

228

patients began
Nipent clinical
trials in 2002

The American Cancer
Society estimates
the number of patients
with advanced-stage
breast cancer

30,700

Advanced-stage breast
cancer cases
supported in 2002

27

24
breast support
clinical studies

12

Nipent was first
approved in
April 2002

Advanced-stage breast
cancer cases
supported in 2002

7

Completed clinical
studies in 2002

4

Completed clinical
studies in 2002

4

Estimated new cases and
deaths for ovarian cancer
in the U.S. in 2003

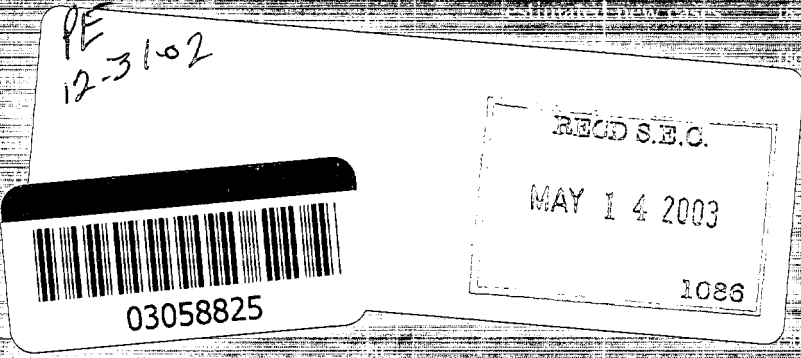
23,300

30,800

Estimated new cases

3,000

patients in the
entire Orathec
clinical program



03058825

4,700

91,800

105,500

SuperGen

Making Life Better

1,500

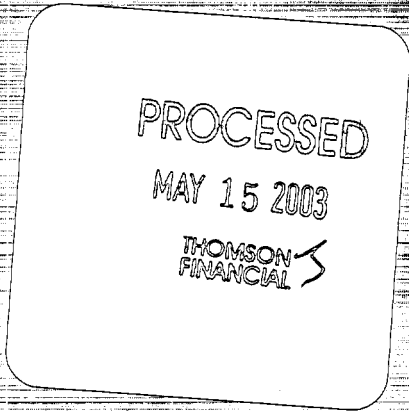
2002 Annual Report

1,850

patients in the Orathec
Phase II studies

patients diagnosed
each year in
the U.S. with AMI

10,000



75,000

new breast cancer
diagnoses worldwide
in 2002

994

14,000

patients diagnosed
each year with AMI

Chemotherapy-related
adverse events in
Orathec clinical studies

300

Estimated new cases

212,600

11
new cancer drugs
approved by FDA in
2002

9
new drugs
approved for
Orathec

9
new drugs
approved for
Orathec

448

409

Chemotherapy-related
adverse events in
Orathec clinical studies

100
patients who
were hospitalized
due to adverse events
in Orathec clinical
studies

100
patients who
were hospitalized
due to adverse events
in Orathec clinical
studies

100
patients who
were hospitalized
due to adverse events
in Orathec clinical
studies

As you move forward through these pages you will see the name Dacogen™.
This is the branded name for decitabine and will be used from this point on.

SuperGen is a pharmaceutical company whose mission is to prolong, improve the quality of, and ultimately save the lives of people with life-threatening diseases, especially cancer.



Joseph
Rubinfeld, Ph.D.

Chairman and Chief Executive Officer

Dear Shareholder:

I find it very difficult to describe the level of pride and accomplishment that I feel as the chief executive officer of SuperGen. In 2002, our 107-person company, assisted by outside vendors, specialists and consultants, enjoyed its strongest and most productive year yet.

For example, we completed the largest randomized clinical program ever conducted in pancreatic cancer with Orathecin™. We also completed patient enrollment in a Phase III clinical study of Dacogen™ as a treatment of myelodysplastic syndrome (MDS). In addition, we received approval from the FDA to market Mitozytrex™, which represented the company's first New Drug Application (NDA). Perhaps the biggest challenge of all, though, was that we began the process of compiling and submitting an NDA for Orathecin.

While all of these accomplishments were ongoing, we engaged in an aggressive effort to improve the bottom line, which resulted in significantly reduced operating expenses and significantly increased product revenues in 2002.

Certainly the industry backdrop for these events was not one of support or encouragement. The national and global economy has been, and remains in, a state of malaise, and the biotech, pharmaceutical and healthcare sectors have been among the hardest hit. Investor confidence continues to be low, but expectations remain high, perhaps too high. The resulting disappointment has been expressed in the stock price of almost every company in these sectors.

However, we have refused to let outside opinions deter us in our mission to establish SuperGen as a preeminent oncology-focused company. In fact, our first-rate clinical, regulatory and commercial teams are operating at the "top of their game."

From a clinical perspective, Orathecin and Dacogen, our lead investigational compounds, and Nipent®, FDA approved to treat hairy cell leukemia, all moved a sizeable step forward in 2002 – that is, each one has accrued to or completed major studies.

SuperGen has never been more ready to establish its position as a preeminent oncology-focused company.

As I previously mentioned, our Phase III clinical randomized program of Orathecin was the largest ever undertaken in pancreatic cancer. The program was comprised of three separate trials and enrolled approximately 1,850 people at over 200 clinical sites around the world. Over the entire Orathecin clinical program, more than 2,700 patients in 43 separate clinical trials participated in our protocols. This included pancreatic cancer patients, as well as patients with a number of other solid tumors and hematologic malignancies.

With much of the external focus on Orathecin, it is easy to overlook the impact that Nipent has had on the success of SuperGen. Indeed, it is not the first time this compound has been ignored.

When Nipent was acquired in 1996, it was approved for the treatment of hairy cell leukemia, a rare disease affecting roughly 500 people each year, and was not thought by many outside our company to have much usefulness beyond this initial orphan indication. However, our expert oncology team long suspected that the compound had great potential. In fact, since its acquisition, we have studied Nipent in more than 10 different indications through 40 clinical trials. Today, we are more convinced than ever before that the drug is benefiting a number of patients with a broad variety of blood cancers. In addition, promising new data has suggested that Nipent may reduce the biggest complication associated with allogeneic blood and bone marrow transplants.

The clinical development of Dacogen has been nothing short of remarkable. In just under two years, our clinical staff developed the protocol for the Phase III MDS study, trained and managed 24 clinical sites nationwide and, working with the investigators, completed patient enrollment.

Beyond MDS, published clinical studies have strongly suggested that Dacogen may become a valuable weapon against sickle cell anemia. The drug has also shown signs of activity in patients with stage IV non-small cell lung cancer and chronic myelogenous leukemia.

On the regulatory front, our expert team enjoyed a most impressive year. The FDA approval of Mitozytrex (mitomycin for injection) represented the first compound that our company has taken from formulation through to FDA approval.

While awaiting word from the FDA on Mitozytrex, work on the Orathecin NDA was in full swing. Tens of thousands of pages were studied, analyzed and formatted in thorough, readable reports that make up the New Drug Application. That work continued into the new year, as the submission of the NDA began on a "rolling" basis.

Commercially, 2002 was the best year in the history of SuperGen. Record revenues, driven by increasingly strong demand for Nipent, surpassed \$15 million. With the massive Orathecin clinical program completed and the budgetary belt tightened, operating expenses fell drastically, translating into considerable bottom line improvement. We expect this improvement to continue into 2003 and beyond, as the Dacogen MDS study concludes and interest in Nipent continues to climb.

Fundamentally, our company is in a strong position. Two financial transactions at the end of 2002 and the beginning of this year brought in more than \$25 million in capital, which not only fortified our balance sheet, but also considerably strengthens our position in negotiations regarding corporate alliances.

SuperGen is establishing its position as a preeminent oncology-focused company. We now have five marketable products (Nipent, Mitozytrex, mitomycin, daunorubicin and the Surface Safe® disposable cleaning system), one lead investigational compound for which we are completing the submission of an NDA (Orathecin), another that is in the latter stages of Phase III testing (Dacogen) and a third, Nipent, that in addition to demonstrating strong sales growth, is being studied for additional uses beyond its original indication.

During my more than forty years in the pharmaceutical industry, I have personally experienced both the highs and lows of bringing a drug to market. For those involved in such a tremendous undertaking – company employees, clinicians, patients and their families, just to name a few – the inevitable delays, the surprising successes and unexpected setbacks can trigger a roller coaster of emotions that can vary wildly from day to day.

However, at the end of this journey, when the compound is on the market and is touching the lives of both patients and their families, there is a remarkable sense of accomplishment, relief and amazement. I have experienced this profound joy on several occasions in my professional career, and as we seek to bring new hope to tens of thousands of cancer patients around the world, recapturing that feeling is what motivates me each and every day.

Sincerely,



Dr. Joseph Rubinfeld,
Chairman and Chief Executive Officer

Estimated new cases and deaths for ovarian cancer in the U.S. in 2003:

23,300

30,800

estimated new cases and deaths for leukemia in the U.S. in 2003

Estimated new cases and deaths for lung cancer in the U.S. in 2003:

91,800

105,500

estimated new cases and deaths for colorectal cancer in the U.S. in 2003

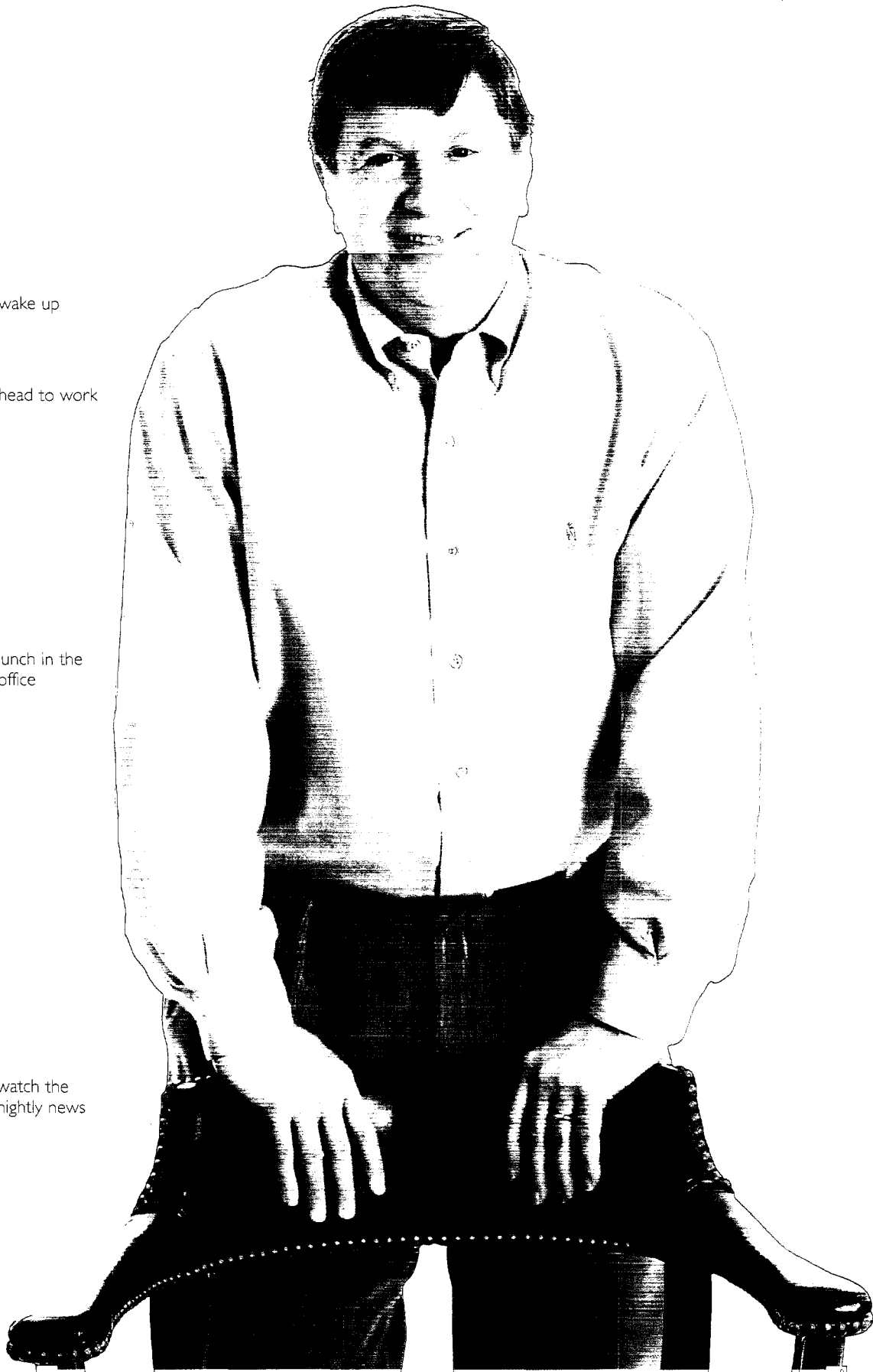
Estimated new cases and deaths for breast cancer in the U.S. in 2003:

212,600

midnight
1:00
2:00
3:00
4:00
5:00
6:00
7:00
8:00
9:00
10:00
11:00
noon
1:00
2:00
3:00
4:00
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8:00
9:00
10:00
11:00
midnight

Bill Sarosky, 53 years old, is the controller and treasurer of the town of Southbury, Connecticut. He has been married to wife Debbie for 19 years.

Bill is an Orathecin patient.



wake up



head to work



lunch in the office



watch the nightly news

Disclaimer: Bill Sarosky is only one of several thousand patients that have received Orathecin in a clinical trial, and he is not representative of the majority of patients in these trials. These patients are very sick and most only live a few months. Orathecin is an investigational drug and is not approved for any commercial use.

Orathecin

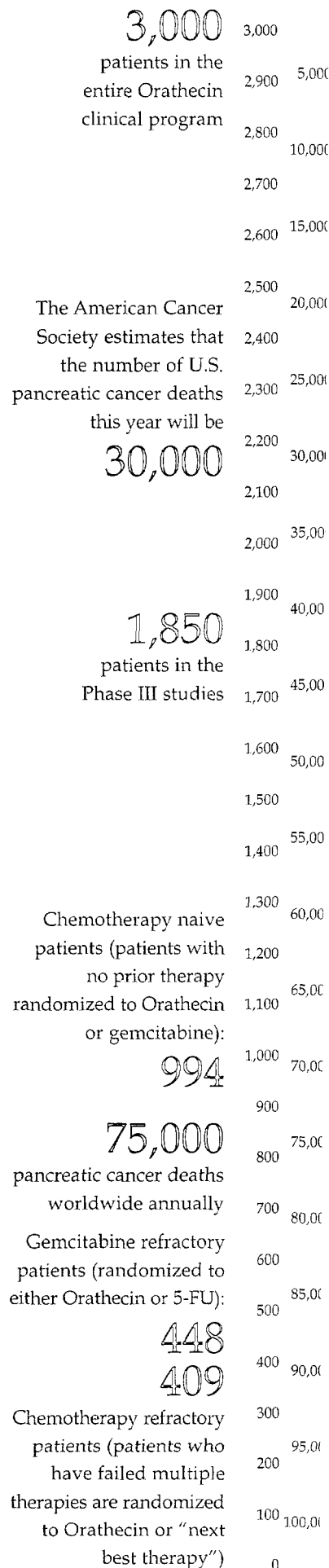
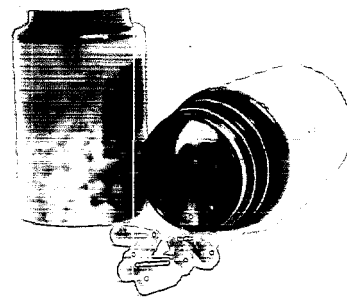
Pancreatic cancer is the fourth-leading cause of cancer deaths in the United States. The average life expectancy after diagnosis is three and a half months for untreated patients. Because the pancreas is located deep in the abdomen, once the cancer is detected, it is usually too late for surgery. The five-year survival rate is less than 5 percent.

In patients with advanced pancreatic cancer, doctors measure the effectiveness of a drug in days and weeks, not months or years. Orathecin is not expected to be a cure, but if approved by the FDA, it may offer patients new hope. Early Orathecin studies suggest that the drug may help some patients live longer after they have failed other therapies.

In April 2002, an independent third-party expert radiology review panel confirmed the results from a previous Phase II clinical study of Orathecin in patients with refractory pancreatic cancer who had failed prior treatments. The U.S. study was conducted at 19 clinical centers and enrolled 58 patients who had failed prior chemotherapy. More than 90 percent of the patients had failed treatment with gemcitabine, and more than 70 percent had failed two or more chemotherapy agent regimens.

Among the 45 patients with measurable disease, 10 patients (22 percent) had independently verified favorable tumor responses; three patients with a greater than 50 percent reduction in tumor size per World Health Organization (W.H.O.) criteria; and seven patients with stabilized disease, having less than 50 percent tumor reduction and no evidence of tumor growth. Median survival time for the 10 patients who responded was more than 10 months. Four of the 10 patients lived for more than a year; two for more than two years, and one for more than three years and is still alive today.

Barring any unforeseen delays, it is anticipated that the "rolling" submission of the Orathecin New Drug Application will be completed by the first half of 2003.



midnight

Vicki Andress, a 56-year old resident of Mondovi, Wisconsin, is a customer service professional. She has 3 children and 8 grandchildren.

Vicki is a Nipent patient.

1:00

2:00

3:00

4:00

5:00

6:00



let dog out

7:00

8:00

9:00

10:00

11:00



walk a mile on a treadmill

noon

1:00

2:00

3:00

4:00

5:00



prepare dinner

6:00

7:00



paint

8:00

9:00

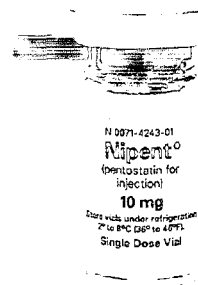
10:00

11:00

midnight

Disclaimer: Nipent is approved by the FDA only for the treatment of hairy cell leukemia in patients with active disease. Clinical trials are ongoing in hairy cell leukemia and a number of other life-threatening conditions.

Nipent (pentostatin for injection), approved for use as a treatment for hairy cell leukemia



Nipent's viability as a key compound was enhanced in late 2002 at the 44th Annual Meeting of the American Society of Hematology (ASH). At the meeting, 12 abstracts were posted and presentations made describing the potential of the drug in a variety of hematologic malignancies.

Nipent is showing signs of activity in clinical trial patients with chronic lymphocytic leukemia (CLL). Data from two clinical studies involving CLL patients, who received Nipent in combination with other therapies, were presented at the ASH annual meeting. In one study, 10 of 11 patients experienced a tumor response. In the second study, one-third of the patients achieved an objective response and 54 percent experienced stable disease. Serious adverse events were limited to myelosuppression, nausea, vomiting and infection.

Perhaps the most encouraging news, however, is for patients requiring blood or bone marrow transplants. Allogeneic blood or bone marrow transplants (where cells are received from a donor, rather than from oneself) have saved or prolonged the lives of thousands of leukemia patients, but many of these patients fall victim to graft-versus-host disease (GVHD), an often-fatal complication wherein immune cells from the transplant donor reject the recipient's normal tissue following the transplant. Nearly half of all allogeneic transplant patients develop GVHD, and of those, approximately one-third will die from the disease. If the threat of GVHD could be eliminated or substantially reduced, then the benefit to transplant patients each year would be important.

At the 2002 ASH meeting, results from a clinical study suggesting the effectiveness of a combination preparative regimen, including Nipent, in allogeneic bone marrow transplant patients with a variety of leukemias and lymphomas, were presented by Dr. Francine Foss of the New England Medical Center in Boston. The study enrolled 90 patients who underwent a regimen of photopheresis, radiation and Nipent two days prior to the allogeneic transplant. The results clearly speak for themselves – 90 percent of patients experienced full bone marrow engraftment, 77 percent achieved remission and acute GVHD was observed in only 10 percent of treated patients.

	228	40+	10,00
patients began Nipent clinical trials in 2002	39	9,75	
	38	9,50	
	37	9,25	
	36	9,00	
People diagnosed each year in the U.S. with CLL:	35	8,75	
	34	8,50	
	33	8,25	
	32	8,00	
	31	7,75	
	30	7,50	
Nipent trials that SuperGen has supported since 1998:	29	7,25	
	28	7,00	
	27	6,75	
	26	6,50	
	25	6,25	
	24	6,00	
24 active Nipent clinical studies	23	5,75	
	22	5,50	
	21	5,25	
	20	5,00	
5,000 people are diagnosed each year in the U.S. with GVHD	19	4,75	
	18	4,50	
	17	4,25	
4,500 people die each year from CLL	16	4,00	
	15	3,75	
	14	3,50	
	13	3,25	
	12	3,00	
12 Nipent abstracts presented at ASH 2002	11	2,75	
	10	2,50	
	9	2,25	
Indications being researched for Nipent:	8	2,00	
	7	1,75	
	6	1,50	
Completed CLL clinical studies in 2002:	5	1,25	
	4	1,00	
	4	75	
	3	50	
500 people are diagnosed each year with hairy cell leukemia	2	25	
	1		

midnight

Dr. Peter Diemer, a 68-year old resident of St. Louis, is a semiretired interventional radiologist who works part time at his son's practice.

Dr. Diemer is a Dacogen patient.

1:00

2:00

3:00

4:00

5:00

6:00

7:00



breakfast

8:00



golf

10:00

11:00

noon

1:00

2:00

3:00

4:00

5:00

6:00



dinner

7:00

8:00



watch TV or
a movie

9:00

10:00

11:00

midnight



Disclaimer: Peter Diemer is only one of several hundred patients that have received Dacogen in a clinical trial, and he is not representative of the majority of patients in these trials. These patients are very sick and often only live a few months. Dacogen is an investigational drug and is not approved for any commercial use.

Dacogen

DNA hypermethylation, which may turn off genes designed to suppress cancer cells, is being recognized by the scientific community as a major factor in the formation of some cancers.

Dacogen can reverse hypermethylation and restore the function of tumor suppressor genes. The drug has been clinically tested in more than 1,000 patients and is currently nearing the end of Phase III testing as a treatment for myelodysplastic syndrome (MDS).

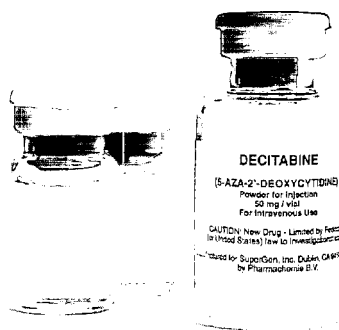
Dacogen's activity in patients with MDS has been seen in several early studies. At the 2002 ASH annual meeting, data from 169 patients involved in a series of Phase II clinical trials were presented. The investigator reported a response rate of 49 percent and a significant increase in platelets in 42 percent of the patients after one cycle of therapy, and in 63 percent of those receiving two cycles. The median survival was 15 months and the two-year survival rate was 34 percent.

Data published in the October 2002 issue of the journal *Blood* (100 (8): 2957-2964) further supports Dacogen's mechanism of action. Nine MDS patients with hypermethylated p15 genes responded to Dacogen.

Over the past several years, a series of encouraging developments have indicated that Dacogen may become a useful treatment for the more than 70,000 patients who suffer from sickle cell anemia, a painful disease that often reduces the life expectancy of its victims by 30 years. Data from a small study were published in the June 2002 issue of *Blood* (99 (11): 3905-3908), noting that Dacogen elevated fetal hemoglobin levels in 100 percent of sickle cell anemia patients. These results complement a previous clinical trial of short-term treatment, published in the October 2000 issue of *Blood* (96 (7): 2379-2384), which also demonstrated up to a fourfold increase in fetal hemoglobin levels in eight sickle cell patients.

Clinical studies to date have shown Dacogen is also active in other hematologic malignancies, such as AML and chronic myelogenous leukemia (CML), and in solid tumors such as lung cancer. These potential indications are being researched through additional ongoing clinical studies.

The Phase III study of Dacogen in the treatment of MDS has completed enrollment and an NDA filing is anticipated in early 2004.



Patients in Phase II study presented at the 2002 ASH Meeting:

169

4,700 people are diagnosed each year in the U.S. with CML

People diagnosed each year in the U.S. with AML:

10,000

14,000 people are diagnosed each year with MDS

11 indications being researched for Dacogen

200 1.0
195
190 2.0
185
180 3.0
175
170 4.0
165
160 5.0
155
150 6.0
145
140 7.0
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85 12.0
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75 13.0
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50 16.0
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40 17.0
35
30 18.0
25
20 19.0
15
10 20.0
5
0

Product and Pipeline Portfolio

Approved Products

Nipent® (pentostatin for injection)
 Mitozytrex™ (mitomycin for injection)
 Mitomycin for injection, USP
 Daunorubicin HCl injection
 Surface Safe®

Product Pipeline

Clinical Testing	PHASE I	PHASE II	PHASE III	APPROVAL PENDING
Paclitaxel (ANDA)	[Progress bar spanning PHASE I, PHASE II, and PHASE III]			[Progress bar ending in PHASE III]
Orathecin	[Progress bar spanning PHASE I and PHASE II]			[Progress bar ending in PHASE II]
Dacogen	[Progress bar spanning PHASE I and PHASE II]			[Progress bar ending in PHASE II]
Nipent (GVHD)	[Progress bar spanning PHASE I and PHASE II]			[Progress bar ending in PHASE II]
Avicine	[Progress bar spanning PHASE I and PHASE II]			[Progress bar ending in PHASE II]
Partaject Busulfan	[Progress bar spanning PHASE I]			[Progress bar ending in PHASE I]
Inhaled Orathecin	[Progress bar spanning PHASE I]			[Progress bar ending in PHASE I]

Formulation and Preclinical Development

VEGF
 Inhaled Paclitaxel
 Cremophor-free Paclitaxel
 Partaject Orathecin
 Extra™ Formulations

In 1991, SuperGen was born with a lofty goal - to become a preeminent oncology-focused company. As the calendar turns on a new year, we are poised to assume that responsibility.

Twelve years ago, there was an idea. Today, there are five marketable products, one drug under review by the FDA, another nearing the end of clinical development and a burgeoning pipeline of additional compounds.

Most important are the successes. Over the past several years, our products and clinical programs have given real hope to scores of people, most especially patients and their families. They personify our mission - to improve the lives of cancer patients.

The goal of becoming a preeminent oncology-focused company is no longer in the distant future. Rather, it is something we foresee in our grasp every single day.

Financials

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, 2002

OR

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

For the transition period from _____ to _____

Commission file number 0-27628

SUPERGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

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

91-1841574
(IRS Employer
Identification Number)

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 whether Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). 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 June 30, 2002, the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$218,673,407. 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 18, 2003 was 32,919,674.

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 22, 2003.

SUPERGEN, INC.

2002 ANNUAL REPORT ON FORM 10-K

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Special Note Regarding Forward-Looking Statements

Our disclosure and analysis in this report contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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, but are not limited to, statements relating to future product developments and launches, including our clinical trials for Orathecin, Nipent, decitabine and our other product candidates, the timing of filing of a new drug application for Orathecin; sales growth; operating performance; our estimated capital needs, and potential market sizes. Our actual results could differ materially from those predicted in the forward-looking statements as a result of risks and uncertainties including, but not limited to, delays and risks associated with conducting clinical trials, product development and obtaining regulatory approval; ability to establish and maintain collaboration relationships; competition; ability to raise funding; continued adverse changes in general economic conditions in the United States and internationally; adverse changes in the specific markets for our products, ability to manage our clinical trials; and ability to launch and commercialize our products. Certain unknown or immaterial risks and uncertainties can also affect our forward-looking statements. Consequently, no forward-looking statement can be guaranteed and you should not rely on these forward-looking statements.

The forward-looking statements reflect our position as of the date of this report, and 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, or other filings. Also note that we provide a cautionary discussion of risks and uncertainties relevant to our business under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”)—Factors Affecting Future Operating Results” in this report. These are currently known and material risks that we think could cause our actual results to differ materially from expected and historical results. Other unknown and immaterial risks besides those listed in this report could also adversely affect us.

PART I

ITEM 1. BUSINESS.

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. We maintain a website on the internet at www.supergen.com.

Overview

We are an emerging pharmaceutical company dedicated to the acquisition, rapid development and commercialization of oncology therapies for solid tumors, hematological malignancies and blood disorders. Our strategy is 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. Instead of engaging in pure discovery research to obtain lead compounds, we license or acquire rights to compounds typically at the pre-clinical or early clinical stage of development that have shown efficacy in humans or in a model relevant to a particular clinical disease. We intend to retain significant participation in the clinical development of our proprietary products by funding and conducting human clinical trials and obtaining regulatory approval ourselves. We believe this will allow us to maximize the commercial value of our products by either directly marketing our products or licensing them on more favorable terms than would be available if licensed earlier in the development cycle.

Currently we have three key compounds, Nipent®, Orathecin™ (also known as rubitecan) and decitabine, which are the focus of our efforts. Nipent is approved by the United States Food and Drug Administration (“FDA”) and marketed by us for the treatment of hairy cell leukemia. Nipent has also shown promise in other diseases and we are conducting a series of clinical trials, including post-marketing 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. We are close to completing three randomized Phase III studies for Orathecin, our lead drug candidate, and submitted the first two (out of three total) sections of a “rolling” New Drug Application (“NDA”) with the FDA. We expect to complete our NDA submission during the second quarter of 2003. In addition, we have been granted “fast track” designation for Orathecin for the treatment of patients with pancreatic cancer who have failed or are resistant to two or more chemotherapy agents, which means that the FDA will facilitate and expedite the development and review of the application. We are also conducting Phase III clinical studies of decitabine in myelodysplastic syndrome, and in March 2003 completed enrollment of patients in this trial. Moreover, we have procured the U.S. sales and marketing rights to the cancer vaccine Avicine™. In addition, our portfolio of products includes Partaject™ delivered busulfan, and inhaled versions of Orathecin and paclitaxel. We received regulatory approval to market our generic daunorubicin for a variety of acute leukemias in November 2001, and in November 2002 received regulatory approval to market Mitozytrex™ (mitomycin for injection), for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed.

Our success will depend upon our competitive strengths and strategies. However, we are a development state company, and as such, our business operation is subject to uncertainties and complexities present in any emerging pharmaceutical company. We have incurred cumulative losses of \$233.2 million as of December 31, 2002, and have never generated enough funds through our operations to support our business. Most of our products are still in development stage, and we will require substantial additional investment in research and development, clinical trials, and in regulatory and sales and marketing activities to commercialize current and future product candidates. Conducting clinical trials is a lengthy, time-consuming and expensive process involving inherent uncertainties and risks, and our studies may be insufficient to demonstrate safety and efficacy to support FDA approval of any of our product candidates in development. If our clinical trials, especially the trials for Orathecin, are not successful, we may not be able to get sufficient funding to continue our trials or conduct new trials, and we would be forced to scale down or cease our business operations. We rely on third party collaborators for research, development, manufacturing, storage and distribution activities, and the failure to maintain or develop such relationships may impair our product development and business operations. In addition, the trading prices for our common stock are highly volatile and will continue to fluctuate in the future because of various factors, some of which are beyond our control. If the trading price of our common stock continues to significantly decline, we may not be able to obtain additional capital that we will need through public or private financing activities.

The above risks and additional risks we face in our business are described in more detail in 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, i.e., products that are advancing through our internal clinical development infrastructure, 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 may result in products with improved delivery and/or administration. The development of these products is subject to the NDA approval process.
- *Expanding our sales and marketing expertise from hematology to the treatment of solid tumors.* We strive to establish 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

Our cancer products currently approved for sale include the following:

<u>Product Category</u>	<u>Product Name</u>	<u>Approved Indication</u>
Cytotoxic Agent	Nipent (Pentostatin for injection)	Hairy Cell Leukemia
Generic Anticancer Agents	Mitomycin	Disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed
	Daunorubicin	Acute lymphocytic leukemia and acute non-lymphocytic leukemia in combination with other approved anticancer drugs
Formulation Technology	Mitozytrex	Disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed

The following table outlines our cancer products in development, their indication or intended use, their therapeutic category, and their regulatory status (our non-oncological products are summarized separately in text under the heading "Non-Oncology Proprietary Products"):

<u>Product Category</u>	<u>Compound</u>	<u>Indication or Intended Use</u>	<u>Therapeutic Category</u>	<u>Regulatory Status</u>
Cytotoxic Agent/ Immunosuppressant	Nipent	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 Autoimmune Disorders	Immunological Immunological	Phase I/II Phase I
Cytotoxic Agent (Oral)	Orathecin	Pancreatic cancer	Cancer	Phase III
		Various other solid tumors	Cancer	Phase I/II
Hypomethylating Cytostatic Agent	Decitabine	Myelodysplastic syndromes	Cancer	Phase III
		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
Vaccine	Avicine	Colorectal cancer	Cancer	Phase II/III
		Pancreatic cancer	Cancer	Phase II/III
Generic Anticancer Agent	Paclitaxel	Solid tumors	Cancer	ANDA filed
Formulation Technologies	Partaject busulfan	Neoplastic meningitis/ Bone marrow transplant	Cancer	Phase I/II
	Partaject Orathecin	Solid tumors	Cancer	Pre-clinical
	Cremophor-free paclitaxel	Solid tumors	Cancer	Pre-clinical
	Inhaled Orathecin	Solid tumors	Cancer	Phase II
	Inhaled paclitaxel	Solid tumors	Cancer	Pre-clinical
Prodrugs	CZ 112	Solid tumors	Cancer	Phase I
Anti-angiogenesis	VEGF	Solid tumors	Cancer	Pre-clinical

* Studies conducted to explore new indications.

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 of action differs from other chemotherapy agents. We believe that Nipent's most unique feature is its selectivity for lymphocytes, which has created 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 2002, 2001, 2000, representing 91%, 96%, and 95% of net sales 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 conducting Phase IV studies in 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 discussing the safety and 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 believe that 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 rheumatoid arthritis and Phase II/III trials in graft-versus-host disease. We are also developing an oral formulation of Nipent, suitable for rheumatoid arthritis and other chronic immune disorders.

2. *Orathecin*

Orathecin, 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. Orathecin is a second-generation topoisomerase I inhibitor that causes single-strand breaks in the DNA of rapidly dividing tumor cells. We believe that Orathecin may have significant advantages over many existing anticancer drugs, including efficacy, a side effect profile, and oral dosing. In particular, we believe that inhibition of bone marrow function is low, 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, Orathecin may provide patients with additional convenience and improved quality of life, and may reduce overall healthcare costs. We believe that Orathecin is a key drug that may be used, when approved, in the treatment of a broad array of solid tumors and hematological malignancies. We are

seeking rapid development of Orathecin and anticipate priority review (or review within 6 months of FDA's accepting our NDA) 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 if approved by the FDA for pancreatic cancer.

Pancreatic Cancer

Pancreatic cancer is associated with high patient mortality, causing more than 75,000 deaths annually in the United States and Europe. Pancreatic cancer is a highly lethal disease, with the poorest likelihood of survival among all of the major malignancies. Based on a 1988-1992 study by the National Cancer Institute, pancreatic cancer accounts for only 2% of all newly diagnosed cancers in the United States each year, but 5% of all cancer deaths. The most commonly used therapies to treat pancreatic cancer include 5-fluorouracil ("5-FU") and gemcitabine.

In May 2000, we presented data from a Phase II study of Orathecin at a meeting of the American Society of Clinical Oncology ("ASCO"). These data support Orathecin's efficacy in pancreatic cancer patients who had failed previous chemotherapy. Of the 45 patients with measurable disease, 22% either experienced a reduction in the size of their tumor or disease stabilization, meaning that the tumor did not continue to grow. After starting Orathecin treatment, median survival for these ten patients was approximately ten months, while 40% of these patients survived more than 12 months and 20% survived more than 24 months.

To date, over 2,700 patients have been treated in clinical studies with Orathecin. In 1998, we commenced three separate stand-alone pivotal Phase III clinical trials with Orathecin for treatment of pancreatic cancer. The three studies are: "Gemcitabine refractory," where patients who failed treatment with gemcitabine 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 gemcitabine. We believe that our Orathecin clinical program is the largest registration program ever undertaken in pancreatic cancer. In FDA's summary basis of approval, the program sizes for the two drugs approved by the FDA for the treatment of pancreatic cancer, gemcitabine and 5-FU, were as follows: gemcitabine had 126 patients in front-line use and 63 patients in second-line use, and 5-FU was approved on data from 20 pancreatic cancer patients. We are close to completing our three randomized Phase III studies in over 1,800 patients with pancreatic cancer at over 200 study sites in North America and Europe. The primary endpoint of these trials is survival. The patient populations for these studies are outlined as follows:

<u>Protocol Description of Three Stand-Alone Phase III Studies</u>	<u>Enrollment Completed</u>	<u>Patients Enrolled</u>
Gemcitabine refractory—Orathecin or 5-FU in patients who have failed gemcitabine	February 2001	448
Chemotherapy refractory—Orathecin or other therapies in patients who have failed other prior therapies	June 2001	409
Chemotherapy naïve—Orathecin or gemcitabine in patients who have not undergone chemotherapy	October 2001	994

Given the large scale, the complexity of the clinical trials, and the inherent uncertainties associated with clinical trials of such magnitude and complexity, there can be no assurance that the data or statistical analysis from our trials will support regulatory approval or that we will not be required to perform additional studies before seeking regulatory approval. For example, the trial design of these studies allows patients who initially were being treated with gemcitabine or other therapies to switch over to treatment 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 our Orathecin studies that have actually crossed over to treatment with Orathecin has significantly exceeded the number anticipated and was greater than 40% in each of the last two studies listed above. The extent of this cross over will likely negatively affect the statistical analysis of the study, making it difficult to determine if the product is effective.

We have submitted the first two (out of three total) sections of a "rolling" New Drug Application with the FDA. We expect to complete our NDA submission during the second quarter of 2003. In addition, we have been granted "fast track" designation for Orathecin for the treatment of patients with pancreatic cancer who have failed or are resistant to two or more chemotherapy agents, which means that the FDA will facilitate and expedite the development and review of the application. However, the FDA approval process may take a significant amount of time and we may not be approved. See "MD&A—Factors Affecting Future Operating Results—We are dependent on the successful outcome of the clinical trials for our lead product candidate Orathecin. If our clinical data for Orathecin cannot support the submission of an NDA with the FDA or if filing or approval of the NDA is delayed, our business will be substantially harmed."

Other Potential Indications

In preclinical studies, Orathecin was shown 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 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.

In addition, we are currently conducting pilot studies using Orathecin in combination with other chemotherapeutic agents. In studies to date, Orathecin has not exhibited significant cardiac, pulmonary, hepatic or renal toxicities that can limit the acute and/or chronic dosages of several chemotherapeutics. To date, dose limiting toxicity associated with Orathecin is hematologic and gastrointestinal disorders. In addition, some studies to date 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 that 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 specific methylation of DNA results in blocking the activity of 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 can reverse 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, we believe researchers have preliminarily shown decitabine to be effective for treating myelodysplastic syndromes ("MDS"). Based on positive results from these studies, we have completed enrollment in a randomized Phase III study at over twenty leading hospitals in the United States with approximately 160 patients, comparing decitabine to best supportive care for MDS. The primary endpoint is time to acute myeloid leukemia or death. This Phase III trial is designed to secure approval in the United States for MDS. Decitabine has received orphan drug designation from the FDA in 1999 for MDS, which designation may provide us with seven years of marketing exclusivity in the United States after FDA approval for MDS. In February 2002, decitabine also received orphan drug designation for MDS from the European Agency for the Evaluation of Medical Products ("EMEA"), the European Union equivalent of the FDA.

Other Indications

In addition to MDS, we believe Phase I/II studies also provide an indication that decitabine may be active in a variety of other hematological malignancies such as acute myeloid leukemia and chronic myeloid leukemia. To date, the major dose limiting toxicity is myelosuppression. We are currently conducting a multi-center Phase II study with decitabine for the treatment of chronic myeloid leukemia in patients who have failed previous Gleevec therapy. Phase I results also suggest that decitabine may be useful 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 and thalassemia using decitabine. Decitabine also received orphan drug designation from the FDA for sickle cell anemia in September 2002.

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 early 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 suggest that patients who responded to the peptides in the vaccine may have a survival benefit. 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. We are seeking a partner before commencing the Phase III program.

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 received ANDA approval for our generic mitomycin in 1998 for the treatment of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. We are currently selling mitomycin in the United States.

Daunorubicin

We received approval of an ANDA for generic daunorubicin for a variety of acute leukemias in 2002. We are currently in the process of commercializing daunorubicin, and are continuing to explore marketing opportunities and/or marketing partners for this product.

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 2003.

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 may 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. Our proprietary Extra technology is a platform technology that employs the use of an inert chemical excipient, cyclodextrin, combined with a drug. Most anticancer drugs are cytotoxic, and most must be administered intravenously. If a vein is missed on injection, the drug can leak to surrounding tissue, causing ulceration that sometimes requires plastic surgery to correct. Our proprietary Extra technology is designed to "shield" the drug from the injection site, thus helping to provide the patient protection from tissue ulceration. It may also increase the relative solubility of hard-to-dissolve anticancer drugs, hence potentially increasing its stability or shelf life. Each of these benefits must be supported by appropriate data and approved by the FDA. We believe that such features, if approved by the FDA, will result in our Extra products having a significant competitive advantage over their counterparts 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.

Mitozytrex

Our first product utilizing our Extra technology, Mitozytrex, which is an Extra formulation of generic mitomycin, was approved by the FDA in November 2002 for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Currently, we cannot promote Mitozytrex as providing any injection site ulceration protection, nor can we promote any increased stability, solubility or shelf life extension, as compared to generic mitomycin. We must

develop and submit additional data to the FDA and receive FDA approval before we can make these claims. We are currently exploring marketing opportunities and/or marketing partners for Mitozytrex.

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, we believe 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 studied for intrathecal treatment of neoplastic meningitis with a Phase I/II study at Duke University Medical Center and a Phase I study with 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.

4. Inhaled Cancer Drugs

In December 1999, we acquired worldwide licenses from Clayton Foundation for Research and its technology transfer organization, Research Development Foundation to make and sell 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 enzymatically to an active agent in

the liver. 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 2004.

7. *VEGF (Anti-Angiogenesis)*

In February 2001, we licensed from Peregrine Pharmaceuticals ("Peregrine") (formerly known as Techniclone Corp.) a platform drug-targeting technology known as Vascular Targeting Agent ("VTA"). The licensed technology is related to Vascular Endothelial Growth Factor ("VEGF"). 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.

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 initiated a small, well-defined and controlled Phase II study to characterize the hypoglycemic and lipid-lowering effects of PZG in Type II diabetes.

Business Relationships and Material Contracts

Strategic, Collaborative and Licensing Relationships and Related Agreements

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 and collaborative relationships and licensing agreements in pursuing our business. Some of our more significant relationships are as follows:

1. The Stehlin Foundation for Cancer Research—Orathecin

In September 1997, we entered into a License Agreement, as subsequently amended in 1999, to license the exclusive worldwide royalty-bearing rights to Orathecin from the Stehlin Foundation for Cancer Research, a Houston, Texas-based cancer research clinic. Under the agreement, we have the right to grant sublicenses, make, import, use, sell, offer for sale and otherwise distribute and exploit the licensed products worldwide, except for Mexico, Canada, Spain, Japan, the United Kingdom, France, Italy and Germany. We must use commercially reasonable efforts to develop the licensed Orathecin products and obtain regulatory approval for the products.

We may, at our sole discretion, enter into agreements with third parties with respect to the development of the licensed products. We must bear our own costs incurred in connection with the development of the products, and, except for the payments described in the agreement, the Stehlin Foundation will bear its own costs incurred in connection with the performance of the research activities that we may request and the Stehlin Foundation agrees to undertake in connection with the development of the licensed products. The development responsibilities under the agreement are coordinated by a committee consisting of an equal number of employees of each party, provided that we have the deciding vote in the event of any disagreement.

The Stehlin Foundation continues to hold the title to all inventions and other intellectual property made solely by employees or consultants of the Stehlin Foundation with respect to Orathecin, and we hold the title to all inventions and other intellectual property made solely by our employees or consultants in connection with activities under the agreement. Title to all inventions and other intellectual property made jointly by employees or consultants of the parties in connection with the agreement are jointly owned by the parties. In the event the Stehlin Foundation elects to license any product (other than the Orathecin products) for human medicinal purposes for any uses that include pancreatic cancer or antineoplastic use, we have the right of first refusal to obtain from the Stehlin Foundation a license under patents owned or controlled by the Stehlin Foundation to market such products.

We are required to pay the Stehlin Foundation approximately \$9.6 million for research, payable in monthly cash payments to the Stehlin Foundation of \$100,000 until the earlier of four years or the receipt of marketing approval by the FDA of Orathecin. Through December 31, 2002, we have paid Stehlin \$8.8 million of this total. 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. We must make milestone payments under the agreement upon (i) notification by the FDA of the acceptance of the first NDA filed for Orathecin, and (ii) our receipt of the FDA notice that it has approved Orathecin for marketing. Each of such payments will be made in shares of unregistered restricted shares of SuperGen common stock at a per share purchase price equal to the average trading price of the shares over a 30-day trading period.

Unless terminated sooner as provided in the agreement, the agreement will continue in full force and effect on a country-by-country and licensed product-by-licensed product basis until there are no remaining royalty payment obligations in a country, at which time the agreement will terminate in its entirety in such country. We will continue to have a perpetual, non-exclusive, royalty-free license, with the right to grant sublicenses, to make, import, use, sell, offer for sale and otherwise distribute and exploit the Orathecin products for human medicinal purposes in such country. We may terminate the agreement with respect to any country with 60 days written notice to the Stehlin Foundation. In addition, if either party materially breaches the agreement, the other party will have certain termination rights. Further, either party may terminate the agreement if the other becomes the subject of a voluntary or involuntary petition in bankruptcy or any proceeding relating to insolvency, receivership or liquidation for the benefit of creditors, if that petition or proceeding is not dismissed with prejudice within 60 days after filing.

2. AVI BioPharma, Inc.—Avicine

In December 1999, we entered into an agreement with AVI to acquire one million shares of AVI common stock, which amounted to approximately 7.5% of AVI's then outstanding common stock, for \$2.5 million cash and 100,000 shares of our common stock at \$28.25 per share. The chief executive officer of AVI at the time was a member of our Board of Directors (who later resigned from our Board in May 2002), and the president and chief executive officer of SuperGen is a member of the Board of Directors of AVI. 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 April 2000, we entered into a United States sales, distribution and development agreement with AVI to become the exclusive distributor and promoter in the United States of any pharmaceutical product containing Avicine.

Under the terms of the agreement, we are responsible for advertising, marketing, selling and promoting Avicine in the United States, and AVI is responsible for product manufacturing, packaging, sterilization and labeling. AVI has granted us an exclusive license to sell the Avicine products in the United States. In the event that AVI or its third party manufacturers are unable to fill product orders for a total of 60 days, then we will have a non-exclusive license to manufacture Avicine products. If AVI is unable to meet its obligations under the agreement for six months, AVI must notify us and the parties will consider steps to preserve our rights to Avicine, including, but not limited to, the grant of a non-exclusive, royalty bearing license to us to develop and sell Avicine products in the United States. Under the agreement, we also obtained the right of first discussion with respect to all of AVI's oncology compounds.

We have formed a joint Clinical Development Committee with AVI to oversee, review and coordinate the implementation of the clinical studies and the pursuit of regulatory approvals in the United States, and we will equally share the costs for the FDA approval process. In addition, any net profits from the sale of Avicine products in the United States will also be split equally among the parties. Further, the parties will jointly determine the optimum development strategy for the international marketplace.

AVI will maintain any patents owned by it or licensed to AVI relating to Avicine as identified and agreed to by the parties, and AVI will use its reasonable commercial efforts to prosecute any agreed upon patent applications. In addition, the parties will consult together and jointly determine patent issues, including patenting strategy, prosecution and response to patent office actions. AVI will be solely responsible for the selection, filing, registration and maintenance of any AVI trademarks related to Avicine in the United States. We have a non-exclusive limited license to use AVI's name and logo in

the United States, and a co-exclusive limited license to use AVI trademarks related to Avicine in the United States, in each instance solely for the purpose of promoting, distributing and selling Avicine products in the United States in accordance with the terms and conditions of the agreement.

In consideration of past research and development performed by AVI, we made an additional equity investment in AVI totaling \$22 million in exchange for 1,684,211 shares of AVI common stock, paid in a combination of \$5 million cash and the issuance of 347,826 shares of our common stock. As part of the agreement, we also have a warrant to acquire an additional 10% of AVI's common stock at an aggregate exercise price equal to \$60 million, or \$35.625 per share. This warrant 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 warrant exercise price. Neither event has occurred as of December 31, 2002.

We will be required to make additional milestone payments to AVI for an aggregate of up to \$80 million, including (a) \$2.5 million in SuperGen stock or cash, upon completion of accrual into the Phase III trial for Avicine; (b) \$2.5 million in SuperGen stock or cash, upon acceptance by the FDA of the NDA submitted for Avicine; (c) \$5 million in SuperGen stock or cash, upon launch of Avicine in the United States, (d) \$10 million in cash, upon the occasion on which annual Avicine product sales by us reach \$100 million; (e) \$15 million in cash, upon the occasion on which annual Avicine product sales by us reach \$250 million; (f) \$20 million in cash, upon the occasion on which annual Avicine product sales by us reach \$500 million; and (g) \$25 million in cash, upon the first occasion on which annual Avicine product sales by us reach \$1 billion. The ability to make milestone payments in SuperGen stock shall be at our option, subject to certain ownership limitations.

Unless terminated sooner as provided in the agreement, the agreement will expire upon the earlier of (a) the date upon which a generic version of Avicine is first sold in the United States by someone other than us, or (b) the date which is fifteen years after the date of regulatory approval of Avicine in the United States, provided that we and AVI may renew the agreement for the United States for (i) further successive one year periods, or (ii) further successive periods of time during which any applicable marketing exclusivity precludes the effective approval by the FDA of any product containing Avicine. In addition, either party may terminate the agreement if the ownership or control of at least 50% of the assets or voting securities of the other party are transferred and, in the non-changing party's reasonable judgment, the other party's new owner or controlling entity is a competitor of the non-changing party in the field of oncology.

3. Peregrine Pharmaceuticals—VEGF (Anti-Angiogenesis)

In February 2001, we entered into a License Agreement to license a platform drug-targeting technology known as Vascular Targeting Agent from Peregrine Pharmaceuticals. The licensed technology is related to Vascular Endothelial Growth Factor. 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.

Under the agreement, we obtained an exclusive, worldwide, royalty-bearing license to Peregrine's patents related to the VEGF technology, which permits us to make, use, import, sell and otherwise exploit and distribute licensed products using the VEGF technology. We may also grant sublicenses under the agreement.

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. The remaining \$347,000 of the payment was recorded to research and development expense. We are also required to pay Peregrine an annual license fee of \$200,000 per year in cash or SuperGen common stock until the first filing of an investigational new drug application ("IND") in the United States utilizing the licensed patents. In addition, 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. The milestone payments could ultimately total approximately \$8.25 million, plus additional royalty payments as required under the agreement. We are required to make milestone payments to Peregrine upon (a) commencement by us of the first Phase III trial in the United States, Europe or Japan for the first therapeutic clinical candidate covered under the licensed patents; (b) commencement by us of Phase III trial in the United States, Europe or Japan for subsequent therapeutic clinical candidates covered under the licensed patents; (c) commencement by us of a Phase II/III trial, if any; (d) receipt of regulatory approval in the United States for the first therapeutic clinical candidate covered under the licensed patents; (e) receipt of regulatory approval in a European nation for the first therapeutic clinical candidate covered under the licensed patents; and (f) receipt of regulatory approval in Japan for the first therapeutic clinical candidate covered under the licensed patents.

The agreement will continue in full force and effect on a country-by-country and licensed product-by-licensed product basis until there are no remaining royalty payment obligations in a country, at which time the agreement will terminate in its entirety in such country, unless terminated sooner as provided in the agreement. Upon termination of the agreement in any country, we will have a non-exclusive, irrevocable, fully paid-up right and license to use and exploit the licensed patents in that country. We may terminate the agreement with respect to any country with 30 days written notice to Peregrine. In addition, if either party materially breaches the agreement, the other party will have termination rights.

4. *AMUR Pharmaceuticals, Inc.*

In September 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 water-soluble class of hormones. We acquired these rights 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. Two of our current directors and two of our former directors were formerly directors of Amur. The president of Amur performed consulting services for SuperGen and was paid \$180,000 in 2002, \$180,000 in 2001, and \$152,000 in 2000 for these consulting services. In addition, in September 1999 this individual was granted an option to purchase 5,000 shares of SuperGen stock.

5. *Clayton Foundation for Research—Camptothecin and Paclitaxel*

Research Agreements

In November 1999, we entered into two research agreements with the Clayton Foundation for Research ("Clayton") a Texas nonprofit corporation, and the Research Development Foundation ("RDF") a Nevada nonprofit corporation, to provide funding to Clayton for use in its research involving cancer therapy and camptothecin under one agreement and cancer therapy and paclitaxel under the second agreement. RDF is affiliated with Clayton and is assigned title to inventions, discoveries and know-how arising out of Clayton's research for patenting and licensing. As set forth in the related license agreements, we obtained exclusive licenses from RDF to any inventions or discoveries arising out of the research funded under the research agreements. Clayton has ongoing research involving cancer therapy, including research regarding each of camptothecin and paclitaxel under the direction of Vernon Knight, M.D., at Baylor College of Medicine in Texas. The paclitaxel research agreement expired by its terms in November 2001, and the camptothecin agreement, which was extended to end of 2002 in May 2002, also expired. The parties are discussing the possibility of entering into a new research agreement.

License Agreements

In November 1999, we entered into two license agreements with RDF to obtain exclusive, worldwide licenses from RDF to produce, make, manufacture, use, sell, rent and lease methods, processes or products involving RDF's camptothecin product and RDF's paclitaxel product, and related proprietary property under the agreements. We have agreed to use commercially reasonable efforts with regard to commercialization of the products under the agreements.

Under the terms of the agreements, RDF may not license any other party rights to deliver camptothecin or paclitaxel, or analogues thereof, alone or in combination with another drug, in liposomes, lipid complexes or other liposome particles to the respiratory tract via aerosol droplets. We also have the right to grant sublicenses to others within the scope of and under the terms and conditions of the agreements. We must provide written notice of any such sublicenses to RDF. We also have the right to review and reference the know-how in any application or filing relating to the proprietary property with any governmental or regulatory authority.

RDF will, at its own expense, file patent applications relating to the proprietary property in the United States and any other countries agreed upon by the parties under the agreements. RDF agrees to use its best efforts to prosecute such patent applications and to maintain any patents issued thereon. We, in our sole discretion, may elect to assume responsibility (and to pay any associated fees and expenses) with respect to any patent applications or patents which RDF intends to abandon. We may abandon any patent applications or patents for which we have assumed responsibility and will not be liable to RDF in any way for such abandonment.

Any improvements on the proprietary property under the agreements, whether patentable, copyrightable or not, now or hereafter made and found by our agents or employees, shall be owned by RDF and will be considered part of the licensed proprietary property under the agreements. The worldwide rights in the corresponding patents, patent applications, copyrights and/or know-how will be the property of RDF subject to all the terms and conditions of the agreements, and will be licensed to us under the applicable agreement.

Upon execution of each of the agreements, we paid RDF an up-front non-refundable license fee consisting of \$410,000 in shares of SuperGen common stock under each agreement. In addition, we must pay RDF royalties based on gross revenues under the agreements. Only one royalty will be payable on a product, regardless of the number of licensed applications and licensed patents of the proprietary property under which such product has been manufactured, used or sold. We will also pay RDF fees received from sublicensees of the licensed proprietary property under the agreements. However, the parties agree that RDF is not entitled to any share of amounts received by us for pilot studies, research and development, the license or sublicense of any intellectual property other than the licensed proprietary property, reimbursement for patent or other expenses, or as consideration for equity or debt in connection with activities under the agreement.

In addition to the up-front license fee and royalties, we must also make milestone payments to RDF in the form of SuperGen common stock with respect to each product under the agreements upon (a) the earlier of (i) approval, or (ii) the date of effectiveness of an IND filed with the FDA for such product; (b) completion of a Phase I human clinical trial for such product and the final report thereon; (c) completion of a Phase II human clinical trial for such product and the final report thereon; (d) completion of any other phase of human clinical trials for such product required by the FDA and the final report thereon; and (e) upon approval by the FDA of an NDA for such product.

The term of each of the agreements is for a period of ten years extending from the first commercial revenue actually collected under the applicable agreement or for the life of the last to expire of the patents or patent applications of the licensed proprietary property thereunder, whichever is earlier, unless sooner terminated by the parties pursuant to the applicable agreement.

6. *Pharmachemie B.V.—Decitabine*

In September 1999, we entered into a Know-How Transfer and Cooperation Agreement with Pharmachemie B.V. Under the agreement, Pharmachemie sold and transferred to us its know-how related to a pharmaceutical product approach for the treatment of leukemia and other hematologic malignancies, called the "Decitabine Project." Under the agreement, we obtained all rights and title with respect to the know-how related to the Decitabine Project, including the related intellectual property rights, such as patent applications, and the exclusive world-wide right to use the know-how for any purpose whatsoever, including the filing of applications for marketing approval of the products. Upon execution of the agreement, we delivered to Pharmachemie shares of SuperGen common stock equal to \$3.4 million aggregate amount.

7. *Warner-Lambert Company—Pentostatin (Nipent)*

In September 1996, we entered into a Purchase and Sale Agreement with the Warner-Lambert Company, pursuant to which we agreed to purchase the exclusive rights to the anticancer drug Nipent from Warner-Lambert for the United States, Canada and Mexico. The assets we acquired included all of Warner-Lambert's unpurified crude concentrate form of pentostatin, from which Nipent is made, and related inventory, new drug application, Canadian new drug submission, intellectual property and customer list.

Under the agreement, we granted Warner-Lambert an irrevocable, non-exclusive, worldwide, perpetual and royalty-free license to use the know-how acquired by us under the agreement (in or outside the territories of the United States, Canada and Mexico) to the extent necessary to manufacture the pentostatin product for sale exclusively outside the United States, Canada and Mexico. Warner-Lambert may sublicense or assign such rights to any third party, subject to the terms of the agreement.

In addition, to the extent not acquired by us under the agreement, Warner-Lambert granted us an irrevocable, non-exclusive, worldwide, perpetual and royalty-free license to use all the technical know-how reasonably required or useful for the manufacture of the pentostatin products under the agreement, and any other intellectual property owned or licensed by Warner-Lambert as of the closing date necessary or helpful in the manufacture of the pentostatin products.

In consideration for the assets and related intellectual property rights acquired by us under the agreement, we paid Warner-Lambert \$2,073,000 in cash and \$1,000,000 in unregistered restricted SuperGen common stock, followed by an additional cash payment of \$500,000.

8. *Cyclex, Inc.*

In March 1994, we entered into a Patent License Agreement with Cyclex, Inc. ("Cyclex") pursuant to which we obtained a license under a patent identified in the agreement to make, use and sell pharmaceutical products for cytotoxic anticancer formulations containing HPBCD and certain other ingredients, for use in the United States. Cyclex agrees that it will not enter into a license agreement with any other parties granting the rights to make, use and sell the licensed products in the United States. The rights granted to us under the agreement are non-transferable, and we may not grant sublicenses thereof.

In consideration of the rights granted under the agreement, we must pay a 3% royalty to Cyclex on our net sales under the agreement. Only one royalty payment is due to Cyclex for the initial sale made by us or for the internal transfer price of each licensed product. The agreement will remain in effect until the expiration of the licensed patent under the agreement, or a final finding of invalidity or withdrawal of the licensed patent, subject to earlier termination for breach.

9. *Janssen Biotech, N.V.*

In March 1994, we entered into a Worldwide License Agreement with Janssen Biotech, N.V. ("Janssen") pursuant to which we obtained from Janssen an exclusive license to make, use and sell the pharmaceutical cytotoxic anticancer formulations containing HPBCD and certain other ingredients as developed by Janssen, for use worldwide except in the United States. We also have the right to grant sublicenses of the product. The rights granted under the agreement are otherwise non-transferable, except to affiliates.

In consideration of the rights granted under the agreement, we must pay a royalty of 4% for the license of the know-how in all countries and a royalty under the patent rights of 3% in those countries where patent rights have been granted. In addition, we paid Janssen a down payment of \$60,000 in connection with the execution of the agreement, and must make additional milestone payments to Janssen during the term of the agreement.

The agreement will remain in effect until the expiration of the last to expire patent rights under the agreement, subject to earlier termination for breach. In the event, however, that after the expiration of the patent rights the know-how under the agreement is still confidential and substantial, then the term of the agreement will be renewed for successive periods of one year each during which our obligations to pay royalties under the agreement will be limited to know-how related royalties.

10. *The Jackson Laboratory*

In August 1993, we entered into a Patent License and Royalty Agreement with The Jackson Laboratory ("Jackson") pursuant to which we obtained an exclusive right and license in and to the patents and patent rights related to three patents identified in the agreement, together with the right to grant sublicenses thereof. Jackson retained a royalty-free, non-exclusive, non-transferable license and right to the patent rights under the agreement for its own research and institutional purposes. We have the right to state in any advertising, promotions or sales that we are the exclusive licensee of Jackson under the patents covered by the agreement.

Upon execution of the agreement, we paid Jackson a one-time reimbursement fee of \$25,000. In addition, we must pay Jackson royalties equal to 2% of the net sales price of any patent products leased or sold by us, and a royalty equal to 10% of the net royalty paid to us on account of any lease or sale of such patent rights and related products. We must also pay Jackson an annual payment of \$2,500 per year, payable each year until the year of the last-to-expire patent rights. We must also pay any expenses for the preparation and filing of new patent applications and patent maintenance fees for all issued patents covered by the agreement.

The agreement may be terminated by Jackson if we cease to carry on our business, fail to pay royalties owed under the agreement or otherwise materially breach the agreement. We may terminate the agreement upon six month's notice to Jackson.

Supply and Distribution Agreements

We have entered into a variety of supply and distribution agreements in pursuing our business. Some of our more significant relationships are as follows:

1. *Abbott Laboratories—Nipent*

In December 1999, we entered into a Nipent U.S. Distribution Agreement with Abbott Laboratories. Under the agreement, we must supply Nipent inventory to Abbott on a consignment basis, for distribution by Abbott within the United States. At no time during the performance of the agreement will title to the products pass from us to Abbott.

As of March 1, 2000, Abbott became the exclusive United States distributor of Nipent for a period of five years under the agreement, with the sole and exclusive right to commercially distribute the product to third parties within the United States. Abbott may sell and distribute Nipent in the United States, collect monies due for those sales, convey a portion of such monies to us four times per year, and retain a portion of the monies collected as the fee for the distribution work. We retain all United States promotional, advertising and marketing rights for Nipent. Upon receipt by Abbott of orders for products under the agreement, Abbott must ship and invoice the products at the wholesale acquisition cost for the product established by us and reported to Abbott.

In January 2000, Abbott made a \$5 million cash payment to us in connection with the granting of the exclusive distribution rights by us to Abbott.

2. Warner-Lambert Company—Pentostatin (Nipent)

In October 1997, we entered into a Supply Agreement with Warner-Lambert Company, pursuant to which we contracted to manufacture and supply the pharmaceutical preparation for human use containing pentostatin in unlabeled sterile filled vials to Warner-Lambert or any entity designated by Warner-Lambert to act on its behalf with respect to the purchase of the product, for sale outside of North America (United States, Canada and Mexico) and Japan.

Under the agreement, we agreed to supply the pentostatin product to Warner-Lambert for sale outside of North America and Japan, and Warner-Lambert agreed to buy its total requirements of the pentostatin product for sale in the designated territories from us or our designee. Title to the products sold to Warner-Lambert or its designee under the agreement and risk of loss will pass to Warner-Lambert or its designee when the products are presented for customs clearance of the country of the designated designation. Warner-Lambert also agreed that: (i) all of the product purchased under the agreement will be purchased for resale or otherwise distributed solely in the designated territory; and (ii) none of the products purchased under the agreement will be resold or otherwise distributed in the United States, Canada or Mexico.

In addition, the agreement contains non-compete obligations whereby Warner-Lambert agrees that it will not, for the longer of (i) the term of the agreement and thereafter for a period of three years or (ii) a period of ten years from the date of the agreement, directly or indirectly, sell pentostatin anywhere in the United States, the Commonwealth of Puerto Rico, Canada or Mexico or have any ownership interest in, or participate in the financing, operation, management or control of any person selling pentostatin in such areas. With respect to regulatory requirements regarding the pentostatin products supplied under the agreement, we are responsible for obtaining and maintaining all registrations required by any governmental or regulatory authority of the United States and Warner-Lambert is responsible for obtaining and maintaining all registrations required by any governmental or regulatory authority of any country in the designated territories.

The agreement will remain in effect for seven years following the day on which we or our designee makes the first delivery of the product to Warner-Lambert or Warner-Lambert's designee, subject to earlier termination by either party for breach.

3. Hauser Technical Services—Pentostatin

In December 2002, we entered into a Pentostatin Supply Agreement with Hauser Technical Services, Inc. ("Hauser"). Under the agreement, Hauser will batch process pentostatin crude concentrate supplied to Hauser by us or parties authorized by us, to yield pentostatin as an active pharmaceutical ingredient ("API"). Hauser must notify us before it may subcontract any part of its responsibilities under the agreement to another party.

Prior to processing each batch of pentostatin crude concentrate under the agreement, we must furnish Hauser (at no cost to Hauser) a sufficient amount of pentostatin crude concentrate. Hauser is not required to store pentostatin crude concentrate for a certain number of batches. The agreement requires Hauser to provide us with the batch records, copies of raw data, all calculated data, exception reports and other documents approved by Hauser's quality assurance department for review prior to shipping any deliverables under the agreement pursuant to our instructions. Hauser must pay the costs of the raw materials (except the pentostatin crude concentrate) used under the agreement.

Hauser agrees to reserve one of its facilities for use pursuant to the agreement. In the event that we do not order certain batches of pentostatin crude concentrate for processing in any contract year during the term of the agreement, we agree to pay Hauser a shortfall payment following the end of such contract year. We must provide Hauser with written forecasts in January and June of each contract year regarding the number of batches of pentostatin crude concentrate that we expect to require Hauser to process over the subsequent 12-month period. In addition, we are solely responsible for applying for, obtaining and paying the costs regarding any approvals from regulatory authorities relating to the registration of the API, and we will own any new drug application supplement in connection therewith. Hauser agrees to reasonably cooperate and assist us in obtaining such approvals.

Under the agreement, we have title to all pentostatin crude concentrate, all work-in-process, all API and deliverables processed for us (including stability samples), standards for pentostatin and the s-isomer standards subject to the agreement. If any damage or loss of the pentostatin crude concentrate occurs prior to the time that Hauser completes the processing of the API, and such damage or loss is the result of Hauser's mishandling of the pentostatin crude concentrate (whether by negligence or breach of its obligations under the agreement), then Hauser will credit us on the next invoice or otherwise reimburse us for the cost of any labor and raw materials paid for by us that were used, damaged or lost. In addition, Hauser would need to pay us a mitigation fee in connection with such loss or damage.

The initial term of the agreement will be for a period of two years from execution. The parties may agree in writing to renew the agreement for additional one-year periods. The agreement may be terminated (i) upon mutual written consent of the parties, (ii) by us upon 30-days written notice to Hauser for any reason or no reason, (iii) by either party in the event of a material breach, insolvency or bankruptcy of the other party, or a force majeure event that continues for at least 60-days following notice by the other party, (iv) by Hauser upon 12-months written notice to us if Hauser or its successors choose to move to a new processing facility, or (v) by Hauser if we do not approve increases to the processing fees under the agreement due to cost increases for the material safety data sheets for the finished API and raw materials. If the agreement is terminated pursuant to clause (ii) or (v) of the preceding sentence, then we will need to reimburse Hauser for the cost of any unique unused raw materials and pay Hauser a termination fee.

4. 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, and an affiliate of SuperGen.

Under the agreement, we granted EuroGen the exclusive European and South African rights to promote, market, distribute 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. The agreement grants EuroGen a non-exclusive limited license to use our name and logo in connection with activities under

the agreement. EuroGen is required to seek and pay for all regulatory approvals and authorizations necessary for the commercial sale of the products in the territories where they market and sell the products.

Pursuant to the profit sharing terms of the agreement, EuroGen must pay us on a quarterly basis a percentage of the net sales revenues of products sold in the designated countries under the agreement.

The term of the agreement will expire fifteen years after the date of regulatory approval of the product under the agreement in the first country within the designated territory, unless terminated sooner for breach, bankruptcy or insolvency of one of the parties. In addition, we may terminate the agreement if EuroGen directly or indirectly develops, markets, sells or otherwise distributes any products within the designated territory which could compete with the products under the agreement, or EuroGen appoints any third party to develop, market, sell or otherwise distribute any such products which could compete with the products under the agreement.

Through December 31, 2002, we had advanced \$906,000 to EuroGen to fund its start-up operations. In December 2002, all but one of the other investors in EuroGen withdrew their ownership interests in the entity, and we became 95% owners of EuroGen. The remaining 5% is owned by Larry Johnson, the President and CEO of EuroGen. The amounts advanced to EuroGen, including the amounts advanced in 2001, totaling \$906,000 are included in Selling, general, and administrative expense in 2002.

5. Yunnan Hande Technological Development Co. Ltd.—Paclitaxel

In May 1997, we entered into a Non-Exclusive Supply Agreement with Yunnan Hande Technological Development Co. Ltd. (“Yunnan”). Yunnan has developed a process for the production of paclitaxel and has sought to implement a process which meets Good Manufacturing Practices of the United States FDA, and we have consulted with Yunnan regarding the development plans for the production of Paclitaxel and other products.

Under the agreement, we agreed to purchase a minimum quantity of paclitaxel before the end of one year from the date of approval of our ANDA for the paclitaxel drug product, on a non-exclusive basis. Yunnan is free to sell paclitaxel to any party in any place and we are free to purchase paclitaxel from third parties. We must pay Yunnan an aggregate of \$1 million during the FDA inspection period for the products.

Terminated Orathecin-Related Agreements with Abbott Laboratories

In December 1999, we entered into a Worldwide Sales, Distribution, and Development Agreement with Abbott Laboratories covering the marketing and sale of Orathecin and a related Common Stock and Option Purchase Agreement. On March 4, 2002, SuperGen and Abbott Laboratories entered into a Termination and Release Agreement providing for the termination of the Orathecin related agreements.

Under the terminated agreements, Abbott was to invest in shares of our common stock and would have participated with us in the marketing and distribution of Orathecin. We would have co-promoted Orathecin with Abbott in the United States and Abbott would have 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 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.

Pursuant to the termination, we regained all marketing rights to Orathecin worldwide and we 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 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. At the same time, we will not receive any further milestone payments from Abbott. In connection with the termination agreement, we also agreed to reimburse Abbott for \$1.6 million in development fees. This amount was subsequently reduced to \$1.2 million in 2002. We paid approximately \$880,000 of this total in March 2002. At December 31, 2002, the remaining amount payable to Abbott was included in Accounts payable and accrued liabilities.

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 \$29.9 million, \$47.8 million, and \$31.4 million, in 2002, 2001, and 2000, respectively, on research and development. We conduct research internally and also through collaborations with third parties, and we intend to maintain our strong commitment to our research and development efforts in the future. Our major research and development projects include Orathecin, decitabine and studies on other indications of Nipent.

Orathecin

While we believe we have a portfolio of product candidates with promise, we have focused much of our attention and resources on developing Orathecin, and from 1998 to December 2002 we have spent approximately 25% of our research and development expenses, or approximately \$58 million, on the Orathecin program, and we expect to spend an additional \$5 million in 2003 to complete the clinical trials for Orathecin and assemble the NDA for regulatory approval for the product. In addition, we must establish sales and marketing capability to support the worldwide sale of Orathecin, either by entering into a sales and marketing agreement with a collaborator or to build up our own sales force, which will involve substantial costs and expenses.

As described earlier in this report, we are close to completing three randomized Phase III studies for Orathecin, and submitted the first two (out of three total) sections of a "rolling" NDA with the FDA. We expect to complete our NDA submission during the second quarter of 2003. In addition, we have been granted "fast track" designation for Orathecin for the treatment of patients with pancreatic cancer who have failed or are resistant to two or more chemotherapy agents, which means that the FDA will facilitate and expedite the development and review of the application. In some cases, a fast track designated product may also qualify for priority review, or review within a six-month time frame from the time an NDA is completed and filed. We cannot, however, guarantee a faster development process, review or approval compared to the conventional FDA procedures, and the approval process may take a significant amount of time. Moreover, conducting clinical trials is a lengthy process and is subject to risks and uncertainties. We cannot guarantee that results from the clinical trials will support the regulatory approval, and we may not be approved. See "MD&A—Factors Affecting Future Operating Results—We are dependent on the successful outcome of the clinical trials for our lead product candidate Orathecin. If our clinical data for Orathecin cannot support the submission of an NDA with the FDA or if filing or approval of the NDA is delayed, our business will be substantially harmed."

If we are successful in obtaining necessary regulatory approval and successfully commercialize the product, we believe sales of Orathecin could generate more than \$100 million in revenues annually,

which could constitute more than 80% of our future revenues. These sales projections are based on the fact that, according to Eli Lilly's 2001 annual report, gemcitabine (the last drug approved for pancreatic cancer) has sales of more than \$500 million dollars annually, yet we believe that gemcitabine and 5-FU do not adequately serve the market of refractory pancreatic cancer patients. In addition, administration of gemcitabine and 5-FU require intravenous injection, while Orathecine is taken orally. We believe that based on these factors, in combination with our commercial experience, we can reasonably expect to achieve at least 20% of the sales of gemcitabine with Orathecine.

Decitabine

Decitabine is a potent hypomethylating agent that we acquired from Pharmachemie B.V., a subsidiary of Teva Pharmaceuticals, in September 1999. During the past three years, we have spent approximately \$5.1 million on the development of and clinical studies relating to decitabine.

In multiple Phase II studies in Europe, we believe researchers have preliminarily shown decitabine to be effective for treating MDS. Based on positive results from these studies, we have completed enrollment in a randomized Phase III study at over twenty leading hospitals in the United States with approximately 160 patients, comparing decitabine to best supportive care for MDS. The primary endpoint is time to acute myeloid leukemia or death. This Phase III trial is designed to secure approval for MDS.

In addition to MDS, Phase I/II studies also provide an indication that decitabine is active in a variety of other hematological malignancies such as acute myeloid leukemia and chronic myeloid leukemia. We are currently conducting a multi-center Phase II study with decitabine for the treatment of chronic myeloid leukemia in patients who have failed previous Gleevec therapy. Phase I results also suggest that decitabine may be effective 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 and thalassemia using decitabine.

Nipent

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 conducting Phase IV studies in 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 discussing the safety and 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 are conducting Phase I clinical trials in both of these indications and have targeted graft-versus-host disease Phase II/III program, which is currently in progress. We are also developing an oral formulation of Nipent, suitable for rheumatoid arthritis and other chronic immune disorders. During the past three years, we have spent approximately \$7.7 million on Phase I, II/III, and Phase IV programs related to different indications for Nipent.

Government Regulation: 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. Orathecine has received orphan drug designation from the FDA for treatment of patients with pancreatic cancer who have failed or are resistant to two or more chemotherapy agents. Decitabine has also received orphan drug designation from the FDA for MDS and sickle cell anemia.

"Fast Track" Approval Process under FDA Modernization Act of 1997. The Food and Drug Administration Modernization Act of 1997 ("FDAMA") essentially codified the FDA's Accelerated Approval regulations for drugs and biologics and established the "fast track" approval program. 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 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 obtained fast track designation for Orathecine for the treatment of patients with locally advanced or metastatic pancreatic cancer that is resistant or refractory to chemotherapies, and intend to seek such designation for other appropriate products. We cannot predict the ultimate impact, if any, of the fast track process on the timing or likelihood of FDA approval of any of our potential products. See "MD&A—Factors Affecting Future Operating Results—The fast track designation of Orathecine may not actually lead to a faster regulatory review or approval."

Approvals in European Union. In 1993, the European Union ("EU") established a system for the registration of medicinal products in the EU and under the system, marketing authorization may be submitted at either a centralized or decentralized level. The centralized procedure is administered by the European Agency for the Evaluation of Medicinal Products. This procedure is mandatory for the approval of biotechnology products and is available at the applicant's option for other innovative products. The centralized procedure provides, for the first time in the EU, for the granting of a single marketing authorization that is valid in all EU member states. A mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the mandatory centralized procedure, under a decentralized procedure. The decentralized procedure creates a new system for mutual recognition of national approvals and establishes procedures for

coordinated EU action on product suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more member states, certifying that identical dossiers are being submitted to all member states for which recognition is sought. Within 90 days of receiving the application and assessment report, each member state must decide whether or not to recognize the approval. The procedure encourages member states to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. If such disputes cannot be resolved within the 90-day period provided for review, the application will be subject to a binding arbitration procedure at the request of the applicant. Alternatively, the application may be withdrawn.

So far, we have applied, through EuroGen, for regulatory approval to market mitomycin and paclitaxel in the United Kingdom and in certain other countries within the EU. After we submit the NDA for Orathecin with the FDA, we intend to make a centralized filing for regulatory approval in EU. Our product candidates will be regulated in Europe as medicinal products.

Approvals outside of the United States and EU. 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.

Off-Label Use. 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 they may 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. If, however, our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

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. We will also need to provide adequate data that supports any "shielding benefit" to the patient, and increased stability, solubility and shelf life, and receive FDA approval before we can make these Extra claims. 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 ANDA 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 ANDA for the changed product; and
- a drug that is a duplicate of, or meets the monograph for, an approved antibiotic drug.

An ANDA 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.

Other Government Regulations

In addition to laws and regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local laws and regulations, as our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds.

Patents and Proprietary Technology

Patents are very important to us in establishing proprietary rights to the products we develop or license. The patent positions of pharmaceutical and biotechnology companies, including the Company, can be uncertain and involve complex legal, scientific, and factual questions. See “MD&A—Factors Affecting Future Operating Results—Our ability to protect our intellectual property rights will be critically important to the success of our business, and we may not be able to protect these rights in the United States or abroad.”

We actively pursue a policy of seeking patent protection when applicable for our proprietary products and technologies, whether they are developed in-house or acquired from third parties. We attempt to protect our intellectual property position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Currently we have acquired licenses to or assignments of at least 37 U.S. patents covering various aspects of our proprietary drugs, including 29 patents for Orathecin, 5 patents for Nipent, 5 patents for our paclitaxel related products and 2 patents for our 5-beta-steroid related compounds. These issued U.S. patents will begin to expire in October 2012. We have been granted patents and have received patent licenses relating to our Extra technology, Partaject, and Oral Prodrug technologies, among which at least 5 patents are issued to us. In addition, we are prosecuting a number of patent applications for drug candidates that we are not actively developing at this time.

There can be no assurance that the patents granted or licensed to us will afford adequate legal protection against competitors or provide significant proprietary protection or competitive advantage. The patents granted or licensed to us could be held invalid or unenforceable by a court, or infringed or circumvented by others. In addition, third parties could also obtain patents that we would need to license or circumvent. Competitors or potential competitors may have filed patent applications or received patents, and may obtain additional patents and proprietary rights relating to proteins, small molecules, compounds, or processes that are competitive with those of the Company.

In general, we obtain licenses from various parties which we deem to be necessary or desirable for the development, manufacture, use, or sale of our products or product candidates. Some of our proprietary products are dependent upon compliance with numerous licenses and agreements. These licenses and agreements may require us to make royalty and other payments, to reasonably exploit the underlying technology of applicable patents, and to comply with regulatory filings. If we fail to comply with these and other terms in these licenses and agreements, we could lose the underlying rights to one or more of these potential products, which would adversely affect our product development and harm our business.

We also have patents or licenses to patents issued outside of the United States, including Europe, Australia, Japan, Canada, Mexico and New Zealand. In addition, we have patent applications pending in these regions and countries as well as in China, Hungary and Israel. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in these countries outside the United States, may limit the protection we have on patents issued or licensed to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the United States. To minimize our costs and expenses and to maintain effective protection, we focus our patent and licensing activities within the European Union, Canada and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

In addition to pursuing patent protection in appropriate cases, we rely on trade secret protection for certain proprietary technology. To protect our trade secrets, we 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.

Registrations and applications for registration of our trademarks and service marks are pending as follows:

- Nipent (registered in the US and Canada; application pending in Mexico);
- Orathecin (applications pending in the US, Canada and Europe);
- Avidac (application pending in the US);
- Dacogen (application pending in the US);
- Dauno Extra (application pending in the US);
- Doxo Extra (applications pending in the US and in Europe);
- Mitozytrex (FDA approved mark for anti-cancer compound; applications pending in the US, Canada and in Europe);

- Partaject (applications pending in the US, Canada and Europe);
- Paxo Extra (application pending in the US);
- Surface Safe (mark for towelettes with antibiotic and antiviral properties; and registered in the US; application pending in Canada).

In addition, our “green bubbles” logo is registered in the United States, and our company name, SuperGen, is registered in the United States for use in pharmaceutical sales, and is the subject of pending applications for those goods in Europe, as well as for manufacturing services in the United States.

Competition

The pharmaceutical industry in general and oncology sector in particular is highly competitive and subject to significant and rapid technological change. 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.

Many of our competitors and research institutions are addressing the same diseases and disease indications and working on products to treat such diseases as we are, and have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Some of our competitors have received regulatory approval of or are developing or testing product candidates that compete directly with our product candidates. For example, while we received orphan drug status for Orathecin and there is currently no competitor in the oral delivery market for the treatment of pancreatic cancer, there are approved drugs for the treatment of pancreatic cancer, including gemcitabine by Eli Lilly. For another example, Berlex’s fludarabine and Ortho Biotech’s cladribine compete with our Nipent in the leukemia market.

In addition, many of these competitors, either alone or together with their customers, have significantly greater experience than we do in developing products, undertaking preclinical testing and clinical trials, obtaining FDA and other regulatory approvals, and manufacturing and marketing products. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing products before we do. If we commence commercial product sales of our product candidates, we will be competing against companies with greater marketing and manufacturing capabilities, areas in which we have limited or no experience. See “MD&A—Factors Affecting Future Operating Results—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. 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. As a result, unless our generic drugs are the first or among the initial few to launch, there is a high risk that our products would not gain meaningful market share, or we would not be able to maintain our price and continue the product line. Moreover, marketing of generic drugs is also subject to regulatory approval, and we may not be able to obtain such approval before our competitors to gain the competitive advantage.

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 key oncology drug candidates, we expect competition over 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 34 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. To date, 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 for our products. 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 mid 2001, and the manufacturer was qualified by the FDA in May 2002. We experienced unusually low inventory levels during the first quarter of 2002, while we were waiting for the new company to be qualified by the FDA. 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. See "MD&A—Factors Affecting Future Operating Results—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 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, 2002, we had 107 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.	70	Chief Executive Officer, President and Director
Edward L. Jacobs	56	Chief Business Officer/Chief Financial Officer
Karl L. Mettinger, M.D., Ph.D.	59	Senior Vice President, Chief Medical Officer
Craig S. Rosenfeld, M.D.	48	Senior Vice President, Chief Scientific 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 its 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 L. 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.

Craig S. Rosenfeld, M.D., joined SuperGen in October 2002 as Senior Vice President and Chief Scientific Officer. Prior to joining SuperGen, Dr. Rosenfeld served as Director of the Bone Marrow Transplant Program for Medical City Dallas Hospital from 1994 through 2002. Between 1990 and 1994,

Dr. Rosenfeld served as Director of the Apheresis Unit for Western Pennsylvania Hospital/Cancer Institute. From 1986 through 1990, Dr. Rosenfeld served as Assistant Director for the Bone Marrow Transplant Program at Pittsburgh Cancer Institute. Prior to this, Dr. Rosenfeld served with the Hematology/Oncology Unit for the Department of Medicine at Montefiore Hospital from 1985 to 1990. Also during this time, Dr. Rosenfeld served as Assistant Professor for the University of Pittsburgh School of Medicine. Dr. Rosenfeld received his B.A. and M.D. Doctrine at the University of Missouri.

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
Timothy L. Enns	V.P., Investor Relations and Business Development	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
John “Tipp” Nelson	V.P., Marketing	Berlex, Ortho McNeil—15 years
Simeon Wrenn, Ph.D.	V.P., Biotechnology	American Home Products, American Cyanamid, Purdue Frederick, Centocor—23 years

Geographic Area Financial Information

We operate in one business segment—human therapeutics. In 2002 and 2001, 97% of our sales were made in the United States and 3% in the European Union. In 2000, 100% of our sales were in the United States.

Available Information

We are subject to the information requirements of the Securities Exchange Act of 1934 (the “Exchange Act”). Therefore, we file periodic reports, proxy statements, and other information with the Securities and Exchange Commission (the “SEC”). Such reports, proxy statements, and other information may be obtained by visiting the Public Reference Room of the SEC at 450 Fifth Street, NW, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

Financial and other information about us is available on our website at www.supergen.com. We make available on our website, free of charge, copies of our annual report on Form 10-K, quarterly

reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. Information on our website does not constitute a part of this annual report on Form 10-K.

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, 2002.

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:

	<u>High</u>	<u>Low</u>
2002		
Quarter ended March 31, 2002	\$14.52	\$4.15
Quarter ended June 30, 2002	7.87	4.05
Quarter ended September 30, 2002	7.10	1.68
Quarter ended December 31, 2002	4.77	1.40
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

Equity Compensation Plan Information

The following table provides certain information with respect to all of the Company's equity compensation plans in effect as of the end of December 31, 2002:

<u>Plan Category</u>	<u>(A) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights(1)</u>	<u>(B) Weighted-average Exercise Price of Outstanding Options, Warrants, and Rights</u>	<u>(C) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A)(2)</u>
Equity compensation plans approved by security holders	4,535,457	\$10.28	576,694
Equity compensation plans not approved by security holders	—	—	—
Total	<u>4,535,457</u>	<u>\$10.28</u>	<u>576,694</u>

- (1) Consists of securities issuable under the 1993 Stock Option Plan and the 1996 Directors' Stock Option Plan.
- (2) Includes 234,013 shares issuable under the 1993 Stock Option Plan, 220,000 shares issuable under the 1996 Directors' Stock Option Plan and 122,681 shares issuable under the 1998 Employee Stock Purchase Plan.

Holder of Record

As of March 18, 2003, there were 552 holders of record of the common stock and approximately 21,600 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

In September 2002, we entered into a Securities Purchase Agreement and related Registration Rights Agreement with several investors for the private placement of shares of our common stock and warrants. In connection with these agreements, we issued 1,806,400 shares of our common stock to the investors at a per share price of \$2.50, for an aggregate amount of \$4,516,000, and issued warrants to the investors for the purchase of the same number of shares. The warrants have the following characteristics: (i) 1,204,269 (66-2/3%) of the warrants have an exercise price of \$4.00 and the other 602,131 (33-1/3%) of the warrants have an exercise price of \$5.00 per share, (ii) the warrants will be exercisable for a term of four years, (iii) the exercise prices of the warrants will be subject to adjustment so that, if we issue any shares of our common stock (including options and warrants, with standard exceptions), at a price that is lower than the respective exercise prices, then the respective exercise prices will be reduced to each such lower price, provided, however, that after 540 days of issuance of the warrants, the respective exercise prices shall not be reduced to less than \$2.50, and (iv) after two years, the warrants will be redeemable by SuperGen if the shares of our common stock are trading at above 200% of the respective exercise prices for twenty consecutive days. As compensation to the placement agent, we paid the placement agent \$310,000 in cash and issued a four-year warrant to an affiliate of the placement agent for the purchase of 118,000 shares of our common stock at an exercise price of \$3.00 per share.

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 15 of Part IV of this Report.

	Year ended December 31,				
	2002	2001	2000	1999	1998
	(Amounts in thousands, except per share data)				
Total revenue	\$ 15,269	\$ 11,451	\$ 7,089	\$ 4,744	\$ 3,004
Net loss	(49,471)	(55,566)	(35,283)	(36,985)	(15,577)
Basic and diluted net loss per share . . .	(1.52)	(1.69)	(1.04)	(1.58)	(0.77)
Total assets	57,333	122,717	163,333	53,478	19,793
Total stockholders' equity	48,002	107,798	149,945	44,768	16,818
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 Orathecic; 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. Our actual results could differ materially from those predicted in the forward-looking statements as a result of risks and uncertainties including, but not limited to, delays and risks associated with conducting clinical trials, product development and obtaining regulatory approval; ability to establish and maintain collaboration relationships; competition; ability to raise funding; continued adverse changes in general economic conditions in the United States and internationally; adverse changes in the specific markets for our products; ability to manage our clinical trials; and ability to launch and commercialize our products. Certain unknown or immaterial risks and uncertainties can also affect our forward-looking statements. Consequently, no forward-looking statement can be guaranteed and you should not rely on these forward-looking statements. For a discussion of the known and material risks that could act our actual results, please see "MD&A—Factors Affecting Future Operating Results" in this report. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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.

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

- Licensing or buying rights to lead compounds rather than engaging in pure discovery research.
- Capitalizing on our existing clinical expertise to maximize the commercial value of our products.
- Utilizing technologies to develop products for improved delivery and administration of existing compounds.
- Expanding the scope of our development efforts in oncology.

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 \$233.2 million for the period from inception through December 31, 2002. These losses included non-cash charges of \$20.0 million for the acquisition of in-process research and development.

We are close to completing three randomized Phase III studies for Orathecic in approximately 1,800 patients with pancreatic cancer at over 200 study sites in North America and Europe. The three studies are: "Gemzar refractory," where patients who failed treatment with Gemzar were randomized to either Orathecic or 5-FU; "Chemotherapy refractory," where patients who have failed multiple types of chemotherapy are randomized to either Orathecic or the next best therapy; and "Chemotherapy

naïve," where patients who have had no prior chemotherapy are randomized to Orathecin or gemcitabine. We commenced the clinical trials in 1998, and more than 2,700 patients have been enrolled in the studies. We have submitted the first two (out of three total) sections of a "rolling" New Drug Application with the FDA. We expect to complete our NDA filing during the second quarter of 2003. In addition, we have been granted "fast track" designation for Orathecin for the treatment of patients with pancreatic cancer who have failed or are resistant to two or more chemotherapy agents, which means that the FDA will facilitate and expedite the development and review of the application.

We have completed enrollment in 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.

We expect to continue to incur operating losses at least through 2003. This is due primarily to projected spending for the ongoing clinical trials and related development of our product candidates, as well as marketing launch expenditures for Orathecin. 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. This amount was subsequently reduced to \$1.2 million in 2002. We paid approximately \$880,000 of this total in March 2002.

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.

We also enter into collaboration relationships with our partners to co-develop and co-promote certain products. In 2000, we entered into agreements with AVI BioPharma, Inc. 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 1 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 judgment by our management. We believe the following critical accounting policies, among others, affect our more significant judgments 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 or until services are performed.

Allowances for estimated returns and product exchanges are based on historical information. If actual product returns and exchanges are greater than our estimates, additional allowances may be required.

Intangible Assets

We have intangible assets related to goodwill and other acquired intangibles such as trademarks, covenants not to compete, and customer lists. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgment. Changes in strategy and/or market conditions could significantly impact these judgments and require adjustments to recorded asset balances. We review intangible assets, as well as other long-lived assets, for impairment whenever events or circumstances indicate that the carrying amount may not be fully recoverable.

Valuation of Investments in Financial Instruments

Investments in financial instruments are carried at fair value with unrealized gains and losses included in accumulated other comprehensive income or loss in stockholders' equity. Our investment portfolio includes equity securities that could subject us to material market risk and corporate obligations that subject us to varying levels of credit risk. If the fair value of a financial instrument has declined below its carrying value for a period in excess of six consecutive months or if the decline is due to a significant adverse event, such that the carrying amount of these investments may not be fully recoverable, the impairment is considered other than temporary. An other than temporary decline in fair value of a financial instrument would be subject to write-down with a charge against net loss. The determination of whether a decline in fair value is other than temporary requires significant judgment, and could have a material impact on our balance sheet and results of operations. Our management reviews the securities within our portfolio for other than temporary declines in value on a regular basis.

Investments in equity securities without readily determinable fair value are carried at cost. We periodically review those carried costs and evaluate whether an impairment has occurred. The determination of whether an impairment has occurred requires significant judgment, as each investment may have unique market or development opportunities.

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 fixed assets for depreciation calculations, and assumptions for valuing options and warrants.

Results of Operations

Year ended December 31, 2002 compared with year ended December 31, 2001

Revenues were \$15.3 million in 2002 compared to \$11.5 million in 2001. Our revenues consist primarily of sales of Nipent, currently approved for the treatment of hairy cell leukemia. Our 2002 revenues included \$12.1 million in Nipent sales in the U.S. and \$800,000 in sales to the European distributor for Nipent. Revenues in 2001 included \$9.7 million in U.S. Nipent sales and \$338,000 in European sales. 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 2003 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 32% in 2002 compared to 26% in 2001. The increased cost of sale percentage in 2002 was primarily due to higher start-up and manufacturing costs and lower yield for Nipent as we qualified a new vendor to manufacture the drug in early 2002. To a lesser extent, the increase was due to higher sales of Nipent in Europe, which were made at a lower unit selling price under a supply agreement for sale outside North America. To the extent that European sales comprise a more significant portion of our total Nipent sales in 2003 we would expect our margins to decrease. Current margins may not be indicative of future margins due to possible variations in manufacturing costs and average selling prices.

Research and development expenses were \$29.9 million in 2002 compared to \$47.8 million in 2001. The decline was due primarily to the completion of enrollment in 2001 of over 1,800 patients into our Phase III clinical trials of Orathecin for pancreatic cancer. Although many of these patients remained on study into 2002, most of the clinical trial expenditures for these patients were incurred in 2001. In 2002 we began enrollment of patients into our Phase III trials for decitabine, but these trials involve fewer patients and the clinical trial costs for this drug are lower than those for Orathecin. We conduct research internally and also through collaborations with third parties, and we intend to maintain our strong commitment to our research and development efforts in the future. Our research and development activities consist primarily of clinical development and the related advancement of our existing product candidates through clinical trials. Our major research and development projects include Orathecin, decitabine and studies of other indications of Nipent. We have focused much of our attention and resources on developing Orathecin, and from December 1998 to December 2002 we have spent approximately 25% of our research and development expenses or approximately \$58 million on the Orathecin program. We expect to spend an additional \$5 million in 2003 to complete the clinical trials for Orathecin and assemble the NDA for regulatory approval for the product. During the past three years, we have spent approximately \$5.1 million on the development of and clinical studies related to decitabine. During the past three years, we have spent approximately \$7.7 million on Phase I, II/III and Phase IV programs related to different indications for Nipent. 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 \$23.5 million in 2002 compared to \$22.1 million in 2001. This increase was due primarily to higher expenditures for patent and copyright legal expenses, liability and life insurance, business development relating to our European start up operations, and administrative salaries and bonuses.

Interest income was \$1.7 million in 2002 compared to \$5.6 million in 2001. The decrease was due to lower available cash balances for investment and a decline in interest rates.

In 2002, we recorded other expense of \$8.5 million, which represented an other than temporary decline in the value of our investments in AVI BioPharma, Inc., Inflazyme, Inc., and Peregrine Pharmaceuticals, Inc.

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.

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. 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 \$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. 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 \$3.2 million in 2000. The decrease was due to lower available cash balances for investment and a decline in interest rates.

Liquidity and Capital Resources

Our cash, cash equivalents and both short and long term marketable securities totaled \$22.4 million at December 31, 2002, compared to approximately \$74.0 million at December 31, 2001. In addition, at December 31, 2002 we held approximately 2.7 million shares of registered stock of AVI BioPharma, Inc., with a market value of \$13.4 million.

On February 26, 2003 we entered into a Securities Purchase Agreement with a number of purchasers for the private placement of Senior Exchangeable Convertible Notes ("Notes") in the principal amount of \$21.25 million and related warrants. The Notes will accrue interest at a rate of 4% per annum. The principal amount of the Notes will be repayable in four equal quarterly installments beginning nine months after the closing of the transaction. The Notes will be, at the option of the investors, in whole or in part, (a) convertible into shares of our common stock at a fixed conversion price of \$4.25 per share, and (b) exchangeable for up to 2,634,211 of our shares of common stock of AVI, at a fixed exchange price of \$5.00 per share. We may pay interest due under the Notes in shares of our common stock at a price tied to the then market price, and subject to certain conditions, we may also elect to pay principal due under the Notes in shares of our common stock and our AVI shares at prices tied to the then market price of our common stock and AVI common stock, respectively. Subject to certain conditions, at any time after the first anniversary of the effectiveness of a registration statement we filed to cover the resale of the securities, all of the outstanding Notes will be redeemable by SuperGen for a cash redemption price at 120% of par plus accrued and unpaid interest. Upon a change of control, the holders will have certain redemption rights, and we may also redeem the Notes, in each case subject to certain conditions and provided that, in the event of our redemption, we will issue to the holders of the Notes certain warrants exercisable for the securities of the acquiring entity and the AVI shares. Our exchange obligations under the Notes are secured by a pledge of the AVI shares. See "MD&A—Factors Affecting Future Operating Results—We substantially increased our outstanding indebtedness with the issuance of certain senior exchangeable convertible notes and we may not be able to pay our debt and other obligations;—The conversion of the notes will have a dilutive effect upon the stockholders."

In September 2002, we entered into a Securities Purchase Agreement and Registration Rights Agreement with several investors for the private placement of shares of our common stock and warrants. In connection with these agreements, we issued 1,806,400 shares of our common stock to the investors at a price per share of \$2.50, for an aggregate of \$4.5 million, and issued warrants to the investors for the purchase of the same number of shares.

The net cash used in operating activities of \$47.7 million in 2002 primarily reflected the net loss for the period of \$49.5 million, plus an increase in accounts receivable of \$2.9 million and decrease in accounts payable and other liabilities of \$4.6 million, offset by a non-cash charge of \$8.5 million due to an other than temporary decline in the value of investments. 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 accrued liabilities of \$2.5 million.

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 million in total. In March 2001 and September 2002, the Board

authorized increases in the number of shares to be acquired under the repurchase plan, but maintained the \$20 million repurchase total. During the year ended December 31, 2002, we repurchased 1,886,000 shares of our common stock at a cost, net of commissions, of \$7.2 million. During the year ended December 31, 2001, we repurchased 963,000 shares of our common stock at a cost, net of commissions, of \$9.1 million. All shares repurchased have been retired.

We believe that our current cash, cash equivalents, marketable securities, and funds raised in February 2003 noted above will satisfy our cash requirements at least through the next twelve months. 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 as of December 31, 2002 are as follows (in thousands):

	Payments Due by Period				
	Total	<1 year	1-3 years	4-5 years	After 5 years
Operating Leases, net	\$16,879	\$1,886	\$6,249	\$4,299	\$4,445
Long term obligations—contractually obligated research funding	3,670	1,525	1,145	770	230
Total contractual cash obligations	<u>\$20,549</u>	<u>\$3,411</u>	<u>\$7,394</u>	<u>\$5,069</u>	<u>\$4,675</u>

The operating lease obligations noted above are net of sublease income. 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 milestone events the achievement of which is subject to a significant number of risks and uncertainties. Since some of the milestone events are revenue-related and payment obligation 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 Financial Accounting Standards Board 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 non-recurring charges for acquired IPR&D at the date of acquisition.

The development of any 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 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 Pharmaceuticals, Inc. 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.

Related Party Transactions

EuroGen Pharmaceuticals Ltd.

In September 2001, we entered into a Supply and Distribution Agreement with EuroGen Pharmaceuticals Ltd., a company incorporated and registered in England and Wales. The agreement was based on arm's length negotiation between the parties. 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 then 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. During 2002, we advanced an additional \$646,000 to EuroGen to fund its operations. In December 2002, all but one of the other investors in EuroGen withdrew their ownership interests in the entity, and we became 95% owners of EuroGen. The remaining 5% is owned by Larry Johnson, the President and CEO of EuroGen. The amounts advanced to EuroGen, including the amounts advanced in 2001, totaling \$906,000 are included in Selling, general, and administrative expense in 2002.

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. One of our board members 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. At the time, the chief executive officer of AVI was a member of our Board of Directors. He later resigned from our board in May 2002. 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 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. Our ownership is less than 20% of AVI's outstanding shares. The investment 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, 2002.

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 was presented on the balance sheet as Payable to AVI BioPharma, Inc. This amount was paid in 2002. In 2002, we recorded \$421,000 in research and development expenses for Avicine. At December 31, 2002, this amount was still payable and is presented on the balance sheet as Payable to AVI BioPharma.

We issued certain senior exchangeable convertible notes in February 2003 to a group of institutional investors. The holders of these may exchange their notes into up to 2,634,211 of our AVI shares six months after the notes issuance at an exchange price of \$5.00 per share, and we pledged the AVI shares to secure our exchange obligation under the notes.

AMUR Pharmaceuticals, Inc.

Two current SuperGen directors and two former 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 2002, \$180,000 in 2001, and \$152,000 in 2000 for these consulting services.

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. During 2002, these warrants were extended for two additional years.

Quark Biotech, Inc.

The president and chief executive officer of SuperGen and one of our directors are directors and stockholders of Quark Biotech, Inc. ("QBI"), a privately-held development stage biotechnology company headquartered in Israel. One former director of SuperGen is currently a director of QBI and one former director of SuperGen was also a director of QBI. 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, 2002. 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.

In January 2002, we subleased a portion of our laboratory at SPRI to QBI. During 2002, we collected \$123,000 in sublease income from QBI. The initial term of the sublease expired on December 31, 2002, but we are continuing to sublease the space to QBI on a month-to-month basis.

The Kriegsman Group

In March 2001, we retained The Kriegsman Group to render advice and assistance with respect to financial public relations and promotions. In addition, in connection with such services, on March 22, 2001, we issued three warrants to The Kriegsman Group, two of which are still outstanding, and as amended in February 2003, the terms of the warrants are as follows: the "A" warrant for the purchase of 200,000 shares of common stock is exercisable at the exercise price of \$10.47 and will expire in February 2006, and the "C" warrant for the purchase of 100,000 shares of common stock is exercisable at the exercise price of \$10.47 and will expire in February 2007. On July 25, 2002, Dr. Joseph Rubinfeld, our President and Chief Executive Officer, became a member of the board of directors of CytRx Corp. Steven Kriegsman, the President of The Kriegsman Group, is also a significant shareholder and President and Chief Executive Officer of CytRx Corp. We paid The Kriegsman Group consulting fees of \$240,000 in 2002 and \$232,500 in 2001.

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 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses financial accounting and reporting for costs associated with an exit or disposal activity and requires such costs to be recognized when the liability is incurred. Previous guidance in EITF No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Certain Costs Incurred in a Restructuring)" required that a liability for an exit cost be recognized at the date of a company's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated by a company after December 31, 2002. The adoption of SFAS 146 is not expected to have a material effect on our financial position or results of operations.

In December 2002, the FASB issued Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" ("SFAS 148"). SFAS 148

amends SFAS 123 to provide alternative methods of transition to Statement of Financial Accounting Standards No. 123 ("SFAS 123") fair value method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure provisions of SFAS 123 and Accounting Principals Board Opinion No. 28, "Interim Financial Reporting," to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. While SFAS 148 does not amend SFAS 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS 148 are applicable to all companies with stock-based employee compensation, regardless of whether they account for that compensation using the fair value method of SFAS 123 or the intrinsic value method of APB 25. Since we account for our stock-based compensation under APB 25, and have no current plans to switch to SFAS 123, the impact of SFAS 148 will be limited to the interim reporting of the effects on net income and earnings per share if the Company accounted for stock-based compensation under SFAS 123. SFAS 148 is effective for fiscal years ended after December 15, 2002.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). FIN 45 requires certain guarantees to be recorded at fair value, which is different from current practice, where a liability is recorded when a loss is probably and reasonably estimable. In addition, FIN 45 also requires a guarantor to make significant new disclosures, even when the likelihood of making any payments under the guarantee is remote, which is another change from current practice. In general, FIN 45 applies to contracts or indemnification agreements that contingently require the guarantor to make payments to the guaranteed party based on changes in an underlying that is related to an asset, liability, or an equity security of the guaranteed party. FIN 45 is applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of the recognition and measurement provision of this interpretation are not currently expected to have a material effect on our financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities." FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applied in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. We do not believe there will be a material effect upon our financial condition or results of operations from the adoption of the provision of FIN 46.

Income Taxes

As of December 31, 2002, we have net operating loss carryforwards for federal income tax purposes of approximately \$229.0 million which expire in the years 2005 through 2022, and federal research and development credit carryforwards of approximately \$4.2 million, which expire in the years 2007 through 2022.

Factors Affecting Future Operating Results

Our business, future operating results and financial condition are dependent upon many factors that are subject to a number of risks and uncertainties. Below we summarize the material risks and uncertainties that are known to us and that may cause our future operating results to be different than our planned or projected results, and that may negatively affect our operating results and financial condition. However, the risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that are not presently known to us or that we currently believe are immaterial may also impair our business operations or financial condition.

Risks Related to Our Financial Condition and Common Stock

We have a history of operating losses and an accumulated deficit, we expect to continue to incur losses for the foreseeable future.

Since inception we have incurred cumulative losses of \$233.2 million through December 31, 2002, and have never generated enough funds through our operations to support our business. These losses include non-cash charges of \$20.0 million for the acquisition of in-process research and development. 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. In the year ended December 31, 2002, we spent \$29.9 million on research and development. Our cash, cash equivalents and marketable securities decreased from \$74 million at December 31, 2001 to \$22.4 million at December 31, 2002. Our losses to date have resulted principally from:

- research and development costs relating to the development of our products and product candidates, including the large scale clinical trials for Orathecin;
- license fees and milestone payments to our collaborators and research institutions, and acquisition of technology or other assets;
- in-process research and development costs and amortization of intangible assets associated with our acquisitions;
- costs and expenses associated with manufacturing, distribution and sales of our products; and
- general and administrative costs relating to our operations.

We expect to continue to incur substantial operating losses at least through 2003.

We are currently unprofitable and may never become profitable.

Since inception, we have funded our research and development activities primarily from private placements and public offerings of our securities, milestone payments and revenues generated primarily 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 limited product revenues, we have incurred substantial net losses.

Our ability to achieve profitability will depend primarily on our ability to obtain regulatory approval for and successfully commercialize Orathecin, our lead product candidate. 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, to obtain regulatory approval for and successfully commercialize decitabine and other product candidates, and to bring to market our other proprietary products, i.e., products that are advancing through our internal clinical development infrastructure, including our Extra products. 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 of any expansion of 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 and other products if and when approved;
- costs and expenses associated with entering into licensing and other collaborative agreements;
- delays in or inadequate commercial sales of Orathecin and other products, once regulatory approvals have been received; and
- expenditures associated with acquiring products, technologies or companies and further developing these assets.

Our products and product candidates, even if successfully developed and approved, may not generate sufficient or sustainable revenues to enable us to be profitable, or to sustain profitability.

We may require additional financing, and an inability to raise the necessary capital or to do so on acceptable terms would threaten the continued success of our business.

We will continue to expend substantial resources for conducting research and development, including costs associated with conducting clinical trials. While we raised \$21.25 million through a senior exchangeable convertible debt offering in February 2003 and anticipate that our capital resources will be adequate to fund operations and capital expenditures for at least the next twelve months, if we experience unanticipated cash requirements during this period, we could require additional funds much sooner. We may raise money by sale of our equity securities or debt, or the exercise of outstanding warrants and stock options. However, given the uncertainties of the market conditions, we may not be able to sell our securities in public offerings or private placements at prices and on terms that are favorable to us, or if at all. Also, the dilutive effect of those fundings could adversely affect our results per share. We may also choose to obtain funding through licensing and other contractual agreements. Such arrangements may require us to relinquish our rights to our technologies, products or marketing territories, or to grant licenses on terms that are not favorable to us. If we fail to obtain adequate funding in a timely manner, or at all, we may be forced to scale back our product development activities, or forced to cease our operations.

Our stock price is highly volatile, and if our price declines further, we may encounter difficulty in raising capital in the equity market.

The trading price of our common stock has fluctuated dramatically in the last two years, from the high of \$15.70 in January 2001 to a historic low of \$1.40 in October 2002. Our stock price is likely to remain volatile in the future, which is subject to the following factors, some of which are beyond our control:

- announcements of regulatory approval or disapproval of our or our competitors' products;
- fluctuations in our financial results;
- announcements of technological innovations or new products by us or our competitors;
- announcements of changes in governmental regulations affecting us or our competitors;
- developments in patent or other proprietary rights affecting us or our competitors;
- public concern as to the safety of products developed by us or other biotechnology and pharmaceutical companies;
- general market conditions;
- severe fluctuations in price and volume in the stock market in general (or in the trading of the stock of pharmaceutical and biotechnology companies in particular) which are unrelated to our operating performance; and

- future sales of common stock by us or by existing stockholders and the perception that such sales could occur.

If the trading price of our common stock continues to significantly fluctuate and decline, we may be unable to obtain additional capital that we may need through public or private financing activities. Because outside financing is still critical to sustain our business operations, large fluctuations in our share price will harm our financing activities and may cause us to significantly alter our business plans or cease operations altogether.

Our equity investment in AVI BioPharma exposes us to equity price risk and any impairment charge would affect our results of operations.

We are exposed to equity price risk on our equity investment in AVI. Currently we own 2,684,211 shares of AVI. In the third quarter of 2002, we recorded an other-than temporary loss of \$8.2 million relating to our holding in AVI, resulting in a reduction of our cost basis in the AVI stock. Under our accounting policy, marketable equity securities are presumed to be impaired if their fair value is less than their cost basis for more than six months, absent compelling evidence to the contrary. At September 30, 2002, AVI common stock had been trading below our original cost basis for more than six months. As there was no compelling evidence to the contrary, we recorded the impairment charge of \$8.2 million in our results of operations. The amount of the charge was based on the difference between the market price of the securities as of September 30, 2002, and our original cost basis. The public trading prices of the shares of AVI have fluctuated significantly since we purchased them and could continue to do so. If the public trading prices of these shares continue to trade below their new cost basis in future periods, we may incur additional impairment charges relating to this investment, which in turn will affect our results of operations.

In addition, the holders of our senior exchangeable convertible notes issued in February 2003 may exchange their notes into up to 2,634,211 of our AVI shares six months after the notes issuance at an exchange price of \$5.00 per share, and we pledged the AVI shares to secure our exchange obligation under the notes. As a result, our ability to gain from the increases of AVI's stock price is limited.

We substantially increased our outstanding indebtedness with the issuance of certain senior exchangeable convertible notes and we may not be able to pay our debt and other obligations.

On February 26, 2003, we privately placed certain senior exchangeable convertible notes in the aggregate principal amount of \$21.25 million with several institutional investors. The notes are payable in four equal quarterly installments beginning in November 2003 and will accrue interest at a rate of 4% per annum. Prior to the issuance of the notes, we did not have any indebtedness. Therefore, by issuing the notes we increased our indebtedness substantially. In addition, the note holders have imposed certain restrictive covenants, including a limit on our future indebtedness and a limit on structuring equity financings with variable pricing. As a result, the issuance of the notes will:

- make it more difficult for us to obtain any necessary financing in the future for working capital, capital expenditures or other purposes;
- significantly increase our interest expense; and
- make us more vulnerable in the event of a downturn in our business.

Currently, our revenues from our operations will not generate sufficient cash flow to satisfy the principal payment under the notes when they become due. Under the terms of the notes, we have the right to pay the principal and interest then due under the notes through the issuance of shares of common stock at a conversion price tied to the then market price. Nevertheless, our principal payment through issuance of shares of our common stock is subject to certain conditions, including limitation based on trading volumes in our common stock at such time. Therefore, we may be required to use cash to pay the principal amount when it is due under the notes. If we decide to make payments under

the notes in cash, we may deplete our financial resources and adversely affect our product development. If we are unable to satisfy our payment obligations under the notes, we will default on the notes.

The conversion of the notes will have a dilutive effect upon the stockholders.

Pursuant to the terms of the senior exchangeable convertible notes we issued in February 2003, the note holders may convert the notes at any time prior to their maturity at a fixed conversion price of \$4.25, and we have the right, subject to certain conditions, to pay the principal and interest then due under the notes through the issuance of shares of common stock at a conversion price tied to the then market price. If we issue shares of our common stock upon the note holders' conversion of the notes or to make payments, such issuance will be dilutive to our stockholders. In addition, if we decide to redeem the notes in connection with a change of control, we will be required to issue to the note holders certain warrants for the securities of the acquiror, which will be dilutive and may negatively affect the deal consideration the stockholders would otherwise receive in absence of such issuance.

Risks Related to Our Industry

Before we can seek regulatory approval of any of our product candidates, we must successfully complete clinical trials, which are expensive and have uncertain outcomes.

Most of our products are in the development stage and, prior to their sale, will require regulatory approval and the commitment of substantial resources. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process, and their results are inherently uncertain. We have incurred and will continue to incur substantial expense for, and we have devoted and expect to continue to devote a significant amount of time to, preclinical testing and clinical trials. In addition, we must overcome all kinds of difficulties and setbacks in our clinical trials, which are an inherent part of the drug development process.

We are currently conducting late stage Phase III clinical trials for two of our product candidates: Orathecin for pancreatic cancer and decitabine for treatment of advanced myelodysplastic syndrome. In addition, we have a broad portfolio of other cancer drugs in various stages of development, including Avicine in colorectal cancer (Phase II), Nipent (for indications other than hairy cell leukemia, Phase IV), Partaject busulfan, inhaled Orathecin (Phase I), and are conducting pre-clinical studies for VEGF, inhaled paclitaxel and Cremophor-free paclitaxel. Clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for any of our product candidates. We expect to commence new clinical trials from time to time in the course of our business as our product development work continues. However, regulatory authorities may not permit us to undertake any additional clinical trials for our product candidates.

In addition, we have ongoing research and pre-clinical projects that may lead to product candidates, but we have not begun clinical trials for these projects. Our pre-clinical or clinical development efforts may not be successfully completed and we may not commence clinical trials as planned.

Our clinical trials may be delayed or terminated, which would prevent us from seeking necessary regulatory approvals.

Completion of necessary 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. For example, the design of our three Orathecin studies are complex, and we have been conducting clinical trials since 1998, which may make statistical analysis difficult and regulatory

approval hard to predict. Our commencement and rate of completion of clinical trials 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;
- inability to obtain FDA approval of our clinical trial protocols;
- slower than expected rate of patient recruitment;
- inability to adequately follow patients after treatment;
- difficulty in managing multiple clinical sites;
- unforeseen safety issues;
- lack of efficacy demonstrated during the clinical trials; or
- government or regulatory delays.

In addition, we have limited experience in conducting and managing clinical trials. We rely on third parties, including contract research organizations, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completing, or in failure to complete, these trials if the third parties fail to perform under our agreements with them.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in compliance with regulatory requirements, if the trial results are negative, inconclusive or if they fail to demonstrate safety or efficacy.

Our clinical trials must be conducted in accordance with the FDA's regulations and are subject to oversight by the FDA and institutional review boards at the medical institutions where the clinical trials are conducted. We outsource our research and development activities with respect to our primary product candidates. We have agreements with third-party contract research organizations ("CRO's") to provide monitors and to manage data for our clinical programs, including the phase III Orathecic program in pancreatic cancer. We and our CRO's are required to comply with current Good Clinical Practices ("GCP's") regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCP's through periodic inspections of study sponsors, principal investigators, and study sites. We are not aware of any material GCP deficiencies with any of these research organizations that might impact regulatory approval of our products. If, however, in the future we or our CRO's fail to comply with applicable GCP's, the clinical data generated in our studies may be deemed unreliable and the FDA may require us to perform additional studies before approving our marketing applications. We cannot assure you that upon inspection the FDA will determine that any of our studies for products in clinical development comply with GCP's. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices regulations and may require large numbers of test subjects. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause us to repeat or terminate a clinical trial. 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 or if the FDA finds deficiencies in the conduct of these trials.

We may encounter other problems and failures in our studies that will cause us or the FDA to delay or suspend the studies. The potential failures will delay development of our product candidates,

hinder our ability to conduct related preclinical testing and clinical trials, and further delay the commencement of regulatory approval process. Moreover, we then may be required to conduct other clinical trials for the product candidates, which will require substantial funding and time. We may be unable to obtain corporate funding or other financing to conduct such clinical trials. The failures or perceived failures in our clinical trials will directly delay our product development and regulatory approval process, damage our business prospect, make it difficult for us to establish collaboration and partnership relationships, and negatively affect our reputation and competitive position in the pharmaceutical community.

If we fail to obtain regulatory marketing approvals of our product candidates in a timely manner, commercialization of our products will be delayed or prevented and we will not be able to generate revenue and achieve profitability.

All new drugs, including our products under development, are subject to extensive and rigorous regulation by the FDA, and comparable agencies 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. Prior to marketing in the United States, a drug must undergo rigorous testing and an extensive regulatory approval process implemented by the FDA under federal law, including the Federal Food, Drug and Cosmetic Act. To receive approval, we or our collaborators must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product is both safe and effective for each indication where approval is sought. 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.

We are currently selling Nipent (which we acquired from the Parke-Davis division of the Warner-Lambert Company in 1996) for the treatment of hairy cell leukemia, and sales of Nipent constitute our principal source of product revenues. We received regulatory approval to market our generic daunorubicin for a variety of acute leukemias in November 2001, and in November 2002 received regulatory approval to market Mitozytrex, our generic drug mitomycin for injection, for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. We have submitted the first two sections of a rolling NDA for Orathecin for the treatment of pancreatic cancer. We have also filed an ANDA for our generic paclitaxel. Our other existing product candidates, including our proprietary drugs, i.e., drugs that are advancing through our internal clinical trials, such as decitabine, and our generic drugs, i.e., drugs for which there is no patent protection and are marketed by multiple sources, will require significant additional development, lengthy clinical trials, regulatory review and approvals, and additional investment before they can be commercialized.

The FDA has substantial discretion in the drug approval process. We generally cannot predict with certainty if or when we might submit for regulatory review of any of our product candidates currently under development. Once we submit our product candidates for review, there cannot be any guarantee that the FDA or other regulatory agencies will grant approvals for any of our products on a timely basis or at all. Any approvals we obtain may not cover all the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contraindications with respect to conditions of use.

Therefore, our product development efforts may not lead to commercial drugs or other products for a number of reasons, including the failure of our product candidates to be safe and effective in clinical trials or because we have inadequate financial or other resources to pursue the programs through the clinical trial process. Except the possibility for Orathecin, we do not expect to be able to market any of our existing product candidates currently in development for a number of years, if at all.

If we fail to obtain regulatory approval of our drug candidates in a timely manner, we will not be able to generate revenues and achieve profitability.

Our failure to obtain separate regulatory approvals to market our product candidates in foreign countries could adversely affect our revenues.

Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. We must obtain separate regulatory approvals in order to market our products in other jurisdictions. Approval in the U.S., or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us, and require additional trials and additional expenses. So far, we have applied, through an affiliate, for regulatory approval to market mitomycin and paclitaxel in the United Kingdom and in certain other countries within the EU. While many of the regulations applicable to our products in these foreign countries are similar to those of the FDA, these requirements may vary widely from country to country and could delay the introduction of our products in those countries. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to commercialize our products in foreign markets.

Currently, Nipent is being sold in Europe. However, our role in Europe is currently limited to that of a supplier, and 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 depend on the efforts of our European distributors. Our revenue from supplying Nipent for European sales is currently insignificant. Our strategy is to obtain regulatory approvals to sell our products in Europe and other parts of the world, and we currently intend to contract with third party licensees or distributors for sales outside the United States. Sales outside the United States in the future may constitute a material source of revenues. As a result, any delays in obtaining regulatory approval from foreign jurisdictions will impair the commercialization of our products and our revenues.

Even if we obtain regulatory approval, we will continue to be subject to extensive government regulation that may cause us to delay the introduction of our products or withdraw our products from the market.

Even if regulatory approval is obtained, later discovery of previously unknown problems may result in restrictions of the product, including withdrawal of the product from the market. Further, governmental approval may subject us to ongoing requirements for post-marketing studies. Even if we obtain governmental approval, our manufacturing facilities and those of our third-party manufacturers are subject to unannounced inspections by the FDA and must comply with the FDA's current GMP's and other regulations. These regulations govern all areas of production, record keeping, personnel and quality control. If we or our third-party manufacturers fail to comply with any of the manufacturing regulations, we may be subject to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution.

Physicians may prescribe drugs for uses that are not described in a product's labeling for uses that differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use. Companies cannot actively promote FDA-approved drugs for off-label uses, but they may disseminate to physicians articles published in peer-reviewed journals. To the extent allowed by law, we intend to disseminate peer-reviewed articles on our products to our physician customers. If, however, our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA. For example, in November 2002 we issued a press release announcing our receipt of FDA approval to market Mitozytrex, our generic drug mitomycin for injection. In March 2003, the FDA issued a "Talk Paper" regarding this press release,

taking the position that we made certain unsupported claims about the drug and did not disclose the serious side effects such as suppressing bone marrow activity. We have responded to the FDA and we are revising our internal procedures to ensure our promotional activities and public disclosure will meet regulatory requirements.

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

Sales of our products depend in part upon the availability of reimbursement from third-party payers, such as government health administration authorities like Medicare/Medicaid, managed care providers and private health insurers. While we have not been challenged by third-party payers with respect to reimbursement of prices for our marketed products, in general third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services, which may effectively limit physicians' ability to select products and procedures.

In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. For example, currently Medicare does not reimburse self-administered products, which could cover some of our product candidates. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, we believe government agencies will continue to propose and pass legislation designed to reduce the cost of healthcare, which could further limit reimbursement for pharmaceuticals, and we anticipate that there will continue to be proposals in the U.S. to implement government control over the pricing or profitability of prescription pharmaceuticals, as is currently the case in many foreign markets. 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. The failure of the government and third-party payers to provide adequate coverage and reimbursement rates for our product candidates could adversely affect the market acceptance of our products, our competitive position and our financial performance.

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. We believe our safety procedures for these materials comply with governmental standards, and we carry insurance coverage we believe is adequate for the size of our business. We believe we are in compliance with all applicable environmental laws and regulations. However, we cannot entirely eliminate the risk of accidental contamination or injury from these materials. If an accident or environmental discharge occurs, we could be held liable for any resulting damages, which could exceed our insurance coverage and financial resources.

We currently outsource our research and development programs involving the controlled use of biohazardous materials. We believe our collaborators have in place safety procedures for these materials that comply with governmental standards. Nevertheless, if an accident does occur, our research and product development will be negatively affected.

Risks Associated with Our Business

We are dependent on the successful outcome of the clinical trials for our lead product candidate Orathecin. If our clinical data for Orathecin cannot support the submission of an NDA with the FDA or if filing or approval of the NDA is delayed, our business will be substantially harmed.

Orathecin is our lead product candidate, which we are developing for the treatment of pancreatic cancer. Pancreatic cancer is a highly lethal disease, with the poorest likelihood of survival among all of the major malignancies. Based on a study on cancer for 1988-1992 by National Cancer Institute, pancreatic cancer accounts for only 2% of all newly diagnosed cancers in the United States each year, but 5% of all cancer deaths. We believe that our Orathecin clinical program is the largest registration program ever undertaken in pancreatic cancer. To date, only two drugs have been approved by the FDA for the treatment of pancreatic cancer—gemcitabine and 5-FU. Based on the FDA's summary basis of approval, the program sizes for those two drugs were as follows: gemcitabine had 126 patients in front-line use and 63 patients in second-line use, and 5-FU was approved on data from 20 pancreatic cancer patients. We have been conducting and are close to completing three randomized Phase III registrational studies in over 1,800 patients with pancreatic cancer at over 200 study sites in North America and Europe. We commenced clinical trials in 1998, and more than 2,700 patients have been enrolled in the studies. Our ongoing Orathecin clinical trials are large and complex and have required a significant amount of financial commitment and human resources. Over the years, we have expended substantial 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, and from 1998 to December 2002 we have spent approximately 25% of our research and development expenses, or approximately \$58 million, on the Orathecin program, and we expect to spend an additional \$5 million in 2003 to complete the clinical trials for Orathecin and assemble the NDA for regulatory approval for the product. In addition, we must establish sales and marketing capability to support the worldwide sale of Orathecin, either by entering into a sales and marketing agreement with a collaborator or to build up our own sales force, which will involve substantial costs and expenses. If we are successful in obtaining necessary regulatory approval and successfully commercialize the product, we believe sales of Orathecin could generate more than \$100 million in revenues annually, which could constitute more than 80% of our future revenues. These sales projections are based on the fact that, according to Eli Lilly's 2001 annual report, gemcitabine (the last drug approved for pancreatic cancer) has sales of more than \$500 million dollars annually, yet we believe that gemcitabine and 5-FU do not adequately serve the market of refractory pancreatic cancer patients. In addition, administration of gemcitabine and 5-FU require intravenous injection, while Orathecin is taken orally. We believe that based on these factors, in combination with our commercial experience, we can reasonably expect to achieve at least 20% of the sales of gemcitabine with Orathecin, although there can be no assurance in this regard even if we receive the regulatory approval.

Given the large scale, the complexity of the clinical trials, and the inherent uncertainties associated with clinical trials of such magnitude and complexity, there can be no assurance that the data or statistical analysis from our trials will support regulatory approval or that we will not be required to perform additional studies before seeking regulatory approval. For example, the trial design of these studies allows patients who initially were being treated with gemcitabine or other therapies to switch over to treatment 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 our Orathecin studies that have actually crossed over to treatment with Orathecin has significantly exceeded the number anticipated and was greater than 40% in two of our Phase III studies. The extent of this

cross over will likely negatively affect the statistical analysis of the study, making it difficult to determine if the product is effective. We cannot predict how this cross-over percentage will affect regulatory approval, but additional trials may be required before we can obtain regulatory approval.

We have submitted the first two sections of a "rolling" NDA with the FDA, and anticipate completing our filing during the second quarter of 2003. However, the approval process may take a significant amount of time and we may not be approved. The FDA's approval of our application will be based on its review of Orathecin's safety and efficacy. Important factors to be taken into account in the FDA's review will include, among other things, the overall survival of patients randomized to receive Orathecin, time to disease progression as well as toxicities seen in patients who were treated with Orathecin. If our Orathecin development activities are unsuccessful for these or other reasons and if we fail to obtain the FDA approval in a timely fashion, if at all, we will not be able to realize the projected revenues, have sufficient funds to support another program or continue our other clinical trials, and we may be forced to substantially scale down our operations.

The fast track designation of Orathecin may not actually lead to a faster regulatory review or approval.

If a drug is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and the drug demonstrates the potential to address unmet medical needs for the condition, the drug sponsor may apply for FDA fast track designation. The fast track classification does not apply to the product alone, but applies to the combination of the product and the specific indication for which it is being studied. Under fast track provisions, the FDA is committed to working with the sponsor for the purpose of expediting the clinical development and evaluation of the drug safety and efficacy for the fast track indication. A fast track designation will allow the pharmaceutical company sponsor to submit a rolling NDA, which will allow the FDA to initiate review of sections of the application before it is complete. In some cases, a fast track designated product may also qualify for priority review, or review within a six-month time frame from the time an NDA is completed and filed.

Although we have obtained a fast track designation from the FDA for Orathecin for the treatment of patients with locally advanced or metastatic pancreatic cancer that is resistant or refractory to two or more chemotherapies, we cannot guarantee a faster development process, review or approval compared to the conventional FDA procedures. Orathecin may not be granted priority review, or review within six months, and our fast track designation may be withdrawn by the FDA if the FDA believes that such designation is no longer supported by emerging data from our clinical development program. Our fast track designation does not guarantee that we will qualify for or be able to take advantage of the accelerated approval procedures, which are procedures that allow the FDA to approve a drug, intended to treat serious or life threatening illnesses, based upon a surrogate end point that is reasonably likely to predict clinical benefit. Even if the accelerated approval procedures are available to us, we may elect to use the traditional approval process for strategic and marketing reasons. If Orathecin is approved under the accelerated approval procedures, we will most likely be required to conduct Phase IV studies to provide confirmatory evidence that Orathecin is safe and effective and provides a clinically meaningful benefit to patients. If we fail to verify that Orathecin is safe, effective and provides a clinically meaningful benefit to patients, our FDA approval can be withdrawn on an expedited basis. Accelerated approval will also require that we submit all promotional labeling and advertising to the FDA for pre-approval prior to dissemination of these materials. Furthermore, if serious adverse effects are identified at any time after marketing, our approval may be rapidly revoked and we will not be allowed to continue to market the drug. If the regulatory approval for Orathecin is delayed, or the approval is withdrawn or revoked for any reason, our business will be substantially harmed.

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

In December 1999, we entered into agreements with Abbott Laboratories pursuant to which Abbott would market and distribute our drug candidate Orathecin and provide milestone payments and invest in our shares of stock. We would have co-promoted Orathecin with Abbott in the United States and Abbott would have 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 transfer 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.

The Orathecin related agreements were terminated by the parties in March of 2002. While we believe that the termination was 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 that we deem very beneficial. Specifically, we regained all marketing rights to Orathecin worldwide, are no longer obligated to share profits from product sales of Orathecin, and Abbott no longer has the option to purchase up to 49% of our outstanding shares, the right of first discussion with respect to our product portfolio and the right of first refusal to acquire us. As a result, we are able to market and sell Orathecin ourselves or to explore strategic partnerships with other pharmaceutical companies.

In connection with these agreements, Abbott made a \$26.5 million investment in our shares of common stock in January 2000, and a \$2.5 million equity milestone payment in July 2001. By terminating the agreement, we have foregone the opportunity to receive future milestone payments and equity investments from Abbott (in the aggregate amount of up to \$52.5 million), potential royalty payments and other benefits from a well established and respected pharmaceutical company, including our access to Abbott's worldwide sales capability. In addition, the termination of the agreements may be perceived negatively by other potential partners, and unless we are successful with our regulatory approval of Orathecin, we may not be able to establish collaboration relationships with established pharmaceutical companies for Orathecin, if we elected to pursue such relationships.

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 regulatory approval and/or their reimbursement support of their use for treatment of additional diseases. We are currently marketing Nipent for hairy cell leukemia, and revenues from selling Nipent provided over 90% of our revenues in the past three years. We believe Nipent has promise for treatment of a variety of diseases and 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 or additional regulatory approvals, we will not be able to increase our revenue above the current level.

If we cannot complete our clinical trials for decitabine and cannot receive regulatory approval, we may not realize future revenues.

We have initiated Phase III clinical trials with decitabine for treatment of advanced myelodysplastic syndrome, and we completed patient enrollment in March 2003. We have also received orphan drug designation for decitabine for the treatment of myelodysplastic syndrome in the United States and

Europe, and for the treatment of sickle cell anemia in the United States. There is no assurance that we will be able to complete our clinical trials, or that the clinical trial results will support submission of an NDA or regulatory approval. Even if we complete the clinical trials and submit an NDA, the approval process may take a significant amount of time and we may not receive approval. Moreover, the future sales of decitabine could constitute a material source of our product revenues. According to a paper published in Nature Review in 2002, decitabine reverses the biological mechanism that has been implicated as a fundamental defect in cancer. We believe that potential sales of this product may equal or exceed that of Orathecin and thus amount to \$100 million annually, although there can be no assurance in this regard even if we receive the regulatory approval. As a result, if our decitabine development activities are unsuccessful for any reason, future revenues will not be realized.

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.

Even if we obtain governmental approval of our product candidates, our manufacturing facilities and those of our contract manufacturers are subject to unannounced inspections by the FDA and must comply with the FDA's cGMP and other regulations. These regulations govern all areas of production, record keeping, personnel and quality control. If we or our contract manufacturers fail to comply with any of the manufacturing regulations, we may be subject to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution.

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 Orathecin. Our manufacturing strategy presents the following risks:

- delays in scale-up to quantities needed for multiple clinical trials or failure to manufacture such quantities to our specifications, or deliver such quantities on the dates we require, could cause delay or suspend 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 cGMP's 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
- in the future 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 product candidates under development, interfere with current sales and entail higher costs.

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 are and 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, and, to our knowledge, none of our manufacturers have had problems complying with regulatory requirements for our products. At this time we do not intend to replace our manufacturing or storage contracts.

However, we may be unable to maintain our current relationships. In the event we need to replace or seek new manufacturing arrangements, we may have difficulty locating and entering into arrangements with qualified contract manufacturers on acceptable terms, if at all. We are aware of only a limited number of companies on a worldwide basis who operate manufacturing facilities in which our products can be manufactured to our specifications and in compliance with cGMP's. It could take several months, or significantly longer for a new contract manufacturing facility to obtain FDA approval and to develop substantially equivalent processes for the production of our products. We may not be able to contract with any of these companies on acceptable terms, if at all. For example, the company that had been purifying our Nipent finished product filed for bankruptcy in mid 2001. We contracted with a new manufacturer for the purification of Nipent in mid 2001, and the manufacturer was qualified by the FDA in May 2002. We experienced unusually low inventory levels during the first quarter of 2002, while we were waiting for the new company to be qualified by the FDA.

Currently we store the majority of the unpurified, bulk form of Nipent at the manufacturer's 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. While the manufacturer carries adequate insurance consistent with industry standard and we also carry insurance for drug storage, such event would inevitably cause delays in distribution and sales of our products and harm our operating results.

We do not currently intend to manufacture any pharmaceutical products, although we continually evaluate our options for commercial production of our products, including the possibility of establishing our own commercial scale manufacturing facility. 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. 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.

If our suppliers cannot provide the product or components we require, our product sales and revenue could be harmed.

We rely on third party suppliers to provide us with certain components used in our products under development, including Orathecin and decitabine. Relying on third party suppliers makes us vulnerable to component part failures and to interruptions in supply, either of which could impair our ability to conduct clinical tests or to ship our products to our customers on a timely basis. Using third party vendors makes it difficult and sometimes impossible for us to maintain quality control, manage inventory and production schedules and control production costs. Vendor lead times to supply us with ordered components vary significantly and can exceed six months or more. Both now and as we expand our need for manufacturing capacity, we cannot be sure that our suppliers will furnish us with required components when we need them. These factors could make it more difficult for us to effectively and efficiently manufacture our products, and could adversely impact our clinical trials, product development and sales of our products.

Some suppliers are our only source for certain product or a particular component, which makes us vulnerable to cost increases and supply interruptions. We generally rely on one manufacturer for each product. We have one manufacturer for the future production of our generic compounds required for both our Extra and generic dosage forms. We rely on one manufacturer for Nipent, a sole source supplier for the purification and processing of pentostatin, which is used in the manufacturing of Nipent, and a sole source supplier for the ingredient used in the purification of pentostatin. We also rely on sole source suppliers for mitomycin products and components used in the production of Mitozytrex.

Vendors may decide to limit or eliminate sales of certain products to the medical industry due to product liability or other concerns. For example, one component used in the purification of pentostatin is no longer commercially available, although we believe our current inventory of this component will last four to five years during which time we believe we will be able to qualify a substitute. Therefore, for products or components for which we rely on a sole source, in the event the supplier decides not to manufacture the product or go out of business, or decides to cut off our supply, we may be unable to locate replacement supply sources, or the sources that we may locate may not provide us with similar reliability or pricing and our business could suffer. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval for a replacement component, produce the component or redesign the related product, which would cause significant delay and could increase our manufacturing costs. Any of these events could adversely impact our sales and results of operations.

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 approximately 34 sales and marketing personnel focusing on the sale of our products to hospitals and hospital buying groups, we have contractual relationships with third parties and anticipate relying on third parties to distribute, sell and market some of our primary products. We currently rely on third parties to distribute our products and expect to continue to do so in the future. For example, Abbott is our exclusive U.S. distributor of Nipent until 2005. 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 other products if we were to receive regulatory approval.

We continue to evaluate our options and explore opportunities with respect to sales and marketing of Orathecin, if approved for sale. We may decide to enter into arrangements with a strategic partner. However, we may not be able to negotiate such arrangement on acceptable terms, if at all. Moreover, such arrangements will involve sharing of sales profit, may require us to relinquish certain rights to our products or marketing territories, and may impose other limitations on our business operations. Further, if we enter into a collaborative relationship with a large pharmaceutical company with established distribution systems and direct sales forces to market Orathecin, we cannot assure you that we will be able to maintain such relationship on acceptable terms, if at all.

If we are unable to enter into third-party arrangements or if our arrangements with third parties are not successful, we will need to substantially expand our sales and marketing force and build our sales and distribution capabilities, which will require significant expenses. We may not succeed in expanding and 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. Our inability to upgrade our sales expertise and in-house sales and distribution capabilities may limit our ability to gain market acceptance for Orathecin worldwide and generate revenues. 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, we will not be able to market or sell our products effectively and our business, financial condition and results of operations will be materially and adversely affected.

Our collaborative relationships with AVI BioPharma, Inc. and other third party collaborators could cause us to expend significant money on development costs with no assurance of financial return.

From time to time we enter into collaboration relationships with third parties to co-develop and market products. For example, we have collaborative relationships with AVI BioPharma, Inc. whereby in exchange for marketing and other rights in the United States for Avicine, AVI's proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors, we made significant equity investments in AVI, and agreed to make substantial milestone payments to fund AVI's clinical development and regulatory activities.

Specifically, in consideration of past research and development performed by AVI, in 1999 and 2000 we made substantial equity investments in AVI in the aggregate amount of more than \$27 million (including \$7.5 million cash and 447,826 shares of our common stock), in exchange for 2,684,211 shares of AVI common stock. Moreover, 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 the time the transactions were entered, the chief executive officer of AVI, Dennis Burger, was a member of our Board of Directors (Mr. Burger resigned from our Board in May of 2002). Our president and chief executive officer 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.

In addition, we also entered into an arrangement with Peregrine Pharmaceuticals in February 2001, pursuant to which we licensed a drug-targeting technology known as Vascular Targeting Agent, which is a proprietary platform designed to specifically target a tumor's blood supply and subsequently destroy the tumor with various attached therapeutic agents. The licensed technology is specially related to Vascular Endothelial Growth Factor. Under the agreement, we made an up-front equity investment in Peregrine of \$600,000 and will be obligated to make 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 we commercialize using the VEGF technology.

The above relationships require substantial financial commitments from us, and at the same time the product developments are subject to the same regulatory requirements, risks and uncertainties associated with the development of our other product candidates. AVI's Avicine will require significant additional expenditures to complete the clinical development necessary to gain marketing approval from the FDA and equivalent foreign regulatory agencies. In addition, Avicine and other 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 collaborative relationships are not successful, our product developments will be adversely affected, and our investments and efforts devoted to the product developments will be wasted.

If we are not able to maintain and successfully establish new collaborative and licensing arrangements with third parties, our product development and business will be harmed.

Our business model is based on establishing collaborative relationships with other parties both to license compounds upon which our products and technologies are based and to manufacture, market and sell our or our collaborators' products. As a development company we must have access to compounds and technologies to license for further development. For example, we licensed the exclusive worldwide royalty-bearing rights to Orathecin from the Stehlin Foundation for Cancer Research, and

we also established relationships with suppliers and manufacturers to manufacture our compounds and products. Additionally, we have a collaborative relationship with AVI for the development, marketing and sales of Avicine. Due to the expense of the drug approval process it is critical for us to have relationships with established pharmaceutical companies to offset some of our development costs in exchange for a combination of development, marketing and distribution rights. We formerly had a significant relationship with Abbott for the sales and marketing of Orathecin. To facilitate the commercialization of Orathecin, we may decide to establish a new collaborative relationship with another party.

We from time to time also enter into discussions with various companies regarding the establishment of new collaborations. If we are not successful in establishing new collaborative partners for our product candidates, we may not be able to pursue further development of such product candidates and/or may have to reduce or cease our current development programs, which would materially harm our business. Even if we are successful in establishing new collaborations, they are subject to numerous risks and uncertainties including the following:

- Our ability to negotiate acceptable collaborative arrangements;
- Our existing collaborative arrangements may not be successful or may not result in commercially viable products;
- Collaborative partners are free to pursue alternative technologies either on their own or with others, including our competitors, for the diseases targeted by our programs and products;
- If our partners fail to fulfill their contractual obligations or terminate the relationships with us, we may be required to seek other partners, or expend substantial resources to pursue these activities independently, which may not be successful; and
- Our ability to manage, interact and coordinate our timelines and objectives with our strategic and collaborative partners may not be successful.

In addition, our collaborators may undergo business combinations, which could have the effect of making a collaboration with us less attractive to them for a number of reasons. For example, if an existing collaborator purchases a company that is one of our competitors, that company could be less willing to continue its collaboration with us. In addition, a company that has a strategy of purchasing companies with attractive technologies might have less incentive to enter into a collaboration agreement with us. Moreover, disputes may arise with respect to the ownership of rights to any technology or products developed with any current or future collaborator. Lengthy negotiations with potential new collaborators or disagreements between us and our collaborators may lead to delays or termination in the research, development or commercialization of product candidates or result in time-consuming and expensive litigation or arbitration.

Any failure in maintaining relationships with our collaborators could materially affect our product development and commercialization.

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

The pharmaceutical industry in general and oncology sector in particular is highly competitive and subject to significant and rapid technological change. Our competitors and probable competitors include established companies such as Eli Lilly & Co., Ortho Biotech, Berlex, Bristol-Myers Squibb Company, Immunex Corp and others.

Many of our competitors and research institutions are addressing the same diseases and disease indications and working on products to treat such diseases as we are, and have substantially greater financial, research and development, manufacturing and marketing experience and resources than we

do and represent substantial long-term competition for us. Some of our competitors have received regulatory approval of or are developing or testing product candidates that compete directly with our product candidates. For example, while we received orphan drug status for Orathecin and there is currently no competitor in the oral delivery market for the treatment of pancreatic cancer, there are approved drugs for the treatment of pancreatic cancer, including gemcitabine by Eli Lilly. For another example, Berlex's fludarabine and Ortho Biotech's cladribine compete with our Nipent in the leukemia market.

In addition, many of these competitors, either alone or together with their customers, have significantly greater experience than we do in developing products, undertaking preclinical testing and clinical trials, obtaining FDA and other regulatory approvals, and manufacturing and marketing products. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing products before we do. If we commence commercial product sales of our product candidates, we will be competing against companies with greater marketing and manufacturing capabilities, areas in which we have limited or no experience.

Developments by competitors may render our product candidates or technologies obsolete or non-competitive. These competitors, either alone or with their customers, may succeed in developing technologies or products that are more effective than ours. We also face and will continue to face intense competition from other companies for collaborative relationships, for establishing relationships with academic and research institutions, and for licenses to proprietary technology.

Our products that are under patent protection face intense competition from competitors' proprietary products. This competition may increase as new products enter the market. We also face increasing competition from lower-cost generic products after patents on our proprietary products expire. Loss of patent protection typically leads to a rapid loss of sales for that product and could affect future results. As new products enter the market, our products may become obsolete or our competitors' products may be more effective or more effectively marketed and sold than our products. If we fail to maintain our competitive position, this could have a material adverse effect on our business and results of operations.

Our competitive positions in our generic drugs are uncertain and subject to risks. The market for generic drugs, including the pricing for generic drugs, is extremely competitive. As a result, unless our generic drugs are the first or among the initial few to launch, there is a high risk that our products would not gain meaningful market share, or we would not be able to maintain our price and continue the product line. Moreover, marketing of generic drugs is also subject to regulatory approval, and we may not be able to obtain such approval before our competitors to gain the competitive advantage.

We are developing generic and Extra products based upon compounds which may be covered by patents held by third parties that are expected to expire or already expired. These compounds may be also the subject of method, formulation, and manufacturing process patents held by third parties. If these patents do not expire as anticipated or are expanded in scope, we will not be able to develop our generic and Extra products as planned.

We developed, or are in the process of developing, and are planning to market several generic and Extra products based on existing compounds. Specifically, with respect to our generic products, we received an ANDA approval of our generic mitomycin for solid tumors, and daunorubicin for a variety of acute leukemias, and have filed an ANDA for our generic paclitaxel. We are currently selling mitomycin and in the process of commercializing daunorubicin.

Our proprietary Extra technology is a platform technology that employs the use of an inert chemical excipient, cyclodextrin, combined with a drug. Most anticancer drugs are cytotoxic, and most must be administered intravenously. If a vein is missed on injection, the drug can leak to surrounding tissue, causing ulceration that sometimes requires plastic surgery to correct. Our proprietary Extra

technology is designed to “shield” the drug from the injection site, thus providing the patient protection from tissue ulceration. It may increase the relative solubility of hard-to-dissolve anticancer drugs, hence increasing its stability or shelf life. However, each of these benefits must be supported by appropriate data and approved by the FDA before we can make any claim in this regard. Our first product utilizing our Extra technology, Mitozytrex, which is an Extra formulation of generic mitomycin, was approved by the FDA in November 2002 for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Currently, we cannot promote Mitozytrex as providing any injection site ulceration protection, nor can we promote any increased stability, solubility or shelf life extension, as compared to generic mitomycin. We must develop and submit additional data to the FDA and receive FDA approval before we can make these claims. We are currently exploring marketing opportunities and/or marketing partners for Mitozytrex.

So far we have spent approximately \$6 million on developing and marketing our generic and Extra products. We have currently completed our pre-commercial investment in developing Mitozytrex, and as of now we have not committed to an internal budget for additional “Extra” development programs. In addition, we have no further generic drug development commitments, as we are focusing on developing our proprietary drug candidates.

We do not hold any intellectual property rights as to the underlying compounds on which our generic or Extra products are based. We may in the future evaluate the generic drugs market and develop additional generic or proprietary Extra products based on these compounds, which may also be the subject of method, formulation and manufacturing process patents held by third parties. Our development of generic or Extra products may also take place prior to, but in anticipation of, the expected expiration of existing patent protection for drugs developed by third parties. However, if existing patent protection on such products is otherwise maintained, extended or expanded, it is unlikely that we will be able to market our own generic or Extra products without obtaining a license from the patent owner, which may not be available on commercially acceptable terms, if at all.

Our ability to protect our intellectual property rights will be critically important to the success of our business, and we may not be able to protect these rights in the United States or abroad.

Our business operation and success depends in part on our ability to obtain patents, protect trade secrets, operate without infringing the proprietary rights of others and prevent others from infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We attempt to protect our intellectual property position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Currently we have acquired licenses to or assignments of at least 37 U.S. patents covering various aspects of our proprietary drugs, including 29 patents for Orathecin, 5 patents for Nipent, 5 patents for our paclitaxel related products and 2 patents for our 5-beta-steroid related compounds. These issued U.S. patents will begin to expire in October 2012. We have been granted patents and have received patent licenses relating to our Extra technology, Partaject, and Oral Prodrug technologies, among which at least 5 patents are issued to us. In addition, we are prosecuting a number of patent applications for drug candidates that we are not actively developing at this time.

From time to time we receive correspondence inviting us to license patents from third parties. 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 product development and harm our business.

We also have patents or licenses to patents issued outside of the United States, including Europe, Australia, Japan, Canada, Mexico and New Zealand. In addition, we have patent applications pending in these regions and countries as well as in China, Hungary and Israel. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in these countries outside the United States, may limit the protection we have on patents issued or licensed to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the United States. To minimize our costs and expenses and to maintain effective protection, we focus our patent and licensing activities within the European Union, Canada and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

The pharmaceutical fields are characterized by a large number of patent filings involving complex legal and factual questions, and, therefore, we cannot predict with certainty whether our patents will be enforced. 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. In addition, third parties may challenge, invalidate or circumvent any of our patents, once they are issued. Thus, any patents that we own or license from third parties may not provide adequate protection against competitors. Our pending patent applications and those we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of 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.

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 product candidates, 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. We carry key man insurance on Dr. Rubinfeld. Except for Dr. Rubinfeld (whose current employment contract will expire by December 31, 2003), none of our officers or employees has any term employment contracts. During 2003, we intend to establish a succession plan for our senior management. We know of no plans by any of our executive officers or key employees to retire or resign from our company. If any of our executive officers decides to leave the company and we cannot locate qualified replacement in time to allow a smooth transition, our business operation may be adversely affected.

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, and we have been successful in hiring, and retaining or replacing our employees. However, we may be at a disadvantage to the extent that potential employees may favor larger, more established employers.

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

Clinical trials and commercial use of our current and potential products may expose us to liability claims from the use or sale of these products. Consumers, healthcare providers, pharmaceutical companies or others selling such products might make claims of this kind. We may experience financial losses in the future due to product liability claims. We have obtained limited product liability insurance coverage for our products and clinical trials, under which the coverage limits are \$10 million per occurrence and \$10 million in the aggregate. While we believe that this insurance is reasonable and adequate, we cannot assure you that this coverage will be adequate to protect us in the event of a claim. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development. We may not be able to obtain or maintain insurance coverage in the future at a reasonable cost or in sufficient amounts to protect us against losses. If third parties bring a successful product liability claim or series of claims against us for uninsured liabilities or in excess of insured liabilities, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates and our business and results of operations will be adversely affected.

Earthquake or other natural or man-made disasters and business interruptions could adversely affect our business.

Our operations are vulnerable to interruption by fire, earthquake, power loss, floods, telecommunications failure and other events beyond our control. In addition, our business operation is susceptible to disruption as a result of natural disasters such as earthquakes. So far we have never experienced any significant disruption of business operation as a result of earthquakes or other natural disasters. While we carry adequate business interruption insurance and have in place a contingency recovery plan, any significant business interruption could cause delays in our drug development and sales and harm our business.

Provisions in our certificate of incorporation, bylaws and applicable Delaware law may prevent or discourage third parties or stockholders from attempting to replace our management.

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.

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. Nevertheless, 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, and may have the effect of preventing or discouraging third parties or stockholders from attempting to replace our management.

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. In particular, our equity investment in AVI BioPharma has fluctuated significantly in 2002, and as a result we wrote down the investment by \$8.2 million as the decline was deemed to be other than temporary. 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-25 in Item 15 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 definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2003. 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 definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2003.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

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 definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2003. Information regarding our Equity Compensation Plans may be found in Part II, Item 5 of this report.

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 definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by April 30, 2003. 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.

ITEM 14. CONTROLS AND PROCEDURES.

(a) Evaluation Of Disclosure Controls And Procedures

Our chief executive officer and our chief financial officer, after evaluating our "disclosure controls and procedures" (as defined in Securities Exchange Act of 1934 (the "Exchange Act") Rules 13a-14(c) and 15-d-14(c)) as of a date (the "Evaluation Date") within 90 days before the filing date of this Annual Report on Form 10-K, have concluded that as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b) Changes In Internal Controls

Subsequent to the Evaluation Date, there were no significant changes in our internal controls or in other factors that could significantly affect our disclosure controls and procedures, nor were there any significant deficiencies or material weaknesses in our internal controls. As a result, no corrective actions were required or undertaken.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

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

1. *Financial Statements.* The following financial statements of the Company 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.
(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.

<u>Exhibit Number</u>	<u>Description of Document</u>
(bb)(s)10.14	Executive Employment, Confidential Information, Invention Assignment, and Arbitration Agreement dated March 1, 2002 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).
(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.

<u>Exhibit Number</u>	<u>Description of Document</u>
(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.
(bb)10.54	Research Agreement (Camptothecin) dated November 15, 1999 between the Registrant and Clayton Foundation for Research.
(bb)10.55	Research Agreement (Paclitaxel) dated November 15, 1999 between the Registrant and Clayton Foundation for Research.
(bb)10.56	License Agreement (Camptothecin) dated November 15, 1999 between the Registrant and Research Development Foundation.
(bb)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.

<u>Exhibit Number</u>	<u>Description of Document</u>
(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.
(ii)10.69	Securities Purchase Agreement dated September 23, 2002 by and between the Registrant and the purchasers named therein.
(ii)10.70	Registration Rights Agreement dated September 23, 2002 by and between the Registrant and the purchasers named therein
(ii)10.71	Form of Warrant dated September 24, 2002 issued to the purchasers under the Securities Purchase Agreement dated September 23, 2002
(ii)10.72	Warrant dated September 24, 2002 issued Paul Revere LLC
(jj)10.73	Registration Rights Agreement dated March 22, 2001 by and between the Registrant and The Kriegsman Group
(jj)10.74	Warrant A Agreement dated March 22, 2001 by and between the Registrant and The Kriegsman Group
(kk)10.75	Securities Purchase Agreement dated February 26, 2003 by and among the Registrant and the purchasers named therein
(kk)10.76	Form of Senior Exchangeable/Convertible Note dated February 26, 2003 issued to the purchasers under the Securities Purchase Agreement dated February 26, 2003
(kk)10.77	Registration Rights Agreement dated February 26, 2003 by and among the Registrant and the purchasers named therein
(kk)10.78	Form of Warrant dated February 26, 2003 issued to the purchasers under the Securities Purchase Agreement dated February 26, 2003
(kk)10.79	Pledge Agreement dated February 26, 2003 executed by the Registrant in favor of the purchasers under the Securities Purchase Agreement dated February 26, 2003
(kk)10.80	Securities Account Control Agreement dated February 26, 2003 by and among the Registrant, the purchasers named therein, and Mellon Investor Services LLC
(ll)10.81	Pentostatin Supply Agreement dated December 13, 2002 between the Registrant and Hauser Technical Services, Inc.
(ll)10.82	License Agreement dated February 13, 2001 between the Registrant and Peregrine Pharmaceuticals, Inc.
23.1	Consent of Ernst & Young LLP, Independent Auditors
99.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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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 the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2002.
- (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.
- (ii) Incorporated by reference from the Registrant's Report on Form 8-K dated September 23, 2002 filed with the Securities and Exchange Commission on October 1, 2002.
- (jj) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (Reg. No. 333-100707) filed with the Securities and Exchange Commission on October 24, 2002.
- (kk) Incorporated by reference from the Registrant's Report on Form 8-K dated February 26, 2003 filed with the Securities and Exchange Commission on February 27, 2003.
- (ll) Confidential treatment is being requested for certain portions of these exhibits.
 - (b) *Reports on Form 8-K.*
None
 - (c) *Exhibits.* See Item 15(a) above.
 - (d) *Financial Statement Schedules.* See Item 15(a) above.

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

Board of Directors and Stockholders
SuperGen, Inc.

We have audited the accompanying consolidated balance sheets of SuperGen, Inc. as of December 31, 2002 and 2001, 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, 2002. 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, 2002 and 2001 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the consolidated financial statements, in 2002 the Company changed its method of accounting for goodwill.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 18, 2003,
except for Note 12, as to which the date is
February 26, 2003

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

	December 31,	
	2002	2001
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,241	\$ 17,650
Marketable securities	12,081	50,178
Accounts receivable, net	5,405	2,509
Due from related parties	402	124
Inventories	2,166	1,833
Prepaid expenses and other current assets	1,771	1,465
Total current assets	30,066	73,759
Marketable securities - non-current	2,100	6,164
Investment in stock of related parties	14,071	29,934
Due from related parties	390	867
Property, plant and equipment, net	5,443	6,345
Developed technology at cost, net	744	1,090
Goodwill, net	731	731
Other intangibles, net	269	426
Restricted cash	3,489	3,367
Other assets	30	34
Total assets	\$ 57,333	\$ 122,717
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 4,506	\$ 8,767
Payable to AVI BioPharma, Inc	421	1,170
Deferred revenue	1,000	1,000
Accrued employee benefits	1,621	1,460
Total current liabilities	7,548	12,397
Deferred rent	616	355
Deferred revenue - non-current	1,167	2,167
Total liabilities	9,331	14,919
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; 32,892,674 and 32,821,163 shares issued and outstanding at December 31, 2002 and December 31, 2001, respectively	33	33
Additional paid in capital	282,010	284,115
Deferred compensation	(47)	(122)
Accumulated other comprehensive gain (loss)	(796)	7,499
Accumulated deficit	(233,198)	(183,727)
Total stockholders' equity	48,002	107,798
Total liabilities and stockholders' equity	\$ 57,333	\$ 122,717

See accompanying notes to consolidated financial statements

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

	Year ended December 31,		
	2002	2001	2000
Revenues:			
Net sales revenue	\$ 14,188	\$ 10,451	\$ 6,102
Other revenue	1,081	1,000	987
Total revenue	<u>15,269</u>	<u>11,451</u>	<u>7,089</u>
Operating expenses:			
Cost of sales	4,491	2,727	1,641
Research and development	29,895	47,833	31,387
Selling, general, and administrative	23,525	22,079	15,964
Acquisition of in-process research and development	—	—	1,585
Total operating expenses	<u>57,911</u>	<u>72,639</u>	<u>50,577</u>
Loss from operations	(42,642)	(61,188)	(43,488)
Interest income	1,662	5,622	8,205
Other expense	<u>(8,491)</u>	<u>—</u>	<u>—</u>
Net loss	<u>\$(49,471)</u>	<u>\$(55,566)</u>	<u>\$(35,283)</u>
Basic and diluted net loss per share	<u>\$ (1.52)</u>	<u>\$ (1.69)</u>	<u>\$ (1.04)</u>
Weighted average shares used in basic and diluted net loss per share calculation	<u>32,542</u>	<u>32,925</u>	<u>33,822</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, 2000	25,478	\$25	\$138,486	(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
Comprehensive loss:							
Net loss	—	—	—	—	—	(49,471)	(49,471)
Other than temporary decline in value of investments	—	—	—	—	8,491	—	8,491
Other comprehensive loss - Change in unrealized gain (loss) on investments	—	—	—	—	(16,786)	—	(16,786)
Comprehensive loss							(57,766)
Issuance of common stock upon exercise of warrants and stock options	9	—	80	—	—	—	80
Issuance of common stock in private placement, net of offering costs of \$310	1,806	2	4,204	—	—	—	4,206
Issuance of common stock to Orphan Europe connection with research agreements	65	—	300	—	—	—	300
Issuance of common stock in connection with employee stock purchase plan	78	—	314	—	—	—	314
Compensation expense from stock option grants to consultants and vendors	—	—	169	—	—	—	169
Amortization of deferred compensation	—	—	—	75	—	—	75
Repurchase of common stock	(1,886)	(2)	(7,172)	—	—	—	(7,174)
Balances at December 31, 2002	32,893	\$33	\$282,010	\$(47)	\$ (796)	\$(233,198)	\$ 48,002

See accompanying notes to consolidated financial statements

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

	Year ended December 31,		
	2002	2001	2000
Operating activities:			
Net loss	\$(49,471)	\$(55,566)	\$(35,283)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,324	1,138	667
Amortization of intangible assets	503	605	891
Amortization of deferred compensation	75	75	230
Amortization of deferred revenue	(1,000)	(1,000)	(894)
Loss on disposal of property and equipment	—	132	13
Other than temporary decline in value of investments	8,491	—	—
Expense related to stock options and warrants granted to non-employees	169	890	657
Non-cash charge related to research or license agreements	300	369	—
Non-cash charge related to acquisition of in-process research and development	—	—	1,585
Changes in operating assets and liabilities:			
Accounts receivable	(2,896)	(486)	(269)
Inventories	(333)	(185)	(280)
Prepaid expenses and other assets	(302)	1,154	1,090
Due from related parties	199	(620)	(371)
Other receivables	—	1,283	3,650
Restricted cash	(122)	(155)	(3,212)
Accounts payable and other liabilities	(4,588)	2,531	5,447
Net cash used in operating activities	<u>(47,651)</u>	<u>(49,835)</u>	<u>(26,079)</u>
Investing activities:			
Purchases of marketable securities	(31,494)	(48,969)	(62,755)
Sales or maturities of marketable securities	72,732	53,124	10,163
Purchase of equity investments	—	(403)	(5,000)
Purchases of property and equipment	(422)	(2,177)	(2,745)
Net cash provided by (used in) investing activities	<u>40,816</u>	<u>1,575</u>	<u>(60,337)</u>
Financing activities:			
Issuance of common stock, net of issuance costs	4,600	4,296	136,997
Repurchases of common stock	(7,174)	(9,117)	(2,396)
Net cash used in financing activities	<u>(2,574)</u>	<u>(4,821)</u>	<u>134,601</u>
Net decrease in cash and cash equivalents	(9,409)	(53,081)	48,185
Cash and cash equivalents at beginning of period	17,650	70,731	22,546
Cash and cash equivalents at end of period	<u>\$ 8,241</u>	<u>\$ 17,650</u>	<u>\$ 70,731</u>
Supplemental Disclosures of Cash Flow Information:			
Non-cash investing and financing activities:			
Issuance of common stock related to research agreement	\$ —	\$ —	\$ 740
Issuance of common stock related to equity investment in related party	—	—	12,174

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") and three 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, with Nipent sales representing 91% in 2002, 96% in 2001 and 95% in 2000. We recognize sales revenue upon shipment and related transfer of title to customers, with allowances provided for bad debt and estimated returns. The allowances for bad debt and sales returns were \$118,000 and \$108,000 at December 31, 2002, and 2001, respectively. Actual amounts for returns and allowances may differ from the our estimates and such differences could be material to the consolidated financial statements. The provision for the allowances was \$112,000 in 2002, \$265,000 in 2001, and \$138,000 in 2000.

Cash advance payments received in connection with distribution agreements or research grants are deferred and recognized ratably over the period of the respective agreements or until services are performed.

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 \$756,000 in 2002, \$593,000 in 2001, and \$806,000 in 2000.

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

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

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 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 results in the establishment of a new cost basis for the security.

During the year ended December 31, 2002, we recorded a write-down of \$8,491,000 related to other than temporary declines in the value of our marketable securities and investment in stock of related parties. We had no such write-downs in 2001 or 2000.

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>2002</u>	<u>2001</u>
Raw materials	\$ 126	\$ 176
Work in process	1,196	960
Finished goods	<u>844</u>	<u>697</u>
	<u>\$2,166</u>	<u>\$1,833</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

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

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 which was estimated to 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>2002</u>	<u>2001</u>
Land and building	\$ 2,433	\$ 2,433
Leasehold improvements	2,591	2,564
Equipment	903	816
Furniture and fixtures	3,386	3,275
Total property and equipment	9,313	9,088
Less accumulated depreciation and amortization	<u>(3,870)</u>	<u>(2,743)</u>
Property, plant and equipment, net	<u>\$ 5,443</u>	<u>\$ 6,345</u>

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. Cost basis of the developed technology was \$1,936,000 at December 31, 2002 and 2001. Accumulated amortization was \$1,192,000 and \$846,000 at December 31, 2002 and 2001, respectively.

Goodwill

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"). Under SFAS 142, which became effective for fiscal years beginning after December 15, 2001, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) 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 impairment of goodwill and intangible assets with indefinite useful lives. We adopted SFAS 142 on January 1, 2002.

Goodwill no longer subject to amortization amounted to approximately \$731,000 at December 31, 2002 and 2001. We performed an impairment test of goodwill as of January 1, 2002, which did not

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

result in an impairment charge at transition. We will continue to monitor the carrying value of goodwill through the annual impairment tests and more frequently if the indicators of impairment arise.

The amortization expense and adjusted net loss for the years ended December 31, 2002, 2001, and 2000 is as follows (in thousands, except per share amounts):

	Year ended December 31,		
	2002	2001	2000
Net loss as reported	\$(49,471)	\$(55,566)	\$(35,283)
Add back: Goodwill amortization expense	—	273	273
Adjusted net loss	\$(49,471)	\$(55,293)	\$(35,010)
Adjusted basic and diluted net loss per share	\$ (1.52)	\$ (1.68)	\$ (1.04)
As reported basic and diluted net loss per share	\$ (1.52)	\$ (1.69)	\$ (1.04)

Intangible Assets

Intangible assets, including trademarks, covenants not to compete, and customer lists, are stated at cost and amortized on a straight-line basis over their estimated useful lives of up to five years. Cost basis of intangible assets was \$787,000 at December 31, 2002 and 2001. Accumulated amortization was \$518,000 and \$361,000 at December 31, 2002 and 2001, respectively.

The expected future annual amortization expense of our intangible assets as of December 31, 2002 is as follows (in thousands):

Year ending December 31,	Amortization Expense
2003	\$158
2004	111
Total	\$269

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:

	2002	2001	2000
Customer A	25%	10%	21%
Customer B	21	12	6
Customer C	15	23	25
Customer D	—	11	—
Customer E	—	1	12
All others	39	43	36
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 account for stock issued to employees in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and comply with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") and Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" ("SFAS 148"). Under APB 25, compensation expense of fixed stock options is based on the difference, if any, on the date of the grant between the fair value of the our stock and the exercise price of the option. We account for stock issued to non-employees in accordance with the provisions of SFAS 123 and EITF No. 96-18, "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services."

Under the intrinsic value method, when the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. The following table illustrates the pro forma effect on net loss and loss per share for the years ended December 31, 2002, 2001 and 2000 had we applied the fair value method to account for stock-based awards to employees:

	Years ended December 31,		
	2002	2001	2000
Net loss, as reported	\$(49,471)	\$(55,566)	\$(35,283)
Add: Stock-based employee compensation expense included in the determination of net loss, as reported	75	75	230
Deduct: Stock-based employee compensation expense that would have been included in the determination of net loss if the fair value method had been applied to all awards . . .	(3,991)	(5,026)	(4,820)
Pro forma net loss	<u>\$(53,387)</u>	<u>\$(60,517)</u>	<u>\$(39,873)</u>
Basic and diluted net loss per common share:			
As reported	\$ (1.52)	\$ (1.69)	\$ (1.04)
Pro forma	\$ (1.64)	\$ (1.84)	\$ (1.18)

Impairment of Long-lived Assets

On January 1, 2002, we adopted Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), which supersedes certain provisions of APB 30, "Reporting the Results of Operations—Reporting the Effects of Disposal

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions,” and supersedes Statement of Financial Accounting Standards No. 121, “Accounting for the Impairment of Long-Lived Assets to be Disposed of.” In accordance with SFAS 144, we evaluate long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable based on expected undiscounted cash flows attributable to that asset. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. No impairment exists as of December 31, 2002.

Recent Accounting Pronouncements

In July 2002, the FASB issued Statement of Financial Accounting Standards No. 146, “Accounting for Costs Associated with Exit or Disposal Activities” (“SFAS 146”). SFAS 146 addresses financial accounting and reporting for costs associated with an exit or disposal activity and requires such costs to be recognized when the liability is incurred. Previous guidance in EITF No. 94-3, “Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Certain Costs Incurred in a Restructuring)” required that a liability for an exit cost be recognized at the date of a company’s commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated by a company after December 31, 2002. The adoption of SFAS 146 is not expected to have a material effect on our financial position or results of operations.

In December 2002, the FASB issued SFAS 148, “Accounting for Stock-Based Compensation—Transition and Disclosure.” SFAS 148 amends SFAS 123 to provide alternative methods of transition to SFAS 123’s fair value method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure provisions of SFAS 123 and APB No. 28, “Interim Financial Reporting,” to require disclosure in the summary of significant accounting policies of the effects of an entity’s accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. While SFAS 148 does not amend SFAS 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS 148 are applicable to all companies with stock-based employee compensation, regardless of whether they account for that compensation using the fair value method of SFAS 123 or the intrinsic value method of APB 25. Since we account for our stock-based compensation under APB 25, and have no current plans to switch to SFAS 123, the impact of SFAS 148 will be limited to the interim reporting of the effects on net income and earnings per share if the Company accounted for stock-based compensation under SFAS 123. SFAS 148 is effective for fiscal years ended after December 15, 2002.

In November 2002, the FASB issued Interpretation No. 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others” (“FIN 45”). FIN 45 requires certain guarantees to be recorded at fair value, which is different from current practice, where a liability is recorded when a loss is probably and reasonably estimable. In addition, FIN 45 also requires a guarantor to make significant new disclosures, even when the likelihood of making any payments under the guarantee is remote, which is another change from current practice. In general, FIN 45 applies to contracts or indemnification agreements that contingently require the guarantor to make payments to the guaranteed party based on changes in an underlying that is related to an asset, liability, or an equity security of the guaranteed party. FIN 45 is applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Summary of Significant Accounting Policies (Continued)

disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of the recognition and measurement provision of this interpretation are not currently expected to have a material effect on our financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities." FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applied in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. We do not believe there will be a material effect upon our financial condition or results of operations from the adoption of the provision of FIN 46.

2. Available-for-Sale-Securities

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
At December 31, 2002:				
U.S. corporate debt securities	\$14,801	\$ 57	\$ —	\$ 14,858
Foreign corporate debt securities	1,371	1	—	1,372
U.S. government debt securities	3,077	10	—	3,087
Marketable equity securities	14,679	9	(873)	13,815
Total	\$33,928	\$ 77	\$(873)	\$ 33,132
At December 31, 2001:				
U.S. corporate debt securities	\$68,363	\$ 530	\$ (3)	\$ 68,890
Foreign corporate debt securities	1,410	—	(11)	1,399
U.S. government debt securities	459	3	—	462
Marketable equity securities	22,919	7,047	(67)	29,899
Total	\$93,151	\$7,580	\$ (81)	\$100,650

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

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

The available-for-sale securities are classified on the balance sheet as follows (in thousands):

	<u>Amortized Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>
At December 31, 2002				
Amounts included in cash and cash equivalents . .	\$ 5,530	\$ —	\$ —	\$ 5,530
Marketable securities, current	12,026	55	—	12,081
Investment in stock of related parties	14,294	—	(873)	13,421
Marketable securities, non-current	<u>2,078</u>	<u>22</u>	<u>—</u>	<u>2,100</u>
Total	<u>\$33,928</u>	<u>\$ 77</u>	<u>\$(873)</u>	<u>\$ 33,132</u>
At December 31, 2001				
Amounts included in cash and cash equivalents . .	\$15,023	\$ —	\$ —	\$ 15,023
Marketable securities, current	49,708	473	(3)	50,178
Investment in stock of related parties	22,499	6,786	—	29,285
Marketable securities, non-current	<u>5,921</u>	<u>321</u>	<u>(78)</u>	<u>6,164</u>
Total	<u>\$93,151</u>	<u>\$7,580</u>	<u>\$ (81)</u>	<u>\$100,650</u>

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

	<u>Fair Value</u>	
	<u>2002</u>	<u>2001</u>
Debt securities		
Due in one year or less	\$17,611	\$ 65,201
Due after one year through three years	<u>1,706</u>	<u>5,550</u>
	19,317	70,751
Marketable equity securities	<u>13,815</u>	<u>29,899</u>
Total	<u>\$33,132</u>	<u>\$100,650</u>

Realized gains and losses on the sale of available-for-sale securities for the years ended December 31, 2002, 2001, and 2000 were not material.

During the year ended December 31, 2002, we recorded a write-down of \$8,491,000 related to other than temporary declines in the value of our marketable securities and investment in stock of related parties. We had no such write-downs in 2001 or 2000.

3. Stockholders' Equity

Private Placement

In September 2002, we entered into a Securities Purchase Agreement and Registration Rights Agreement with several investors for the private placement of shares of our common stock and warrants. In connection with these agreements, we issued 1,806,400 shares of our common stock to the investors at a per share price of \$2.50, for an aggregate amount of \$4,516,000, and issued warrants to

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Stockholders' Equity (Continued)

the investors for the purchase of the same number of shares. The warrants have the following characteristics: (i) 1,204,269 of the warrants have an exercise price of \$4.00 and the other 602,131 of the warrants have an exercise price of \$5.00 per share, (ii) the warrants will be exercisable for a term of four years, (iii) the exercise prices of the warrants will be subject to adjustment so that, if we issue any shares of our common stock (including options and warrants, with certain exceptions), at a price that is lower than the respective exercise prices, then the respective exercise prices will be reduced to each such lower price, provided, however, that after 540 days of issuance of the warrants, the respective exercise prices shall not be reduced to less than \$2.50, and (iv) after two years, the warrants will be redeemable by SuperGen, at our option, at \$0.25 per warrant, if the shares of our common stock are trading at above 200% of the respective exercise prices for twenty consecutive days.

As compensation to the placement agent, we paid the placement agent \$310,000 in cash and issued a four-year warrant to an affiliate of the placement agent for the purchase of 118,000 shares of our common stock at an exercise price of \$3.00 per share. Using the Black-Scholes valuation method, we calculated the value of these warrants to be \$176,000, which was treated as part of the cost of the offering.

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.

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 and September 2002, the Board authorized increases in the number of shares to be acquired under the repurchase plan, but maintained the \$20,000,000 repurchase total.

During the year ended December 31, 2002, we repurchased 1,886,000 shares of our common stock at a cost, net of commissions, of \$7,174,000. During the year ended December 31, 2001, we repurchased 963,000 shares of our common stock at a cost, net of commissions, of \$9,117,000. All shares repurchased have been retired.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Stockholders' Equity (Continued)

Warrants

At December 31, 2002, warrants to purchase the following shares of our common stock were outstanding:

Number of Shares	Exercise Price	Issue Date	Expiration Date
118,000	\$ 3.00	2002	2006
1,204,269	4.00	2002	2006
602,131	5.00	2002	2006
230,000	10.35	1997	2007
200,000	10.47	2001	2004
500,000	11.00	1998	2004
1,045,000	13.50	1997	2007
86,489	18.00 - 22.075	1999	2004
200,000	40.00	2000	2004
<u>4,185,889</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, 2002, we have reserved shares of common stock for future issuance as follows:

Stock options outstanding	4,535,457
Stock options available for grant	454,013
Warrants to purchase common stock	4,185,889
Shares available for Employee Stock Purchase Plan	<u>122,681</u>
	<u>9,298,040</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 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).

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Stock Option Plans (Continued)

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, 2000	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	3,705,962	13.57	2,679,490	
Granted at fair value	1,314,300	3.71		2.53
Exercised	(833)	6.50		
Forfeited	(483,972)	17.62		
Balance at December 31, 2002	<u>4,535,457</u>	\$10.28	3,188,761	

Information concerning the options outstanding at December 31, 2002 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 \$3.38	830,100	\$ 2.35	8.46	266,000	\$ 2.77
3.680 to 5.875	704,221	4.96	7.60	366,951	5.23
5.880 to 7.625	836,569	6.33	4.81	749,069	6.29
7.938 to 12.25	750,214	10.48	7.19	624,399	10.42
12.438 to 15.375	927,722	14.43	5.74	818,051	14.62
15.875 to 68.00	486,631	30.06	7.00	364,291	29.37
\$ 0.135 to \$68.00	<u>4,535,457</u>	\$10.28	6.73	<u>3,188,761</u>	\$11.45

Pro forma information regarding the results of operations and net loss per share (Note 1) is determined as if we had accounted for our employee stock options using the fair value method. Under this method, the fair value of each option granted is estimated on the date of grant using the Black-

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Stock Option Plans (Continued)

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

	Years ended December 31,		
	2002	2001	2000
Risk-free interest rate	4.17%	5.48%	5.91%
Dividend yield	—	—	—
Expected volatility	0.834	0.760	0.761
Expected life (in years)	5.0	5.0	5.0

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.

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, 2002, 2001, and 2000, we recorded amortization of deferred stock compensation expense of \$75,000, \$75,000, and \$230,000, 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 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. During the year ended December 31, 2002, we paid Peregrine \$200,000 in connection with this agreement, which we charged to Research and development expense.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Acquisition Activity (Continued)

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.

In September 2002, we extended the terms of the two-year warrants to purchase 200,000 shares of our common stock by two additional years. We calculated the Black-Scholes valuation of this warrant extension at \$2,000, which we charged to Research and development expense in 2002.

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.

During 2002, we paid the Research Development Foundation \$274,000 in connection with the research agreement, which we charged to Research and development expense.

Orathecin

In September 1997, we acquired exclusive worldwide rights to a patented anticancer compound, Orathecin, 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.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Acquisition Activity (Continued)

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 Stehlin approximately \$9.6 million for research and must make cash royalty payments and cash or stock milestone payments to Stehlin as we develop and commercialize Orathecin. In accordance with these agreements, we paid Stehlin \$1,200,000 in 2002, \$2,400,000 in 2001, and \$2,400,000 in 2000. Through December 31, 2002, we have paid Stehlin \$8.8 million of the \$9.6 million total.

6. Termination of 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 would have 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. This amount was subsequently reduced to \$1.25 million in 2002. We paid \$880,000 of this total in March 2002. At December 31, 2002, \$370,000 remained payable to Abbott, and was included in Accounts payable and accrued liabilities at that date.

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 in January 2000. 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 \$2,167,000 and \$3,167,000 are included in current and non-current deferred revenue at December 31, 2002 and 2001, 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 was included in Due from related parties on the balance sheet at that date.

During 2002, we advanced an additional \$646,000 to EuroGen to fund its operations. In December 2002, all but one of the other investors in EuroGen withdrew their ownership interests in the entity, and we became 95% owners of EuroGen. The remaining 5% is owned by Larry Johnson, the President and CEO of EuroGen. The amounts advanced to EuroGen, including the amounts advanced in 2001, totaling \$906,000 are included in Selling, general, and administrative expense in 2002. EuroGen is now a consolidated entity.

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. One of our board members 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"). At the time, the chief executive officer of AVI was a member of our Board of Directors. He later resigned from our Board in May 2002. The president and chief executive officer of SuperGen was and continues to be 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 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

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Related Party Transactions (Continued)

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 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, 2002.

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. This amount was paid during 2002. In 2002, we recorded \$421,000 in research and development expenses for Avicine. At December 31, 2002, this amount was still payable 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 2002, \$180,000 in 2001, and \$152,000 in 2000 for these consulting services.

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). During 2002, these warrants were extended for two additional years.

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.

In January 2002, we subleased a portion of our laboratory at SPRI to QBI. During 2002, we collected \$123,000 in sublease income from QBI. The initial term of the sublease expired on December 31, 2002, but we are continuing to sublease the space to QBI on a month-to-month basis.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Related Party Transactions (Continued)

The Kriegsman Group

In March 2001, we retained The Kriegsman Group to render advice and assistance with respect to financial public relations and promotions. In addition, in connection with such services, on March 22, 2001, we issued warrants to The Kriegsman Group: one "A" warrant for the purchase of 200,000 shares of Common Stock at the exercise price of \$10.47, and one "C" warrant for the purchase of 100,000 shares of Common Stock at the exercise price of \$11.02, which was not vested as of December 31, 2002. On July 25, 2002, Dr. Joseph Rubinfeld, our president and chief executive officer, became a member of the board of directors of CytRx Corp. Steven Kriegsman, the president of The Kriegsman Group, is also a significant shareholder and president and chief executive officer of CytRx Corp. We paid The Kriegsman Group consulting fees of \$240,000 in 2002 and \$232,500 in 2001.

Other

At December 31, 2002, 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 2002, 2001, and 2000 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 2004.

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>
2003	\$ 2,204	\$318
2004	2,266	248
2005	2,326	177
2006	2,175	91
2007 and thereafter	8,745	—
	<u>\$17,716</u>	<u>\$834</u>

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Rent expense was \$1,948,000 in 2002, \$2,090,000 in 2001, and \$481,000 in 2000. These amounts were net of sublease income of \$450,000 in 2002, \$237,000 in 2001 and \$110,000 in 2000.

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, 2002.

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, 2002.

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,	
	2002	2001
Net operating loss carryforwards	\$ 81,137	\$ 65,751
Purchased in-process technology	2,086	2,219
Research and development credit carryforwards	6,833	5,168
Capitalized research and development	6,452	8,281
Other	1,339	1,740
	97,847	83,159
Total deferred tax assets		
Valuation allowance	(97,847)	(83,159)
	\$ —	\$ —
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 \$14,668,000 during 2002 and by \$21,919,000 during 2001.

As of December 31, 2002 we have net operating loss carryforwards for federal income tax purposes of approximately \$229,000,000 which expire in the years 2005 through 2022, and federal research and development credit carryforwards of approximately \$4,200,000, which expire in the years 2007 through 2022.

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.

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 \$297,000 in 2002, \$294,000 in 2001, and \$144,000 in 2000.

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 2002, we issued 44,097 and 33,606 shares through the ESPP at \$4.46 and \$3.48, respectively. 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. As of December 31, 2002, 122,681 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, 2002 and 2001:

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(Amounts in thousands, except per share data)			
2002				
Net sales	\$ 1,344	\$ 5,614	\$ 657	\$ 6,573
Cost of sales	728	1,738	161	1,864
Net loss	(12,081)	(10,945)	(20,112)	(6,333)
Basic and diluted net loss per share.	(0.37)	(0.34)	(0.63)	(0.19)
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)

12. Subsequent Event—Issuance of Exchangeable Convertible Notes

On February 26, 2003 we entered into a Securities Purchase Agreement ("Purchase Agreement") for the private placement of Senior Exchangeable Convertible Notes ("Notes") in the principal amount of \$21.25 million and related warrants, and a Registration Rights Agreement.

The Notes will accrue interest at a rate of 4% per annum. The principal amount of the Notes shall be repayable in four equal quarterly installments beginning nine months after the closing of the transactions. The Notes are, at the option of the investors, in whole or in part, (a) convertible into

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

12. Subsequent Event—Issuance of Exchangeable Convertible Notes (Continued)

shares of the Common Stock of SuperGen, at a fixed conversion price of \$4.25 per share, and (b) exchangeable for up to 2,634,211 shares of common stock of AVI BioPharma, Inc. currently owned by SuperGen (the "AVI Shares") at a fixed exchange price of \$5.00 per share. We may pay interest due under the Notes in shares of our common stock at a price tied to the then market price, and subject to certain conditions, we may also elect to pay principal due under the Notes in shares of our common stock and AVI Shares at prices tied to the then market price of our common stock and AVI common stock, respectively. Subject to certain conditions, at any time after the first anniversary of the effectiveness of the Registration Statement, all of the outstanding Notes will be redeemable by us for a cash redemption price at 120% of par plus accrued and unpaid interest. Upon a Change of Control (as defined under the Notes), the holders will have certain redemption rights, and we may also redeem the Notes, in each case subject to certain conditions and provided that, in the event of our redemption, we will issue to the holders of the Notes certain warrants exercisable for the securities of the acquiring entity and the AVI Shares. Our exchange obligations under the Notes are secured by a pledge of the AVI Shares.

The fair value of the AVI Shares at February 26, 2003 is \$8.5 million, compared to \$13.4 million at December 31, 2002.

In connection with the issuance of the Notes, we issued warrants to the note holders for the purchase of an aggregate of 1,997,500 shares of SuperGen common stock ("Warrants"). The Warrants will be exercisable for a term of four years at an exercise price of \$5.00 per share.

As compensation to the placement agent, we paid the placement agent \$1,452,000 in cash and issued a five-year warrant to an affiliate of the placement agent for the purchase of 363,125 shares of our common stock at an exercise price of \$4.00 per share.

Certification under Section 302(a) of the Sarbanes-Oxley Act of 2002

I, Joseph Rubinfeld, certify that:

1. I have reviewed this annual report on Form 10-K of SuperGen, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

By: /s/ JOSEPH RUBINFELD

Joseph Rubinfeld, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Certification under Section 302(a) of the Sarbanes-Oxley Act of 2002

I, Edward Jacobs, certify that:

1. I have reviewed this annual report on Form 10-K of SuperGen, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

By: /s/ EDWARD L. JACOBS

Edward L. Jacobs
Chief Business Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

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 Form S-8 (Registration No. 333-86644) pertaining to the 1996 Directors' Stock Option Plan and 1998 Employee Stock Purchase 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, the Form S-3 (Registration No. 333-95177) for the registration of 136,130 shares of common stock, and the Form S-3 (Registration No. 333-100707) for the registration of 3,930,800 shares of common stock and related prospectuses, of our report dated February 18, 2003, except for Note 12 as to which the date is February 26, 2003, 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, 2002.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 27, 2003

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Rubinfeld, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of SuperGen, Inc. on Form 10-K for the year ended December 31, 2002 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of SuperGen, Inc.

By: /s/ JOSEPH RUBINFELD

Name: Joseph Rubinfeld

Title: President and Chief Executive Officer

I, Edward Jacobs, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of SuperGen, Inc. on Form 10-K for the year ended December 31, 2002 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of SuperGen, Inc.

By: /s/ EDWARD JACOBS

Name: Edward Jacobs

Title: Chief Business Officer and
Chief Financial Officer

Board of Directors

Joseph Rubinfeld, Ph.D.
Founder, Chairman and Chief Executive Officer
SuperGen, Inc.

Additional Board Members



Charles J. Casamento
President & CEO
Questcor Pharmaceuticals



Thomas V. Girardi
Senior Partner
Girardi & Keese



Walter J. Lack
Managing Partner
Engstrom, Lipscomb & Lack



James S. J. Manuso, Ph.D.
President & CEO
Galencia Pharmaceuticals, Inc.



Michael D. Young,
M.D., Ph.D.
Chairman & CSO
Strategic Healthcare
Development, LLC

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
Ezetx, Sequus Pharmaceuticals,
Trixex Pharmaceuticals,
Adria Laboratories,
Johnson & Johnson

Karl Mettinger, M.D., Ph.D.
Senior Vice President,
Chief Medical Officer
Ivax, KABI, Karolinska Institute

Craig Rosenfeld, M.D.
Senior Vice President,
Chief Scientific Officer
Medical City Dallas Hospital,
Western Pennsylvania Hospital

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

Timothy Enns
Vice President, Investor Relations
& Business Development
Sequus, Adria Laboratories, Upjohn

Fredrick 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, WEDCO, Syncon, Adria
Laboratories, Neorex

Tipp Nelson
Vice President, Marketing
Berlex, Johnson & Johnson

Simeon Wrenn, Ph.D.
Vice President, Biotechnology
American Home Products,
American Cyanamid, Purdue Frederick,
Centocor

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800.353.1075 Tel
925.560.0101 Fax

Independent Auditors
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Palo Alto, CA 94304

Transfer Agent
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Services, LLC
Overpeck Center
85 Challenger Road
Ridgefield Park, NJ 07660
800.522.6645 Tel
www.malloninvestor.com

Annual Meeting
The annual meeting of
stockholders will be held
from 2:00 p.m. to 5:00 p.m.
on May 22, 2003, at
The Four Points Hotel
by Sheraton
5115 Hopyard Road
Pleasanton, CA 94588
925.460.8800 Tel

NASDAQ: SUPG

For information about the company, stockholders and other interested parties
may contact the Investor Relations Department at the company headquarters,
or visit the company website 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.

