturity.

Our investments in marketable equity securities are subject to fluctuations from market value changes in stock prices. Non-marketable equity securities are carried at cost. We periodically monitor the liquidity progress and financing activities of these entities to determine if impairment write-downs are required.

We do not use or hold derivative financial instruments.

We operate primarily in the United States and all product sales are denominated in U.S. dollars. Accordingly, we do not have any exposure to foreign currency rate fluctuations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

All information required by this item is included on pages F-1 to F-24 in Item 14 of Part IV of this Report and is incorporated into this item by reference.

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

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information regarding our Board of Directors is incorporated by reference to the section entitled "Election of Directors" appearing in our proxy statement for the annual meeting of stockholders to be filed with the Commission by April 30, 2002. Certain information with respect to persons who are or may be deemed to be executive officers of the Registrant is set forth under the caption "Executive Officers of the Registrant" in Part I of this report.

ITEM 11. EXECUTIVE COMPENSATION.

Information regarding executive compensation is incorporated by reference to the information set forth under the caption "Executive Compensation" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2002.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth under the caption "Voting Securities of Principal Stockholders and Management" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2002.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Information regarding certain relationships and related transactions is incorporated by reference to the information set forth under the caption "Certain Transactions" in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2002. Certain of our relationships and related transactions are addressed in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Report.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

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

1. *Financial Statements.* The following financial statements of the Company and the Report of Ernst & Young LLP, Independent Auditors, are included in Part IV of this Report on the pages indicated:

	<u>Page</u>
Report of Ernst & Young LLP, Independent Auditors	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statement of Changes in Stockholders' Equity	F-4
Consolidated Statements of Cash Flows	F-5
Notes to Consolidated Financial Statements	F-6

2. *Financial Statement Schedules.*

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or the notes thereto.

3. *Exhibits:*

<u>Exhibit Number</u>	<u>Description of Document</u>
(f)3.1	Amended and Restated Certificate of Incorporation of the Registrant.
(ff)3.2	Bylaws of the Registrant, as amended and restated through May 30, 2001
(m)4.1	Specimen Common Stock Certificate.
(a)4.2	Form of Representative's Warrant.
(a)4.3	Form of Warrant Agreement dated March 11, 1996 (including form of Common Stock Purchase Warrant).
(l)10.1	Form of Indemnification Agreement between the Registrant and each of its directors and officers.
(cc)(s)10.2	1993 Stock Option Plan (as amended through July 11, 2000).
(i)(s)10.3	Forms of stock option agreements under the 1993 Stock Option Plan.
(n)(s)10.4	1996 Directors' Stock Option Plan, as amended effective February 7, 2001
(c)(s)10.5	Employees and Consultants Stock Option Agreement/Plan.
(n)(s)10.6	1998 Employee Stock Purchase Plan, as amended February 7, 2001
(b)(q)10.7	Patent License and Royalty Agreement dated August 30, 1993 between the Registrant and The Jackson Laboratory.
(b)(q)10.8	Worldwide License Agreement dated March 1, 1994 between the Registrant and Janssen Biotech, N.V.
(b)(q)10.9	Patent License Agreement dated March 1, 1994 between the Registrant and Cyclex Inc.
(b)(q)10.10	Patent License and Royalty Agreement dated November 15, 1993 between the Registrant and The Long Island Jewish Medical Center.
(b)(q)10.11	License Agreement dated February 1, 1995 between the Registrant and Pharmos Corporation.

Exhibit Number	Description of Document
(i)10.12	Common Stock Sale/Repurchase Agreement dated August 6, 1997 between Israel Chemicals, Ltd. ("ICL") and the Registrant.
(m)10.13	First Amendment to Common Stock Sale/Repurchase Agreement between ICL and the Registrant dated November 12, 1997.
(m)(s)10.14	Amended and Restated Employment, Confidential Information and Invention Assignment Agreement dated January 1, 1998 between the Registrant and Joseph Rubinfeld.
(f)10.15	Office Building Lease dated June 23, 2000 between the Registrant and Koll Dublin Corporate Center, L.P
(d)10.16	Purchase and Sale Agreement dated as of September 30, 1996 between the Registrant and Warner-Lambert Company, a Delaware corporation.
(e)(q)10.17	Asset Purchase Agreement dated January 15, 1997 between the Registrant and Immunex Corporation, a Washington corporation.
(e)10.18	Bishop Ranch Business Park Building Lease dated October 14, 1996 between the Registrant and Annabel Investment Company, a California partnership.
(g)(q)10.19	License Agreement between Inflazyme Pharmaceuticals Ltd. and the Registrant dated April 11, 1997.
(g)(q)10.20	Nonexclusive Supply Agreement between the Registrant and Yunnan Hande Technological Development Co. Ltd. dated May 7, 1997.
(g)10.21	Assignment and Assumption Agreement between the Registrant and R&S, LLC dated April 17, 1997.
(h)10.22	Convertible Secured Note, Option and Warrant Purchase Agreement dated June 17, 1997 among the Registrant, Tako Ventures, LLC and, solely as to Sections 5.3 and 5.5 thereof, Lawrence J. Ellison (the "Tako Purchase Agreement").
(r)10.23	Amendment No. 1 to the Tako Purchase Agreement dated March 17, 1999.
(j)10.24	Form of Common Stock Purchase Agreement among the purchasers and the Registrant dated August 29, 1997.
(j)(q)10.25	License Agreement between Stehlin Foundation for Cancer Research and the Registrant dated September 3, 1997.
(j)10.26	Letter Agreement dated August 13, 1997 between the Registrant and South Bay Construction, Inc.
(k)(q)10.27	Supply Agreement dated October 20, 1997 between the Registrant and Warner-Lambert Company.
(l)10.28	Standard Industrial/Commercial Multi-Tenant Lease dated October 13, 1997 between R&S, LLC and Quark Biotech, Inc.
(t)10.29	Registration Rights Agreement dated November 23, 1998.
(o)10.30	Agreement and Plan of Reorganization by and among the Registrant, Royale Acquisition Corp., and Sparta Pharmaceuticals, Inc. dated January 18, 1999.
(r)10.31	Stock Purchase Agreement between the Registrant and Tako dated January 29, 1999.
(r)10.32	Standard Industrial/Commercial Multi-Tenant Lease dated February 12, 1999 between the Registrant and Sea Cliff Properties, a California general partnership (for the premises at 1075 Serpentine Lane, Pleasanton, California, Suite A).

Exhibit Number	Description of Document
(r)10.33	Standard Industrial/Commercial Multi-Tenant Lease dated February 12, 1999 between the Registrant and Sea Cliff Properties, a California general partnership (for the premises at 1075 Serpentine Lane, Pleasanton, California, Suite B).
(r)10.34	Secured Promissory Note Commitment dated March 25, 1999 issued by the Registrant to Tako Ventures LLC.
(r)10.35	Common Stock Purchase Warrant dated March 25, 1999.
(p)(q)10.36	Letter of Intent regarding Nipent Manufacturing.
(t)10.37	Common Stock Purchase Agreement dated November 23, 1998.
(q)(u)10.38	Know-How Transfer and Cooperation Agreement dated September 10, 1999 between the Registrant and Pharmachemie B.V.
(u)10.39	Agreement to Terminate and Release of Collateral dated September 30, 1999 between the Registrant and Tako Ventures, LLC.
(w)10.40	First Amendment to Agreement and Plan of Reorganization by and among the Registrant, Royale Acquisition Corp. and Sparta Pharmaceuticals, Inc. dated May 15, 1999
(x)10.41	Form of Warrant Agreement dated August 12, 1999 between the Registrant and ChaseMellon Shareholder Services (including form of Common Stock Purchase Warrant).
(y)10.42	Amended & Restated Registration Rights Agreement dated September 1, 1999 between the Registrant and SMALLCAP World Fund, Inc.
(y)10.43	Purchase Agreement dated September 15, 1999 between the Registrant and The Tail Wind Fund Ltd., Carriage Partners, LLC, and LBI Group Inc.
(y)10.44	Supplement Agreement dated September 23, 1999 between the Registrant and the Tail Wind Fund, Ltd.
(y)10.45	Registration Rights Agreement dated September 15, 1999 between the Registrant and The Tail Wind Fund Ltd., Carriage Partners, LLC, and LBI Group Inc.
(y)10.46	Form of Warrant Agreement between Registrant and Clipperbay & Co.
(y)10.47	Form of Warrant Agreement between Registrant and The Tail Wind Fund Ltd., Carriage Partners, LLC, and LBI Group Inc.
(z)(q)10.48	Common Stock and Option Purchase Agreement, dated December 21, 1999 between the Registrant and Abbott Laboratories
(z)10.49	Form Registration Rights Agreement
(z)(q)10.50	Worldwide Sales, Distribution, and Development Agreement, dated December 21, 1999 between the Registrant and Abbott Laboratories
(z)(q)10.51	U.S. Distribution Agreement, Dated December 21, 1999 between the Registrant and Abbott Laboratories
(aa)10.52	Registration Rights Agreement dated December 15, 1999 between the Registrant and AVI BioPharma, Inc.
(aa)10.53	Subscription Agreement dated December 1, 1999 between the Registrant and AVI BioPharma, Inc.
(aa)(q)10.54	Research Agreement (Camptothecin) dated November 15, 1999 between the Registrant and Clayton Foundation for Research

Exhibit Number	Description of Document
(aa)(q)10.55	Research Agreement (Paclitaxel) dated November 15, 1999 between the Registrant and Clayton Foundation for Research
(bb)(q)10.56	License Agreement (Camptothecin) dated November 15, 1999 between the Registrant and Research Development Foundation
(bb)(q)10.57	License Agreement (Paclitaxel) dated November 15, 1999 between the Registrant and Research Development Foundation
(ee)(q)10.58	Amendment No. 1 to License Agreement dated November 1, 1999 between the Registrant and the Stehlin Foundation for Cancer Research
(ee) 10.59	United States of America Sales, Distribution, and Development Agreement dated April 4, 2000 between the Registrant and AVI BioPharma, Inc.
(ee) 10.60	Common Stock and Warrant Purchase Agreement dated April 4, 2000 between the Registrant and AVI BioPharma, Inc.
(dd) 10.61	Registration Rights Agreement dated April 4, 2000 between the registrant and AVI BioPharma, Inc.
(ee) 10.62	Asset Purchase Agreement dated February 18, 2000 between the Registrant and AMUR Pharmaceuticals, Inc.
(ee) 10.63	Patent and Intellectual Property Assignment Agreement dated September 27, 2000 between the Registrant and AMUR Pharmaceuticals, Inc.
(dd) 10.64	Registration Rights Agreement dated September 27, 2000 between the registrant and AMUR Pharmaceuticals, Inc.
(dd) 10.65	Warrant Agreement dated December 23, 1998 between the Registrant and Jesup & Lamont Securities Corporation
(dd) 10.66	Warrant Agreement dated October 4, 1999 between the Registrant and Paulson Investment Company, Inc.
(gg)(q) 10.67	Supply and Distribution Agreement dated September 21, 2001 between the Registrant and EuroGen Pharmaceuticals Ltd.
(hh) 10.68	Termination and Release Agreement dated March 4, 2002 between the Registrant and Abbott Laboratories
23.1	Consent of Ernst & Young LLP, Independent Auditors.

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- (a) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (Reg. No. 333-476-LA) filed with the Securities and Exchange Commission January 18, 1996.
 - (b) Incorporated by reference from Amendment No. 1 to the Registrant's Registration Statement on Form SB-2 (Reg. No. 333-476-LA) filed with the Securities and Exchange Commission February 26, 1996.
 - (c) Incorporated by reference from the Registrant's Report on Form S-8 filed with the Securities and Exchange Commission on July 1, 1996.
 - (d) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on October 15, 1996.
 - (e) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 1997.

- (f) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on August 11, 2000.
- (g) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 1997.
- (h) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on July 2, 1997.
- (i) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 1997.
- (j) Incorporated by reference from Amendment No. 2 on Form S-3 to the Registrant's Registration Statement on Form SB-2 (Reg. No. 333-476-LA) filed with the Securities and Exchange Commission on October 6, 1997.
- (k) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 1997.
- (l) Incorporated by reference from Amendment No. 3 on Form S-3 to the Registrant's Registration Statement on Form SB-2 (Reg. No. 333-476-LA) filed with the Securities and Exchange Commission on November 5, 1997.
- (m) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 19, 1998.
- (n) Incorporated by reference from the Registrant's Proxy Statement filed with the Securities and Exchange Commission on April 17, 2001.
- (o) Incorporated by reference from the Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on January 28, 1999.
- (p) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 1998.
- (q) Confidential treatment has been previously granted for certain portions of these exhibits.
- (r) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 1999.
- (s) Indicates a management contract or compensatory plan or arrangement.
- (t) Incorporated by reference from the Registrant's Report on Form 10-K/A filed with the Securities and Exchange Commission on May 14, 1999.
- (u) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on November 15, 1999.
- (v) Incorporated by reference from the Registrant's Registration Statement on Form S-8 (Reg. No. 333-87369) filed with the Securities and Exchange Commission on September 17, 1999.
- (w) Incorporated by reference from the Registrant's Registration Statement on Form S-4 (Reg. No. 333-80517) filed with the Securities and Exchange Commission on June 11, 1999.
- (x) Incorporated by reference from the Registrant's Report on Form 8-A filed with the Securities and Exchange Commission on August 12, 1999.
- (y) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-88051) filed with the Securities and Exchange Commission on September 29, 1999.

- (z) Incorporated by reference from the Registrant's Report on Form 8-K/A dated December 22, 1999 filed with the Securities and Exchange Commission on January 7, 2000.
- (aa) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-95177) filed with the Securities and Exchange Commission on January 21, 2000.
- (bb) Incorporated by reference from Amendment No. 1 to the Registrant's Registration Statement on Form S-3 (Reg. No. 333-95177) filed with the Securities and Exchange Commission on March 16, 2000.
- (cc) Incorporated by reference from the Registrant's Registration Statement on Form S-8 (Reg. No. 333-44736) filed with the Securities and Exchange Commission on August 29, 2000.
- (dd) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-52326) filed with the Securities and Exchange Commission on December 20, 2000.
- (ee) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 23, 2001.
- (ff) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2001.
- (gg) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2001.
- (hh) Incorporated by reference from the Registrant's Report on Form 8-K dated March 4, 2002 filed with the Securities and Exchange Commission on March 8, 2002.
 - (b) *Reports on Form 8-K.*
None
 - (c) *Exhibits.* See Item 14(a) above.
 - (d) *Financial Statement Schedules.* See Item 14(a) above.

REPORT OF INDEPENDENT AUDITORS

Board of Directors and Stockholders
SuperGen, Inc.

We have audited the accompanying consolidated balance sheets of SuperGen, Inc. as of December 31, 2001 and 2000, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of SuperGen, Inc. at December 31, 2001 and 2000 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 19, 2002
except for Note 6, paragraph 2, as to which the date is
March 4, 2002

SUPERGEN, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 17,650	\$ 70,731
Marketable securities	50,178	21,044
Accounts receivable	2,509	2,023
Other receivables	67	1,350
Inventories	1,833	1,648
Prepaid expenses and other current assets	1,398	2,520
Total current assets	73,635	99,316
Marketable securities—non-current	6,164	38,828
Investment in stock of related parties	29,934	13,250
Due from related parties	991	371
Property, plant and equipment, net	6,345	5,438
Developed technology at cost, net	1,090	1,264
Goodwill and other intangibles, net	1,157	1,588
Restricted cash	3,367	3,212
Other assets	34	66
Total assets	\$122,717	\$163,333
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 9,122	\$ 8,024
Payable to AVI BioPharma, Inc	1,170	—
Deferred revenue	1,000	1,000
Accrued employee benefits	1,460	1,197
Total current liabilities	12,752	10,221
Deferred revenue—non-current	2,167	3,167
Total liabilities	14,919	13,388
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value; 2,000,000 shares authorized; none outstanding	—	—
Common stock, \$.001 par value; 150,000,000 shares authorized; 32,821,163 and 33,383,723 shares issued and outstanding at December 31, 2001 and December 31, 2000, respectively	33	33
Additional paid in capital	284,115	287,677
Deferred compensation	(122)	(197)
Accumulated other comprehensive gain (loss)	7,499	(9,407)
Accumulated deficit	(183,727)	(128,161)
Total stockholders' equity	107,798	149,945
Total liabilities and stockholders' equity	\$122,717	\$163,333

See accompanying notes to consolidated financial statements

SUPERGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year ended December 31,		
	2001	2000	1999
Revenues:			
Net sales revenue	\$ 10,451	\$ 6,102	\$ 4,744
Other revenue	1,000	987	—
Total revenue	11,451	7,089	4,744
Operating expenses:			
Cost of sales	2,727	1,641	2,032
Research and development	47,833	31,387	17,346
Selling, general, and administrative	22,079	15,964	10,517
Acquisition of in-process research and development	—	1,585	10,850
Total operating expenses	72,639	50,577	40,745
Loss from operations	(61,188)	(43,488)	(36,001)
Interest income	5,622	8,205	1,016
Amortization of loan commitment fee	—	—	(2,000)
Net loss	<u>\$(55,566)</u>	<u>\$(35,283)</u>	<u>\$(36,985)</u>
Basic and diluted net loss per share	<u>\$ (1.69)</u>	<u>\$ (1.04)</u>	<u>\$ (1.58)</u>
Weighted average shares used in basic and diluted net loss per share calculation	<u>32,925</u>	<u>33,822</u>	<u>23,352</u>

See accompanying notes to consolidated financial statements

SUPERGEN, INC.
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid in Capital	Deferred Compensation	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total
	Shares	Amount					
Balances at January 1, 1999	20,970	\$21	\$ 72,818	—	\$ (128)	\$ (55,893)	\$ 16,818
Comprehensive loss:							
Net loss	—	—	—	—	—	(36,985)	(36,985)
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	123	—	123
Comprehensive loss							(36,862)
Issuance of common stock and warrants in connection with private placements, net of offering costs of \$2,156	2,759	3	36,440	—	—	—	36,443
Issuance of common stock for acquisition of in-process research and development and license agreements	280	—	5,356	—	—	—	5,356
Issuance of common stock to Clayton Foundation in connection with research agreements	36	—	1,191	—	—	—	1,191
Issuance of common stock to AVI BioPharma, Inc	100	—	2,825	—	—	—	2,825
Issuance of common stock and warrants in connection acquisition of Sparta Pharmaceuticals, Inc	429	—	9,370	—	—	—	9,370
Issuance of common stock upon exercise of warrants and stock options	820	1	5,489	—	—	—	5,490
Issuance of common stock in connection with employee stock purchase plan	23	—	227	—	—	—	227
Issuance of common stock to Tako Ventures, LLC	61	—	379	—	—	—	379
Issuance of warrants to Tako Ventures, LLC in connection with promissory note	—	—	2,000	—	—	—	2,000
Compensation expense from stock option grants to consultants and vendors	—	—	1,419	—	—	—	1,419
Deferred compensation	—	—	947	(947)	—	—	—
Amortization of deferred compensation	—	—	—	112	—	—	112
Balances at December 31, 1999	25,478	25	138,461	(835)	(5)	(92,878)	44,768
Comprehensive loss:							
Net loss	—	—	—	—	—	(35,283)	(35,283)
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	(9,402)	—	(9,402)
Comprehensive loss							(44,685)
Issuance of common stock in connection with follow-on public offering, net of offering costs of \$606	1,465	1	61,303	—	—	—	61,304
Issuance of common stock upon exercise of warrants and stock options	5,239	5	48,823	—	—	—	48,828
Issuance of common stock to Abbott Laboratories	933	1	26,499	—	—	—	26,500
Issuance of common stock to AVI BioPharma, Inc., net of offering costs of \$45	348	1	12,128	—	—	—	12,129
Issuance of common stock for acquisition of in-process research and development	38	—	1,460	—	—	—	1,460
Issuance of common stock to Clayton Foundation in connection with research agreements	47	—	740	—	—	—	740
Issuance of common stock in connection with employee stock purchase plan	21	—	410	—	—	—	410
Compensation expense from stock option grants to consultants and vendors	—	—	657	—	—	—	657
Amortization of deferred compensation	—	—	—	230	—	—	230
Reversal of deferred compensation due to employee termination	—	—	(408)	408	—	—	—
Repurchase of common stock	(185)	—	(2,396)	—	—	—	(2,396)
Balances at December 31, 2000	33,384	33	287,677	(197)	(9,407)	(128,161)	149,945
Comprehensive loss:							
Net loss	—	—	—	—	—	(55,566)	(55,566)
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	16,906	—	16,906
Comprehensive loss							(38,660)
Issuance of common stock upon exercise of warrants and stock options	158	—	1,428	—	—	—	1,428
Issuance of common stock to Abbott Laboratories	182	1	2,499	—	—	—	2,500
Issuance of common stock to Clayton Foundation in connection with research agreements	21	—	369	—	—	—	369
Issuance of common stock in connection with employee stock purchase plan	39	—	368	—	—	—	368
Compensation expense from stock option grants to consultants and vendors	—	—	890	—	—	—	890
Amortization of deferred compensation	—	—	—	75	—	—	75
Repurchase of common stock	(963)	(1)	(9,116)	—	—	—	(9,117)
Balances at December 31, 2001	32,821	\$33	\$284,115	\$(122)	\$ 7,499	\$(183,727)	\$107,798

See accompanying notes to consolidated financial statements

SUPERGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,		
	2001	2000	1999
Operating activities:			
Net loss	\$(55,566)	\$(35,283)	\$(36,985)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,138	667	506
Amortization of intangible assets	605	891	404
Amortization of deferred compensation	75	230	112
Amortization of deferred revenue	(1,000)	(894)	—
Loss on sale or disposal of property and equipment	132	13	—
Amortization of loan commitment fee	—	—	2,000
Expense related to stock options and warrants granted to non-employees	890	657	1,419
Non-cash charges related to acquisition of in-process research and development	—	1,585	10,850
Non-cash charges related to acquisition of license agreements	369	—	916
Changes in operating assets and liabilities:			
Accounts receivable	(486)	(269)	(1,005)
Inventories	(185)	(280)	(123)
Prepaid expenses and other assets	1,154	1,090	(2,166)
Due from related parties	(620)	(371)	—
Other receivables	1,283	3,650	—
Restricted cash	(155)	(3,212)	—
Accounts payable and other liabilities	2,531	5,447	467
Net cash used in operating activities	(49,835)	(26,079)	(23,605)
Investing activities:			
Purchases of marketable securities	(48,969)	(62,755)	(5,725)
Sales or maturities of marketable securities	53,124	10,163	2,240
Purchase of equity investments	(403)	(5,000)	(2,500)
Purchase of property and equipment	(2,177)	(2,745)	(457)
Acquisition of Sparta Pharmaceuticals, net of cash acquired	—	—	510
Net cash provided by (used in) investing activities	1,575	(60,337)	(5,932)
Financing activities:			
Issuance of common stock, net of issuance costs	4,296	136,997	43,469
Repurchase of common stock	(9,117)	(2,396)	—
Net cash provided by (used in) financing activities	(4,821)	134,601	43,469
Net increase (decrease) in cash and cash equivalents	(53,081)	48,185	13,932
Cash and cash equivalents at beginning of period	70,731	22,546	8,614
Cash and cash equivalents at end of period	\$ 17,650	\$ 70,731	\$ 22,546
Supplemental Disclosures of Cash Flow Information:			
Non-cash investing and financing activities:			
Issuance of common stock related to acquisition of developed technology	\$ —	\$ —	\$ 1,040
Issuance of common stock related to research agreement	—	740	1,191
Issuance of common stock related to equity investment in related party	—	12,174	2,825

See accompanying notes to consolidated financial statements

SUPERGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Description of Business

SuperGen, Inc. ("SuperGen", "we", "us" or the "Company") was incorporated in California in March 1991. We changed our state of incorporation to Delaware in 1997. We are an emerging pharmaceutical company dedicated to the acquisition, rapid development and commercialization of oncology therapies for solid tumors and hematological malignancies. We operate in one industry segment.

Principles of Consolidation

Our consolidated financial statements include the accounts of Sparta Pharmaceuticals, Inc. ("Sparta") from August 12, 1999, the date of acquisition, and two wholly-owned subsidiaries, which are immaterial.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ from those estimates.

Revenue Recognition

Our net sales relate principally to two pharmaceutical products. We recognize sales revenue upon shipment and related transfer of title to customers, with allowances provided for estimated returns and exchanges. Cash advance payments received in connection with distribution agreements or research grants are deferred and recognized ratably over the period of the respective agreements.

Our principal customers are clinics, hospitals and hospital buying groups in the United States and drug distributors and wholesalers in the United States and Europe. We do not require collateral from our customers.

Advertising Expense

Advertising costs are expensed as incurred. We incurred advertising costs of \$593,000 in 2001, \$806,000 in 2000, and \$731,000 in 1999.

Research and Development

Research and development expenditures, including direct and allocated expenses, are charged to expense as incurred. These expenditures include salaries and employee-related expenses; fees paid to physicians, hospitals, or other research institutions for clinical and pre-clinical studies; fees paid to outside contractors for monitoring of clinical sites or collection and analysis of data; costs associated with the research and manufacture of clinical drug supplies; and payments made under technology license agreements prior to regulatory approval of drug candidates.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents include bank demand deposits, certificates of deposit, marketable securities with maturities of three months or less when purchased and money market funds which invest

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

primarily in U.S. government obligations and commercial paper. These instruments are highly liquid and are subject to insignificant market risk.

Marketable securities consist of corporate or government debt securities and equity securities that have a readily ascertainable market value and are readily marketable. These investments are reported at fair value. All marketable securities are designated as available-for-sale, with unrealized gains and losses included in accumulated other comprehensive gain/loss in equity. A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings, and would result in the establishment of a new cost basis for the security.

Equity Investments

Equity investments in securities without readily determinable fair value are carried at cost. We periodically review those carried at cost and evaluate whether an impairment has occurred. We believe the amounts continue to be realizable.

Inventories

Inventories are stated at the lower of cost (using the first-in, first-out method) or market value. Inventories were as follows at December 31 (in thousands):

	<u>2001</u>	<u>2000</u>
Raw materials	\$ 176	\$ 176
Work in process	960	720
Finished goods	697	752
	<u>\$1,833</u>	<u>\$1,648</u>

Bulk materials for our primary pharmaceutical product must be purified at a United States Food and Drug Administration ("FDA") approved facility that meets stringent Good Manufacturing Practices standards. We currently use a single vendor to perform this manufacturing process using our own equipment located at the vendor's site. The vendor that had been performing the manufacturing of Nipent filed for bankruptcy in mid-2001. We transferred our manufacturing equipment from that vendor's site to another vendor that is now performing the manufacturing. We have contracted with a separate vendor to manufacture the Nipent finished dosage at its approved facility. In addition, we store the majority of our bulk raw materials at a single storage location. Although there are a limited number of vendors who may be qualified to perform these services, we believe that other vendors could be engaged to provide similar services on comparable terms. However, the time required to locate and qualify other vendors or replace lost bulk inventory could cause a delay in manufacturing that might be financially and operationally disruptive.

Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation of building, office and manufacturing equipment and furniture and fixtures is provided on a straight-line basis over the estimated original useful lives of the respective assets, which range from 3 to 31 years. Prior to 2001, manufacturing equipment was amortized to cost of sales on a units-manufactured basis expected to

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

approximate six years. Leasehold improvements are amortized over the shorter of the life of the lease or their estimated useful lives using the straight-line method.

Property, plant and equipment consist of the following at December 31 (in thousands):

	<u>2001</u>	<u>2000</u>
Land and building	\$2,433	\$2,433
Leasehold improvements	2,564	1,566
Equipment	816	741
Furniture and fixtures	3,275	2,605
Total property and equipment	9,088	7,345
Less accumulated depreciation and amortization	(2,743)	(1,907)
Property, plant and equipment, net	\$6,345	\$5,438

Developed Technology

Developed technology related to the acquisition of Nipent is being amortized to cost of sales on a units-manufactured basis over a period expected to approximate six years. Developed technology related to other acquired products is being amortized on a straight-line basis over five years. Accumulated amortization was \$846,000 and \$672,000 at December 31, 2001 and 2000, respectively.

Intangible Assets

Intangible assets, including trademarks, covenants not to compete, acquired workforce and customer lists, are stated at cost and amortized on a straight-line basis over their estimated useful lives of six months to five years. Goodwill, which represents the excess of acquisition cost over the net assets acquired, is being amortized on a straight-line basis over five years. As of December 31, 2001 and 2000, accumulated amortization was \$999,000 and \$630,000, respectively.

Major Customers

Our major customers include a number of buying groups. The percentage of sales of each of these major customers to total net sales for the years ended December 31 were as follows:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Customer A	23%	25%	15%
Customer B	12	6	8
Customer C	11	—	—
Customer D	10	21	8
Pfizer (Warner-Lambert Company)	3	—	27
Customer E	1	12	7
All others	40	36	35
Total	100%	100%	100%

SUPERGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

Net Loss per Common Share

Basic and diluted net loss per common share is computed by dividing net loss by the weighted average number of shares outstanding during the year.

As we have reported operating losses each period since our inception, the effect of assuming the exercise of options and warrants would be anti-dilutive and, therefore, basic and diluted loss per share are the same. The anti-dilutive securities that we have omitted from the calculation of basic net loss per common share are disclosed in Notes 3 and 4.

Stock-Based Compensation

We grant stock options for a fixed number of shares to employees with an exercise price equal to the fair value of the shares at the date of the grant. We account for stock option grants in accordance with APB Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and related Interpretations because the alternative fair value accounting provided under FASB Statement No. 123, *Accounting for Stock-Based Compensation* ("FAS 123") requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of our employee stock options equals the market price of the underlying stock on the date of the grant, no compensation expense is recognized.

For stock-based compensation arrangements to non-employees, we apply the Black-Scholes fair value approach. The equity awards to non-employees are subject to re-measurement over their vesting terms and the resulting value is recognized as expense over the period of services received.

Impairment of Long-lived Assets

In accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" ("FAS 121"), we review long-lived assets, including property and equipment and goodwill, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under FAS 121, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is assessed using discounted cash flows. Through December 31, 2001, there have been no such losses.

Recent Accounting Pronouncements

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 141, "Business Combinations" ("SFAS 141"), and No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"). SFAS 141 requires that all business combinations be accounted for by the purchase method of accounting and changes the criteria for recognition of intangible assets acquired in a business combination. The provisions of SFAS 141 apply to all business combinations initiated after June 30, 2001. We do not expect that the adoption of SFAS 141 will have a material effect on our financial position or results of operations. SFAS 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized; however, these assets must be reviewed at least annually for impairment. Intangible assets with finite useful lives will continue to be amortized over their respective useful lives. The standard also establishes specific guidance for testing for impairment of goodwill and

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

intangible assets with indefinite useful lives. The provisions of SFAS 142 will be effective for our fiscal year 2002. At December 31, 2001, we had approximately \$730,000 in goodwill that will no longer be subject to amortization.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"). SFAS 144 amends existing accounting guidance on asset impairment and provides a single accounting model for long-lived assets to be disposed of. Among other provisions, the new rules change the criteria for classifying an asset as held-for-sale. The standard also broadens the scope of businesses to be disposed of that qualify for reporting as discontinued operations, and changes the timing of recognizing losses on such operations. The provisions of SFAS 144 will be effective for our fiscal year 2002. We do not expect that the adoption of SFAS 144 will have a material effect on our financial statements.

2. Available-for-Sale Securities

The following is a summary of available-for-sale securities (in thousands):

	<u>Amortized Cost</u>	<u>Unrealized Gains (Losses)</u>	<u>Fair Value</u>
At December 31, 2001:			
U.S. corporate debt securities	\$ 68,363	\$ 527	\$ 68,890
Foreign corporate debt securities	1,410	(11)	1,399
U.S. government debt securities	459	3	462
Marketable equity securities	<u>22,919</u>	<u>6,980</u>	<u>29,899</u>
Total	<u>\$ 93,151</u>	<u>\$ 7,499</u>	<u>\$100,650</u>
At December 31, 2000:			
U.S. corporate debt securities	\$124,054	\$ 349	\$124,403
U.S. government debt securities	3,848	7	3,855
Marketable equity securities	<u>22,666</u>	<u>(9,763)</u>	<u>12,903</u>
Total	<u>\$150,568</u>	<u>\$(9,407)</u>	<u>\$141,161</u>

Balance sheet classification:

At December 31, 2001:			
Amounts included in cash and cash equivalents	\$ 15,023	\$ —	\$ 15,023
Marketable securities, current	49,708	470	50,178
Investment in stock of related parties	22,499	6,786	29,285
Marketable securities, non-current	<u>5,921</u>	<u>243</u>	<u>6,164</u>
Total	<u>\$ 93,151</u>	<u>\$ 7,499</u>	<u>\$100,650</u>
At December 31, 2000:			
Amounts included in cash and cash equivalents	\$ 68,553	\$ (14)	\$ 68,539
Marketable securities, current	21,024	20	21,044
Investment in stock of related parties	22,499	(9,749)	12,750
Marketable securities, non-current	<u>38,492</u>	<u>336</u>	<u>38,828</u>
Total	<u>\$150,568</u>	<u>\$(9,407)</u>	<u>\$141,161</u>

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Available-for-Sale-Securities (Continued)

Available-for-sale securities at December 31, by contractual maturity, are shown below (in thousands):

	Fair Value	
	2001	2000
Debt securities		
Due in one year or less	\$ 65,201	\$ 89,583
Due after one year through three years	5,550	38,675
	70,751	128,258
Marketable equity securities	29,899	12,903
Total	\$100,650	\$141,161

Realized gains and losses on the sale of available-for-sale securities for the years ended December 31, 2001, 2000, and 1999 were not material.

3. Stockholders' Equity

Follow-On Offering of Common Stock

In March 2000, we concluded a public follow-on offering of our common stock. We issued 1,465,000 shares of registered stock, resulting in net proceeds to the Company of approximately \$61,300,000.

Private Placements

In September 1999, we issued 561,000 shares of unregistered common stock to an institutional investor. As part of this transaction we also issued to the investor three-year warrants to purchase 336,600 shares of our common stock at a price of \$20.00 per share. As partial compensation to the placement agent, we issued 30,855 five-year warrants to purchase unregistered common stock at \$20.00 per share. After deducting \$500,000 in commissions and fees from the gross proceeds of \$9,099,000, the net proceeds from this transaction totaled \$8,599,000.

In September 1999, we issued 469,819 shares of unregistered common stock to a group of institutional investors. As part of this transaction we also issued to the investors three-year warrants to purchase 140,946 shares of our common stock at a price of \$22.50 per share. Additionally, the investors were issued two-year warrants to purchase an aggregate of 140,946 shares of our common stock, with 46,981, 46,981 and 46,984 warrants having exercise prices of \$30, \$45 and \$60 per share, respectively. As partial compensation to the placement agent, we issued five-year warrants to purchase 26,161 shares of our common stock at \$22.075 per share. After deducting \$495,000 in commissions and fees from the gross proceeds of \$8,250,000, the net proceeds from this transaction totaled \$7,755,000.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Stockholders' Equity (Continued)

In September 1999, we issued 64,243 shares of unregistered common stock to an institutional investor. As part of this transaction we also issued three-year warrants to purchase 19,273 shares of our common stock at a price of \$22.1875 per share. Additionally, the investor was issued two-year warrants to purchase an aggregate of 19,273 shares of our common stock, with 6,244, 6,244 and 6,245 warrants having exercise prices of \$30, \$45 and \$60 per share, respectively. As partial compensation to the placement agent, we issued five-year warrants to purchase 3,975 shares of our common stock at \$22.01 per share. After deducting \$75,000 in commissions and fees from the gross proceeds of \$1,250,000, the net proceeds from this transaction totaled \$1,175,000.

In August 1999, we issued 463,600 shares of registered common stock to an institutional investor. As part of this transaction we also issued to the investor three-year warrants to purchase 231,800 shares of common stock at a price of \$18.00 per share and granted registration rights in connection with these warrants. As partial compensation to the placement agent, we issued 25,498 five-year warrants to purchase unregistered common stock at \$18.00 per share. After deducting \$414,000 in commissions and fees from the gross proceeds of \$7,520,000, the net proceeds from this transaction totaled \$7,106,000.

In May 1999, we issued 1,000,000 shares of registered common stock to an institutional investor, for net proceeds totaling \$9,728,000. In June 1999, we issued 200,000 shares of registered common stock to two institutional investors. The net proceeds from these two institutional investors totaled \$2,080,000.

The stock issuance transactions noted above reflected discounts to the market price of our stock at the transaction dates. These discounts resulted from prior discussions with the investors and the selling prices per share were based on a negotiated average market price. We believe that the selling prices were reasonable in light of the volatility of our stock price, the magnitude of the transactions, and our capital needs.

In June 1997, we entered into an agreement with Tako Ventures, LLC ("Tako"), an investment entity controlled by Lawrence J. Ellison, Founder and Chairman of Oracle Corporation, for a private placement of our common stock and issuance of warrants. This agreement contains provisions regarding sales or issuances of stock below a set minimum price during a specified time period. Sales or issuances of stock below the set minimum price will result in adjustments to the exercise price of the Tako warrants and the issuance of additional shares of common stock, at no cost, to Tako. As the sales price of the shares sold in a December 1998 private placement was below the minimum price, we issued an additional 107,333 shares in 1999 to Tako and reduced the warrant exercise price for 230,000 shares from \$13.50 to \$10.35.

The stock purchase agreement with Tako also gave Tako certain rights to participate in future sales of common stock at comparable terms and conditions. In January 1999, Tako exercised its rights and purchased 61,350 shares of unregistered common stock for a purchase price of \$379,000, net of fees. Tako was granted registration rights in connection with this transaction.

Stock Repurchase Plan

In September 2000, the SuperGen Board of Directors authorized a stock repurchase plan to acquire, in the open market, an aggregate of up to 1,000,000 shares of our common stock, at prices not to exceed \$22.00 per share or \$20,000,000 in total. In March 2001, the Board authorized the repurchase of an additional 1,000,000 shares, but maintained the \$20,000,000 repurchase total. During the year

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Stockholders' Equity (Continued)

ended December 31, 2001, we repurchased 963,000 shares of our common stock at a cost, net of commissions, of \$9,117,000. During the year ended December 31, 2000, we repurchased 184,500 shares of our common stock at a cost, net of commissions, of \$2,396,000. All shares repurchased have been retired.

Warrants

At December 31, 2001, warrants to purchase the following shares of our common stock were outstanding:

Number of Shares	Exercise Price	Issue Date	Expiration Date
1,045,000	\$ 13.50	1997	2007
230,000	10.35	1997	2007
200,000	10.47	2001	2004
500,000	11.00	1998	2004
706,142	18.00 - 22.50	1999	2002 - 2004
200,000	40.00	2000	2002
6,372	55.05 - 57.35	1999	2002
3,816	90.12 - 655.31	1999	2002
<u>2,891,330</u>			

In March 2001, we entered into agreements with a consultant to perform certain financial consulting and public relations services. In connection with these agreements, we issued the consultant a three-year warrant to purchase 200,000 shares of unregistered common stock at an exercise price of \$10.47. We calculated the value of the warrant at \$758,000 using the Black-Scholes valuation model, utilizing an expected volatility of 0.762, risk-free interest rate of 5.88%, and expected life of three years. The value of our stock at the date of grant was \$8.09. The warrants became fully vested in September 2001, and the value of \$758,000 was charged to Selling, general and administrative expense in 2001.

Stock Reserved for Future Issuance

At December 31, 2001 we have reserved shares of common stock for future issuance as follows:

Stock options outstanding	3,705,962
Stock options available for grant	1,278,841
Warrants to purchase common stock	2,891,330
Shares available for Employee Stock Purchase Plan	<u>200,384</u>
	<u>8,076,517</u>

4. Stock Option Plans

We have 6,763,000 shares of common stock authorized for issuance upon the grant of incentive stock options or nonstatutory stock options to employees, directors, and consultants under our stock option plans. The number of shares to be purchased, their price, and the terms of payment are

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Stock Option Plans (Continued)

determined by the Company's Board of Directors, provided that the exercise price for incentive stock options cannot be less than the fair market value on the date of grant. The options granted generally expire ten years after the date of grant and become exercisable at such times and under such conditions as determined by the Board of Directors (generally over a four or five year period).

A summary of the Company's stock option activity and related information follows:

	Options Outstanding			Weighted Average Fair Value At Grant Date
	Number of Shares	Weighted Average Exercise Price	Options Exercisable	
Balance at January 1, 1999	3,232,176	\$ 9.08	1,825,972	
Granted at fair value	657,353	14.77		\$8.95
Granted at less than fair value	124,000	12.56		8.76
Exercised	(557,233)	6.68		
Forfeited	(96,333)	8.41		
Balance at December 31, 1999	3,359,963	10.72	2,113,791	
Granted at fair value	971,320	26.14		18.78
Exercised	(710,742)	10.02		
Forfeited	(330,396)	21.26		
Balance at December 31, 2000	3,290,145	14.36	2,164,066	
Granted at fair value	688,450	9.64		6.32
Granted at greater than fair value	24,000	19.30		5.51
Exercised	(141,533)	9.49		
Forfeited	(155,100)	17.63		
Balance at December 31, 2001	<u>3,705,962</u>	\$13.57	2,679,490	

Information concerning the options outstanding at December 31, 2001 is as follows:

Range	Options outstanding			Options exercisable	
	Number	Weighted average exercise price	Weighted average remaining contractual life	Number exercisable	Weighted average exercise price
\$0.135 to \$5.88	421,521	\$ 4.54	4.49	421,521	\$ 4.54
6.00 to 7.44	763,686	6.36	5.70	654,935	6.24
7.50 to 11.75	758,772	10.13	8.30	409,008	10.50
11.81 to 14.94	618,539	13.33	7.48	373,795	13.69
15.00 to 22.63	620,913	16.75	6.42	558,071	16.32
23.63 to 68.00	522,531	32.86	8.30	262,160	32.65
\$0.135 to \$68.00	<u>3,705,962</u>	\$13.57	6.88	<u>2,679,490</u>	\$12.34

Pro forma information regarding net loss and net loss per share is required by FAS 123. We calculated this pro-forma information using the fair value method of accounting for employee stock

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Stock Option Plans (Continued)

options under that Statement. We estimated the fair value for these options at the date of grant using the Black-Scholes option valuation model with the following assumptions:

	Years ended December 31,		
	2001	2000	1999
Risk-free interest rate	5.48%	5.90%	5.34%
Dividend yield	—	—	—
Expected volatility	0.8	0.8	0.7
Expected life (in years)	5.0	5.0	4.9

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting requirements and are fully transferable. Employee stock options have characteristics significantly different than those of traded options. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility and changes in the subjective input assumptions can materially affect the estimate of fair value of an employee stock option. Therefore, in our opinion, existing option valuation models do not necessarily provide a reliable single measure of the fair value of our employee stock options.

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

	Years ended December 31,		
	2001	2000	1999
Pro forma net loss (in thousands)	\$(60,424)	\$(39,922)	\$(40,148)
Pro forma basic and diluted net loss per share	(1.84)	(1.18)	(1.72)

During the year ended December 31, 1999, in connection with the grant of certain stock options to employees and officers, we recorded deferred stock compensation for financial statement reporting purposes of \$947,000, representing the difference between the exercise price and the deemed fair value of our common stock for financial reporting purposes on the date the stock options were granted. Deferred compensation is included as a component of stockholders' equity and is being amortized to expense on a straight line basis over four years, the vesting period of the options. During the years ended December 31, 2001, 2000 and 1999, we recorded amortization of deferred stock compensation expense of \$75,000, \$230,000 and \$112,000, respectively. During the year ended December 31, 2000, we reversed \$408,000 of deferred compensation, representing the value of unvested stock options forfeited upon the departure of an officer of the Company.

5. Acquisition Activity

Peregrine Pharmaceuticals—VEGF License

In February 2001, we completed a transaction to license a platform drug-targeting technology known as Vascular Targeting Agent ("VTA") from Peregrine Pharmaceuticals, formerly known as Techniclone Corp. The licensed technology is specifically related to Vascular Endothelial Growth Factor ("VEGF"). The agreement required an up-front payment of \$600,000, which included the acquisition of 150,000 shares of Peregrine common stock valued at \$253,000. These shares are carried as part of

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Acquisition Activity (Continued)

Marketable Securities—non-current. The remaining \$347,000 of the payment was recorded to research and development expense.

The terms of the agreement require that we pay milestone payments and royalties to Peregrine based on the net revenues of any drugs commercialized using the VEGF technology. These payments could ultimately total \$8 million. No amounts have been paid under the agreement to date. In addition, we are required to pay Peregrine an annual license fee of \$200,000 per year until the first filing of an IND utilizing the licensed patents.

AMUR Pharmaceuticals, Inc. Intellectual Property

In September 2000, we acquired all of the intellectual property of AMUR Pharmaceuticals, Inc. (“Amur”) in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at \$40.00 per share. Amur’s proprietary technology is based on a new water-soluble class of hormones. Investigation of these hormones determined that a specific portion, phosphocholine, confers water solubility to the hormones. Amur’s previously conducted research and development has shown that phosphocholine may be attached to other compatible molecules representing a novel patented drug delivery technology.

Research using this technology had commenced but required extensive pre-clinical development and had not fully demonstrated its technological feasibility. Accordingly, we recorded a charge of \$1,585,000 to acquired in process research and development (“IPR&D”) in September 2000.

Clayton Foundation for Research—Inhaled Drugs

In December 1999, we entered into a licensing and research agreement with the Clayton Foundation for Research and its technology transfer organization, Research Development Foundation. Under the terms of the licensing agreement, we acquired worldwide rights to inhaled versions of formulations of camptothecins, including Orathecin™, and taxanes, including paclitaxel (Taxol®). The license rights were acquired for 28,799 shares of common stock with an aggregate value of \$916,000, which we charged to research and development in 1999. The license agreement contained certain guarantees related to the price of our stock issued in the acquisition. In January 2001, since the value of our stock had declined, we issued the Research Development Foundation an additional 21,210 shares of our stock. These shares were valued at \$369,000, which we charged to research and development expense in 2001.

The Clayton Foundation agreed to perform the research in exchange for 36,130 shares of common stock, which we valued at \$1,191,000. As the research had not started at December 31, 1999, the total was included in prepaid expenses and other assets at that date. The amount was charged to research and development expense in 2000. In December 2000, we issued an additional 46,613 shares of common stock to the Clayton Foundation in connection with the second year of research. These shares were valued at \$740,000 and the total was included in prepaid expenses at December 31, 2000, and charged to research and development in 2001.

Decitabine

In September 1999, we acquired the worldwide rights to decitabine, a chemotherapeutic agent owned by Pharmachemie B.V., a subsidiary of Teva Pharmaceuticals. Decitabine, which has received

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Acquisition Activity (Continued)

orphan drug status from the FDA, is currently in clinical testing for acute leukemias and other hematological malignancies. Each year, over 50,000 new cases of acute leukemias and hematological malignancies are reported in the United States. The FDA has not granted marketing approval to use decitabine for the treatment of any disease.

The acquisition involved an exchange of 171,123 shares of unregistered SuperGen common stock valued at \$3,400,000, which we charged to IPR&D. In assigning the purchase price to IPR&D, we considered, among other factors, our intentions for the future use of the acquired project, its stage of completion, the lack of alternative future uses of the technology, and that no other tangible or intangible assets were acquired.

Sparta Pharmaceuticals, Inc.

In August 1999, we completed our acquisition of Sparta Pharmaceuticals, Inc., a biopharmaceutical company engaged in developing technologies and drugs for the treatment of a number of life-threatening diseases, including cancer, cardiovascular disorders, chronic metabolic diseases, and inflammation.

On the effective date of the merger Sparta became a wholly-owned subsidiary of SuperGen. We issued 429,082 shares of our common stock, with a fair value of \$7,800,000, and 220,945 common stock warrants, with a fair value of \$1,558,000, to former Sparta stockholders. We assumed approximately 2.9 million options and warrants to purchase Sparta common stock and converted such options to SuperGen options and warrants to acquire approximately 110,600 shares of SuperGen common stock. The \$12,000 value of the options assumed was included in the purchase price and as a component of stockholders' equity in the consolidated financial statements. Additionally, we recorded transaction related costs of approximately \$262,000, which when aggregated with the above consideration brought the total cost of the acquisition to \$9,632,000.

The acquisition was accounted for by the purchase method of accounting and, accordingly, the results of operations of Sparta for the period from August 1999 are included in the accompanying consolidated financial statements. Assets acquired and liabilities assumed were recorded at their estimated fair values. Approximately \$7,450,000 of the purchase price was allocated to acquired IPR&D. The Sparta research and development programs currently in process were valued as follows:

5-FP	\$3,430,000
PZG	1,380,000
Partaject™ drug delivery method	2,640,000
	<u>\$7,450,000</u>

We recorded this acquired IPR&D to expense at the date of acquisition.

The allocation of the purchase price for Sparta resulted in goodwill of approximately \$1.4 million and intangibles and work force value of \$500,000. Goodwill and intangibles are being amortized over five years. The work force value was amortized over six months.

The following unaudited pro forma financial summary is presented as if the operations of the Company and Sparta were combined as of January 1, 1999. The unaudited pro forma combined results are not necessarily indicative of the actual results that would have occurred had the acquisition been

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Acquisition Activity (Continued)

consummated at that date, or of the future operations of the combined entities. Nonrecurring charges, such as the acquired in-process research and development charge of \$7,450,000 are not reflected in the following pro forma financial summary:

Pro forma financial summary

	Year ended December 31, 1999
	(unaudited) (in thousands, except per share amounts)
Net sales	\$ 5,032
Net loss	(31,514)
Basic and diluted net loss per share	\$ (1.35)

Surface Safe™ Product Line Acquisition

In July 1999, we acquired the Surface Safe product line from Aldorr, Inc., a medical technology development company. Surface Safe is a two-step towelette disposable cleaning system used to decontaminate work surfaces where chemotherapeutic preparation is conducted. Aldorr assigned us patents and trademarks related to the Surface Safe product line and granted us an irrevocable, exclusive, worldwide, perpetual and royalty-free license to use the licensed know-how and any other intellectual property owned or licensed by Aldorr related to the Surface Safe product line. Aldorr has agreed not to compete with us in this marketplace for a period of five years. We also obtained a customer list from Aldorr, Inc. The aggregate value of the 79,546 shares of our unregistered common stock paid to Aldorr, Inc. was estimated to be \$1,040,000, and was allocated to the covenant not to compete, the customer list, trademark, and the developed technology based on estimated fair values on the acquisition date. The recorded assets are being amortized over five years.

Orathecin (rubitecan)

In September 1997, we acquired exclusive worldwide rights to a patented anticancer compound, Orathecin, (generic name rubitecan, also formerly known as RFS2000 or 9-NC), from the Stehlin Foundation for Cancer Research ("Stehlin"). We also agreed to make monthly cash payments to Stehlin of \$100,000 until the earlier of the date of FDA marketing approval of Orathecin or four years. Our agreement with Stehlin also calls for additional payments in SuperGen common stock upon the achievement of specified milestones and royalties on any product sales.

In November 1999, we amended our agreement with Stehlin to broaden the definition of licensed compounds to include certain analogues of Orathecin. Under this amendment, we increased our monthly cash payments to \$200,000 for 2000 and 2001 and are required to seek commercial applications for Orathecin. We are required to pay the Stehlin Foundation approximately \$10 million for research and must make cash royalty payments and cash or stock milestone payments to the Stehlin Foundation as we develop and commercialize Orathecin. In accordance with these agreements, we paid Stehlin \$2,400,000 in 2001, \$2,400,000 in 2000, and \$1,200,000 in 1999.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Agreements with Abbott Laboratories

In December 1999, we entered into two agreements with Abbott Laboratories ("Abbott"), a Common Stock and Option Purchase Agreement and a Worldwide Sales, Distribution and Development Agreement relating to Orathecin. Under these agreements, Abbott was to invest in shares of our common stock and would participate with us in the marketing and distribution of Orathecin. We would have co-promoted Orathecin with Abbott in the United States and Abbott had exclusive rights to market Orathecin outside of the United States. In the United States market, we would have shared profits from product sales equally with Abbott, while outside of the United States market, Abbott would have paid us royalties and transfers fees based on product sales. Abbott was obligated to purchase up to \$81.5 million in shares of our common stock over a period of time. In addition, Abbott had an option to purchase up to 49% of the shares of our common stock outstanding at the time of the exercise at \$85 per share. Abbott also had a right of first discussion with respect to our product portfolio and a right of first refusal to acquire us. In connection with these agreements, Abbott made a \$26.5 million equity investment in January 2000 and a \$2.5 million equity milestone payment in July 2001.

On March 4, 2002, SuperGen and Abbott mutually terminated the Common Stock and Option Purchase Agreement and the Worldwide Sales, Distribution and Development Agreement. We regained all marketing rights to Orathecin worldwide and are no longer obligated to share profits from product sales of Orathecin. Abbott no longer has the right or obligation to purchase the remaining aggregate amount of \$52.5 million of shares of our common stock, no longer has the option to purchase up to 49% of our outstanding shares, no longer has the right of first discussion with respect to our product portfolio, and no longer has a right of first refusal to acquire us. In connection with this termination agreement, we agreed to reimburse Abbott for development work they completed on our behalf totaling \$1.6 million. This amount was included in Accounts payable and accrued liabilities at December 31, 2001.

In December 1999, we also entered into a Nipent distribution agreement with Abbott, which is still in effect. Beginning March 1, 2000, Abbott became the exclusive U.S. distributor of Nipent for a period of five years. We retain U.S. marketing rights for Nipent. Under this agreement, Abbott made a \$5 million cash payment to the Company. This amount was included in deferred revenue and is being recognized as other revenue ratably over the term of the agreement. The unamortized balances of \$3,167,000 and \$4,167,000 are included in current and non-current deferred revenue at December 31, 2001 and 2000, respectively.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Related Party Transactions

EuroGen Pharmaceuticals Ltd.

In September 2001, we entered into a Supply and Distribution Agreement with EuroGen Pharmaceuticals Ltd. ("EuroGen"), a company incorporated and registered in England and Wales. Under the agreement, we granted EuroGen the exclusive European and South African rights to promote and sell certain of our existing generic and other products or compounds. The agreement also establishes a process for granting EuroGen rights to sell additional products in Europe and South Africa, subject to our compliance with our other existing licensing and distribution arrangements. After complying with these existing obligations, we will be required to offer EuroGen the option to obtain European and South African rights to our future products. EuroGen will seek and pay for all necessary regulatory approvals and authorizations necessary for the commercial sale of the products in the territories where they market and sell the products.

At December 31, 2001 we had loaned EuroGen \$260,000 under a line of credit arrangement designed to cover start-up expenses. This amount is included in Due from related parties on the balance sheet. If EuroGen is unable to adequately fund its operations, we may not recover amounts owed to us or realize any income or benefit from the relationship.

KineMed, Inc.

In November 2001, we made an equity investment of \$150,000 to acquire 100,000 shares of Series A Convertible Preferred stock of KineMed, Inc., a start-up biotech company. The president and chief executive officer of KineMed is a former director of SuperGen. The president and chief executive officer of SuperGen is a member of the Board of Directors of Kinemed. We have accounted for this investment under the cost method as our ownership is less than 20% of KineMed's outstanding shares. This investment is included on the balance sheet in Investment in stock of related parties.

AVI BioPharma, Inc.

In December 1999, we entered into an agreement with AVI BioPharma, Inc. ("AVI"). The chief executive officer of AVI is a member of our Board of Directors. The president and chief executive officer of SuperGen is a member of the Board of Directors of AVI. Under the terms of the agreement, we acquired one million shares of AVI common stock, which amounted to approximately seven and one half percent (7.5%) of AVI's outstanding common stock, for \$2.5 million cash and 100,000 shares of our common stock at \$28.25 per share. We also acquired exclusive negotiating rights for the United States market for Avicine, AVI's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors. Avicine is a non-toxic immunotherapy that neutralizes the effect of a tumor-associated antigen on cancer cells, while stimulating the body's immune system to react against the foreign tumor.

In July 2000, we finalized an agreement with AVI to obtain the U.S. marketing rights for Avicine. We issued 347,826 shares of our common stock along with \$5 million in cash to AVI as payment for our investment, in exchange for 1,684,211 shares of AVI common stock. As part of this agreement, we obtained the right of first discussion to all of AVI's oncology compounds and an option to acquire an additional 10% of AVI's common stock for \$35.625 per share. This option is exercisable for a three-year period commencing on the earlier of the date the FDA accepts the NDA submitted for Avicine or the date on which the closing price of AVI's common stock exceeds the option exercise price. We have accounted for the investment in AVI under the cost method as our ownership is less

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Related Party Transactions (Continued)

than 20% of AVI's outstanding shares and is classified as available-for-sale. No value has been ascribed to the option as neither of the measurements have been achieved as of December 31, 2001.

Avicine will require significant additional expenditures to complete the clinical development necessary to gain marketing approval from the FDA and equivalent foreign regulatory agencies. As part of this agreement, we are obligated to make additional payments to AVI based on successful achievement of developmental, regulatory approval, and commercialization milestones over the next several years that could total \$80 million. In 2001, we recorded \$1.2 million in research and development expenses relating to our share of the development costs for Avicine. At December 31, 2001, this amount had not been paid to AVI and is presented on the balance sheet as Payable to AVI BioPharma, Inc.

AMUR Pharmaceuticals, Inc.

Two SuperGen directors were formerly directors of AMUR Pharmaceuticals, Inc., a privately-held company conducting research and development work partially funded by SuperGen. The president of Amur performed consulting services for SuperGen and was paid \$180,000 in 2001, \$152,000 in 2000 and \$68,000 in 1999 for these consulting services. In addition, in September 1999 this individual was granted an option to purchase 5,000 shares of SuperGen stock. Using the Black-Scholes option valuation model, this option was valued at \$44,000 and amortized to expense over one year.

In September 2000, we acquired all of the intellectual property of Amur in exchange for 37,795 shares of our common stock and two-year warrants to purchase 200,000 shares of our common stock at \$40.00 per share (see Note 5).

Quark Biotech, Inc.

Two SuperGen director/stockholders are directors and stockholders of Quark Biotech, Inc. ("QBI"), a privately-held development stage biotechnology company headquartered in Israel. In June 1997, we made an equity investment of \$500,000 in QBI's preferred stock, which represents less than 1% of the company's outstanding shares as of December 31, 2001. Our investment in QBI is carried at cost and is included in "Investment in stock of related parties." In November 1997, we leased approximately one-third of the laboratory square footage at the SuperGen Pharmaceutical Research Institute ("SPRI") to QBI for \$3,000 per month for three years, plus its pro-rata share of specified common expenses. We also completed certain building and laboratory improvements and purchased furniture on behalf of QBI for a total of approximately \$750,000, of which \$300,000 was reimbursed by QBI in 1997. In the first quarter of 2000, we terminated the lease with QBI and we took possession of the entire laboratory space and related property, plant, and equipment at SPRI.

Other

In March 1999, we entered into a promissory note with Tako, whereby Tako agreed to advance us up to \$5,000,000 through December 31, 1999. Advances under this agreement would be secured by substantially all our assets. In connection with this transaction, we issued Tako a five-year warrant to acquire 500,000 shares of unregistered common stock at an exercise price of \$11.00 per share. We calculated the value of the warrant at \$2,000,000 using the Black-Scholes valuation model. In September 1999, we terminated this promissory note thereby releasing any security interest that Tako had in our assets. The value of the warrant was charged to expense in 1999.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Related Party Transactions (Continued)

At December 31, 2001, we owned 10% of a privately-held company performing research and development work almost exclusively for SuperGen as well as selling SuperGen certain research supplies. We paid this company \$360,000 in 2001, \$360,000 in 2000, and \$448,000 in 1999 for services and supplies. We carry our investment in this company at no value.

8. Commitments and Contingencies

We lease our primary administrative facility under a 10 year non-cancellable operating lease, which may be renewed for an additional five-year period. The terms of the lease require us to establish and maintain two irrevocable and unconditional letters of credit to secure our obligations under the lease. The financial institution issuing the letters of credit requires us to collateralize our potential obligations under the lease by assigning to the institution approximately \$3.2 million in certificates of deposit. The certificates of deposit are included in the balance sheet under "Restricted cash." Upon achievement of certain milestones and the passage of time, the amounts of the letters of credit are subject to reduction or elimination.

We are also leasing additional office space in a building adjacent to our laboratory facility under two leases which both terminate in 2006. Half of the space has been subleased under a non-cancellable lease terminating at the same time as our master lease. The other half of the space has been subleased through June 2002.

Future minimum rentals and sublease income under all operating leases with terms greater than one year are as follows (in thousands):

<u>Year ending December 31,</u>	<u>Minimum rental obligations</u>	<u>Sublease income</u>
2002	\$ 2,129	\$231
2003	2,204	164
2004	2,266	171
2005	2,326	177
2006 and thereafter	10,920	91
	<u>\$19,845</u>	<u>\$834</u>

Rent expense, was \$2,090,000 in 2001, \$481,000 in 2000, and \$283,000 in 1999. These amounts were net of sublease income of \$237,000 in 2001 and \$110,000 in 2000. We received no sublease income in 1999.

We have entered into technology license agreements allowing us access to certain technologies. These agreements generally require royalty payments based upon the sale of approved products incorporating the technology under license. No sales of such products have occurred as of December 31, 2001.

We have also entered into manufacturing and service agreements for certain manufacturing services, the supply of research materials and the performance of specified research studies. These agreements require payments based upon the performance of the manufacturing entity, delivery of the research materials or the completion of the studies. No such payments were required as of December 31, 2001.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows (in thousands):

	December 31,	
	2001	2000
Net operating loss carryforwards	\$ 65,751	\$ 47,445
Purchased in-process technology	2,219	2,222
Research and development credit carryforwards	5,168	2,892
Capitalized research and development	8,281	6,689
Other	1,740	1,992
Total deferred tax assets	83,159	61,240
Valuation allowance	(83,159)	(61,240)
Net deferred tax assets	\$ —	\$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$21,919,000 during 2001 and \$18,860,000 during 2000.

As of December 31, 2001 we have net operating loss carryforwards for federal income tax purposes of approximately \$188,000,000 which expire in the years 2005 through 2021. At December 31, 2001, we had federal research and development credit carryforwards of approximately \$3,400,000, which expire in the years 2007 through 2021.

Utilization of our net operating loss carryforwards may be subject to substantial annual limitations due to ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating losses before utilization.

10. Employee Benefit Plans

We have adopted a 401(k) Profit Sharing Plan (the "401(k) Plan") for all eligible employees with over six months of service. We may be obligated to make contributions to the plan to comply with statutory requirements. Voluntary employee contributions to the 401(k) Plan may be matched 50% by the Company, up to 3% of each participant's annual compensation. Our expense relating to contributions made to employee accounts under the 401(k) Plan was approximately \$294,000 in 2001, \$144,000 in 2000, and \$120,000 in 1999.

In 1998 we established the 1998 Employee Stock Purchase Plan ("ESPP") and reserved 100,000 shares of Common Stock for issuance thereunder. The number of shares reserved under the plan was increased by 200,000 in 2001. Employees participating in the ESPP are granted the right to purchase shares of common stock at a price per share that is the lower of 85% of the fair market value of a share of Common Stock on the first day of an offering period, or 85% of the fair market value of a share of Common Stock on the last day of that offering period.

In 2001, we issued 16,936 and 22,650 shares through the ESPP at \$10.07 and \$8.71, respectively. In 2000, we issued 8,554 and 12,150 shares through the ESPP at \$24.17 and \$16.74, respectively. In 1999,

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Employee Benefit Plans (Continued)

we issued 9,022 and 14,173 shares through the ESPP at \$15.19 and \$6.38, respectively. As of December 31, 2001, 200,384 shares are reserved for future issuance under the ESPP.

11. Quarterly Financial Data (Unaudited)

Following is a summary of the quarterly results of operations for the years ended December 31, 2001 and 2000:

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(Amounts in thousands, except per share data)			
2001				
Net sales	\$ 1,557	\$ 3,294	\$ 2,593	\$ 3,007
Cost of sales	362	914	623	829
Net loss	(12,968)	(13,740)	(13,447)	(15,412)
Basic and diluted net loss per share.	(0.39)	(0.42)	(0.41)	(0.47)
2000				
Net sales	\$ 695	\$ 2,861	\$ 450	\$ 2,096
Cost of sales	124	650	163	703
Net loss	(7,539)	(7,908)	(9,893)	(9,943)
Basic and diluted net loss per share.	(0.27)	(0.24)	(0.30)	(0.30)

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Consent of Ernst & Young LLP, Independent Auditors

We consent to the incorporation by reference in Form S-8 and the Post-Effective Amendment No. 1 to the Form S-8 (Registration No. 333-07295) pertaining to the 1993 Stock Option Plan, 1996 Director's Stock Option Plan and Employees and Consultants Stock Option Agreement/Plan, the Form S-8 (Registration No. 333-58303) pertaining to the 1993 Stock Option Plan, and 1998 Employee Stock Purchase Plan, the Form S-8 (Registration No. 333-87369) pertaining to the 1993 Stock Option Plan, the Form S-8 (Registration No. 333-44736) pertaining to the 1993 Stock Option Plan, the Post-Effective Amendment No. 6 on Form S-3 to Form SB-2 (Form SB-2 No. 333-476-LA) for the registration of 4,477,402 shares of common stock and 328,500 warrants to purchase common stock, the Form S-3 (Registration No. 333-88051) for the registration of 2,014,036 shares of common stock, the Form S-3 (Registration No. 333-52326) for the registration of 697,533 shares of common stock, and the Form S-3 (Registration No. 333-95177) for the registration of 136,130 shares of common stock and related prospectuses, of our report dated February 19, 2002, except for Note 6, paragraph 2, as to which the date is March 4, 2002, with respect to the consolidated financial statements of SuperGen, Inc. included in the Annual Report on Form 10-K for the year ended December 31, 2001.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 28, 2002

SENIOR MANAGEMENT TEAM

Joseph Rubinfeld, Ph.D.

Chairman and Chief Executive Officer
Amgen, Bristol-Myers Squibb, Cetus, Schering-Plough

In addition to cofounding Amgen, Dr. Rubinfeld invented the Polaroid ten-second instant film developing system in 1961 and biodegradable detergent in 1963, for which he was awarded the prestigious Common Wealth Award in 1984.

Edward Jacobs

Chief Business Officer and Chief Financial Officer
Etex, Sequus Pharmaceuticals, Trilex Pharmaceuticals, Adria Laboratories, Johnson & Johnson

Karl Mettinger, M.D., Ph.D.

Senior Vice President, Chief Medical Officer
Ivax, KABI, Karolinska Institute

Frank Brenner

Vice President, National Accounts
Adria Laboratories, Lederle International, Cetus Corporation

L. Robert Cohen

Vice President, Investor Relations & Finance
Pfizer, Johnson & Johnson, Prudential Securities

Timothy Enns

Vice President, Marketing
Upjohn, Adria Laboratories, Sequus

Frederick Grab, Ph.D.

Vice President, Compliance & Regulatory
Bristol-Myers Squibb, Adria Laboratories, Wyeth Laboratories

Audrey Jakubowski, Ph.D.

Vice President, Regulatory Affairs
Bristol-Myers Squibb, DuPont

R. David Lauper, Pharm. D., FAPhA.

Vice President, Professional Services
Bristol-Myers Squibb, Cetus-Chiron

Robert Marshall

Vice President, Sales
OTN, IVEDCO, Syncor, Adria Laboratories, Neorex

Lawrence Romel

Vice President, Clinical Operations
ONYX, Sequus, Neurex, Kendall

Howard Sands, Ph.D.

Vice President, Pre-Clinical Research
Sparta Pharmaceuticals, DuPont

Simeon Wrenn, Ph.D.

Vice President, Biotechnology
American Home Products, American Cyanamid, Purdue Frederick, Centocor

BOARD OF DIRECTORS

Joseph Rubinfeld, Ph.D.

Founder, Chairman, and Chief Executive Officer
SuperGen, Inc.

Denis Burger, Ph.D.

Chief Executive Officer
AVI BioPharma, Inc.

Thomas V. Girardi

Senior Partner
Girardi & Keese

Walter J. Lack

Managing Partner
Engstrom, Lipscomb & Lack

James S. J. Manuso, Ph.D.

General Partner, PrimeTech Partners
Chairman, Advanced Genetic Systems
Vice Chairman, Symbionics

Daniel Zurr, Ph.D.

Chief Executive Officer
Quark Biotechnology Inc.

CORPORATE HEADQUARTERS

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Tel: 800.353.1075 Fax: 925.560.0101

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TRANSFER AGENT

Mellon Investor Services, LLC
Overpeck Center
85 Challenger Rd.
Ridgefield Park, NJ 07660
Tel: 800.522.6645
www.melloninvestor.com

ANNUAL MEETING

The annual meeting of stockholders will be held from 2:00 to 5:00 PM on May 29, 2002, at SuperGen's corporate headquarters, 4140 Dublin Blvd., Dublin, CA 94568.

NASDAQ: SUPG

For information about the company, stockholders and other interested parties may contact the Investor Relations Department at company headquarters, or visit the company web site at: www.supergen.com.

Inquiries regarding stock certificates, transfer requirements, address changes and related matters should be directed to the Transfer Agent at the address given above.

