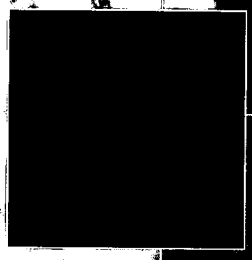
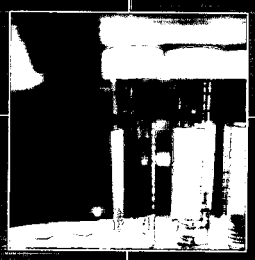
SUPERGEN

BUILDING FOR GROWTH

ANNUAL REPORT



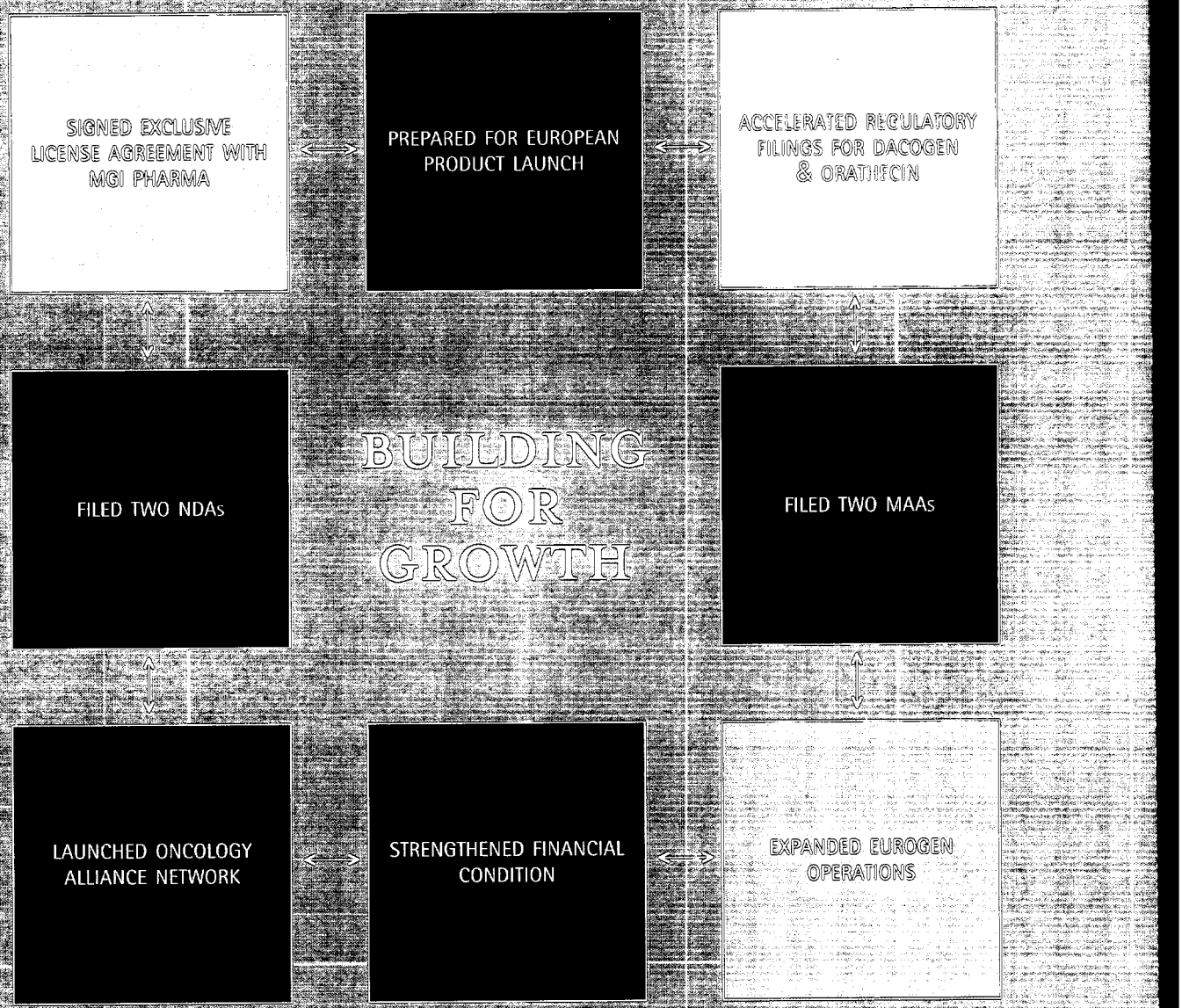


Statement Regarding Forward-Looking Statements: This Annual Report contains predictions, estimates and other forward-looking statements that involve [redacted] risks and uncertainties about our business, including, but not limited to, our expectation that the FDA will provide a decision on our NDA for Dacogen [redacted] during the second quarter of 2005, our belief that Dacogen will be approved and commercialized in both the U.S. and the E.U., our belief that EuroGen will launch its first [redacted] in five major E.U. markets during 2005, our expectation that Nipent will contribute substantially to our revenues in 2005, our expectation that Paclitaxel [redacted] approval in the E.U. during 2005, and our expectation that we will select one or more new compounds for in-licensing by mid-year 2005. In some cases, forward-looking statements may be identified by the usage of words such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," [redacted] or guidance, or the negative of such words and other similar terminology. While this discussion represents our current judgment on the future direction [redacted] these statements involve known and unknown risks and uncertainties that may cause our or our industry's results, level of activity, performance or [redacted] to be materially different from those expressed or implied by the forward-looking statements. Certain unknown or immaterial risks and uncertainties can [redacted] our forward-looking statements. Forward-looking statements not specifically described above also may be found in other sections of this report. We disclaim [redacted] intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. For a discussion of [redacted] known and material risks that could affect our actual results, please see "Factors Affecting Future Operating Results" in this Annual Report.

SUPERGEN

BUILDING FOR GROWTH

SuperGen is dedicated to serving the needs of oncology and hematology patients worldwide. In order to accomplish this mission, our corporate infrastructure must be capable of supporting both current and future products through clinical development, regulatory review and commercialization. Our future growth depends on a solid product portfolio, sustainable revenue streams, strategic partnerships and a secure financial position. Throughout 2004, our energies were focused on implementing measures and activities that will make SuperGen a stronger company from the inside out. In this year's annual report, we are pleased to share with you how SuperGen is "Building for Growth," through strategic actions designed to enhance our infrastructure and ultimately increase value for our stockholders.


SIGNED EXCLUSIVE LICENSE AGREEMENT WITH MGI PHARMA
PREPARED FOR EUROPEAN PRODUCT LAUNCH
ACCELERATED REGULATORY FILINGS FOR DACOGEN & ORATHECIN
FILED TWO NDAs
BUILDING FOR GROWTH
FILED TWO MAAs
LAUNCHED ONCOLOGY ALLIANCE NETWORK
STRENGTHENED FINANCIAL CONDITION
EXPANDED EUROGEN OPERATIONS

DEAR STOCKHOLDER,

By any measure, 2004 was a dynamic year for SuperGen. Significant progress was made in positioning our company for future growth. Despite some challenges, we remained focused on our strategic objectives and implemented the measures necessary to transition from our foundation as a drug development company to a viable commercial enterprise serving hematology and oncology patients. Much work still needs to be done, but SuperGen enters the new year stronger — organizationally, commercially and financially — and eager to move forward.

ENSURING FUTURE REVENUE WITH A TRANSFORMING DEAL

In September 2004, we announced an exclusive worldwide licensing agreement with MGI PHARMA for the further development and commercialization of Dacogen™ (decitabine) injection, our investigational anticancer therapeutic for the treatment of myelodysplastic syndromes (MDS). This deal truly transformed SuperGen and is expected to be a significant driver of our future growth.

MGI's belief in Dacogen's potential is reflected in the terms of our agreement. MGI's $40 million equity investment at $10 per share represented approximately a 56 percent premium to SuperGen's market price at the time of the deal. MGI also committed to spend a minimum of $15 million on future development of Dacogen, and SuperGen will receive up to an additional $45 million, based on completion of specific regulatory and commercialization milestones. Several of these milestones were achieved during 2004, and we will potentially earn up to $25 million in milestone payments during 2005. Most importantly, assuming we receive requested regulatory approvals for Dacogen, SuperGen will receive a continuing revenue stream from Dacogen royalties for all indications, at a rate of 20 percent escalating up to 30 percent, based on worldwide sales for the life of the 20-year agreement.

We believe MGI is the right partner for Dacogen, with financial resources and commercial infrastructure that will ensure more rapid penetration of the MDS market and expand development for additional indications. MGI plans to initiate a Phase III trial of Dacogen for the treatment of acute myelogenous leukemia (AML) in early 2005 and will evaluate its potential for use outside of MDS and AML.

PLACING A PRIORITY ON REGULATORY PROGRESS

Accelerating our regulatory filings for both Dacogen and Orathecin™ (rubetican) capsules was a key strategic objective during 2004. SuperGen submitted two New Drug Applications (NDAs) with the United States (U.S.) Food and Drug Administration (FDA) and two Marketing Authorization Applications (MAAs) with the European Agency for the Evaluation of Medicinal Products (EMEA) for Dacogen and Orathecin respectively, through our subsidiary, EuroGen Pharmaceuticals Limited.

The Dacogen NDA was submitted to the FDA early in the fourth quarter and accepted for review on December 31, 2004. We anticipate the FDA's decision during the third quarter of 2005. Our MAA was accepted by the EMEA for review in late October 2004, and a decision on the European filing for Dacogen should come within the same time period as the FDA decision.

SuperGen withdrew its U.S. NDA for Orathecin on December 30, 2004. This NDA was originally submitted to the FDA on January 26, 2004, with a target Prescription Drug User Fee Act (PDUFA) date of November 26, 2004. During the fourth quarter, at the FDA's request, SuperGen submitted additional clinical data from a trial of Orathecin as a first-line treatment for pancreatic cancer, as well as new analyses of data from the studies in second- and third-line patients. These data were classified as a major amendment by the FDA, triggering an extension of the review period and moving the PDUFA date to February 26, 2005.

Withdrawing the Orathecin NDA at this advanced stage of the regulatory process was not an easy decision, but we believe it was in the best interest of SuperGen and our stockholders. Initial feedback from the FDA and our external consultants indicates that the current data will not support the approval of Orathecin as a single agent in refractory patients. The NDA included data on 1,900 pancreatic cancer patients, and we continue to believe that Orathecin has clinical utility. Hopefully, we will learn more from the FDA's report on its review, which we just received in early 2005 and are beginning to analyze.

From a clinical perspective, Orathecin may have better prospects for approval in the U.S. as a combination therapy. Preliminary studies using Orathecin as a single agent clearly demonstrate activity, and our recently completed Phase I work in refractory cancer patients produced objective response rates and disease stabilization. Based on these results, SuperGen is proceeding with the non-randomized portion of our planned Phase III trial of Orathecin in combination with gemcitabine, which started in early 2005. Beyond that, we will determine the feasibility of pursuing further U.S. development based on what we learn from the FDA report.

We think our action regarding the U.S. NDA for Orathecin has absolutely no effect on the status of our European filing. We remain confident that our randomized study in second- and third-line patients showed a benefit in those who received Orathecin. We are optimistic that we have provided sufficient information to the EMEA to be persuasive.

CONSOLIDATING OUR INFRASTRUCTURE FOR COMMERCIALIZATION

SuperGen underwent a substantial reorganization in 2004, restructuring several departments, consolidating management functions, creating more rational, efficient and responsive decision-making processes and downsizing our workforce by approximately 15 percent. This effort included establishing an internal Business Development Advisory Committee to identify potential products for in-licensing or acquisition. Approximately 30 "Best in Class" late Phase II hematological and/or oncological drugs have already been screened, and several candidates have been selected for further review by senior management. This is an active, ongoing and dynamic process.

Corporate governance was a key initiative in 2004, and we are developing a system of checks and balances that we expect will enhance our ability to meet the growing demands on publicly traded companies like us within the new regulatory environment as influenced by the Sarbanes-Oxley Act.

We also strengthened our management ranks by adding and promoting key individuals. Wayne Davis, Vice President for Clinical Operations, was hired to solidify internal clinical capabilities and Joi Ninomoto was promoted to Vice President, Medical Affairs to recognize her excellence in developing a "Best in Class" Medical Affairs group. Both of these individuals have made valuable contributions since joining SuperGen and we are pleased to have them on our team.

STRENGTHENING OUR FINANCIAL CONDITION

SuperGen ended the year with an improved financial position, with $57 million in operating cash, which included $40 million from MGI's equity investment. Strict adherence to our budgeting discipline resulted in an average quarterly net cash burn rate of approximately $6 million, a major accomplishment considering we completed four regulatory filings this year.

Our financial performance was challenged by Medicare price rollbacks, which negatively impacted Nipent® (pentostatin for injection) sales in the U.S. during the first half of the year. SuperGen's dedicated sales and marketing team was able to reverse this trend by working directly with our physician network. The impressive recovery in Nipent revenues, which increased from $0.7 million in the first quarter of 2004 to approximately $5 million in the fourth quarter, is due to their diligent efforts.

During 2005, we anticipate that Dacogen will be approved and commercialized in both the U.S. and the European Union (E.U.), and these events will trigger up to $25 million in additional milestones to SuperGen before year-end. If Dacogen is approved during the third quarter, SuperGen could begin receiving royalties from sales during 2005.

FACING THE CHALLENGES & SEIZING THE OPPORTUNITIES

While prospects for Orathecin remain uncertain at this time, our strategic plan has always assumed we would need to grow our product pipeline through in-licensing or acquisition. Several strong candidates have emerged from our extensive screening process, and we expect to select one of these during 2005. Most likely, this will be a late Phase II or Phase III product, but we will also consider marketed products and platform technologies that have produced solid product candidates.

We have exciting plans for our European subsidiary during 2005. EuroGen will launch its first commercial product, Nipent, in at least five major E.U. markets. Nipent has recently generated renewed interest in the hematology community as the subject of several published scientific studies that examine its activity in treating Chronic Lymphocytic Leukemia (CLL), as well as Graft versus Host Disease (GvHD). The promising data generated by these studies contribute to a growing body of scientific evidence on Nipent's utility, which suggests continued sales momentum during the coming year.

BUILDING FOR FUTURE GROWTH

My first year as your president and chief executive officer has been both demanding and exciting. Building a global pharmaceutical company is an ambitious goal that takes time and patience. Thanks to a truly extraordinary team of dedicated and talented people, SuperGen has made remarkable progress this year, putting in place the strategic, financial and operational elements that I believe will enable us to grow in the years ahead. I am proud of all we have accomplished and personally grateful for the support of our employees, our Board of Directors and our stockholders. We can look forward to our future with confidence.

Sincerely,

James S. J. Manuso, Ph.D.
President and Chief Executive Officer


RAISED $74 MILLION
EXPANDED SALES EFFORTS
INCREASED NIPENT REVENUES
SECURED EQUITY INVESTMENT, MILESTONES & FUTURE ROYALTIES FROM MGI PHARMA
Decitabine

REINFORCING OUR CAPITAL BASE – SuperGen needs a secure financial foundation to fund its growth. In 2004, our strategic plans included four regulatory filings for our two lead product candidates and development of the commercial and marketing infrastructure necessary for a successful launch upon approval. During the first quarter, we raised $34 million through a private placement to address these near-term objectives. We realized, however, that our vision of building a viable company demanded a more secure financial profile.

STRENGTHENED
OUR FINANCIAL CONDITION

Several measures implemented during 2004 reinforced the existing financial foundation by increasing SuperGen's capital resources, bolstering our financial position, managing operational expenses and enhancing and establishing new sources of revenue. Consequently, SuperGen can fund reasonable levels of clinical development for future products and can continue to drive its business development plans with confidence.

SECURING A STRONG STRATEGIC COLLABORATION

Most significantly, we granted an exclusive license to MGI for the development and commercialization of Dacogen. This agreement transformed our financial position by strengthening the balance sheet with a $40 million equity infusion and providing access to up to an additional $45 million in cash payments upon completion of specific regulatory and commercialization milestones. SuperGen has already achieved several of these milestones, earning $12.5 million from MGI in 2004, and we will potentially receive up to another $25 million in milestones during 2005. MGI has committed to funding the future development of Dacogen with a minimum of $15 million, ensuring that appropriate resources are committed to move Dacogen forward in additional indications. SuperGen will receive royalties from Dacogen starting at 20 percent and increasing to 30 percent, based on worldwide sales. If Dacogen is approved this year, the new revenue stream could begin contributing to our bottom line during 2005.

EXPANDING SALES EFFORTS

SuperGen also focused on increasing sales during 2004. Nipent sales experienced pressure from Medicare price rollbacks during the first half of the year. We were able to reverse this trend by expanding direct outreach to our physician network and implementing targeted regional programs on reimbursement issues and procedures. Our efforts resulted in consecutive quarterly sales increases throughout 2004, with Nipent net sales rising from $0.7 million in the first quarter to $5 million in the fourth quarter.

IMPLEMENTING BETTER CONTROLS

We instituted stronger financial controls over our operations, which reduced the risk of premature operational and capital expenditures and enabled us to keep our burn rate on target. New cost-benefit analysis procedures ensure that we allocate our financial resources for new products wisely in advance of full commercialization and marketing activities. Each of these measures taken during 2004 has helped us attain a new level of fiscal strength and financial discipline that will allow SuperGen to focus on reaching long-term profitability.

PREPARING THE FOUNDATION – SuperGen established an international commercialization plan in 2004 to support the potential of two product approvals, Dacogen and Orathecin, within a one-year time frame in both the United States and Europe. Additionally, we planned to assume responsibility for European sales, marketing and distribution activities of Nipent. Our plan assembled the structural elements required for launching our products in five key E.U. markets.

A CORPORATE INFRASTRUCTURE THAT PAVES THE ROAD TO COMMERCIALIZATION

FRAMING OUR KEY AUDIENCES

SuperGen's commercialization team developed an extensive program of 12 Scientific Advisory Boards (SABs), held across the U.S. market. Awareness of Dacogen as an MDS therapeutic agent increased substantially among leading cancer specialists as a result of these SABs. Structured as professional forums for the exchange of scientific and clinical information, these meetings allowed us to initiate a valuable dialogue and build our brand with hundreds of physicians. They generated insights that will frame the product marketing campaigns for Dacogen and Orathecin, if approved.

Most significantly, we launched an oncology alliance network in cooperation with Pharmatech and ION, two leading oncology organizations. This major initiative allows us access to more than 6,000 oncologists who will purchase products directly, attend marketing events and clinical forums and participate as investigators on cooperative trials. This network is a valuable asset that we expect will be vital to our long-term success.

MOBILIZING FOR MANUFACTURING

Another important piece of the infrastructure was assembling demonstration and scale-up batches of Dacogen, as well as clinical supplies of Orathecin for both the U.S. and E.U. For Nipent, several quality assurance and quality control audits pertaining to manufacturing were completed, distribution procedures for contract manufacturers were established, and we strengthened our patent portfolio with regard to Nipent manufacturing processes.

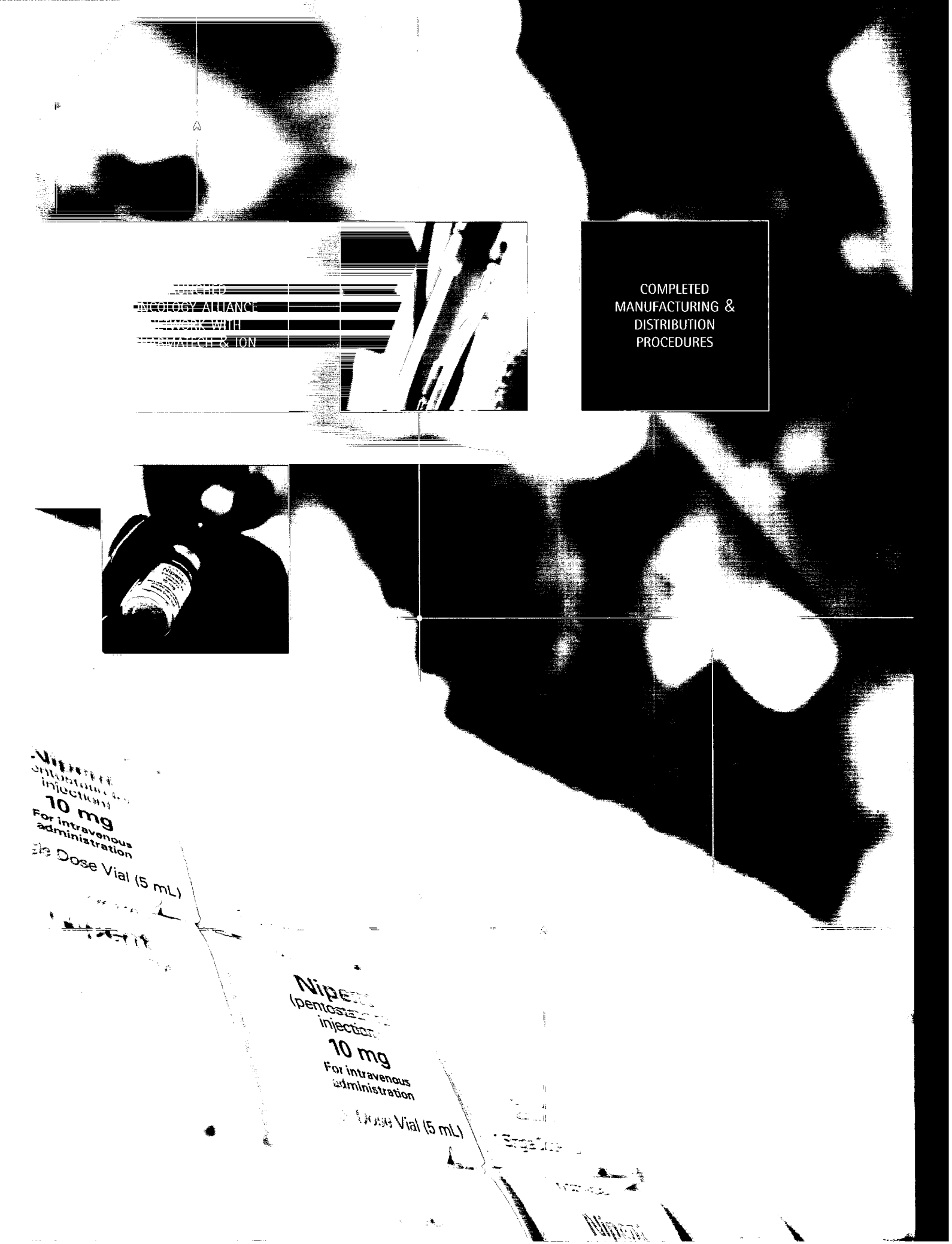
EXTENDING INDICATIONS

We also commenced Phase IV Nipent post-marketing trials in GvHD, both in children and adults, CLL and low-grade lymphoma. These studies are accumulating clinical data that we expect will demonstrate Nipent's utility in other treatment regimens. A full cost and clinical benefit analysis was completed, and we are exploring the feasibility of converting the Phase IV post-marketing trials to a registration trial during 2005.

Our 2005 Compassionate Use Program and Launch Plan for Orathecin was also completed during 2004 in anticipation of the original PDUFA date during the fourth quarter. We believe the subsequent withdrawal of our U.S. NDA filing at year-end has no bearing on our regulatory filing in Europe, and Orathecin remains on track for regulatory review by the EMEA during 2005.

REMODELING & RENEWING OUR PIPELINE

As 2004 drew to a close, SuperGen anchored its commercialization scaffold by finalizing the Dacogen exclusive licensing agreement with MGI. As the agreement required, Dacogen manufacturing operations were transitioned to MGI during the fourth quarter. SuperGen is proud of our collaboration with MGI. We strongly believe that we forged the right partnership with the right company, which will provide an efficient path to market for Dacogen. SuperGen enters the new year ready and able to grow its pipeline by acquiring, developing and commercializing promising new products.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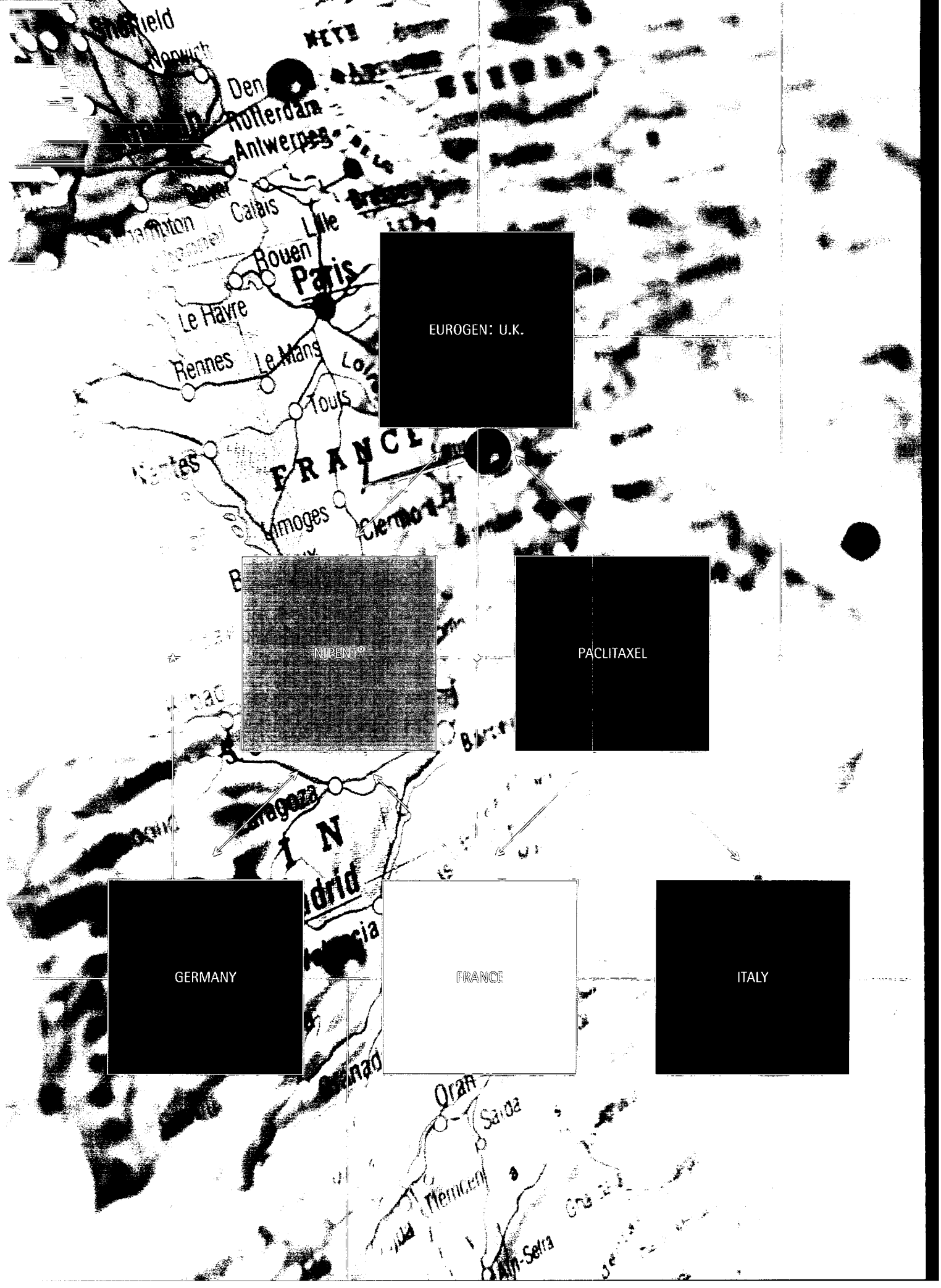

EUROGEN: U.K.
NIPENT®
PACLITAXEL
GERMANY
FRANCE
ITALY

EXTENDING SALES AND MARKETING REACH – SuperGen's long-term growth depends in part on our ability to extend our sales and marketing operations beyond the United States. A European presence is a necessary and critical component of SuperGen's strategy to become a truly global pharmaceutical company. Our subsidiary, EuroGen, manages the development of our commercial operations in key European markets and aggressively seeks opportunities to in-license new products that will expand SuperGen's product pipeline.

EXPANSION

OF EUROGEN TO BROADEN MARKET REACH

MANAGING REGULATORY FILINGS & MARKETING RIGHTS

EuroGen's activities during 2004 centered on preparing and submitting MAAs for both Orathecin and Dacogen with the EMEA. Both filings were accepted for review, and decisions on these two products are anticipated during 2005. Under the terms of our exclusive licensing agreement with MGI, EuroGen is the primary interface with the EMEA and will manage the remaining stages of the approval process for Dacogen.

In addition, during 2004 SuperGen reacquired the rights to market Nipent outside of the U.S. from Pfizer. By mid-year 2005, EuroGen should assume responsibility for all sales, marketing and distribution of Nipent from Pfizer's marketing partner, Wyeth Pharmaceuticals. Nipent will be EuroGen's first product launch in Europe during the summer of 2005.

SUPPORTING OUR COMMERCIALIZATION IN EUROPEAN MARKETS

EuroGen dedicated much of 2004 to improving its marketing infrastructure. We identified and selected specific European countries as our primary sales territories, representing up to 80 percent of the potential sales volume for our products. Initially, EuroGen will market SuperGen's products directly to cancer centers of excellence in the United Kingdom, France, Germany and Italy. EuroGen has already begun the process of assembling a small, highly select team of pharmaceutical sales representatives with significant oncology and hematology experience in these primary markets. During 2005, EuroGen plans to expand its operations to Spain, Austria and Ireland and establish a network of independent distributors to promote the sales of its products in other European countries.

LEVERAGING OUR INVESTMENT FOR FUTURE GROWTH

Considerable energy and resources have been spent building EuroGen this year, but we believe we can leverage this investment to yield important growth opportunities for SuperGen. With an established European sales and marketing infrastructure, we believe SuperGen is an attractive marketing partner for smaller pharmaceutical companies seeking a commercial presence in this region. As an extension of SuperGen's business development operations, EuroGen can actively seek to in-license new products for development, including those specifically targeted for European markets. EuroGen strengthens our foundation and expands our market reach, creating new opportunities to grow our product pipeline.

A FOCUSED MISSION – Developing and commercializing new cancer treatments is our mission. SuperGen's corporate strategy is to license or acquire rights to late-stage compounds that have already shown efficacy in humans within a particular disease. By doing so, we can control time and expense associated with drug commercialization, focus our energy on optimizing drug performance and deliver that drug to patients in need.

BUILDING

A PRODUCT PORTFOLIO ENGINEERED FOR GROWTH

A GROWING REVENUE STREAM FROM IN-LICENSED COMPOUNDS

At the bedrock of SuperGen's portfolio are products that penetrate the oncology and hematology markets. Mitomycin, Nipent and Surface Safe® are all in-licensed or developed compounds contributing to our current revenue stream. During 2004, interest increased in Nipent's utility for treatment of GvHD in both child and adult bone marrow transplant patients. Growing demand and higher product pricing increased Nipent revenues by 16 percent. With the transfer of marketing rights to SuperGen and a European launch planned for summer of 2005, we expect Nipent to contribute substantially to SuperGen's revenues in the coming year.

AN EVOLVING PRODUCT PIPELINE

In 2004, we filed NDAs for two investigational cancer therapeutics, Dacogen for MDS and Orathecin for advanced pancreatic cancer, with the FDA. We also filed MAAs with the EMEA for regulatory approval in the E.U.

However, based on feedback from the FDA, SuperGen withdrew its NDA for Orathecin at year-end. Upon review of the FDA's full report, we will decide on the future development of Orathecin in the U.S. Orathecin is still scheduled for review by the EMEA during 2005.

Additionally, Paclitaxel, our generic equivalent to Taxol®, a widely used cancer therapeutic, received U.S. approval in 2004 and European approval is expected in 2005. SuperGen does not intend to market Paclitaxel in the U.S., but through EuroGen, we will market Paclitaxel in Europe upon approval.

PARTNERING TO OPTIMIZE COMMERCIALIZATION

During the third quarter, we granted MGI an exclusive license to Dacogen to ensure that this drug will reach the market as expeditiously as possible. Importantly, MGI has committed to fund further development costs of Dacogen for additional indications. Milestone payments and future royalties from Dacogen will support SuperGen's continued effort to develop new and exciting cancer treatments.

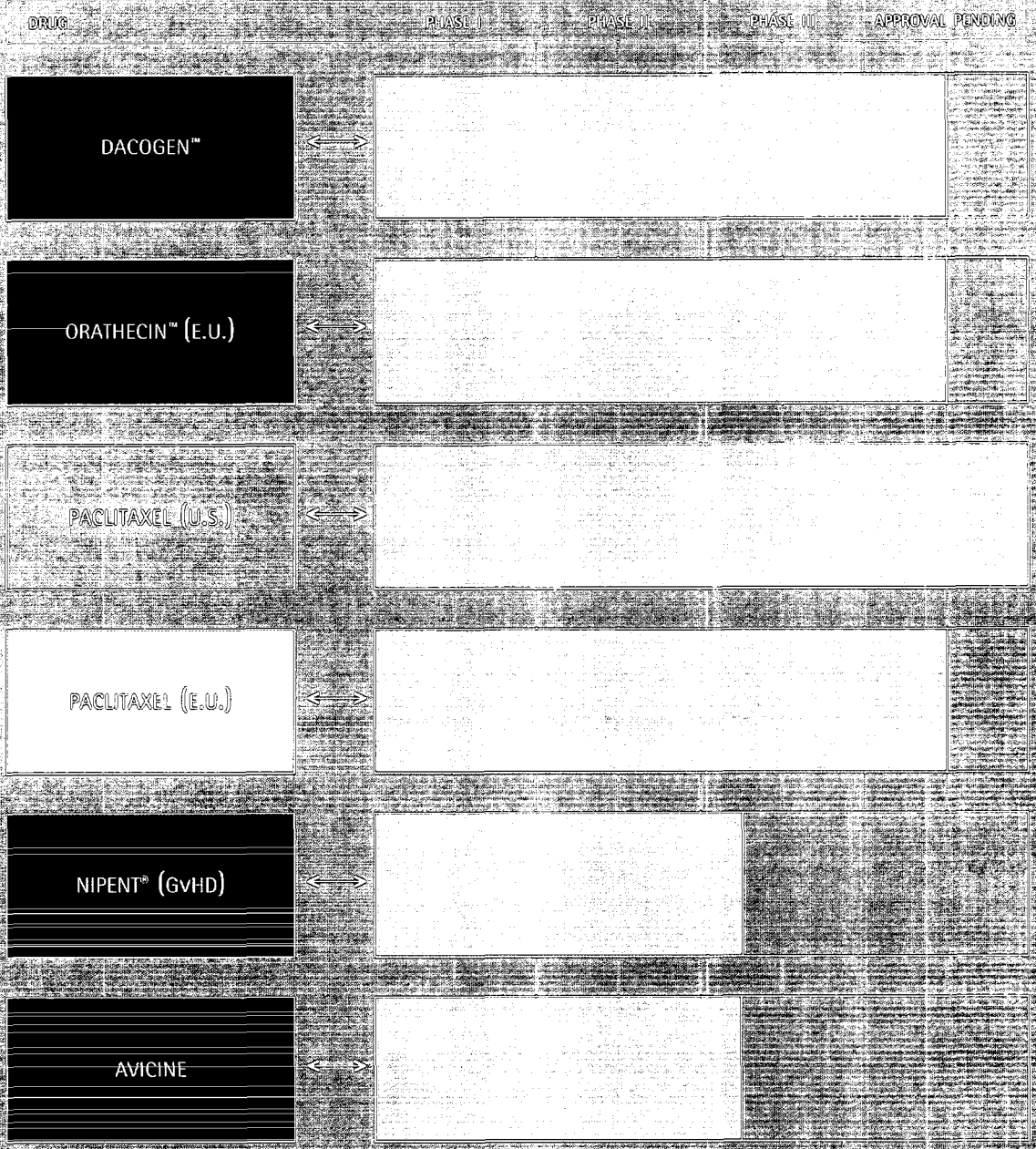
TRANSFORMING THE COMPANY THROUGH IN-LICENSING & ACQUISITIONS

We have begun the process of expanding our product pipeline. A rigorous screening of more than 30 new product candidates has identified several leading compounds for potential in-licensing, and we expect to select one or more for development by mid-year 2005. While we have focused primarily on therapeutic products, we will also consider drug delivery platform technologies that would complement SuperGen's product portfolio.

Developing a solid product portfolio that can generate consistent revenues takes patience. SuperGen's commitment remains steadfast to build a strong portfolio of oncology and hematology products and deliver value to our stockholders.


NIPENT®
ORATHECIN™
PACLITAXEL
SURFACE SAFE®

PRODUCT PIPELINE



IN SUMMARY

Today, SuperGen is quite different from the company we were just a short year ago. The internal improvements we made to our organization, our processes, and our commercial practices during 2004 reinforced our foundation, moved our products closer to market and sharpened our focus. Collectively, we believe these changes have made us a stronger company.

SuperGen is now capable of supporting future growth because our finances are sound. We raised capital, eliminated all balance sheet debt, implemented better cost controls and expanded our sales efforts. We structured a strategic partnership with financial terms that provide both milestone payments and a royalty revenue stream upon product commercialization, which will sustain us as we continue to build our revenue base.

SuperGen's commercialization infrastructure can now effectively execute strategic marketing programs because we installed the proper key structural elements. We developed our primary audience and customer base, refined our manufacturing protocols, mobilized our distribution networks and strengthened our patent portfolio.

SuperGen now has even broader market reach through EuroGen, which is building a carefully selected marketing team and distribution network that will be ready to support commercialization of our products, as well as those of other companies in several major European markets.

Throughout this report, we have shown some of the ways in which we have been "Building for Growth." We believe this ongoing process is the path to realizing our most important goals. With a sound infrastructure that will enable us to continue to grow, we believe we can succeed in improving patients' lives and delivering value to our stockholders.

SUPERGEN

FINANCIALS 04

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, 2004

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	**91-1841574**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
4140 Dublin Blvd., Suite 200, Dublin, CA	**94568**
(Address of principal executive offices)	(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, 2004, the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $279,172,873. 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 4, 2005 was 51,142,214.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III incorporate by reference information from the definitive proxy statement for the Registrant's Annual Meeting of Stockholders to be held on May 12, 2005.

SUPERGEN, INC.

2004 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 Section 27A of the Securities Act and Section 21E of the Exchange Act, and 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 statements include statements such as: the timing of receiving FDA approval of our NDA filing for Dacogen; the timing of receiving EMEA approval of our MAA filings for Orathecin and Dacogen; our estimates about becoming profitable; our forecasts regarding our research and development expenses; our expectation that EuroGen will generate revenue by the end of 2005; and our statements regarding the sufficiency of our cash to meet our operating needs. 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 and managing our clinical trials; developing products and obtaining regulatory approval; ability to establish and maintain collaboration relationships; competition; ability to obtain funding; ability to protect our intellectual property; our dependence on third party suppliers; risks associated with the hiring and loss of key personnel; adverse changes in the specific markets for our products; 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—Factors Affecting Future Operating Results" in this report. These are currently known and material risks that we believe 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 a pharmaceutical company dedicated to the development and commercialization of therapies for solid tumors, hematological malignancies and blood disorders. Currently, we have three key compounds that are the primary focus of our efforts: Dacogen™ (decitabine) for injection, Orathecin™ (rubitecan) capsules and Nipent® (pentostatin for injection).

On January 26, 2004, we submitted a New Drug Application ("NDA"), under accelerated approval procedures with the U.S. Food and Drug Administration ("FDA") for Orathecin for the treatment of pancreatic cancer patients that had failed one or more therapies. The filing was accepted by the FDA and indicated a target Prescription Drug User Fee Act ("PDUFA") date of November 26, 2004. At the request of the FDA, during November 2004 we submitted additional clinical data from a trial of Orathecin as a first-line treatment for pancreatic cancer as well as new analyses of data from the pivotal study in 2nd and

3rd line patients. The FDA classified these data as a Major Amendment, which triggered an extension of the review period by 90 days resulting in a revised target PDUFA date of February 26, 2005. Based on further discussions and feedback with both the FDA and consultants helping us dialog with the FDA, it was determined the current package for Orathecin was not sufficient to gain approval at this time in the United States and we announced the withdrawal of the NDA in January 2005. During the 2005 first quarter we received the findings from the FDA and will review these findings and determine the most appropriate course of action in the future for Orathecin in the United States.

During July 2004, we submitted a Marketing Authorization Application ("MAA") to the European Agency for the Evaluation of Medicinal Products ("EMEA") seeking approval of Orathecin. The MAA for Orathecin was submitted by our European subsidiary, EuroGen Pharmaceuticals Ltd. ("EuroGen") and will be reviewed under the EMEA Centralized Procedure, where marketing authorization is applied for in all 25 European Union ("EU") Member States simultaneously. EMEA procedures generally provide that a decision on the Orathecin MAA will usually occur within 12 months of acceptance of the submission. Our European filing for Orathecin remains on track and is not affected by the withdrawal of our NDA for Orathecin in the United States.

During March 2004, we reported the results from our randomized Phase III study of Dacogen as a treatment for myelodysplastic syndromes ("MDS"). On November 1, 2004, we submitted an NDA with the FDA for Dacogen. The filing was accepted by the FDA and indicated a target PDUFA date of September 1, 2005. The acceptance for review of the NDA represents the FDA's determination that the application is sufficiently complete to permit a substantive review.

On October 1, 2004, we submitted a MAA to the EMEA seeking approval of Dacogen. The MAA for Dacogen was submitted by EuroGen and will be reviewed under the EMEA Centralized Procedure, where marketing authorization is applied for in all 25 EU Member States simultaneously. EMEA procedures generally provide that a decision on the Dacogen MAA will usually occur within 12 months of acceptance of the submission.

On September 1, 2004, we announced the signing of a definitive agreement granting MGI PHARMA ("MGI") exclusive worldwide rights to the development, manufacture, commercialization and distribution of Dacogen. Under the terms of the agreement, MGI made a $40.0 million equity investment in us at $10.00 per share and will pay us up to $45.0 million upon achievement of specified regulatory and commercialization milestones. If Dacogen is approved we will receive a royalty on worldwide net sales starting at 20% and escalating to a maximum of 30%. MGI has also committed to fund further development costs associated with Dacogen at a minimum of $15.0 million over a three year period. The transaction closed on September 22, 2004.

Nipent is approved by the FDA and EMEA for the treatment of hairy cell leukemia and is marketed by us in the United States and Europe. The European distribution is currently handled by Wyeth Pharmaceuticals ("Wyeth") under a distribution agreement. We have completed several Phase IV clinical trials, or post-marketing trials, and continue to conduct trials intended to expand Nipent's potential use beyond the treatment of patients with hairy cell leukemia to indications including chronic lymphocytic leukemia ("CLL") non-Hodgkin's lymphoma ("NHL"), and graft-versus-host disease ("GvHD"). We have commercialization rights for each of these compounds, and intend to market them directly in the United States through our sales force, and either directly or indirectly in additional international markets.

Strategy

We commercialize products by pursuing a strategy of identifying and acquiring pharmaceutical compounds in the late stages of development, which allows us to minimize the time, expense and technical risk associated with drug research. Rather than engage in discovery research to obtain lead compounds, we license or acquire rights to compounds that have shown initial efficacy in humans or in a model relevant to

a particular disease at the pre-clinical or early clinical stages of development. Our primary objective in the pursuit of this strategy is to be a leading supplier and developer of therapies for solid tumors, hematological malignancies and blood disorders. Key elements of our strategy include:

Expanding commercialization of our current products and launching each new product when approved by the FDA or other regulatory agencies such as the EMEA. We intend to focus significant resources associated with enhancing commercialization efforts with our existing products or the launch of new approved marketed products. As part of our commercialization efforts, we will or may be required to:

- hire additional sales, marketing and medical affairs personnel;
- develop and implement appropriate indigent support programs;
- develop and implement Phase IV clinical trials to explore additional combination and single agent uses for marketed products;
- develop and implement physician, pharmacist and nursing education programs to fully understand the impact and advantages of treating cancer patients;
- develop and produce collateral material regarding the appropriate uses of marketed drugs as Nipent or Orathecin (if approved); and
- further develop and refine marketing plans with respect to all marketed drugs.

It is our intent to continue to increase our presence within the oncology marketplace through our commercialization initiatives, and we believe such efforts will also benefit our existing product, Nipent, and new approved products.

Expanding our sales and market penetration of the therapeutic anti-cancer market. We have endeavored to establish a leadership position in the market of hematological products. This market exists within the overall anti-cancer market. We believe we are prudently expanding our sales and marketing organization in the hematology space and expanding our brand into solid tumors to support commercialization of our existing and any new products. This expansion primarily entails increasing the number of direct sales representatives we employ to call on oncologists and hematologists. The expansion also entails additional investment in marketing and branding initiatives to extend our name recognition further into the therapeutic anti-cancer market.

Globalizing our commercial presence. We believe that the global market opportunity for our products is meaningfully greater than the market opportunity in the United States alone. Therefore, as more of our products are approved for marketing in the United States, we intend to penetrate the worldwide market for anti-cancer products. The expansion of our subsidiary, EuroGen, is the next step in this strategy, intended to ultimately create a meaningful presence for our products in five major countries of the EU. EuroGen is primarily a registration, sales and marketing organization. Previously, EuroGen has filed registration documentation to sell mitomycin and paclitaxel. During 2004, EuroGen filed registration documentation for Orathecin and Dacogen and transferred the Nipent MAA from Pfizer to EuroGen. EuroGen is not expected to penetrate all European markets in the near future. The markets for anti-cancer products in the United Kingdom, Germany, France, Italy and Spain represent approximately 80 percent of the current anti-cancer market in Western Europe. We expect EuroGen to generate revenue by the end of 2005 from sales of one or more of our products. We intend to penetrate other areas outside of the United States through partners and distributors.

Capitalizing on our existing clinical expertise and regulatory development to maximize the commercial value of our products. We intend to expand potential applications of our products both within existing labeling for our products and through supporting physician-initiated interest in clinical trials in therapeutic areas beyond our products' approved indications. This expansion entails managing numerous additional

clinical studies and regulatory interactions for our key products. This process is complex whether it is conducted through our clinical department for formal label expansion or whether the trials are supported and managed through our Medical Affairs department. Over 20 physicians have initiated clinical studies with Nipent that are currently being managed by our Medical Affairs department for a wide range of diseases. We believe companies are open to working with us because of our corporate expertise with the developmental, regulatory and marketing aspects of maximizing the value of products in this market segment. We believe our clinical development experience serves to increase the value of our product portfolio.

Licensing or buying rights to later stage compounds. We identify and seek to license or buy rights to products or compounds that are 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 discovery research and reduces the risk of failure in developing a commercially viable product. Orathecin, Dacogen and Nipent were each acquired through this process. We believe our ability to navigate products through clinical development, the FDA and other regulatory agencies makes us a more attractive partner for companies seeking to sell or license later stage products or compounds.

Summary of Products and Products in Development

Dacogen

Dacogen, a pyrimidine analog that decreases the amount of methylation at certain DNA sites, is an active therapeutic product that we acquired from Pharmachemie in September 1999. Aberrant DNA methylation has been implicated as a fundamental factor in the development of all cancers. Researchers have determined that an increase in specific methylation of DNA can result in blocking the activity of genes, thereby reducing the degree of cellular antigen expression and potentially causing chemotherapy resistance. In clinical studies, researchers have demonstrated that Dacogen can reverse the methylation of DNA, potentially leading to re-expression of genes and a resulting re-differentiation and maturation of the cancer cells back to pre-cancer levels. Researchers have also produced evidence that Dacogen treatment may reverse drug resistance by restoring the sensitivity of tumors to treatment by drugs such as cisplatin.

Myelodysplastic Syndromes

MDS is a bone marrow disorder characterized by the production of abnormally functioning, immature blood cells. According to the American Cancer Society, there are an estimated 10,000-20,000 new cases of MDS in the United States each year. In the majority of afflicted patients, MDS results in death from bleeding and infection. In other patients, MDS can transform to acute myelogenous leukemia ("AML") a disease with a high mortality rate.

In multiple Phase II studies in Europe, researchers demonstrated that Dacogen is active and potentially efficacious for treating patients with MDS. Based on positive results from these European Phase II studies, we conducted a randomized Phase III study in the United States. This Phase III trial was designed to support regulatory approval of Dacogen for the treatment of patients with MDS in the United States and Europe. During the American Society for Hematology meeting in December 2004, we reported results from our randomized Phase III study of Dacogen for injection as a treatment for MDS. The study enrolled 170 patients at 22 North American sites, with 89 randomized to Dacogen plus supportive care and 81 randomized to supportive care only. Supportive care included antibiotics, growth factors and/or transfusions. The presentation included results from both primary endpoints of the study, response rate (CR + PR) per IWG MDS criteria as well as time to AML transformation or death.

Patients randomized to the Dacogen arm had a significantly superior response rate compared to patients randomized to the best supportive care arm, 17 % versus 0%, $p < 0.001$. Responses to Dacogen

treatment were seen in all IPSS groups enrolled in the study. The median duration or response was 266 days. Dacogen responders versus all non-responders had a median of 491 versus 274 AML-free days until death, a median of 657 versus 384 days of survival and remained or became RBC/platelet transfusion independent during response. Median time to AML transformation or death in all patients was 340 days for the Dacogen arm versus 219 days for the best supportive care arm (p= 0.043 Wilcoxon, 0.160 Log-rank). All analyses were specified by the protocol. We and our clinical advisors believe that these data are clinically significant and these data were used to form the basis of our NDA and MAA for Dacogen.

More adverse events were reported for patients randomized to the Dacogen arm. Leucopenia and febrile neutropenia were observed more frequently in patients given Dacogen, as were nausea, constipation, diarrhea, vomiting, pneumonia, arthralgia, headache and insomnia. Severe adverse events observed more frequently in patients randomized to Dacogen, categorized as Grade 3 or 4, were leucopenia and febrile neutropenia. The rates of Grade 3-4 sepsis were similar (8 percent in the Dacogen arm versus 6 percent in the supportive care only arm). The mortality rate for patients on study is 12% for Dacogen and 9% for supportive care. This difference in mortality rates was not statistically significant.

Dacogen received orphan drug designation in the United States and Europe, which may provide us with seven years of marketing exclusivity in the United States and ten years marketing exclusivity in Europe, if Dacogen is approved by regulatory authorities for MDS. In addition, the FDA has granted us "fast track" designation for Dacogen. However, the FDA approval process may take a significant amount of time and Dacogen may not be approved.

On November 1, 2004, we submitted an NDA to the FDA for Dacogen. The submission was accepted for filing by the FDA and indicated a target PDUFA date of September 1, 2005. The acceptance for review of the NDA represents the FDA's determination that the application is sufficiently complete to permit a substantive review.

On October 1, 2004, we submitted a MAA to the EMEA seeking approval of Dacogen. The MAA for Dacogen was submitted by EuroGen, and will be reviewed under the EMEA Centralized Procedure, where marketing authorization is applied for in all 25 EU Member States simultaneously. EMEA procedures generally provide that a decision on the Dacogen MAA will usually occur within 12 months of acceptance of the submission.

On September 1, 2004, we announced the signing of a definitive agreement granting MGI exclusive worldwide rights to the development, manufacture, commercialization and distribution of Dacogen. Under the terms of the agreement, MGI made a $40.0 million equity investment in us at $10.00 per share and will pay us up to $45.0 million upon achievement of specified regulatory and commercialization milestones. If Dacogen is approved we will receive a royalty on worldwide net sales starting at 20% and escalating to a maximum of 30%. MGI has also committed to fund further development costs associated with Dacogen at a minimum of $15.0 million over a three year period. The transaction closed on September 22, 2004.

Orathecin

Orathecin is an oral chemotherapy compound in the camptothecin class, licensed from the Stehlin Foundation for Cancer Research ("Stehlin") in 1997. Orathecin is a second-generation topoisomerase I inhibitor that causes single-strand breaks in the DNA of rapidly dividing tumor cells. Based on our developmental program and clinical trial results, we believe that Orathecin may have significant advantages over many existing anti-cancer drugs, including efficacy, side effect profile and oral dosing. In particular, we believe that inhibition of bone marrow function is low, due in part to Orathecin's 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 were mild to moderate hematological toxicities, low-grade cystitis, infrequent and mild hair loss and gastrointestinal disorders. As an oral drug that can be taken at home, we believe treatment with Orathecin would be more convenient, may reduce overall healthcare costs, and may

provide patients with an improved quality of life. We believe that Orathecin is a key drug that may be used in the treatment of a broad array of solid tumors and hematological malignancies. Orathecin received orphan drug designation for pancreatic cancer in both the United States and Europe, which may provide us with seven years of marketing exclusivity in the United States and ten years of marketing exclusivity in Europe, if Orathecin is approved by regulatory authorities for this disease. Similar marketing exclusivity is available in Japan.

On January 26, 2004, we submitted an NDA under accelerated approval procedures to the FDA for Orathecin for the treatment of pancreatic cancer patients that have failed one or more therapies. The filing was accepted by the FDA and indicated a target PDUFA date of November 26, 2004. At the request of the FDA, we submitted during November 2004 additional clinical data from a trial of Orathecin as a first-line treatment for pancreatic cancer as well as new analyses of data from the pivotal study in 2nd and 3rd line patients. The FDA classified these data as a Major Amendment, which triggered an extension of the review period by 90 days, resulting in a revised target PDUFA date of February 26, 2005. Based on further discussions and feedback with both the FDA and consultants helping us dialog with the FDA, it was determined the current package for Orathecin was not sufficient to gain approval at this time in the United States and we announced the withdrawal of the NDA in January 2005. During the 2005 first quarter we received the findings from the FDA and will review these findings and determine the most appropriate course of action in the future for Orathecin in the United States.

During July 2004, we submitted a MAA to the EMEA seeking approval of Orathecin. The MAA for Orathecin was submitted by our European subsidiary, EuroGen, and will be reviewed under the EMEA Centralized Procedure, where marketing authorization is applied for in all 25 EU Member States simultaneously. EMEA procedures generally provide that a decision on the Orathecin MAA will usually occur within 12 months of acceptance of the submission. Our European filing for Orathecin remains on track and is not affected by the withdrawal of the NDA for Orathecin in the United States.

Pancreatic Cancer

Pancreatic cancer causes more than 75,000 deaths per year globally. Based on a 1988-1992 study by the National Cancer Institute ("NCI") pancreatic cancer accounts for only 2% of all newly diagnosed cancers in the United States each year, but results in 5% of all cancer deaths. The most commonly used therapies to treat pancreatic cancer include 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. These data support Orathecin's efficacy in pancreatic cancer patients who had failed previous chemotherapy. Of the 45 patients with measurable disease, 10% experienced either a reduction in the size of their tumor or disease stabilization, meaning that the tumor did not grow. After starting Orathecin treatment, the median survival for these 10 patients was approximately 10 months. Four of them survived more than 12 months and two survived more than 24 months.

To date, over 2,700 patients in our clinical studies have been treated with Orathecin. We believe that our Orathecin clinical program is the largest regulatory registration program ever undertaken in pancreatic cancer. In 1998, we commenced three stand-alone Phase III clinical trials with Orathecin for treatment of advanced 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 failed multiple types of chemotherapy were randomized to either Orathecin or the physician's best choice therapy; and "Chemotherapy naïve," where patients who had no prior chemotherapy were randomized to Orathecin or gemcitabine. In the FDA's summary basis of approval, the program sizes for 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.

The primary endpoint of these trials was survival. The patient populations for the Orathecin Phase III clinical studies are as follows:

Protocol Description of Three Stand-Alone Phase III Studies	Enrollment Completed	Patients Enrolled
Gemcitabine refractory	February 2001	448
Chemotherapy refractory	June 2001	409
Chemotherapy naïve	October 2001	994

Given the large scale of the Orathecin clinical program and the inherent uncertainties associated with clinical trials of such magnitude and complexity, the data and statistical analysis from these trials may not support regulatory approval. For example, the design of these trials allowed patients who initially were being treated with gemcitabine or other therapies to cross over to treatment with Orathecin. At the time the trials were designed, we believed that the percentage of patients who would cross over for treatment with Orathecin would be in the range of 10% to 20% of the total enrolled patients. The number of patients in our trials who actually crossed over to treatment with Orathecin significantly exceeded the number anticipated and was nearly 50% in two of our Phase III studies. The extent of this cross over has negatively affected the statistical analysis of the study with respect to the overall survival analysis, making it difficult to determine if the product is efficacious with respect to survival.

In May 2003, we announced data from one of our Phase III studies of Orathecin in patients with advanced pancreatic cancer, most of whom had previously failed two or more chemotherapy treatments. The study randomized 409 patients to either Orathecin or "best medical therapy." The primary study end-point was overall survival with secondary endpoints, including tumor response and time to disease progression. We did not meet the primary endpoint, although we did meet two of the secondary end-points. The two secondary end-points were independent of a cross-over effect whereas the primary end-point was not. It remains uncertain whether the released data, and the data from our other clinical trials, will be sufficient to support regulatory approval for Orathecin, and additional trials may be required before we can obtain regulatory approval.

Other Potential Indications

In addition to studies relating to pancreatic cancer, pre-clinical studies have shown Orathecin to be active in more than 30 human and animal tumor models in indications such as breast, lung, colorectal, ovarian, gastric and prostate cancers, as well as sarcomas. We have pursued numerous Phase I/II trials using Orathecin both as a single therapeutic agent and in combination with other anti-cancer agents in solid tumors and hematological malignancies.

In addition, we are currently conducting the 30 patient, non-randomized portion, of a phase III study using Orathecin in combination with gemcitabine. In other combination studies to date, Orathecin has not exhibited significant cardiac, pulmonary, hepatic or renal toxicities that often limit the acute and/or chronic dosages of several chemotherapeutics. The primary dose-limiting toxicities associated with Orathecin are hematologic and gastrointestinal disorders.

Nipent

Nipent inhibits a key enzyme in the DNA synthesis process and results in cytotoxicity, primarily in lymphocytes, with little other known effect on normal tissue. We acquired Nipent from the Parke-Davis division of the Warner-Lambert Company (Pfizer) in 1996 and the remaining European rights in February 2004. Wyeth is the current distributor outside of the United States. 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 since 2000.

Hairy Cell Leukemia

We are selling Nipent directly in the United States for the treatment of hairy cell leukemia, a type of B-lymphocytic leukemia. Wyeth sells Nipent outside the United States under a distribution agreement we acquired in February 2004. Warner-Lambert had initially retained a worldwide, royalty-free license to sell Nipent, but sold these rights to us in February 2004.

Other Indications

Phase IV trials suggest that Nipent may have activity in a variety of other hematologic cancers. We are conducting Phase IV studies for treatment of hematological malignancies and disorders, such as CLL, NHL, and cutaneous and peripheral T-cell lymphomas.

In addition, Nipent has shown activity in various autoimmune diseases, including GvHD, bone marrow transplantation and multiple sclerosis. We believe that the United States markets for GvHD and various autoimmune diseases are larger than the market for hairy cell leukemia. We are conducting Phase I clinical trials in autoimmune conditions and Phase II trials in GvHD, and developing an oral formulation of Nipent, which may be suitable for more chronic administration.

Other Products and Product Candidates

In addition to our three key compounds, Dacogen, Orathecin, and Nipent, we have the following products and product candidates:

Product Category	Compound	Indication or Intended Use	Therapeutic Category	Regulatory Status
Generic Anti-Cancer Products	Mitomycin	Solid tumors	Cancer	Marketed
	Daunorubicin	Acute leukemias	Cancer	Marketed
	Paclitaxel	Solid tumors	Cancer	Approved
Non-Pharmaceutical Product	Surface Safe®	Surface Decontaminate		Marketed
Formulation Products	Mitozytrex	Solid tumors	Cancer	Approved
	Inhaled Orathecin	Solid tumors	Cancer	Phase II
	Partaject busulfan	Neoplastic meningitis/ bone marrow transplant	Cancer	Phase I/II
	Partaject Orathecin	Solid tumors	Cancer	Pre-clinical
	CZ 112	Solid tumors	Cancer	Phase I
	Cremophor-free paclitaxel	Solid tumors	Cancer	Pre-clinical
Product Candidates	Avicine	Therapeutic Vaccine	Cancer	Phase II
	VEGF	Anti-angiogenesis	Cancer	Pre-clinical

Generic Anti-Cancer Products

We have developed generic versions of existing anti-cancer agents as part of our proprietary formulation product development efforts. We believe that the total estimated United States sales for generic anti-cancer 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, 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 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 approval of an ANDA 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 and we are also a contract supplier for another distributor in the United States.

Daunorubicin. We received approval of an ANDA for generic daunorubicin for a variety of acute leukemias in 2001. We have entered into a letter of intent to provide this product to a United States distributor on a contract manufacturing basis.

Paclitaxel. We filed an ANDA for generic paclitaxel with the FDA in August 1998. During November 2004, we received approval from the FDA of our ANDA Paclitaxel Injection, 6 mg/mL, packaged in 30 mg/5 mL and 100 mg/16.7 mL multiple-dose vials. Paclitaxel belongs to the group of medicines called antineoplastics. The drug is equivalent to Bristol-Myers Squibb's Taxol® Injection; an anti-tumor agent that has become one of the most widely used anti-cancer products. Paclitaxel Injection's approved indication is identical to Taxol and is indicated as treatment for a variety of cancers. At this time we will not directly market this product, but are in discussions with United States distributors to license out the ANDA.

Non-Pharmaceutical Product

Surface Safe. Surface Safe is a two-step disposable towelette cleaning system used to decontaminate work surfaces where chemotherapeutic preparation is conducted, which we acquired in July 1999 from Aldorr, Inc., a medical technology development company. 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.

Formulation Products

We have focused the application of our technologies on the development of improved formulations of existing anti-cancer 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.

Mitozytrex. Our first product utilizing our formulation technology, Mitozytrex, which is a 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. We cannot promote Mitozytrex as providing any injection site ulceration protection, nor can we promote any commercially viable increased stability, solubility or shelf life extension, as compared to generic mitomycin. We must develop and submit additional data to the FDA in NDA supplements and receive FDA approval for additional claims. We are currently exploring marketing opportunities and/or marketing partners for Mitozytrex.

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 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 underway.

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 mechanisms 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 GlaxoSmithKline for the palliative treatment of CML. It is 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.

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 Stehlin 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.

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 for 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.

Product Candidates

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 and has completed Phase II clinical trials for colorectal and pancreatic cancer.

VEGF (Anti-Angiogenesis). In February 2001, we licensed from Peregrine Pharmaceuticals (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. We are currently in the process of exploring marketing opportunities and/or marketing partners for this product.

Proprietary Formulation Technology

We have developed several applications for our proprietary formulation technology, a platform technology that employs the use of an inert chemical excipient, cyclodextrin, combined with a drug. Most anti-cancer 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 formulation 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 anti-cancer drugs, hence potentially increasing its stability or shelf life. Each of these benefits must be supported by appropriate data and approved by the FDA as part of an NDA filing. We believe that such features, if approved by the FDA, will result in our formulation 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 formulation technology from Janssen Biotech, N.V. ("Janssen") and others.

Non-Oncology Proprietary Products

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

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.

AM 454 is a DHEA phosphocholine derivative which may have utility in obesity and diabetes.

Research and Development

Because of the stage of our development and the nature of our business, we expend significant resources on research and development activities. We expended $24.0 million in 2004, $26.3 million in 2003, and $29.9 million in 2002 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 Dacogen, Orathecin, and studies on additional uses for Nipent.

Dacogen

From 1999 through 2004, we have spent approximately $11.3 million on the pre-clinical and clinical development of Dacogen. Dacogen is our investigational anti-cancer therapeutic for the treatment of patients with MDS. We submitted an NDA for Dacogen to the FDA on November 1, 2004 and it was accepted for filing on December 31, 2004. A response is expected from the FDA by September 1, 2005. On October 1, 2004, EuroGen submitted a MAA for Dacogen to the EMEA. The submission was accepted for review on October 25, 2004. EMEA procedures provide that a decision on the Dacogen MAA will usually occur within 12 months of acceptance of the submission.

In September 2004, we licensed to MGI the exclusive worldwide rights to the development, commercialization and distribution of Dacogen for all indications. We will continue to pursue regulatory approvals of Dacogen for the treatment of MDS in the United States and Europe, with assistance from MGI, provided that all development of Dacogen will be transitioned to MGI no later than the end of 2005. MGI will assume full development responsibilities following the transition to them. MGI is required to

fund further development costs associated with Dacogen at a minimum of $15 million over a three year period.

Orathecin

From 1998 through 2004 we have spent approximately $69.9 million on the Orathecin program. On January 26, 2004, we submitted an NDA under accelerated approval procedures to the FDA for Orathecin for the treatment of pancreatic cancer patients that have failed one or more therapies. The filing was accepted by the FDA and indicated a target PDUFA date of November 26, 2004. At the request of the FDA, during November 2004 we submitted additional clinical data from a trial of Orathecin as a first-line treatment for pancreatic cancer as well as new analyses of data from the pivotal study in 2nd and 3rd line patients. The FDA classified these data as a Major Amendment, which triggered an extension of the review period by 90 days, resulting in a revised target PDUFA date of February 26, 2005. Based on further discussions and feedback with both the FDA and consultants helping us dialog with the FDA, it was determined the current package for Orathecin was not sufficient to gain approval at this time in the United States and we announced the withdrawal of the NDA in January 2005. During the 2005 first quarter we received the findings from the FDA and will review these findings and determine the most appropriate course of action in the future for Orathecin in the United States.

During July 2004, we submitted a MAA to the EMEA seeking approval of Orathecin. The MAA for Orathecin was submitted by our European subsidiary, EuroGen, and will be reviewed under the EMEA Centralized Procedure, where marketing authorization is applied for in all 25 EU Member States simultaneously. EMEA procedures generally provide that a decision on the Orathecin MAA will usually occur within 12 months of acceptance of the submission. Our European filing for Orathecin remains on track and is not affected by the withdrawal of the NDA for Orathecin in the United States.

Nipent

Through December 31, 2004, we have spent approximately $14.5 million on Phase I, II, and Phase IV programs related to different potential indications for 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. We are conducting Phase IV studies for treatment of hematological malignancies and disorders, such as CLL, NHL, cutaneous and peripheral T-cell lymphomas and acute and chronic GvHD. Nipent has received orphan drug designation by the FDA for treatment of CLL and cutaneous T-cell lymphoma.

Sales and Marketing

We currently have 37 employees focused on sales, marketing, and sales support of our products to cancer hospitals and clinics in the United States. The large majority of these hospitals are members of hospital buying groups. We have focused our efforts on selling to these groups since because 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., Oncology Supply, Cardinal Healthcare, 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. In addition, we have partnership arrangements with Group Physician Organizations including Pharmatech, U.S. Oncology, and National Oncology Alliance.

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 to improve market penetration of Nipent. 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 and compliance with FDA and foreign regulations. We maintain oversight of the quality control function of our third-party manufacturers 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 because 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 ("GMPs") 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 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.

In December 1997, we received approval from the FDA to commercially manufacture Nipent at one of our designated vendor's manufacturing sites 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. This company went out of business in late 2004. However, we have contracted with another manufacturer to purify Nipent, and we do not anticipate any interruptions to our supply of drug available for sale. 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 *"Risk Factors—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 doing so would reduce costs or improve control and flexibility of product supply.

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. 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 Stehlin, 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. 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, Stehlin will bear its own costs incurred in connection with the performance of the research activities that we may request and Stehlin 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.

Stehlin continues to hold the title to all inventions and other intellectual property made solely by employees or consultants of Stehlin 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 Stehlin 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 Stehlin a license under patents owned or controlled by Stehlin to market such products.

We were required to pay Stehlin approximately $9.6 million for research. Our agreement with Stehlin also calls for additional payments in our common stock upon the achievement of specified milestones and royalties on any product sales. We must make milestone payments under the agreement upon (a) notification by the FDA of the acceptance for filing of the first NDA submitted for Orathecin and (b) our receipt of the FDA notice that it has approved Orathecin for marketing. Each of such payments will be made in restricted shares of our common stock at a per share purchase price equal to the average trading price of the shares over a 30-day trading period. Through December 31, 2004, we have paid Stehlin all of the $9.6 million required for research. During the year ended December 31, 2004, the FDA accepted for filing our NDA submission for Orathecin. This triggered a required milestone payment to Stehlin of $500,000. We made the milestone payment through the issuance of 63,969 shares of unregistered common stock, which was calculated based on the average trading price of our stock during the 30-day period preceding the payment date.

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 Stehlin. 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. *Pharmachemie—Dacogen*

In September 1999, we entered into a Know-How Transfer and Cooperation Agreement with Pharmachemie. 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, 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 our common stock equal to $3.4 million aggregate amount.

3. *Warner-Lambert Company (Pfizer)—Nipent*

In September 1996, we entered into a Purchase and Sale Agreement with the Warner-Lambert Company (now Pfizer), pursuant to which we agreed to purchase the exclusive rights to the anti-cancer 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 and certain intellectual property.

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 $2.1 million in cash and $1.0 million in unregistered shares of our common stock, followed by an additional cash payment of $500,000.

In February 2004, we entered into a Purchase and Sale Agreement with Pfizer Inc. to acquire European marketing rights for Nipent. We paid Pfizer $1,000,000 under this agreement.

4. *Peregrine Pharmaceuticals—VEGF*

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 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.

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 our 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.

5. *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. In 2002, these warrants were extended for two additional years but expired unexercised in 2004.

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

License Agreements

In November 1999, we entered into two license agreements with the Clayton Foundation for Research ("Clayton"), a Texas nonprofit corporation, and the Research Development Foundation ("RDF"), a Nevada nonprofit corporation, 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 agreed

to use commercially reasonable efforts with regard to commercialization of the products under the agreements. The paclitaxel license agreement was subsequently terminated in 2003.

Under the terms of the camptothecin agreement, RDF may not license any other party rights to deliver camptothecin, 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 agreement. 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 agreement. 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 that 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 agreement, 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 agreement. 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 our common stock under each original agreement. In addition, we must pay RDF royalties based on gross revenues under the camptothecin agreement. 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 agreement. 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 our common stock with respect to each product under the camptothecin agreement upon (a) the earlier of (1) approval or (2) 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 the camptothecin agreement 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 agreement.

7. *Cyclex, Inc.*

In March 1994, we entered into a Patent License Agreement with Cyclex, Inc. pursuant to which we obtained a license under a patent identified in the agreement to make, use and sell pharmaceutical products for cytotoxic anti-cancer 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.

8. *Janssen Biotech, N.V.*

In March 1994, we entered into a Worldwide License Agreement with Janssen, pursuant to which we obtained from Janssen an exclusive license to make, use and sell the pharmaceutical cytotoxic anti-cancer 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. We paid $350,000 in 2003 following the approval of Mitozytrex.

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.

9. *The Jackson Laboratory*

In September 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, which relate to our proprietary formulation technology, 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 materials 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.

10. *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 percent 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 a former member of our board of directors was a member of the board of directors of AVI through March 2004. 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 an 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 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 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 $22.0 million in exchange for 1,684,211 shares of AVI common stock, paid in a combination of $5.0 million cash and the issuance of 347,826 shares of our common stock. As part of the agreement, we have a warrant to acquire up to an additional 10% of AVI's common stock at an aggregate exercise price equal to $60.0 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 had occurred as of December 31, 2004.

We will be required to make additional milestone payments to AVI for an aggregate of up to $80.0 million, including (a) $2.5 million in our stock or cash, upon completion of accrual into the Phase III trial for Avicine; (b) $2.5 million in our stock or cash, upon acceptance by the FDA of the NDA submitted for Avicine; (c) $5.0 million in our stock or cash, upon launch of Avicine in the United States, (d) $10.0 million in cash, when our annual Avicine product sales reach $100.0 million; (e) $15.0 million in cash, when our annual Avicine product sales reach $250.0 million; (f) $20.0 million in cash, when our annual Avicine product sales reach $500.0 million; and (g) $25.0 million in cash, when our annual Avicine product sales reach $1.0 billion. The ability to make milestone payments in our stock shall be at our option, subject to 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 15 years after the date of regulatory approval of Avicine in the United States, provided that the we and AVI may renew the agreement for the United States for (1) further successive one year periods, or (2) 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.

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 exclusively 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 $5.0 million cash payment to us in connection with the granting of the exclusive distribution rights by us to Abbott. In March 2003, we paid Abbott $500,000 for the right to terminate the agreement at our option, for a stated fee that decreases over time to $1.5 million at March 2005. In February 2005, we paid $1.5 million to Abbott to terminate this agreement effective March 1, 2005.

2. *Warner-Lambert Company (Pfizer)—Nipent*

In October 1997, we entered into a Supply Agreement with Warner-Lambert Company (Pfizer), 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.

In February 2004, we entered into a Purchase and Sale Agreement with Pfizer Inc. to terminate this Supply Agreement and to acquire European marketing rights for Nipent. We paid Pfizer $1.0 million under this agreement.

3. *Hauser Technical Services—Pentostatin (Nipent)*

In December 2002, we entered into a Pentostatin Supply Agreement with Hauser Technical Services, Inc., ("Hauser"). Under the agreement, Hauser batch processed pentostatin crude concentrate supplied to Hauser by us or parties authorized by us, to yield pentostatin as an active pharmaceutical ingredient ("API").

In April 2003, Hauser Inc., Hauser's parent company, and its wholly-owned subsidiaries filed for reorganization under chapter 11 ("Hauser Companies"). The Hauser Companies have sold their operating businesses and have proposed a liquidating plan of reorganization. The Pentostatin Supply Agreement was not included in the sale. We have recovered, with Hauser's consent and cooperation, our 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 and certain related equipment previously held by Hauser. We do not believe that we have any remaining obligations to Hauser.

4. *EuroGen Pharmaceuticals Ltd.*

In September 2001, we entered into a Supply and Distribution Agreement with EuroGen, our majority owned subsidiary. 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, which include giving certain third parties a right of first discussion, we will be required to offer EuroGen the option to obtain European and South African rights to certain of our other 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.

The term of the agreement will expire 15 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.

During 2001, we 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 were charged to Selling, general, and administrative expense in 2002. In 2003 and 2004, the results of EuroGen are included in our consolidated operations in Selling, general and administrative expenses. During the years ended December 31, 2004 and 2003, we have recorded expenses of $2,269,000 and $325,000, respectively, related to the EuroGen.

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

In May 1997, we entered into a Non-Exclusive Supply Agreement, as subsequently amended in August 1997 and 2001, 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 that meets current GMPs, 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 paid Yunnan an aggregate of $1.0 million during the FDA inspection period for the products.

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 drug products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical testing, 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 pre-clinical testing, an IND is submitted to 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 include the chemical structure of the compound, how the compound is manufactured, the results of animal studies and other previous experiments, the method by which it is believed to work in the human body and how, where and by whom the proposed new studies will be conducted. All clinical trials must be conducted in accordance with good clinical practices ("GCPs"). In addition, an Institutional Review Board ("IRB") at the hospital or clinic where the proposed studies will be conducted, must review and approve the protocol. The IRB has a responsibility to monitor the study for any safety issues. Progress reports on the status of the clinical trials must be submitted at least annually to the FDA. The FDA may, at any time during a clinical trial, impose a 'clinical hold' if they have any safety concerns about a trial. If such a case occurs, the clinical trial cannot continue until the FDA is satisfied that it is appropriate to proceed.

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 trials generally involve 20 to 80 healthy volunteers or patients and typically take approximately one year to complete. These trials are designed to evaluate a drug's safety profile and may include studies to assess the optimal safe dosage range. Phase I clinical studies also evaluate how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action.

Phase II clinical trials. In Phase II clinical trials, controlled studies are conducted on approximately 100 to 300 patients with the targeted disease. The primary purpose of these trials is to evaluate the safety of the drug in the target patient population but often preliminary efficacy data is also obtained. These studies generally take approximately two years and may be conducted concurrently with Phase I clinical trials. For anti-cancer drugs, the first human studies are referred to as Phase I/II studies because they evaluate safety and preliminary efficacy directly in the target patient population. This is done because most anti-cancer drugs are very toxic and cannot be administered to healthy volunteers, as is typical in Phase I studies.

Phase III clinical trials. This phase typically lasts about three years and usually involves 1,000 to 3,000 patients. Phase III trials typically compare an investigational agent against a product that is already approved for use in that indication. During these trials, physicians record observations as defined in the sponsor's protocol onto "case report" forms. These data are monitored regularly by company clinical monitors as well as the participating physician. There are specific requirements for the physician to report any adverse reactions that may result from the use of the drug. Company clinical monitors visit the sites regularly and transmit the data back to the company for analysis and ultimately for presentation to the FDA.

Marketing application. Companies have the opportunity to interact with health authorities, including both the FDA in the United States or the EMEA in the EU, during the course of a drug development program. Most companies take advantage of this access to these agencies to gain further insights about the kinds of data that will be expected in their marketing application. After the completion of the clinical trial phase, a company must compile all of the chemistry, manufacturing, preclinical and clinical data into a marketing application. In the United States, this is called an NDA; in the EU, it is called a MAA. This is a significant amount of information, often in excess of 100,000 pages, and it will be reviewed by these health authorities.

Both the FDA and the EMEA review these submissions for overall content and completeness before accepting them for review and may request additional information. Once an application is accepted for filing, each agency independently begins its in-depth review. In both the United States and Europe, there are specified timeframes for the health authorities to complete their review. The review process may be extended if an agency requests additional information or clarification regarding information already

provided in the submission. In the United States, the FDA may refer the application to an appropriate advisory committee, for a recommendation as to whether the application should be approved but the FDA is not bound by this recommendation. If FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter. The latter typically contains a number of conditions that must be met in order to secure final approval. 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 specific 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. The details of the review and approval process in Europe have general similarities to that outlined for the United States.

Marketing approval. When a health authority grants marketing approval to a drug, it can now be made available for physicians in that country or region to prescribe for their patients. Periodic safety reports must be submitted to health authorities who are very diligent to monitor the use of new drugs introduced to the market. Regulatory agencies around the world place great emphasis on pharmacovigilance, which is a term used to describe the need for companies to monitor any adverse events occurring in patients using the drug.

Phase IV clinical trials and post marketing studies. In addition to studies requested by the FDA as a condition of approval, trials may be conducted to generate more information about the drug. These studies may generate publications that broaden the use of the drug and its acceptance in the medical community.

"Fast Track." 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 development of the product. The FDA Modernization Act of 1997 specifies that the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. For a product designated as fast track, FDA may agree to accept the NDA in discreet sections to accelerate their review. This process is called a "rolling" review or a "rolling" NDA.

SuperGen obtained fast track designation for Orathecin for the treatment of patients with locally advanced or metastatic pancreatic cancer, and Dacogen for the treatment of patients with MDS, 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.

Approvals in European Union. In 1993, the EU established a system for the registration of medicinal products in the EU whereby marketing authorization may be submitted at either a centralized or decentralized level. The centralized procedure is administered by the EMEA. 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 provides a 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.

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. SuperGen had completed centralized filings for both Orathecin and Dacogen in the 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 most other countries 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, pricing approval is required in many countries; there can be no assurance that the resulting prices would be sufficient to generate an acceptable return on investment.

Off-Label Use. Physicians may prescribe drugs for uses that are not described in the product's labeling. 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 but it does limit 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, like *The New England Journal of Medicine*, that discuss off-label uses of marketed products. To the extent allowed, we may disseminate peer-reviewed articles on our products to our physician customers.

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 ("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 needs to include manufacturing information but does 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 is absorbed 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 may involve the controlled use of hazardous materials such as chemicals, viruses and various radioactive compounds.

Market Exclusivity

The commercial success of a product, once it is approved for marketing, will primarily depend on a company's ability to create and sustain market share and exclusivity. Market exclusivity can be created and maintained by a number of methods, including, but not limited to: patents, trade secrets, know-how, trademarks, branding and a variety of market exclusivity provisions. One such provision offers marketing exclusivity to drugs developed for the treatment of rare diseases.

Orphan Drug Designation

The United States, EU, Japan and Australia all have an enacted an "orphan drug" or rare disease program for drugs intended to treat rare diseases. Orphan drug designation must be requested before submitting an application for marketing approval. After the granting of an orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly. When a product with orphan drug status receives marketing approval for the indication for which it has such designation, the product is entitled to marketing exclusivity, which means the regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years in the United States, ten years in Europe and Japan and four years in Australia.

Orathecin has received orphan drug designation from the FDA and the EMEA for treatment of patients with refractory pancreatic cancer. Dacogen also received orphan drug designation from the FDA and EMEA for treatment of patients with MDS and sickle cell anemia.

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 us, can be uncertain and involve complex legal, scientific, and factual questions. See *"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 United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. To date, we have acquired licenses to or assignments of over 50 United States patents covering various aspects of our proprietary drugs and technologies, including 36 patents for various aspects of Orathecin and related products, six patents under our Nipent product portfolio, although none covers the use of Nipent in an intravenous injectable formulation for the treatment of hairy cell leukemia, six patents for our paclitaxel related products, one patent for Dacogen used in combination with an anti-neoplastic agent for the treatment of cancer, and two patents for our Surface Safe products. These issued United States patents will begin to expire in October 2012. We have been granted patents and have received patent licenses relating to our proprietary formulation technology, non-oncology and Partaject

technologies, among which at least five patents are issued or licensed 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 the products we are developing.

In general, we obtain licenses from various parties that 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 on the EU, 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.

Trade Secrets and Trademarks

We also 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 Argentina, Austria, Australia, Bosnia-Herzegovina, Brazil, Benelux, Canada, Chile, Costa Rica, Czech Republic, Germany, Ecuador, El Salvador, Estonia, France, Great Britain, Georgia, Greece, Guatemala, Hong Kong, Honduras, Ireland, Italy, Jamaica, Japan, Lithuania, Latvia, Nicaragua, Norway, New Zealand, Panama, Poland, Portugal, Paraguay, Romania, Slovak Republic, South Africa, South Korea, Serbia-Montenegro, Switzerland, Taiwan, Ukraine, the United States and Uruguay; application pending in Mexico);

- SuperGen is registered in Australia, the EU, Hong Kong, Japan, Taiwan and the United States for use in pharmaceutical sales, and is the subject of pending applications for those goods in Canada and South Korea, as well as for manufacturing services in the United States;
- Orathecin is registered in Australia and the EU; pending applications in Canada, Japan and the United States;
- Dacogen is registered in Japan; pending applications in Australia, Canada, the EU and the United States;
- Mitozytrex is the subject of pending applications in Canada, Japan, the EU and the United States;
- Partaject is registered in the EU; pending applications in Canada and the United States;
- Surface Safe is registered in the United States; pending applications in Canada and the EU;
- EuroGen is registered in Hong Kong; pending applications in Australia, Canada, the EU, Japan and the United States;
- "Green bubbles" logo is registered in the United States; pending applications in Canada and the EU.

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 Aventis AG, Berlex Laboratories, Bristol-Myers Squibb Company, Eli Lilly & Co., Glaxo Smithkline, Novartis AG, Pfizer, Pharmion 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. In addition, Berlex Laboratories' fludarabine competes with Nipent in the leukemia market and Dacogen faces competition from Pharmion's Vidaza.

In addition, many of these competitors, either alone or together with their customers, have significantly greater experience than we do in developing products, undertaking pre-clinical 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 "*Factors Affecting Future Operating Results—If we fail to compete effectively against other pharmaceutical companies, 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.

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.

Employees

As of December 31, 2004, we had 109 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 consider our relations with employees to be good.

Geographic Area Financial Information

We operate in one business segment—human therapeutics. In 2004, 89% of our sales were made in the United States and 11% were made in the EU. In 2003 and 2002, 97% of our sales were made in the United States and 3% in the EU.

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 ("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 a website (*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 a 10,000 square foot industrial building that we own in Pleasanton, California. We also possess a five year lease to a 20,000 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 not currently subject to any pending material legal proceedings.

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

None

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 sales information for our common stock for each quarterly period in the two most recent fiscal years as reported on the Nasdaq National Market:

	High	Low
2004		
Quarter ended March 31, 2004	$14.14	$6.10
Quarter ended June 30, 2004	9.43	6.08
Quarter ended September 30, 2004	8.05	4.50
Quarter ended December 31, 2004	7.99	5.00
2003		
Quarter ended March 31, 2003	$ 4.05	$2.10
Quarter ended June 30, 2003	7.24	2.77
Quarter ended September 30, 2003	8.65	4.11
Quarter ended December 31, 2003	11.40	7.44

Holders of Record

As of March 4, 2005, there were 579 holders of record of the common stock and approximately 23,000 beneficial stockholders.

Dividends

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

Recent Sales of Unregistered Securities

None

ITEM 6. SELECTED FINANCIAL DATA.

The information set forth below is not necessarily indicative of results of future operations and should be read in conjunction with the financial statements and notes thereto appearing in Item 15 of Part IV of this report.

	Year ended December 31,				
	2004	2003	2002	2001	2000
	(Amounts in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Total revenue	$ 31,993	$ 11,494	$ 15,269	$ 11,451	$ 7,089
Cost of sales	4,135	3,865	4,491	2,727	1,641
Research and development	23,978	26,312	29,895	47,833	31,387
Selling, general and administrative	28,800	24,436	23,525	22,079	15,964
Acquisition of in-process research and development	—	—	—	—	1,585
Loss from operations	(24,920)	(43,119)	(42,642)	(61,188)	(43,488)
Other income (expense)	(21,940)	(10,351)	(6,829)	5,622	8,205
Net loss	$(46,860)	$(53,470)	$(49,471)	$ (55,566)	$ (35,283)
Basic and diluted net loss per common share	$ (1.04)	$ (1.56)	$ (1.52)	$ (1.69)	$ (1.04)
Shares used to compute basic and diluted net loss per common share	44,953	34,276	32,542	32,925	33,822

	As of December 31,				
	2004	2003	2002	2001	2000
Balance Sheet Data:					
Cash, cash equivalents, marketable securities, investments, and restricted cash and investments	$ 67,047	$ 39,926	$ 39,982	$ 77,359	$133,815
Other current assets	22,444	9,035	9,744	5,807	7,541
Property, plant and equipment, net	3,635	4,420	5,443	6,345	5,438
Other assets	1,531	1,355	2,164	33,206	16,539
Total assets	$ 94,657	$ 54,736	$ 57,333	$122,717	$163,333
Convertible debt, net of discounts	$ —	$ 13,593	$ —	$ —	$ —
Other current liabilities	20,517	11,821	7,548	12,752	10,221
Non-current liabilities	927	2,475	1,783	2,167	3,167
Stockholders' equity	73,213	26,847	48,002	107,798	149,945
Total liabilities and stockholders' equity	$ 94,657	$ 54,736	$ 57,333	$122,717	$163,333
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 contain 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 likelihood receiving FDA approval of our NDA for Dacogen; the timing of receiving EMEA approval of our MAA filings for Orathecin and Dacogen; our expectations regarding milestone revenues under our agreement with MGI; 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. 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 and managing our clinical trials, developing products and obtaining regulatory approval; ability to establish and maintain collaboration relationships; competition; ability to obtain funding; ability to protect our intellectual property; our dependence on third party suppliers; risks associated with the hiring and loss of key personnel; adverse changes in the specific markets for our products; and ability to launch and commercialize our products including our ability to achieve the milestones that may entitle us to receive royalty payments from MGI. 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 "Factors Affecting Future Operating Results" in this section of the 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 a pharmaceutical company dedicated to the development and commercialization of therapies for solid tumors, hematological malignancies, and blood disorders. Our strategy is to commercialize products by minimizing the time, expense and technical risk associated with drug research through identifying and acquiring pharmaceutical compounds in the later stages of development. Our primary objective is to become a leading supplier of therapies for solid tumors, hematological malignancies, and blood disorders.

Since our incorporation in 1991 we have devoted substantially all of our resources to our product development efforts. Currently we have three key compounds, Orathecin, Dacogen and Nipent, that are the focus of our efforts.

Orathecin. During January 2004, we submitted an NDA to the FDA for Orathecin. The filing was accepted by the FDA and indicated a target PDUFA date of November 26, 2004. At the request of the FDA, we submitted during November 2004 additional clinical data from a trial of Orathecin as a first-line treatment for pancreatic cancer as well as new analyses of data from the pivotal study in 2nd and 3rd line patients. The FDA classified these data as a Major Amendment, which triggered an extension of the review period by 90 days resulting in a revised target PDUFA date of February 26, 2005. Based on further discussions and feed back with both the FDA and consultants helping us dialog with the FDA it was determined the current package for Orathecin was not sufficient to gain approval at this time in the United States and we announced the withdrawal of the NDA in January 2005. During the 2005 first quarter we received the findings from the FDA and intend to review these findings and determine the most appropriate course of action in the future for Orathecin in the United States. During July 2004, we submitted a MAA seeking approval of Orathecin to the EMEA. EMEA procedures generally provide that a decision on the Orathecin MAA will usually occur within 12 months of acceptance of submission which could result in a decision by them in the second half of 2005. Our European filing for Orathecin remains

on track and is not affected by the withdrawal of the NDA for Orathecin in the United States. There can be no guarantee that the EMEA will approve Orathecin.

Dacogen. During March 2004, we reported results from our randomized Phase III study of Dacogen for injection as a treatment for MDS. In October 2004, we submitted a MAA seeking approval of Dacogen to the EMEA. EMEA procedures generally provide that a decision on the Dacogen MAA will usually occur within 12 months of acceptance of submission which could result in a decision by them in the second half of 2005 or early 2006. In November 2004, we submitted an NDA to the FDA for Dacogen. The filing was accepted at the end of 2004 by the FDA and indicated a target PDUFA date of September 1, 2005. There can be no guarantee that the FDA or EMEA will approve Dacogen. During September 2004, we executed a definitive agreement granting MGI exclusive worldwide rights to the development, manufacture, commercialization and distribution of Dacogen. Under the terms of the agreement, MGI made a $40.0 million equity investment in us and will pay us up to $45.0 million in specific regulatory and commercialization milestones. If Dacogen is approved, we could receive a royalty on worldwide net sales starting at 20% and escalating to a maximum of 30%. MGI has also committed to fund further development costs associated with Dacogen at a minimum of $15.0 million over a three year period.

Nipent. Nipent is approved by the FDA and EMEA for the treatment of hairy cell leukemia and is marketed by us in the United States and Europe. Nipent has also shown promise in other diseases and we are conducting a series of post-marketing Phase IV clinical trials for CLL, NHL, cutaneous and peripheral T-cell lymphomas and GvHD.

Other Products. Our portfolio of other products includes Partaject-delivered busulfan, and inhaled versions of Orathecin and paclitaxel. We also market Surface Safe. We have also received regulatory approval to market our generic daunorubicin for a variety of acute leukemias and 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. Moreover, we hold United States sales and marketing rights to the cancer vaccine Avicine. We are continually evaluating our product portfolio to determine whether it is appropriate for us to dedicate the resources needed to commercialize these products ourselves or whether we would be better served selling or licensing the rights to develop these products to third parties.

To date, our product revenues have been limited and are derived primarily from sales of Nipent, which we are marketing in the United States and distributed in Europe for the treatment of hairy cell leukemia. Most of our products are still in the development stage, and we will require substantial additional investments 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.

As a result of our substantial research and development expenditures and minimal product revenues, we have incurred cumulative losses of $333.5 million through December 31, 2004, and have never generated enough funds through our operations to support our business. We expect to continue to incur operating losses at least through 2006.

Ultimately, 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, MGI's success in commercializing Dacogen, if approved, increases in sales and marketing expenses related to the launch of new products and our ability to control our costs and operating expenses. If the results from our clinical trials are not positive, 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. Moreover, if our products are not approved or commercially accepted we

will remain unprofitable for longer than we currently anticipate. Additionally, we might be forced to substantially scale down our operations or sell certain of our assets, and it is likely the price of our stock would decline precipitously.

Critical Accounting Policies

Our management discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and reported disclosures. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, intangible assets, valuation of investments and derivative instruments. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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 Nipent and, to a lesser extent, mitomycin. We recognize sales revenue upon shipment and related transfer of title to customers, and collectibility is reasonably assured. Allowances are established for estimated product returns and exchanges.

Allowances for product returns and exchanges are based on historical information and known trends from external sources. The costs of product exchanges, which include actual product costs and related shipping charges, are included in cost of sales. In estimating returns, we analyze historical returns and sales patterns, the remaining shelf life of inventory, and changes in demand. We continually assess our historical experience and adjust our allowances as appropriate. If actual product returns and exchanges are greater than our estimates, additional allowances may be required.

Cash advance payments received in connection with distribution agreements, license agreements, or research grants are deferred and recognized ratably over the period of the respective agreements or until services are performed. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred. We recognize milestone fees upon completion of specified milestones according to contract terms. Deferred revenue represents the portion of research payments received that has not been earned.

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 to be other than temporary. An other than temporary decline in fair value of a financial instrument would be subject to a write-down resulting in a charge against earnings. 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. The prices of some of our marketable securities, in particular AVI, are subject to considerable volatility. Decreases in the fair value of these securities may significantly impact our results of operations.

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.

Derivative Instruments

In connection with our June 2003 convertible debt transaction, we issued to the note holders warrants to purchase 2,634,211 shares of common stock of AVI at $5.00 per share. As of December 31, 2004, we owned sufficient shares of AVI to cover the potential obligation. These warrants are considered to be a derivative and have been recorded on the balance sheet at fair value. The accounting for derivatives is complex, and requires significant judgments and estimates involved in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the warrants is based on various assumptions input into the Black-Scholes pricing model. Such assumptions include the estimated market volatility and interest rates used in the determination of fair value. The use of different assumptions may have a material effect on the estimated fair value amount and the results of operations.

Results of Operations

Year ended December 31, 2004 compared with year ended December 31, 2003:

Revenues

	2004	2003	Change Dollar	Change Percent
		(in thousands)		
Net product revenues	$13,127	$11,437	$ 1,690	14.8%
Development and license revenue	18,866	—	18,866	—
Other revenue	—	57	(57)	—

The increase in net product revenues in 2004 was due primarily to a 16% increase in sales of Nipent, our drug currently approved for the treatment of hairy cell leukemia, due to an increase in demand and higher product pricing resulting from our acquisition of European marketing rights for Nipent in 2004. Sales in 2004 included approximately $1.5 million in sales to Europe, compared to $315,000 in 2003. 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 have not had 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.

The increase in development and license revenue relates to our license agreement entered into with MGI PHARMA, Inc. in September 2004. Development and license revenue consisted of $12.5 million in milestone payments relating to the filing of Dacogen with the FDA and EMEA, $3.6 million for Dacogen development, and $2.7 million in amortization of deferred revenue in connection with the upfront payment received from MGI.

Costs and operating expenses

	2004	2003	Change	
		(in thousands)	Dollar	Percent
Cost of sales	$ 4,135	$ 3,865	$ 270	7.0%
Research and development	23,978	26,312	(2,334)	(8.9)
Selling, general and administrative	28,800	24,436	4,364	17.9

Cost of sales as a percentage of net product revenues was 32% in 2003 compared to 34% in 2002. The decrease in cost of sales percentage is due primarily to higher pricing of Nipent in Europe due to our acquisition of European marketing rights for Nipent in 2004. Current margins may not be indicative of future margins due to possible variations in product mix, average selling prices, and manufacturing costs.

The decrease in research and development expenses was due primarily to lower expenditures relating to our clinical studies of Orathecin, which declined by $1.8 million in 2004 over 2003, and Nipent, which declined by $424,000, offset by increases in clinical trial expenses for Dacogen of $609,000. We substantially completed our Orathecin Phase III studies in 2004 and filed an NDA with the FDA in January 2004. Our clinical studies for Dacogen continued through 2004, culminating with our filing of an NDA with the FDA and an MAA with the EMEA in late 2004.

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 have included Orathecin, Dacogen, and studies of other indications of Nipent. We have focused much of our attention and resources on developing Orathecin, and from 1998 through 2004, we have spent approximately $69.9 million on the Orathecin program. From 2000 through 2004, we have spent approximately $14.5 million on the development of and clinical studies related to Dacogen, and from 1998 through 2004, we have spent approximately $11.3 million on Phase I, II/III, and Phase IV programs related to different indications of 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.

The increase in selling, general and administrative expenses consists of an increase in sales and marketing expenses of approximately $3.8 million and an increase in general and administrative expenses of $0.5 million. The increase in sales and marketing expenses related primarily to expenditures for market research, speakers programs, advertising placement, and conferences and symposiums associated with pre-launch activities for Orathecin and Dacogen. In connection with our license agreement with MGI we are being reimbursed for approximately $1.0 million of the sales and marketing expenses for Dacogen in 2004.

Other income (expense)

	2004	2003	Change	
		(in thousands)	Dollar	Percent
Interest income	$ 624	$ 474	$ 150	31.6%
Interest expense	(2,338)	(3,981)	(1,643)	(41.3)
Amortization of deemed discount on convertible debt	(12,657)	(13,738)	(1,081)	(7.9)
Other than temporary decline in investments	(7,851)	—	7,851	—
Change in valuation of derivatives	282	6,894	(6,612)	(95.9)

The increase in interest income is due to higher available cash balances due to a private placement of our common stock in March 2004 with net proceeds of $32.5 million and the stock purchase and license agreements with MGI in September 2004 with net proceeds of $36.8 million.

Interest expense in 2004 declined due to the declining balance of our convertible notes entered into in two transactions in February and June 2003. The convertible notes were fully repaid at December 31, 2004, primarily through the issuance of our common stock.

Amortization of deemed discount on convertible debt declined as our convertible notes from the February 2003 transaction were fully repaid in February 2004 and the notes from June 2004 were repaid by December 2004.

During 2004, we recorded an other than temporary decline in the value of our investment in the stock of AVI. We did not incur any other than temporary declines in the value of our investments in 2003.

Income related to the change in derivative valuation in 2003 represented the change in the valuation of two separate derivatives. In our February 2003 exchangeable convertible debt transaction, the notes contained a feature that allowed holders of the notes to receive a portion of the principal and interest in 2,634,211 shares of AVI at $5.00 per share. The initial value ascribed to this derivative was $2.3 million. The ability of the note holders to exchange the notes into shares of AVI was eliminated in our June 2003 convertible debt transaction, so the entire derivative value at that time of $2.5 million was taken to other income. As part of the June 2003 convertible debt transaction and the February Notes restructuring, we issued to the note holders warrants to purchase 2,634,211 shares of AVI at $5.00 per share. These warrants represent a derivative instrument and were valued at $10.1 million using the Black-Scholes pricing model on June 24, 2003. Through December 31, 2003, the value of this derivative had decreased by $4.6 million, which was recorded as other income. As the fair value of the common stock of AVI has fluctuated significantly in the past two years and is expected to do so in the future given the volatility of the AVI stock, the valuation of the derivative in future periods may have a significant impact on our results of operations. At December 31, 2004, the value of this derivative had declined by $3.9 million, which was recorded as other income. This amount was reduced by a charge of $3.6 million relating to the derivative accounting treatment of initially unregistered warrants issued in connection with the private placement of shares of our common stock in March 2004.

Year ended December 31, 2003 compared with year ended December 31, 2002:

Revenues

	2003	2002	Change	
		(in thousands)	Dollar	Percent
Net product revenues	$11,437	$14,188	$(2,751)	(19.4)%
Other revenue	57	1,081	(1,024)	(94.7)

The decrease in net product revenues in 2003 was due primarily to lower sales of Nipent, our drug currently approved for the treatment of hairy cell leukemia. Nipent sales were $10.1 million in 2003 compared to $12.6 million in 2002. The decline in Nipent sales was due to an increase in wholesaler purchases prior to a price increase that went into effect at the beginning of the fourth quarter 2003, which resulted in a significant decline in sales in the fourth quarter, which traditionally had been a high-volume quarter. In addition, the price increase had an impact on the average wholesale price, a key determining factor in Medicare reimbursement, and resulted in lower than expected demand for Nipent as the reimbursement for Nipent was impacted. Sales in 2003 included approximately $315,000 in sales to Europe, compared to $400,000 in 2002. 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 did 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.

Costs and operating expenses

	2003	2002	Change	
		(in thousands)	Dollar	Percent
Cost of sales	$ 3,865	$ 4,491	$ (626)	(13.9)%
Research and development	$26,312	$29,895	$(3,583)	(12.0)
Selling, general and administrative	$24,436	$23,525	$ 911	3.9

Cost of sales as a percentage of net product revenues was 34% in 2003 compared to 32% in 2002. The increase in cost of sales percentage in 2003 was due to a larger portion of our sales being related to generic mitomycin, which was sold at lower margins than Nipent. In addition, raw material costs for mitomycin increased in 2003.

The decrease in research and development expenses was due primarily to lower expenditures relating to our Phase I/II and Phase III clinical trials of Orathecin, which declined by $3.6 million in 2003 over 2002. Most of our Phase I/II studies of Orathecin in various indications were completed in late 2002. In addition, we completed enrollment of over 1,800 patients into the three Phase III Orathecin trials for pancreatic cancer in 2001, and the expenditures for these trials continued to decline as patients completed the studies. Although the Phase III clinical trials for Dacogen increased by $0.7 million from 2002 to 2003, the Phase III trials conducted for Dacogen have not been as costly as the Orathecin trials.

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, Dacogen, and studies of other indications of Nipent. We have focused much of our attention and resources on developing Orathecin, and from 1998 through 2003, we have spent approximately $65.0 million on the Orathecin program. From 2000 through 2003, we have spent approximately $7.9 million on the development of and clinical studies related to Dacogen, and from 1998 through 2003, we have spent approximately $12.5 million on Phase I, II/III, and Phase IV programs related to different indications of Nipent.

The increase in selling, general and administrative expenses consists of an increase in general and administrative expenses of $1.6 million, offset by decreases in sales and marketing expenses of approximately $0.7 million. The declines in sales and marketing expenses were attributed to lower salaries and bonuses, due to staff attrition that has not yet been replaced, as well as reduced spending on trade shows and conferences. The increase in general and administrative expenses was due to higher administrative salaries and bonuses, which included non-cash charges for stock compensation related to the modification of and acceleration of stock options associated with the change in status or departure of certain management, higher costs for investor relations and business development activities, and $0.6 million relating to the write off of one of our equity investments.

Other income (expense)

	2003	2002	Change	
		(in thousands)	Dollar	Percent
Interest income	$ 474	$ 1,662	$ (1,188)	(71.5)%
Interest expense	(3,981)	—	3,981	—
Amortization of deemed discount on convertible debt	(13,738)	—	13,738	—
Change in valuation of derivatives	6,894	—	6,894	—
Other than temporary decline in investments	—	(8,491)	(8,491)	—

The decrease in interest income was due to lower available cash and marketable securities balances and a decline in interest rates in 2003.

Interest expense in 2003 included $3.1 million of amortization of prepaid financing costs, and $0.9 million in interest incurred on the 4% interest bearing convertible debt issued in February and June 2003. Non-cash amortization of deemed discount on the convertible debt was $13.7 million.. No such amounts were recorded in 2002 as there was no debt issued in 2002.

Income related to the change in derivative valuation represents the change in the valuation of two separate derivatives. In our February 2003 exchangeable convertible debt transaction, the February Notes contained a feature that allowed holders of the notes to receive a portion of the principal and interest in 2,634,211 shares of AVI at $5.00 per share. The initial value ascribed to this derivative was $2.3 million. The ability of the note holders to exchange the notes into shares of AVI was eliminated in our June 2003 convertible debt transaction, so the entire derivative value at that time of $2.5 million was taken to other income. As part of the June 2003 convertible debt transaction and the February Notes restructuring, we issued to the note holders warrants to purchase 2,634,211 shares of AVI at $5.00 per share. These warrants represent a derivative instrument and were valued at $10.1 million using the Black-Scholes pricing model on June 24, 2003. Through December 31, 2003, the value of this derivative had decreased by $4.6 million. This change in value has been recorded as other income in 2003. As the fair value of the common stock of AVI has fluctuated significantly in the past two years and is expected to do so in the future given the volatility of the AVI stock, the valuation of the derivative in future periods may have a significant impact on our results of operations.

During 2002, we recorded an other than temporary decline in the value of our investments in the stocks of AVI, Peregrine Pharmaceuticals, Inc., and Inflazyme, Inc. We did not incur any similar other than temporary decline in the value of our investments in 2003.

Liquidity and Capital Resources

Our cash, cash equivalents, and both short and long-term marketable securities totaled $56.8 million at December 31, 2004, compared to $14.6 million at December 31, 2003. In addition, we held 2,684,211 shares of registered stock of AVI, most of which are held as security for the warrants we issued to convertible debt holders to purchase the 2,634,211 AVI shares at $5.00 per share. The AVI shares had a

market value of $6.2 million at December 31, 2004, and are classified on the balance sheet under non-current "Restricted cash and investments."

The net cash used in operating activities in 2004 was $24.5 million, which consisted primarily of the net loss of $46.9 million, plus $2.7 million in amortization of deferred revenue and an increase of accounts receivable of $17.2 million, less depreciation of $1.1 million, amortization of prepaid financing costs of $1.8 million, amortization of deemed discount on convertible debt of $12.7 million, an other than temporary decline in the value of investments of $7.9 million, and increases in prepaid expenses of $1.0 million, accounts payable of $1.1 million, and deferred revenue of $13.1 million. The net cash used in operating activities in 2003 was $36.8 million, which consisted primarily of the net loss of $53.5 million, less $13.7 million non-cash amortization of deemed discount on our convertible debt, $3.1 million amortization of prepaid financing costs, $1.2 million in depreciation expense, and $4.9 million decline in accounts receivable, offset by $6.9 million non-cash change in the valuation of derivatives. The net cash used in operating activities in 2002 was $47.7 million, which consisted primarily of the net loss of $49.5 million, an increase in accounts receivable of $2.9 million and the reduction of accounts payable and other liabilities totaling $4.6 million, offset by the other than temporary decline in value of investments of $8.5 million.

Net cash provided by investing activities was $131,000 in 2004, which consisted primarily of $28.3 million in proceeds from the sales or maturities of marketable securities and $10.7 million cash released from the collateral account, less $37.6 million used in the purchases of marketable securities and $1.0 million for the purchase of intangible assets. Net cash used in investing activities in 2003 was $5.0 million, which consisted primarily of $10.6 million raised in our June convertible debt transaction that was transferred to a cash collateral account, and purchases of marketable securities of $8.1 million, offset by sales and maturities of marketable securities of $13.9 million. Net cash provided by investing activities in 2002 was $39.8 million, and primarily related to the sales and maturities of marketable securities of $72.7 million, net of purchases of $32.5 million.

Net cash provided by financing activities was $57.7 million, which consisted solely of proceeds from the issuance of common stock, net of issuance costs. Net cash provided by financing activities was $39.6 million in 2003, due primarily to the issuance of a total of $42.5 million in convertible notes in separate transactions in February and June 2003, offset by the payment of $3.4 million in prepaid financing costs. Net cash used in financing activities was $2.6 million in 2002, and related primarily to issuances and repurchases of our common stock.

February 2003 Notes Financing. On February 26, 2003 we entered into a Securities Purchase Agreement for the private placement of Senior Exchangeable Convertible Notes ("February Notes") in the principal amount of $21.25 million. The February Notes accrued interest at a rate of 4% per year. The principal amount of the February Notes was repayable in four equal quarterly installments beginning nine months after the closing of the transaction. The February Notes were, 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 shares of common stock of AVI that we own (the "AVI Shares") at a fixed exchange price of $5.00 per share. In connection with the issuance of the February Notes, we also issued warrants to the note holders for the purchase of an aggregate of 1,997,500 shares of our common stock. These warrants will be exercisable for a term of five years at an exercise price of $5.00 per share.

June 2003 Notes Financing and February Notes Restructuring. On June 24, 2003, we closed a private placement transaction in which we issued the June Notes, in the aggregate principal amount of $21.25 million, to the same holders of our outstanding February Notes. The June Notes were payable in four equal quarterly installments beginning March 31, 2004, and accrued interest at a rate of 4% per year. Pursuant to the terms of the June Notes, the note holders could elect to convert, at any time prior to maturity, their June Notes into shares of our common stock at a fixed price of $6.36. We could also elect to

pay the principal and interest then due under the June Notes, subject to certain conditions, through the issuance of shares of our common stock at a conversion price equal to: (a) with respect to the interest payment, 95% of the arithmetic average of the weighted average price of our common stock on each of the five consecutive trading days immediately preceding payment and (b) with respect to the principal payment, as of any date of determination, 90% of the arithmetic average of the weighted average price of our common stock on any 15 trading days designated by the note holders during the 20 trading days immediately preceding such date. In addition, the note holders had a right of first refusal to purchase their pro rata portion of the greater of one-third of the securities offered by us for sale or $5.0 million worth of such offered securities.

Concurrent with the issuance of the June Notes, we restructured our outstanding February Notes. Pursuant to the restructuring, the holders of the February Notes converted half of the principal amount ($10.6 million) plus accrued and unpaid interest thereon into shares of our common stock at the fixed conversion price of $4.25, thereby causing the remaining $10.6 million principal amount of the outstanding February Notes to have a final maturity date of February 26, 2004. The remaining February Notes were amended to remove the feature permitting the holders to exchange such notes into the AVI shares at an exchange price of $5.00, and to remove our ability to use the AVI shares valued at market at the time of repayment to repay the outstanding principal amount.

In addition, in connection with the issuance of the June Notes and the restructuring of the February Notes, we issued to the note holders warrants to purchase the 2,634,211 AVI shares at an exercise price of $5.00 per share.

During the years ended December 31, 2004 and 2003, we issued 4.8 million and 3.9 million shares of our common stock, respectively, in payment of principal and interest on the February and June Notes. As of December 31, 2004, all principal from both the February Notes and June Notes was repaid.

March 2004 Private Placement. On March 5, 2004, we entered into a Securities Purchase Agreement with several investors for the private placement of shares of unregistered common stock and warrants. In connection with this agreement, we issued 4.9 million shares of our common stock to the investors at a per share price of $7.00, for an aggregate purchase amount of $34.3 million, and warrants to purchase 735,000 shares of our common stock. The warrants have a term of five years and a per share exercise price of $10.00. As compensation to the placement agent, we paid the placement agent $1.7 million in cash, which was treated as part of the cost of the offering. Net proceeds from the offering were $32.5 million.

Stock Purchase and License Agreements with MGI PHARMA, Inc. In September 2004, we executed a Stock Purchase Agreement and License Agreement with MGI. In accordance with the Stock Purchase Agreement, we issued 4 million shares of our common stock to MGI at $10.00 per share, for aggregate proceeds totaling $40.0 million. In connection with this transaction, we paid the placement agent, The Kriegsman Group, $3.2 million in cash and issued Kriegsman a warrant exercisable for 400,000 shares of our common stock at an exercise price of $10.00 per share.

Our contractual obligations as of December 31, 2004 are as follows (in thousands):

	Payments Due by Period				
	Total	< 1 year	1-3 years	4-5 years	After 5 years
Operating leases, net	$13,327	$2,114	$6,700	$4,513	$—
Long term obligations—contractually obligated research funding	1,675	325	1,045	295	10
Total contractual cash obligations	$15,002	$2,439	$7,745	$4,808	$10

The operating lease obligations noted above are net of sublease income of $340,000. The contractually obligated research funding noted above consists primarily of required payments to Peregrine, RTP Pharma and The Clayton Foundation. We are also obligated to potentially spend up to $88.0 million in milestone and development related payments to AVI and Peregrine for development of Avicine and VEGF technologies, respectively. 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. Because 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 have financed our operations primarily through the issuance of equity and debt securities and the receipt of milestone payments in connection with collaborative agreements. We believe that our current cash, cash equivalents, marketable securities and other investments will satisfy our cash requirements through at least December 31, 2005. We may pursue additional financing options, including the selling of additional shares of stock in public or private offerings.

We believe that our need for additional funding will increase in the future, especially if we acquire new product technologies for development and sale, and our ability to continue raising 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 raise money by the sale of our equity securities or debt, or the exercise of outstanding warrants and stock options by the holders of such warrants or options. However, given uncertain market conditions and the volatility of our stock price, 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, if at all. 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 will be forced to scale back our product development activities, or our operations in a manner that will ensure we can discharge our obligations as they come due in the ordinary course of business at least through December 31, 2005.

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 regulatory approvals and authorizations necessary for the commercial sale of the products in the territories where they market and sell the products. During 2001 we 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. Larry Johnson, the president and chief executive officer of EuroGen, owns the remaining 5%. The amounts advanced to EuroGen, including the amounts advanced in 2001, totaling $906,000 were charged to Selling, general, and administrative expense in 2002. In 2003 and 2004, the

results of EuroGen are included in our consolidated operations in Selling, general and administrative expenses. During the years ended December 31, 2004 and 2003, we have recorded expenses of $2,269,000 and $325,000, respectively, related to the EuroGen.

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, and in March 2003 we invested an additional $30,000 to acquire 15,000 shares. The president and chief executive officer of KineMed is one of our former directors. Our current president and chief executive officer 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 percent of KineMed's outstanding shares. This investment is included on the balance sheet in Investment in stock of related parties.

In late 2004, we reached an agreement with KineMed whereby we granted them exclusive worldwide rights to the development, manufacture, commercialization and distribution of proprietary property we own relating to etiocholandione and etiocholanolone compounds. Under the terms of the license agreement and upon successful commercialization we could earn future royalty revenue on worldwide sales. In addition, we have termination rights and rights of first refusal on new oncological uses.

AVI BioPharma, Inc.

In December 1999, we entered into an agreement with 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. Our former president and chief executive officer was a member of the board of directors of AVI through March 2004. The transaction was approved by members of our board of directors who had no interest in the transaction and evaluated the transaction with input from members of our financial and scientific staffs. We currently own 2,684,211 shares of AVI common stock.

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 an 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 United States marketing rights for Avicine. We issued 347,826 shares of our common stock along with $5.0 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 for filing 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, 2004.

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 $80.0 million. In 2003 and 2002, we recorded $144,000 and $421,000, respectively, in research

and development expenses for Avicine. At December 31, 2004, the sum of these expenses, or $565,000, was still payable and is presented on the balance sheet as Payable to AVI BioPharma, Inc.

Quark Biotech, Inc.

Our current president/chief executive officer and our former president/chief executive officer are directors and stockholders of Quark Biotech, Inc. ("QBI"), a privately-held development stage biotechnology company. In June 1997, we made an equity investment of $500,000 in QBI's preferred stock, which represents less than 1% of QBI'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 January 2002, we subleased a portion of our laboratory space to QBI. During 2003 and 2002, we collected $56,000 and $123,000, respectively, in sublease income from QBI. The initial term of the sublease expired on December 31, 2002, but we continued to sublease the space to QBI on a month-to-month basis until August 2003.

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 per share 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 per share and will expire in February 2007. On July 25, 2002, our former 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 $220,000 in 2003 and $240,000 in 2002. In 2004, The Kriegsman Group acted as the placement agent in our stock purchase and license agreements with MGI PHARMA, Inc., and we paid Kriegsman $3.2 million in cash and issued Kriegsman a warrant exercisable for 400,000 shares of our common stock at an exercise price of $10.00 per share. The warrant will be exercisable for a term of five years, and we have registered for resale the common stock issuable upon exercise of the warrant. We calculated the fair value of the warrant issued to Kriegsman at $1,436,000, using the Black-Scholes model.

Family Relationships

We employ a number of individuals who are immediate family members of Dr. Joseph Rubinfeld, our former president and chief executive officer, who also served as chief scientist and chairman emeritus during 2004. None of these family members are our officers or directors. Dr. Rubinfeld resigned as chief scientist and chairman emeritus in January 2005.

Recently Issued Accounting Standards

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards 123R, "Share-Based Payment—An Amendment of FASB Statements No. 123 and 95" ("SFAS 123R"), which eliminated the ability to account for share-based compensation transactions using APB 25. SFAS 123R will instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. SFAS 123R is effective for public companies in periods beginning after June 15, 2005. We will be required to implement the standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be

measured and recognized on July 1, 2005. Current estimates of option values using the Black Scholes method (as shown above) may not be indicative of results from valuation methodologies ultimately adopted. The adoption of SFAS 123R will have a material impact on our results of operations. We are currently evaluating which method we will use to adopt SFAS123R.

In March 2004, the FASB approved Emerging Issues Task Force (EITF) Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The objective of this issue is to provide guidance for identifying other-than-temporarily impaired investments. EITF No. 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued EITF No. 03-1-1, which delayed the effective date of EITF No. 03-1, with the exception of certain disclosure requirements. We do not believe that the adoption of EITF No. 03-1 will have a material impact on our financial condition and results of operations.

Income Taxes

As of December 31, 2004, we have net operating loss carryforwards for federal income tax purposes of approximately $295.0 million which expire in the years 2005 through 2024, and federal research and development credit carryforwards of approximately $5.5 million, which expire in the years 2008 through 2023.

Factors Affecting Future Operating Results

The following section lists some, but not all, of the risks and uncertainties that may have a material adverse effect on our business, financial condition and results of operations. You should carefully consider these risks in evaluating our company and business. Our business operations may be impaired if any of the following risks actually occur, and by additional risks and uncertainties that we do not know of or that we currently consider immaterial. In such case, the trading price of our common stock could decline.

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

Risks Related to Dacogen, Orathecin and Nipent

If we do not receive regulatory approval for Dacogen, our future revenues may be limited and our business would be harmed.

Our NDA submission for Dacogen was accepted for filing by the FDA on December 31, 2004. We expect that the FDA will review and act on the NDA by September 2005. Our European subsidiary, EuroGen Pharmaceuticals Ltd., submitted an MAA for Dacogen to the EMEA, which submission was accepted for review on October 25, 2004. EMEA procedures provide that a decision on the Dacogen MAA will usually occur within 12 months of acceptance of the submission.

The primary data analysis from our Phase III study of Dacogen indicates that the patients who were randomized to the Dacogen arm of the study had an increased time to progression to AML or death ($p=0.042$ Wilcoxon test, $p=0.198$ Log-rank test), compared to patients randomized to supportive care only. Both analyses were specified in the protocol. Although the results from the Log-rank test were not statistically significant, we believe that these data are clinically significant and formed the basis of our NDA submission. In addition, adverse events were reported more frequently for patients randomized to the Dacogen arm, as compared to those receiving supportive care, specifically, Leucopenia, febrile neutropenia, nausea, constipation, diarrhea, vomiting, pneumonia, arthralgia, headache and insomnia. Severe adverse events were observed more frequently in patients randomized to Dacogen. The mortality rate for patients in the study was 12% for Dacogen and 9% for supportive care. Consequently, there is no assurance that the FDA will agree with our assessment that Dacogen provides a clinically significant

benefit, that the FDA will not take the position that the studies failed for statistical reasons, or that we will not be required to conduct additional large scale clinical trials. Even if this data supports the submission of an NDA, the approval process may take a significant amount of time and we may never receive approval. If Dacogen is unsuccessful for any reason, including if the results of the Phase III study are deemed insufficient from either a clinical or statistical basis by the FDA, our future revenues would be limited and our business would be harmed. Additionally, we might be forced to substantially scale down our operations or sell certain of our assets, and it is likely the price of our stock would decline precipitously.

In addition, pursuant to our license agreement with MGI, we are expecting to receive payments from MGI in connection with the achievement of certain regulatory milestones. If these regulatory milestones are not met, we will not receive these payments and our financial condition and business would be harmed.

We are relying on European regulatory approval and successful commercialization of Orathecin. If our MAA submission for Orathecin does not support regulatory approval by the EMEA for any reason, our business will be harmed.

On July 1, 2004 our European subsidiary, EuroGen Pharmaceuticals Ltd., submitted an MAA for Orathecin to the EMEA. This application is being reviewed under the EMEA Centralized Procedure, where marketing authorization is applied for in all 25 European Union member states simultaneously. EMEA procedures provide that a decision on the Orathecin MAA will usually occur within 12 months of acceptance of the submission.

Even though the EMEA accepted our submission for filing, the EMEA may not ultimately approve our MAA for Orathecin. The approval process may take a significant amount of time and approval of our application will be based on the agency's review of Orathecin's safety and efficacy. Important factors that the EMEA will take into account in its review and analysis include, among other things, time to disease progression and objective tumor response as well as toxicities seen in patients who were treated with Orathecin.

Given the large scale of the Orathecin clinical program, the complexity of the clinical trials and the inherent uncertainties associated with clinical trials of such magnitude and complexity, the data and statistical analysis from these trials may not support regulatory approval or we may be required to perform additional studies before obtaining regulatory approval. For example, the design of these trials allowed patients who initially were being treated with gemcitabine or other therapies to cross over to treatment with Orathecin. At the time the trials were designed, we believed that the percentage of patients who would cross over for treatment with Orathecin would be in the range of 10% to 20% of the total enrolled patients. The number of patients in our trials who actually crossed over to treatment with Orathecin significantly exceeded the number anticipated and was nearly 50% in two of our Phase III studies. The extent of this cross over has negatively affected the statistical analysis of the study, making it difficult to determine if the product is efficacious with respect to survival.

In May 2003, we announced data from one of our Phase III studies of Orathecin in patients with advanced pancreatic cancer, most of whom had previously failed two or more chemotherapy treatments. The study randomized 409 patients to either Orathecin or "best medical therapy." The primary study end-point was overall survival with secondary end-points, including objective tumor response and time to disease progression. We did not meet the primary end-point, although we did meet two of the secondary end-points. The two secondary end-points were independent of a cross-over effect, whereas the primary end-point was not. The released data, and the data from our other clinical trials, may not be sufficient to support regulatory approval for Orathecin, and additional trials may be required before we can obtain regulatory approval.

If, for any reason, the EMEA ultimately determines not to approve our application for Orathecin, we would be unable to proceed with our current plans for commercializing Orathecin in Europe. Additionally, we might be forced to scale down our expansion effort with our European operations or sell certain of our assets, and it is likely the price of our stock could decline.

We are currently conducting clinical trials with Orathecin as a combination therapy. If these clinical trials do not support regulatory approval, our business may be harmed.

In early January 2005 we announced the withdrawal of our NDA for Orathecin based on feedback from the FDA that the data package we submitted in support of the drug would not be sufficient to gain regulatory approval. However, we are continuing to conduct clinical trials with Orathecin as a combination therapy while we review and determine whether or not we will continue to pursue regulatory approval for Orathecin. Clinical trials are expensive to conduct, time-consuming and have uncertain outcomes. We will incur substantial expense while conducting these studies, and if we are unable to complete the studies, or if the results of the studies do not support regulatory approval of Orathecin as a combination therapy, we will incur significant operating losses and our business will be harmed.

If we receive regulatory approval of Orathecin for the treatment of patients with refractory pancreatic cancer, Orathecin may not be commercially successful.

If Orathecin receives regulatory approval, whether in Europe, in the United States if we pursue regulatory approval with the FDA, or ultimately as a combination therapy, patients and physicians may not readily accept it, which would result in lower than projected sales and substantial harm to our business. Acceptance will be a function of Orathecin being clinically useful and demonstrating superior therapeutic effect with an acceptable side effect profile as compared to currently existing or future treatments. In addition, even if Orathecin does achieve market acceptance, we may not be able to maintain that market acceptance over time if new products are introduced that are more favorably received than Orathecin or render Orathecin obsolete.

If we receive regulatory approval of Dacogen for the treatment of patients with myelodysplastic syndromes, Dacogen may not be commercially successful.

If Dacogen receives regulatory approval in the United States or Europe, patients and physicians may not readily accept it, which would result in lower than projected sales and substantial harm to our business through the receipt of lower royalty revenue from MGI.

If we are unable to expand our clinical support for use of Nipent to treat additional diseases our revenues will not expand as planned.

Part of our strategy involves expanding the market opportunities for our approved drugs, including Nipent, by seeking clinical support of their use for treatment of patients with additional diseases. We are currently marketing Nipent for the treatment of patients with hairy cell leukemia, and revenues from selling Nipent provided 80 - 90% of our revenues for the past three years. We are conducting a series of clinical trials with Nipent, including Phase IV trials for CLL, NHL, cutaneous and peripheral T-cell lymphomas and Phase II/III studies for GvHD. If our Nipent clinical trials are not successful, we will not be able to increase our revenue from Nipent.

Risks Related to Our Financial Condition and Common Stock

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

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 is marketed in the United States for the treatment of patients with hairy cell

leukemia. Our substantial research and development expenditures and limited revenues have resulted in significant net losses. We have incurred cumulative losses of $333.5 million from inception through December 31, 2004, and our products have not generated sufficient revenues to support our business during that time. We expect to continue to incur substantial operating losses at least through 2006 and may never achieve profitability.

Whether we achieve profitability depends primarily on the following factors:

- our ability to obtain regulatory approval for Dacogen, the successful commercialization of Dacogen by MGI, to successfully commercialize Orathecin in Europe, and to develop and obtain regulatory approval of Nipent for indications other than hairy cell leukemia;
- our ability to bring to market other proprietary products that are advancing through our internal clinical development infrastructure;
- our ability to successfully expand our product pipeline through in-licensing and product acquisition;
- our ability to successfully market Nipent in Europe as planned;
- our research and development efforts, including the timing and costs of clinical trials;
- our competition's ability to develop and bring to market competing products;
- our ability to control costs and expenses associated with manufacturing, distributing and selling our products, as well as general and administrative costs related to conducting our business;
- costs and expenses associated with entering into licensing and other collaborative agreements; and
- delays in production or inadequate commercial sales of Dacogen, Orathecin and other products, once regulatory approvals have been received.

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

We will require additional funding to expand our product pipeline, strengthen our commercialization efforts and expand our European operations, and if we are unable to raise the necessary capital or to do so on acceptable terms, our planned expansion and continued survival could be harmed.

We will continue to spend substantial resources on expanding our product pipeline, strengthening our commercialization efforts for our existing products, developing new avenues of revenue for Nipent, scaling-up of European operations to market, selling and distributing our existing and future products, and conducting research and development, including clinical trials for other products and product candidates. We anticipate that our capital resources will be adequate to fund operations and capital expenditures through 2005. However, if we experience unanticipated cash requirements during this period, we could require additional funds much sooner. We may raise money by the sale of our equity securities or debt, or the exercise of outstanding warrants and stock options by the holders of such warrants and options. However, given uncertain market conditions and the volatility of our stock price, 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, if at all. Also, the dilutive effect of additional financings could adversely affect our per share results. We may also choose to obtain funding through licensing and other contractual agreements. For example, we recently licensed the worldwide rights to the development, commercialization and distribution of Dacogen to MGI. 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 will be forced to scale back our product development activities, or be forced to cease our operations.

Our collaborative relationship with MGI may not produce the financial benefits that we are anticipating, which could cause our business to suffer.

In addition to raising money by selling our equity securities to MGI in connection with the license agreement, we also expect to record development and license revenue from payments made to us by MGI upon the achievement of regulatory and commercialization milestones. However, we may fail to achieve these milestones, either because we are unable to secure regulatory approval of Dacogen or due to our inability to expend the resources to commence sales of Dacogen as prescribed by the license agreement. In addition, the license agreement contemplates that MGI will pay us (i) a certain portion of revenues payable to MGI as a result of MGI sublicensing the rights to market, sell and/or distribute Dacogen, to the extent such revenues are in excess of the milestone payments, and (ii) a 20% royalty increasing to a maximum of 30% on annual worldwide net sales of Dacogen. We cannot guarantee that we will ever receive these payments, as MGI may choose not to sublicense Dacogen at all, nor can we be assured that MGI will expend the resources to sell Dacogen worldwide, or be successful in doing so.

Our equity investment in AVI 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. During the year ended December 31, 2004, we recorded a write-down of $7.9 million related to other than temporary decline in the value of our equity investment in AVI, resulting in a reduction of our cost basis in the AVI shares. 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. As of June 30, 2004, the AVI shares had been trading below our original cost basis for more than six months. Since there was no compelling evidence to the contrary, we recorded the impairment charge of $7.9 million in our results of operations. The amount of the charge was based on the difference between the market price of the shares as of June 30, 2004 and our adjusted cost basis. The public trading prices of the AVI shares 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, in connection with the restructuring of our February Notes and the issuance of the June Notes, we issued three-year warrants to the June Note holders exercisable into 2,634,211 of our AVI shares at an exercise price of $5.00 per share, and we pledged the AVI shares to secure our obligation under the June Notes. These warrants expire on December 31, 2006.

Product Development and Regulatory Risks

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

Most of our products are in the developmental 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.

We have a portfolio of cancer drugs in various stages of development, including Nipent (for indications other than hairy cell leukemia, Phase IV), Partaject busulfan (Phase I/II), inhaled Orathecin (Phase I/II), Orathecin capsules as a combination therapy (Phase II) and we have been conducting pre-clinical studies for VEGF and Cremophor-free paclitaxel. In addition, we expect to commence new clinical trials from time to time in the course of our business as our product development work continues. Conducting clinical trials is a lengthy, time consuming and expensive process and the 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, pre-clinical testing and clinical trials.

However, regulatory authorities may not permit us to undertake any additional clinical trials for our product candidates. If we are unable to complete our clinical trials, our business will be severely harmed and the price of our stock will likely decline.

We have ongoing research and pre-clinical projects that may lead to product candidates, but we have not begun clinical trials for these projects. If we do not successfully complete our pre-clinical trials, we could 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 clinical trials may take several years or more. The length of a clinical trial varies substantially according to the type, complexity, novelty and intended use of the product candidate. For example, our three Phase III Orathecin clinical trials lasted from 1998 through the end of 2003. The length of time and complexity of these studies make statistical analysis difficult and regulatory approval unpredictable. The commencement and rate of completion of our 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.

If we are unable to achieve a satisfactory rate of completion of our clinical trials, our business will be significantly harmed.

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 continuous oversight by the FDA and institutional review boards at the medical institutions where the clinical trials are conducted. We outsource certain aspects of our research and development activities to contract research organizations ("CROs"). We have agreements with these CROs for certain of our clinical programs. We and our CROs are required to comply with GCPs, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of study sponsors, principal investigators, and study sites. If our CROs or we fail to comply with applicable GCPs, the clinical data generated in our studies may be deemed unreliable and the FDA may require us to perform additional studies before approving our applications. In addition, our clinical trials must be conducted with product candidates produced under current GMPs, and may require a large number 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 achieving 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 would cause us or the FDA to delay or suspend the studies. The potential failures would delay development of our product candidates, hinder our ability to conduct related pre-clinical testing and clinical trials and further delay the commencement of the regulatory approval process. Moreover, we may then be required to conduct other clinical trials for the product candidates, which would require substantial funding and time. We may be unable to obtain funding to conduct such clinical trials. The failures or perceived failures in our clinical trials would delay our product development and the regulatory approval process, damage our business prospects, make it difficult for us to establish collaboration and partnership relationships and negatively affect our reputation and competitive position in the pharmaceutical industry.

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

Sales of our products in foreign jurisdictions will be subject to separate regulatory requirements and marketing approvals. Approval in the United States, or in any one foreign jurisdiction, does not ensure approval in any other jurisdiction. The process of obtaining foreign approvals may result in significant delays, difficulties and expenses for us, and may require additional clinical trials. So far, we have applied through our subsidiary EuroGen for regulatory approval to market Orathecin, mitomycin and paclitaxel in the United Kingdom and in other countries within the European Union. Although many of the regulations applicable to our products in these foreign countries are similar to those promulgated by the FDA, many of these requirements also vary widely from country to country, which could delay the introduction of our products in those countries. Failure to comply with these regulatory requirements or to obtain required approvals would impair our ability to commercialize our products in foreign markets.

Nipent is currently sold in Europe, and in early 2004 we acquired the rights to distribute and market Nipent there directly. We plan to commence distribution and marketing Nipent in Europe in the second half of 2005. However, our revenue from sales of Nipent in Europe is currently insignificant, and there is no guarantee that our distribution and marketing efforts will result in significantly increased revenues. Our strategy is to obtain regulatory approvals to sell our products in Europe and elsewhere, and we intend to contract with third-party licensees or distributors for sales outside the United States. Delays in obtaining regulatory approval from foreign jurisdictions will impair the commercialization of our products and would delay anticipated 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 of our products is obtained, later discovery of previously unknown problems may result in restrictions of a product, including withdrawal of that product from the market. Further, governmental approval may subject us to ongoing requirements for post-marketing studies. For example, despite receipt of governmental approval, the facilities of our third-party manufacturers are still subject to unannounced inspections by the FDA and must continue to comply with GMPs and other regulations. These regulations govern all areas of production, record keeping, personnel and quality control. In the past, our third-party manufacturers have experienced delayed FDA approval, which adversely affected our ability to supply Nipent in 2002. 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 and/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. 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 suppression of bone marrow activity. We revised our internal procedures to help ensure our promotional activities and public disclosure will meet regulatory requirements. Nonetheless, any warning or enforcement actions by the FDA could harm our reputation in the market, result in significant fines or have other results that would harm our business.

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 health administration authorities like Medicare/Medicaid, managed care providers and private health insurers. 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 a particular product. 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 United States 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 biohazardous materials at our facilities. We believe our safety procedures for these materials comply with all applicable environmental laws and regulations, and we carry insurance coverage we believe is adequate for the size of our business. 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 certain of 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.

Additional Risks Associated with Our Business

If the third-party manufacturers upon whom we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the delivery of, or be unable to meet demand for, our products.

Because we have no manufacturing facilities, we rely on third parties for manufacturing activities related to all of our products. As we develop new products and increase sales of our existing products, we must establish and maintain relationships with manufacturers to produce and package sufficient supplies of our finished pharmaceutical products, including Nipent. Reliance on third party manufacturing presents the following risks:

- delays in scale-up to quantities needed for multiple clinical trials, or failure to (a) manufacture such quantities to our specifications or (b) deliver such quantities on the dates we require, which could cause delay or suspension of clinical trials, regulatory submissions and commercialization of our products;
- inability to fulfill our commercial needs if market demand for our products increases suddenly, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand;
- potential relinquishment or sharing of intellectual property rights to any improvements in the manufacturing processes or new manufacturing processes for our products; and
- unannounced ongoing inspections by the FDA and corresponding state agencies for compliance with GMPs, regulations and foreign standards, and failure to comply with any of these regulations and standards may subject us to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution.

Any of these factors could delay clinical trials or commercialization of our product candidates under development, interfere with current sales and entail higher costs. For example, a failed production batch of Nipent in the second quarter of 2003 affected our ability to supply Nipent and adversely affected our sales.

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 may lead to the loss or destruction of the bulk concentrate. Even if the manufacturer's and our insurance coverage is adequate, such event would inevitably cause delays in distribution and sales of our products and harm our operating results.

Our business may be harmed if the manufacture of our products is interrupted or discontinued.

We may be unable to maintain our relationships with our third-party manufacturers. If 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 GMPs. 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 Nipent filed for bankruptcy in mid 2001. Shortly thereafter we contracted with a new manufacturer for the purification of Nipent, and that manufacturer was qualified by the FDA by 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. The company that had been purifying Nipent filed for reorganization under Chapter 11 and has ceased operations in late 2004. We are in the process of contracting with another manufacturer for the purification of Nipent. If the new manufacturer is not qualified by the FDA or if the new manufacturer should go out of business, we may not have adequate inventory levels to sustain our business while we identify and contract with another manufacturer for the purification of Nipent.

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

We rely on third-party suppliers to provide us with numerous components used in our products under development, including Orathecin and Dacogen. Relying on third-party suppliers makes us vulnerable to component failures and interruptions in supply, either of which could impair our ability to conduct clinical trials or to ship our products to our customers on a timely basis. Using third-party suppliers 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 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 a particular component, which makes us vulnerable to cost increases and supply interruptions. We generally rely on one manufacturer for each product. We rely on one manufacturer for Nipent, a sole source supplier for the 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 Surface Safe.

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. In the event one of our sole source suppliers decides not to manufacture the component, goes 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 may not be able to successfully commercialize our products.

We currently have limited sales and marketing resources. Although we have approximately 37 sales, marketing and sales support personnel focusing on the sale of our products to hospitals and hospital buying groups, we must expand our sales and marketing organization to support commercialization of our new products. Building up our sales capabilities will require significant expenditures. 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. We may not be able to upgrade our in-house sales expertise which may limit our ability to gain market acceptance for our products worldwide and generate revenues. If we fail to establish successful sales and marketing capabilities, 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.

We intend to enter into strategic partnerships for the commercialization of our products outside of the United States. However, we may not be able to negotiate acceptable arrangements with partners, if at all. Moreover, such arrangements may involve sharing of profits from sales, requirements to relinquish certain of our rights to our products or marketing territories and impositions of other limitations on our operations.

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 our products or our collaborators' products. It is critical that we gain 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 Research. Due to the expense of the drug approval process we must have relationships with established pharmaceutical companies to offset some of our development costs in exchange for a combination of development, marketing and distribution rights.

From time to time we enter into discussions with various companies regarding the establishment of new collaborations. If we are not successful in establishing new 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:

- our ability to negotiate acceptable collaborative arrangements;
- the collaboration making us less attractive to potential acquirers;
- freedom of our collaborative partners to pursue alternative technologies either on their own or with others, including our competitors, for the diseases targeted by our programs and products;
- the potential failure of our partners to fulfill their contractual obligations or their decision to terminate our relationships, in which event we may be required to seek other partners, or expend substantial resources to pursue these activities independently; and
- our ability to manage, interact and coordinate our timelines and objectives with our 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 may be less willing to continue its collaboration with us. 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 collaborators or disagreements between us and our collaborators may lead to delays in or termination of the research, development or commercialization of product candidates or result in time consuming and expensive litigation or arbitration.

Our collaborative relationships with third parties could cause us to expend significant funds on development costs with no assurance of financial return.

From time to time we enter into collaborative relationships with third parties to co-develop and market products. For example, we entered into an agreement 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 specifically related to VEGF. 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 could ultimately total $8.25 million. In addition, we will pay royalties to Peregrine based on the net revenues of any drugs we commercialize using the VEGF technology.

These 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. The compounds that are the subject of these collaborative agreements may prove to be ineffective, may fail to receive regulatory approvals, may be unprotectable by patents or other intellectual property rights, or may not be otherwise 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.

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.

The success of our operations depends in part on our ability to obtain patents, protect trade secrets, operate without infringing the proprietary rights of others and enforce our proprietary rights against accused infringers.

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 United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. To date, we have acquired licenses to or assignments of over 40 U.S. patents covering various aspects of our proprietary drugs and technologies, including 37 patents for various aspects of Orathecin and related products, five patents under our Nipent product portfolio, although none covers the use of Nipent for the treatment of patients with hairy cell leukemia, six patents for our paclitaxel related products, one patent for Dacogen used in combination with an anti-neoplastic agent for the treatment of cancer, and two patents for our Surface Safe product. These issued United States patents will begin to expire in October 2012. We have been granted patents and have received patent licenses relating to our proprietary formulation technology, non-oncology and Partaject technologies, among which at least five patents are issued or licensed to us. In addition, we are prosecuting a number of patent applications for drug candidates that we are not actively developing at this time.

We also have patents, licenses to patents and pending patent applications in Europe, Australia, Japan, Canada, Mexico and New Zealand, among other countries. In addition, we have patent applications pending in China, Hungary and Israel. Limitations on patent protection, and the differences in what constitutes patentable subject matter, may limit the protection we have on patents issued or licensed to us in these countries. 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 patent protection or to license any patent in a 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 industry is 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 effectively. Competitors may have filed applications for, or been issued patents on, 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 which may have been issued to others. In addition, third parties may challenge, invalidate or circumvent any of our patents. Thus, any patents that we own or license from third parties may not provide adequate protection against competitors, if at all. 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 with adequate claim scope, if at all.

In addition to pursuing patent protection in appropriate instances, we also rely on trade secret protection or regulatory marketing exclusivity 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.

In the pharmaceutical industry there has been, and we believe that there will continue to be, significant litigation 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 litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If a lawsuit against us is 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 that we would prevail in a lawsuit filed against us or that we could obtain any licenses required under any patents on acceptable terms, if at all.

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.

If we fail to compete effectively against other pharmaceutical companies, our business will suffer.

The pharmaceutical industry in general and the oncology sector in particular is highly competitive and subject to significant and rapid technological change. Our competitors and probable competitors include companies such as Aventis SG, Berlex Laboratories, Bristol-Myers Squibb Company, Eli Lilly & Co., GlaxoSmithKline, Novartis AG, Pfizer, Pharmion 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. 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. In addition, Berlex Laboratories' fludarabine competes with Nipent in the leukemia market, and Dacogen faces potential competition from Pharmion's Vidaza, which was approved by the FDA in the first half of 2004.

Many of these competitors have significantly greater experience than we do in developing products, undertaking pre-clinical 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 sales of

our product candidates, we will be competing against companies with greater marketing expertise and manufacturing capabilities, areas in which we have limited or no experience.

We also face intense competition from other companies for collaborative relationships, for establishing relationships with academic and research institutions, and for licenses to proprietary technology.

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 if we were not able to obtain such approval before our competitors, we would lose our competitive advantage. Failure to maintain our competitive position could have a material adverse effect on our business and results of operations.

The pharmaceutical industry in general and the oncology sector in particular is subject to significant and rapid technological change. Developments by competitors may render our product candidates or technologies obsolete or non-competitive.

Our competitors may succeed in developing technologies or products that are more effective than ours. Additionally, our products that are under patent protection face intense competition from competitors' proprietary products. This competition may increase as new products enter the market.

A number of our competitors have substantially more capital, research and development, regulatory, manufacturing, marketing, human and other resources and experience than we have. As a result, our competitors may:

- develop products that are more effective or less costly than any of our current or future products or that render our products obsolete;
- produce and market their products more successfully than we do;
- establish superior proprietary positions; or
- obtain FDA approval for labeling claims that are more favorable than those for our products.

We will 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 decline in sales for that product and could affect our 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. Technological advances, competitive forces and loss of intellectual property protection rights for our products may render our products obsolete.

We are developing products based upon compounds that may be covered by patents held by third parties that are expected to expire or already expired. These compounds may also be 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 products as planned.

We developed, or are in the process of developing, and are planning to market several generic and proprietary formulation products based on existing compounds. Specifically, with respect to our generic products, we received approval of Abbreviated Antibiotic Drug Applications for our generic mitomycin for solid tumors and daunorubicin for a variety of acute leukemias, and have filed an Abbreviated New Drug Application for our generic paclitaxel.

Our proprietary formulation technology is a platform technology that employs the use of an inert chemical excipient, cyclodextrin, combined with a drug. Most anti-cancer 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 formulation technology is designed to "shield" the drug from the injection site, thus providing the patient protection from tissue ulceration. This technology may increase the relative solubility of hard-to-dissolve anti-cancer 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 proprietary formulation technology, a formulation of generic mitomycin, was approved by the FDA in November 2002 as 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. 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 would be required to develop and submit additional data to the FDA and receive FDA approval before we could make these claims.

Through December 31, 2004, we have spent approximately $6.4 million on developing and marketing our generic and proprietary formulation products. We have completed our pre-commercial investment in developing Mitozytrex, and as of now we have not committed to an internal budget for additional proprietary formulation 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 proprietary formulation products are based. We may in the future evaluate the generic drug market and develop additional generic or proprietary 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 proprietary 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 proprietary formulation products without obtaining a license from the patent owner, which may not be available on commercially acceptable terms, if at all.

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 and 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. We do not know whether this coverage will be adequate to protect us in the event of a claim. 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.

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

Further, our success is dependent on key personnel, including members of our senior management and scientific staff. If any of our executive officers decides to leave and we cannot locate a 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, however to the extent these employees favor larger, more established employers, we may be at a disadvantage.

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

Our operations are vulnerable to interruption by fire, power loss, floods, telecommunications failure and other events beyond our control. In addition, our operations are susceptible to disruption as a result of natural disasters such as earthquakes. So far we have never experienced any significant disruption of our operations as a result of earthquakes or other natural disasters. Although we have 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 percent 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 percent 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, United States corporate obligations, and United States 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.

As part of our June 2003 convertible debt transaction, we issued to the note holders warrants to purchase 2,634,211 shares of common stock of AVI at $5.00 per share. These warrants are considered a derivative and were valued on the balance sheet at $10.1 million using the Black-Scholes method on June 24, 2003. On December 31, 2004, the value of the derivative had declined to $1.6 million. As the fair value of the common stock of AVI has fluctuated significantly in the past two years, the valuation of the derivative may have a significant impact on our results of operations.

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-26 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.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures.

Based on their evaluation as of December 31, 2004, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective to ensure the information required to be disclosed by us in reports that we file or submit under the securities exchange act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework ("the COSO Framework"). Our management has concluded that, as of December 31, 2004, our internal control over financial reporting was effective based on these criteria.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
SuperGen, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control, that SuperGen, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). SuperGen, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that SuperGen, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, SuperGen, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of SuperGen, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004 of SuperGen, Inc. and our report dated March 15, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 15, 2005

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 15, 2004 (the "Proxy Statement").

The names of our executive officers and their ages, titles and biographies as of February 26, 2005 are set forth below.

Executive Officers

Name	Age	Position
James S. J. Manuso, Ph.D.	56	President, Chief Executive Officer and Director
Edward L. Jacobs	58	Chief Operating Officer
Audrey Jakubowski, Ph.D.	62	Senior Vice President, Regulatory Affairs
Michael Molkentin	50	Chief Financial Officer

James S.J. Manuso, Ph.D., has served as our president and chief executive officer since January 1, 2004, as our chief executive officer-elect from September 2003 to December 2003 and as a director since February 2001. Dr. Manuso is co-founder and immediate past president and chief executive officer of Galenica Pharmaceuticals, Inc. Immediately prior to this appointment, he was president of Manuso, Alexander & Associates, Inc., management consultants and financial advisors to pharmaceutical and biotechnology companies since 1992. Dr. Manuso co-founded and was general partner of PrimeTech Partners, a venture management partnership that developed biotechnology companies, from 1998 to 2002. He serves on the boards of two privately-held companies, including Quark Biotech, Inc. and KineMed, Inc. Previously, he served on the boards of Galenica Pharmaceuticals, Inc., Symbiontics, Inc., Supratek Pharma, Inc., and Inflazyme Pharmaceuticals, Inc. Dr. Manuso earned an A.B. with Honors in Economics and Chemistry from New York University, a Ph.D. in Experimental Psychophysiology from the Graduate Faculty of The New School University, where he was a New School Scholar, a Certificate in Health Systems Management from Harvard Business School, and an Executive M.B.A. from Columbia Business School where he was an Equitable Companies Scholar. Dr. Manuso is the author of over 30 chapters, articles and books on topics including health care systems general management and biotech company development. He has taught at Columbia, Georgetown, Waseda University (Japan) and elsewhere and he has delivered invited addresses to the American Medical Association, the Biotechnology Industry Association, the Securities Industry Association and many other professional associations.

Edward L. Jacobs rejoined us in October 2001 as chief business officer and chief financial officer, and in October 2003 became our chief operating officer. From February 2001 through September 2001, he served as president and chief executive officer of ETEX Corporation. He originally came to us 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 Corp., The Upjohn Company (Adria Labs, Inc.) and Johnson & Johnson (McNeil). Mr. Jacobs received a B.A. in Political Science/Journalism from California State University at Northridge.

Audrey Jakubowski, Ph.D., joined us as vice president, regulatory affairs in August 1998 and served in that capacity until October 2003 when she became senior vice president, regulatory affairs. In January 2004, she was also given responsibility for quality assurance. Prior to joining us, Dr. Jakubowski was vice president, regulatory affairs and quality at Systemix, Inc. from June 1996 to July 1998. From October 1989 through June 1996, Dr. Jakubowski was executive director and then vice president of worldwide regulatory affairs for The DuPont Merck Pharmaceutical Company. From November 1979 through October 1989, Dr. Jakubowski was first director of regulatory affairs, dermatology products at Westwood Pharmaceuticals, followed by director of international regulatory affairs, R&D products for Bristol Myers' research and development division. Prior to that, Dr. Jakubowski completed post-doctoral fellowships in molecular biology at the Roswell Park Memorial Institute and clinical endocrinology at Buffalo Children's Hospital. Dr. Jakubowski received her Ph.D. in physical chemistry at SUNY Buffalo and her B.A. at Seton Hall College.

Michael Molkentin joined us as chief financial officer and corporate secretary in October 2003. Prior to joining us, Mr. Molkentin served as interim chief financial officer at Aradigm Corporation from May 2000 to September 2002. From January 1995 to April 2000, Mr. Molkentin served as division controller for Thermo Finnigan Corporation, a subsidiary of Thermo Electron. Mr. Molkentin served in a variety of financial management positions with technology companies, including field controller of Vanstar Corporation, controller of Republic Telcom Systems, Inc. and corporate controller of Computer Automation, Inc. Mr. Molkentin is a CPA and received a B.B.A. in accounting from Bernard M. Baruch College in New York City, New York.

Karl L. Mettinger, M.D., Ph.D. served as chief medical officer during all of 2004. Dr. Mettinger left the Company in January 2005.

Audit Committee Financial Expert

Information regarding the financial expert(s) on the Audit Committee is incorporated by reference to the Proxy Statement.

Audit Committee

Information regarding the Audit Committee is incorporated by reference to the Proxy Statement.

Code of Ethics

Information regarding the Code of Ethics is incorporated by reference to the Proxy Statement.

Corporate Governance Guidelines

Information regarding Corporate Governance Guidelines is incorporated by reference to the Proxy Statement.

Section 16(a) Beneficial Ownership Reporting Compliance

Information regarding Section 16(a) beneficial ownership reporting compliance is set forth under "Voting Securities of Principal Stockholders and Management" in the Proxy Statement, which information is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

Information regarding executive compensation is incorporated by reference to the information set forth under the caption "Executive Compensation" in the Proxy Statement.

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

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth under the caption "Voting Securities of Principal Stockholders and Management" in the Proxy Statement. 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 the Proxy Statement. 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. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Information regarding principal auditor fees and services is set forth under "Principal Accounting Fees and Services" in the Proxy Statement, which information is incorporated herein by reference.

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. *All Financial Statements:*

The following financial statements and the Reports of Ernst & Young LLP, Independent Registered Public Accounting Firm, are included in Part IV of this Report on the pages indicated:

	Page
Reports of Independent Registered Public Accounting Firm	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:*

Exhibit Number	Description of Document
(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.
(l)10.1	Form of Indemnification Agreement between the Registrant and each of its directors and officers.
(**)(cc)10.2	1993 Stock Option Plan (as amended through July 11, 2000).
(**) (i)10.3	Forms of stock option agreements under the 1993 Stock Option Plan.
(**)(n)10.4	1996 Directors' Stock Option Plan, as amended effective February 7, 2001.
(**)(t)10.5	2003 Stock Plan
(**)(s)10.6	1998 Employee Stock Purchase Plan, as amended effective March 1, 2004.
(*)(b)10.7	Patent License and Royalty Agreement dated August 30, 1993 between the Registrant and The Jackson Laboratory.
(*)(b)10.8	Worldwide License Agreement dated March 1, 1994 between the Registrant and Janssen Biotech, N.V.
(*)(b)10.9	Patent License Agreement dated March 1, 1994 between the Registrant and Cyclex Inc.
(*)(b)10.10	Patent License and Royalty Agreement dated November 15, 1993 between the Registrant and The Long Island Jewish Medical Center.
(*)(b)10.11	License Agreement dated February 1, 1995 between the Registrant and Pharmos Corporation.
(*)(u)10.12	Know-How Transfer and Cooperation Agreement dated September 10, 1999 between the Registrant and Pharmachemie B.V.
(**)(a)10.13	Employment, Confidential Information, Invention Assignment and Arbitration Agreement dated January 1, 2004 between Registrant and Joseph Rubinfeld.
(**)(a)10.14	Executive Employment and Confidential Information and Invention Assignment Agreement dated January 1, 2004 between Registrant and James Manuso.

Exhibit Number	Description of Document
(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)10.17	Asset Purchase Agreement dated January 15, 1997 between the Registrant and Immunex Corporation, a Washington corporation.
(*)(x)10.18	Drug Substance Validation and Supply Agreement dated July 2, 2003.
(*)(g)10.19	License Agreement between Inflazyme Pharmaceuticals Ltd. and the Registrant dated April 11, 1997.
(*)(g)10.20	Nonexclusive Supply Agreement between the Registrant and Yunnan Hande Technological Development Co. Ltd. dated May 7, 1997.
(h)10.21	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)10.22	Amendment No. 1 to the Tako Purchase Agreement dated March 17, 1999.
(r)10.23	Stock Purchase Agreement between the Registrant and Tako dated January 29, 1999.
(*)(j)10.24	License Agreement between Stehlin Foundation for Cancer Research and the Registrant dated September 3, 1997.
(*)(ee)10.25	Amendment No. 1 to License Agreement dated November 1, 1999 between the Registrant and the Stehlin Foundation for Cancer Research.
(*)(k)10.26	Supply Agreement dated October 20, 1997 between the Registrant and Warner-Lambert Company.
(o)10.27	Agreement and Plan of Reorganization by and among the Registrant, Royale Acquisition Corp., and Sparta Pharmaceuticals, Inc. dated January 18, 1999.
(w)10.28	First Amendment to Agreement and Plan of Reorganization by and among the Registrant, Royale Acquisition Corp. and Sparta Pharmaceuticals, Inc. dated May 15, 1999.
(r)10.29	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)10.30	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).
(*)(z)10.31	Common Stock and Option Purchase Agreement , dated December 21, 1999 between the Registrant and Abbott Laboratories.
(z)10.32	Form Registration Rights Agreement.
(*)(z)10.33	Worldwide Sales, Distribution, and Development Agreement, dated December 21, 1999 between the Registrant and Abbott Laboratories.
(*)(z)10.34	U.S. Distribution Agreement, Dated December 21, 1999 between the Registrant and Abbott Laboratories.
(aa)10.35	Registration Rights Agreement dated December 15, 1999 between the Registrant and AVI BioPharma, Inc.
(aa)10.36	Subscription Agreement dated December 1, 1999 between the Registrant and AVI BioPharma, Inc.
(ee)10.37	Common Stock and Warrant Purchase Agreement dated April 4, 2000 between the Registrant and AVI BioPharma, Inc.
(ee)10.38	United States of America Sales, Distribution, and Development Agreement dated April 4, 2000 between the Registrant and AVI BioPharma, Inc.

Exhibit Number	Description of Document
(dd)10.39	Registration Rights Agreement dated April 4, 2000 between the registrant and AVI BioPharma, Inc.
(bb)10.40	License Agreement (Camptothecin) dated November 15, 1999 between the Registrant and Research Development Foundation.
(bb)10.41	License Agreement (Paclitaxel) dated November 15, 1999 between the Registrant and Research Development Foundation
(ee)10.42	Asset Purchase Agreement dated February 18, 2000 between the Registrant and AMUR Pharmaceuticals, Inc.
(ee)10.43	Patent and Intellectual Property Assignment Agreement dated September 27, 2000 between the Registrant and AMUR Pharmaceuticals, Inc.
(*)(gg)10.44	Supply and Distribution Agreement dated September 21, 2001 between the Registrant and EuroGen Pharmaceuticals Ltd.
(hh)10.45	Termination and Release Agreement dated March 4, 2002 between the Registrant and Abbott Laboratories.
(ii)10.46	Securities Purchase Agreement dated September 23, 2002 by and between the Registrant and the purchasers named therein.
(ii)10.47	Registration Rights Agreement dated September 23, 2002 by and between the Registrant and the purchasers named therein.
(ii)10.48	Form of Warrant dated September 24, 2002 issued to the purchasers under the Securities Purchase Agreement dated September 23, 2002.
(ii)10.49	Warrant dated September 24, 2002 issued Paul Revere LLC.
(jj)10.50	Registration Rights Agreement dated March 22, 2001 by and between the Registrant and The Kriegsman Group.
(jj)10.51	Warrant A Agreement dated March 22, 2001 by and between the Registrant and The Kriegsman Group.
(kk)10.52	Securities Purchase Agreement dated February 26, 2003 by and among the Registrant and the purchasers named therein.
(kk)10.53	Form of Senior Exchangeable/Convertible Note dated February 26, 2003 issued to the purchasers under the Securities Purchase Agreement dated February 26, 2003.
(kk)10.54	Registration Rights Agreement dated February 26, 2003 by and among the Registrant and the purchasers named therein.
(kk)10.55	Form of Warrant dated February 26, 2003 issued to the purchasers under the Securities Purchase Agreement dated February 26, 2003.
(kk)10.56	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)10.57	Securities Account Control Agreement dated February 26, 2003 by and among the Registrant, the purchasers named therein, and Mellon Investor Services LLC.
(*)(l)10.58	Pentostatin Supply Agreement dated December 13, 2002 between the Registrant and Hauser Technical Services, Inc.
(*)(m)10.59	License Agreement dated February 13, 2001 between the Registrant and Peregrine Pharmaceuticals, Inc.
(y)10.60	Securities Purchase Agreement dated June 24, 2003 by and among the Registrant and the purchasers named therein.
(y)10.61	Form of Senior Convertible Note dated June 24, 2003 issued to the purchasers under the Securities Purchase Agreement dated June 24, 2003.
(y)10.62	Registration Rights Agreement dated June 24, 2003 by and among the Registrant and the purchasers named therein.

Exhibit Number	Description of Document
(y)10.63	Form of Warrant dated June 24, 2003 issued to the purchasers under the Securities Purchase Agreement dated June 24, 2003.
(y)10.64	Amended and Restated Pledge Agreement dated June 24, 2003 executed by the Registrant in favor of the purchasers under the Securities Purchase Agreement dated June 24, 2003.
(y)10.65	Amended and Restated Securities Account Control Agreement dated June 24, 2003 by and among the Registrant, the purchasers named therein and Mellon Investor Services LLC.
(y)10.66	Collateral Account Agreement dated June 24, 2003.
(y)10.67	Conversion and Amendment Agreement dated June 24, 2003.
(y)10.68	Amended and Restated Convertible Notes dated June 24, 2003.
(c)10.69	Securities Purchase Agreement dated as of March 5, 2004 by and among the Registrant and the purchasers named therein.
(c)10.70	Registration Rights Agreement dated as of March 5, 2004 by and among the Registrant and the purchasers named therein.
(c)10.71	Form of Warrant dated as of March 5, 2004 for issuance under the Securities Purchase Agreement dated March 5, 2004 by and among the Registrant and the purchasers named therein.
(*)(p)10.72	Purchase and Sale Agreement dated February 17, 2004 between the Registrant and Pfizer Inc.
(*)(q)10.73	Amended and Restated License Agreement effective September 21, 2004 between the Registrant and MGI PHARMA, Inc.
(q)10.74	Common Stock Purchase Agreement dated August 31, 2004 between the Registrant and MGI PHARMA, Inc.
(q)10.75	Investor Rights Agreement dated August 31, 2004 between the Registrant and MGI PHARMA, Inc.
(q)10.76	Warrant dated September 22, 2004 issued to The Kriegsman Group.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer under Section 302(a) of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer under Section 302(a) of the Sarbanes-Oxley Act of 2002
32.1	Certifications 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.

(*) Confidential treatment has been previously granted for certain portions of these exhibits.

(**) Indicates a management contract or compensatory plan or arrangement.

(a) Incorporated by reference from the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 2004.

(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 8-K filed with the Securities and Exchange Commission on March 10, 2004.

(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 the Registrant's Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2003.

(m) Incorporated by reference from the Registrant's Report on Form 10-K/A filed with the Securities and Exchange Commission on May 12, 2003.

(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 May 10, 2004.

(q) Incorporated by reference from the Registrant's Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2004.

(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) Incorporated by reference fro the Registrant's Registration Statement on Form S-8 (Reg. No. 333-120505) filed with the Securities and Exchange Commission on November 15, 2004.

(t) Incorporated by reference from the Registrant's Proxy Statement filed with the Securities and Exchange Commission on April 18, 2003.

(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 10-Q filed with the Securities and Exchange Commission on August 14, 2003.

(y) Incorporated by reference from the Registrant's Report on Form 8-K dated June 24, 2003 filed with the Securities and Exchange Commission on June 25, 2003.

(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.

(b) *Exhibits.* See Item 15(a) above.

(c) *Financial Statement Schedules.* See Item 15(a) above

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
SuperGen, Inc.

We have audited the accompanying consolidated balance sheets of SuperGen, Inc. as of December 31, 2004 and 2003, 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, 2004. 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 standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of SuperGen, Inc. at December 31, 2004 and 2003 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of SuperGen, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 15, 2005

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

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,394	$ 5,055
Marketable securities	18,235	7,511
Restricted cash and investments	—	10,629
Accounts receivable, net	4,926	507
Development revenue receivable from MGI PHARMA, Inc.	12,809	—
Due from related parties	—	319
Inventories	3,306	3,965
Prepaid financing costs	—	1,811
Prepaid expenses and other current assets	1,403	2,433
Total current assets	79,073	32,230
Marketable securities, non-current	188	1,921
Investment in stock of related parties	798	883
Due from related parties, non-current	93	118
Property, plant and equipment, net	3,635	4,420
Developed technology at cost, net	—	365
Goodwill	731	731
Other intangibles, net	677	111
Restricted cash and investments, non-current	9,432	13,927
Other assets	30	30
Total assets	$ 94,657	$ 54,736
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 4,644	$ 3,558
Convertible debt, current portion, net of discounts	—	13,593
Derivative liability	1,607	5,505
Payable to AVI BioPharma, Inc.	565	565
Deferred revenue	11,572	—
Accrued payroll and employee benefits	2,129	2,193
Total current liabilities	20,517	25,414
Deferred rent	927	808
Deferred revenue, non-current	—	1,667
Total liabilities	21,444	27,889
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; 51,127,314 and 37,022,356 shares issued and outstanding at December 31, 2004 and 2003, respectively	51	37
Additional paid in capital	406,789	316,578
Accumulated other comprehensive gain (loss)	(99)	(3,100)
Accumulated deficit	(333,528)	(286,668)
Total stockholders' equity	73,213	26,847
Total liabilities and stockholders' equity	$ 94,657	$ 54,736

See accompanying notes to consolidated financial statements

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

	Year Ended December 31,		
	2004	2003	2002
Revenues:			
Net product revenue	$ 13,127	$ 11,437	$ 14,188
Development and license revenue from MGI PHARMA, Inc.	18,866	—	—
Other revenue	—	57	1,081
Total revenues	31,993	11,494	15,269
Costs and operating expenses:			
Cost of product revenue	4,135	3,865	4,491
Research and development	23,978	26,312	29,895
Selling, general, and administrative	28,800	24,436	23,525
Total operating expenses	56,913	54,613	57,911
Loss from operations	(24,920)	(43,119)	(42,642)
Interest income	624	474	1,662
Interest expense	(2,338)	(3,981)	—
Amortization of deemed discount on convertible debt	(12,657)	(13,738)	—
Other than temporary decline in value of investments	(7,851)	—	(8,491)
Change in valuation of derivatives	282	6,894	—
Net loss	$(46,860)	$(53,470)	$(49,471)
Basic and diluted net loss per common share	$ (1.04)	$ (1.56)	$ (1.52)
Weighted average shares used in basic and diluted net loss per common share calculation	44,953	34,276	32,542

See accompanying notes to consolidated financial statements

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

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Deferred Compensation	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total
Balances at January 1, 2002	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
Comprehensive loss:							
Net loss	—	—	—	—	—	(53,470)	(53,470)
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	(2,304)	—	(2,304)
Comprehensive loss							(55,774)
Issuance of common stock upon conversion of senior convertible notes and payment of related interest	3,889	4	16,706	—	—	—	16,710
Issuance of common stock to Peregrine Pharmaceuticals in connection with license agreement	62	—	200	—	—	—	200
Issuance of common stock upon exercise of stock options, net of 39 shares surrendered as proceeds	361	—	1,108	—	—	—	1,108
Issuance of common stock in connection with employee stock purchase plan	83	—	308	—	—	—	308
Amortization of deferred compensation	—	—	—	6	—	—	6
Reversal of deferred compensation due to employee termination	—	—	*(41)*	*41*	—	—	—
Compensation expense from stock option and warrant grants to consultants and vendors	—	—	250	—	—	—	250
Compensation expense from issuance of warrants to placement agent of senior convertible notes	—	—	1,440	—	—	—	1,440
Beneficial conversion of warrants issued in connection with issuance of senior convertible notes	—	—	13,995	—	—	—	13,995
Compensation expense related to acceleration of stock option grants	—	—	1,493	—	—	—	1,493
Repurchase of common stock	(266)	—	(891)	—	—	—	(891)
Balances at December 31, 2003	37,022	37	316,578	—	(3,100)	(286,668)	26,847
Comprehensive loss:							
Net loss	—	—	—	—	—	(46,860)	(46,860)
Other than temporary decline in value of investments	—	—	—	—	7,851	—	7,851
Other comprehensive loss—Change in unrealized gain (loss) on investments	—	—	—	—	(4,850)	—	(4,850)
Comprehensive loss							(43,859)
Issuance of common stock upon conversion of senior convertible notes and payment of related interest	4,750	5	26,788	—	—	—	26,793
Issuance of common stock to MGI Pharma, net of offering costs of $2,058	4,000	4	23,658	—	—	—	23,662
Issuance of common stock and warrants in private placement, net of offering costs of $1,775	4,900	5	32,520	—	—	—	32,525
Issuance of common stock to Peregrine Pharmaceuticals in connection with license agreement	19	—	200	—	—	—	200
Issuance of common stock to Stehlin Foundation for milestone payment in connection with license agreement	64	—	500	—	—	—	500
Issuance of common stock upon exercise of stock options, net of 14 shares surrendered as proceeds	311	—	1,220	—	—	—	1,220
Issuance of common stock in connection with employee stock purchase plan	61	—	342	—	—	—	342
Compensation expense from stock option and warrant grants to consultants and vendors	—	—	200	—	—	—	200
Net change in valuation of warrants issued in connection with private placement	—	—	3,616	—	—	—	3,616
Compensation expense from issuance of warrants to placement agent of MGI Pharma stock issuance	—	—	513	—	—	—	513
Compensation expense related to acceleration of stock option grants	—	—	654	—	—	—	654
Balances at December 31, 2004	51,127	$ 51	$ 406,789	$ —	$ (99)	$ (333,528)	$ 73,213

See accompanying notes to consolidated financial statements

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

	Year ended December 31,		
	2004	2003	2002
Operating activities:			
Net loss	$(46,860)	$(53,470)	(49,471)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,058	1,191	1,324
Amortization of prepaid financing costs	1,811	3,064	—
Amortization of intangible assets	799	537	503
Amortization of deferred compensation	—	6	75
Amortization of deemed discount on convertible debt	12,657	13,738	—
Amortization of deferred revenue	(2,720)	—	(1,000)
Interest on convertible debt paid in common stock	543	460	—
Change in valuation of derivatives	(282)	(6,894)	—
Other than temporary decline in value of investments	7,851	—	8,491
Stock compensation for modification of employee options	654	1,493	—
Expense related to stock options and warrants granted to non-employees	200	250	169
Milestone, license, and research payments made in common stock	700	200	300
Write-off of investment in EpiGenX	—	250	—
Cash option paid in modification of distribution agreement	—	(500)	—
Changes in operating assets and liabilities:			
Accounts receivable and development revenue receivable	(17,228)	4,898	(2,896)
Inventories	659	(1,799)	(333)
Prepaid expenses and other assets	1,030	(521)	(302)
Due from related parties	344	355	199
Restricted cash and investments	(36)	229	(122)
Accounts payable and other liabilities	1,141	(40)	(4,588)
Deferred revenue	13,138	—	—
Net cash used in operating activities	(24,541)	(36,553)	(47,651)
Investing activities:			
Purchases of marketable securities	(37,612)	(8,056)	(32,494)
Sales or maturities of marketable securities	28,336	13,627	72,732
Proceeds from convertible debt transferred to restricted cash and investments	—	(10,625)	—
Purchase of intangible assets	(1,000)	—	—
Release of restricted cash from collateral account	10,680	—	—
Purchases of property and equipment	(273)	(168)	(422)
Net cash provided by (used in) investing activities	131	(5,222)	39,816
Financing activities:			
Proceeds from issuance of common stock, net of issuance costs	57,749	1,415	4,600
Prepaid financing costs	—	(3,435)	
Proceeds from issuance of convertible debt	—	42,500	
Repurchases of common stock	—	(891)	(7,174)
Net cash provided by (used in) financing activities	57,749	39,589	(2,574)
Net increase (decrease) in cash and cash equivalents	33,339	(2,186)	(10,409)
Cash and cash equivalents at beginning of period	5,055	7,241	17,650
Cash and cash equivalents at end of period	$ 38,394	$ 5,055	$ 7,241
Supplemental Disclosure of Non-Cash Financing Activities:			
Valuation of warrants issued to placement agent in connection with convertible debt transactions	$ —	$ 1,440	$ —
Valuation of warrants issued to placement agent in connection with license agreement	$ 513	$ —	$ —
Beneficial conversion and deemed discount in connection with convertible debt	$ —	$ 26,395	$ —
Conversion of convertible notes into common stock	$ 26,250	$ 16,250	$ —
Supplemental Disclosure of Cash Flow Information:			
Interest expense paid in cash during the year	$ —	$ 440	$ —

See accompanying 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 a pharmaceutical company dedicated to the development and commercialization of oncology therapies for solid tumors, hematological malignancies and blood disorders. We operate in one industry segment.

Principles of Consolidation

Our consolidated financial statements include the accounts of EuroGen Pharmaceuticals Ltd. ("EuroGen"), Sparta Pharmaceuticals, Inc. ("Sparta") and two wholly-owned subsidiaries, which are immaterial. Intercompany accounts and transactions are eliminated in consolidation.

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.

Fair Value of Financial Instruments

The fair values of our cash equivalents and marketable securities are based on quoted market prices. The fair value of accounts receivable, accounts payable, and convertible debt are considered to be representative of their respective fair values at December 31, 2004 and 2003.

Revenue Recognition

Our net sales relate principally to two pharmaceutical products, with Nipent sales representing 87% in 2004, 85% in 2003, and 89% in 2002. We recognize sales revenue upon shipment and related transfer of title to customers, and collectibility is reasonably assured, with allowances provided for bad debt and estimated returns. The allowances for bad debt and sales returns were $275,000, $275,000, and $118,000 at December 31, 2004, 2003, and 2002, respectively. Actual amounts for returns and allowances may differ from our estimates and such differences could be material to the consolidated financial statements. The provision for the allowances was $63,000 in 2004, $691,000 in 2003, and $112,000 in 2002.

Cash advance payments received in connection with distribution agreements, license agreements, or research grants are deferred and recognized ratably over the period of the respective agreements or until services are performed. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred. We recognize milestone fees upon completion of specified milestones according to contract terms. Deferred revenue represents the portion of research payments received that has not been earned.

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. We operate in one business segment—human therapeutics. In 2004, 89% of our sales were made in the United States and 11% were made in the EU. In 2003 and 2002, 97% of our sales were made in the United States and 3 percent in the EU.

1. Summary of Significant Accounting Policies (Continued)

Advertising Expense

Advertising costs are expensed as incurred. We incurred advertising costs of $424,000 in 2004, $319,000 in 2003, and $756,000 in 2002.

Research and Development

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

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents include bank demand deposits, certificates of deposit, marketable securities with maturities of three months or less when purchased and money market funds which invest 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 stockholders' 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, 2004, we recorded a write-down of $7,851,000 related to other than temporary decline in the value of our equity investment in AVI BioPharma, Inc. ("AVI"). During the year ended December 31, 2002, we recorded $8,491,000 related to other than temporary declines in the value of this investment and other marketable securities. We had no such write-downs in 2003.

Restricted Cash and Investments

Under certain operating lease agreements and in connection with our convertible debt, we are required to set aside cash and/or investments as collateral. At December 31, 2004 and 2003, we had $9,432,000 and $24,556,000, respectively, of restricted cash and investments related to such agreements.

Equity Investments

Equity investments in securities without readily determinable fair value are carried at cost. These investments are included in marketable securities and investment in stock of related parties on the balance sheet. We periodically review those carried at cost and evaluate whether an impairment has occurred. During 2003, we determined that the value of an equity investment that we made in 2002 was impaired due to the poor financial condition of the company. As a result, the entire cost of the investment of $250,000

1. Summary of Significant Accounting Policies (Continued)

was charged to Selling, general and administrative expense in 2003. We had no such write-offs in 2004 or 2002. We believe the remaining equity investment 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):

	2004	2003
Raw materials	$ 83	$ 108
Work in process	1,040	2,481
Finished goods	2,183	1,376
	$3,306	$3,965

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 had been using a single vendor to perform this manufacturing process using our own equipment located at the vendor's site. We have contracted with a separate vendor to manufacture the Nipent finished dosage at its approved facility. In addition, we store the majority of our bulk raw materials at a single storage location. Although there are a limited number of vendors who may be qualified to perform these services, we believe that other vendors could be engaged to provide similar services on comparable terms. However, the time required to locate and qualify other vendors or replace lost bulk inventory could cause a delay in manufacturing that might be financially and operationally disruptive. The company that performed the manufacturing of Nipent went out of business in late 2004. However, we have contracted with another manufacturer to purify Nipent, and we do not anticipate any interruptions to our supply of drug available for sale.

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. 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):

	2004	2003
Land and building	$ 2,433	$ 2,433
Leasehold improvements	2,607	2,592
Equipment	983	962
Furniture and fixtures	3,597	3,491
Total property and equipment	9,620	9,478
Less accumulated depreciation and amortization	(5,985)	(5,058)
Property, plant and equipment, net	$ 3,635	$ 4,420

1. Summary of Significant Accounting Policies (Continued)

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, 2004 and 2003. Accumulated amortization was $1,936,000 and $1,571,000 at December 31, 2004 and 2003, respectively.

Goodwill

Goodwill and indefinite lived intangible assets are reviewed annually, or more frequently if impairment indicators arise, for impairment. Intangible assets with finite useful lives are amortized over their respective useful lives. Goodwill no longer subject to amortization amounted to approximately $731,000 at December 31, 2004 and 2003.

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 these intangible assets was $787,000 at December 31, 2004 and 2003. Accumulated amortization was $787,000 and $676,000 at December 31, 2004 and 2003, respectively.

In February 2004, we entered into a Purchase and Sale Agreement with Pfizer Inc. to acquire European marketing rights for Nipent, our drug that is currently approved for marketing in the United States for hairy cell leukemia. We paid Pfizer $1,000,000 under this agreement and have classified this amount in Other intangibles in the accompanying balance sheet. This amount is being amortized over 31 months, the estimated life of the benefit period. Accumulated amortization at December 31, 2004 was $323,000. We expect to record amortization of $387,000 in 2005 and $290,000 in 2006.

Derivative Financial Instruments

We have issued warrants for common stock of another entity in connection with issuances of convertible debt. These warrants are considered to be a derivative financial instrument in accordance with Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments," and are recorded at fair value. The changes in the fair value of the derivative financial instruments are recognized in current earnings in each reporting period.

1. Summary of Significant Accounting Policies (Continued)

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:

	2004	2003	2002
Customer A	27%	15%	21%
Customer B	21	38	9
Customer C	12	3	2
Customer D	8	8	25
Customer E	8	24	6
Customer F	4	—	15
All others	20	12	22
Total	100%	100%	100%

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 and assumed conversion of convertible debt would be anti-dilutive and, therefore, basic and diluted loss per share are the same. The computation of diluted net loss per share for the year ended December 31, 2004 excludes the impact of options to purchase 6,502,052 shares of common stock and warrants to purchase 7,183,319 shares of common stock. The computation of diluted net loss per share for the year ended December 31, 2003 excludes the impact of options to purchase 5,326,349 shares of common stock, warrants to purchase 6,834,808 shares of common stock, and 4,515,671 shares of common stock issuable upon conversion of senior convertible notes. The computation of diluted net loss per share for the year ended December 31, 2002 excludes the impact of options to purchase 4,535,457 shares of common stock and warrants to purchase 4,185,889 shares of common stock.

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 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

1. Summary of Significant Accounting Policies (Continued)

December 31, 2004, 2003 and 2002 had we applied the fair value method to account for stock-based awards to employees (in thousands, except per share amounts):

	Year ended December 31,		
	2004	2003	2002
Net loss, as reported	$(46,860)	$(53,470)	$(49,471)
Add: Stock-based employee compensation expense included in the determination of net loss, as reported	654	1,499	75
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	(8,266)	(5,901)	(3,991)
Pro forma net loss	$(54,472)	$(57,872)	$(53,387)
Basic and diluted net loss per common share:			
As reported	$ (1.04)	$ (1.56)	$ (1.52)
Pro forma	$ (1.21)	$ (1.69)	$ (1.64)

Impairment of Long-lived Assets

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, 2004.

Reclassification

We have reclassified interest receivable on equity and debt securities at December 31, 2003 from current and non-current marketable securities and restricted cash to other current assets to conform to the current year presentation.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards 123R, "Share-Based Payment—An Amendment of FASB Statements No. 123 and 95" ("SFAS 123R"), which eliminated the ability to account for share-based compensation transactions using APB 25. SFAS 123R will instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. SFAS 123R is effective for public companies in periods beginning after June 15, 2005. We will be required to implement the standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. Current estimates of option values using the Black Scholes method (as shown above) may not be indicative of results from valuation methodologies ultimately adopted. The adoption of SFAS 123R will have a material impact on our results of operations. We are currently evaluating which method we will use to adopt SFAS123R.

1. Summary of Significant Accounting Policies (Continued)

In March 2004, the FASB approved Emerging Issues Task Force (EITF) Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The objective of this issue is to provide guidance for identifying other-than-temporarily impaired investments. EITF No. 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued EITF No. 03-1-1, which delayed the effective date of EITF No. 03-1, with the exception of certain disclosure requirements. We do not believe that the adoption of EITF No. 03-1 will have a material impact on our financial condition and results of operations.

2. Available-for-Sale-Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
At December 31, 2004				
U.S. corporate debt securities	$35,845	$ —	$ (3)	$35,842
U.S. government debt securities	16,111	1	(15)	16,097
Marketable equity securities	6,577	59	(140)	6,496
Total	$58,533	$ 60	$ (158)	$58,435
At December 31, 2003:				
U.S. corporate debt securities	$ 9,174	$ 17	$ (1)	$ 9,190
U.S. government debt securities	14,127	6	(1)	14,132
Marketable equity securities	14,427	247	(3,368)	11,306
Total	$37,728	$270	$(3,370)	$34,628

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

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
At December 31, 2004				
Amounts included in cash and cash equivalents	$33,704	$ 1	$ (1)	$33,704
Marketable securities, current	18,252	—	(17)	18,235
Amounts included in investment in stock of related parties	120	—	(2)	118
Amounts included in restricted cash and investments	6,322	—	(132)	6,190
Marketable securities, non-current	135	59	(6)	188
Total	$58,533	$ 60	$ (158)	$58,435
At December 31, 2003				
Amounts included in cash and cash equivalents	$ 3,643	$ —	$ —	$ 3,643
Marketable securities, current	7,501	11	(1)	7,511
Amounts included in investment in stock of related parties	265	—	(62)	203
Amounts included in restricted cash and investments	24,654	3	(3,307)	21,350
Marketable securities, non-current	1,665	256	—	1,921
Total	$37,728	$270	$(3,370)	$34,628

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

	Fair Value	
	2004	2003
Debt securities		
Due in one year or less	$51,939	$21,783
Due after one year through three years	—	1,539
	51,939	23,322
Marketable equity securities	6,496	11,306
Total	$58,435	$34,628

Realized gains and losses on the sale of available-for-sale securities for the years ended December 31, 2004, 2003, and 2002 were not material.

During the year ended December 31, 2004, we recorded a write-down of $7,851,000 related to other than temporary decline in the value of our equity investment in AVI BioPharma, Inc. During the year ended December 31, 2002, we recorded $8,491,000 related to other than temporary declines in the value of this investment and other marketable securities. We had no such write-downs in 2003.

3. Stockholders' Equity

Private Placement

On March 5, 2004, we entered into a Securities Purchase Agreement with several investors for the private placement of shares of unregistered common stock and warrants. In connection with this agreement, we issued 4,900,000 shares of our common stock to the investors at a per share price of $7.00, for an aggregate purchase amount of $34,300,000, and warrants to purchase 735,000 shares of our common stock. The warrants have a term of five years and a per share exercise price of $10.00. As compensation to the placement agent, we paid the placement agent $1,735,000 in cash, which was treated as part of the cost of the offering. Net proceeds from the offering were $32,525,000.

The common stock and warrants we issued in the private placement transaction were initially unregistered. We filed a registration statement on Form S-3 with the Securities and Exchange Commission ("SEC") on March 23, 2004 to register the shares issued in the private placement as well as the shares to be issued upon exercise of the warrants. In accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," the warrants were included as a liability and valued at fair market value until we met the criteria under EITF 00-19 for permanent equity. We valued the warrants at $3,307,000 on March 5, 2004 using the Black-Scholes method with the following assumptions: a risk-free interest rate of 2.81%, volatility of 0.89, and a dividend yield of 0%. The registration statement on Form S-3 was declared effective by the SEC on March 31, 2004. We re-valued the warrants on that date at $6,923,000 using the Black-Scholes method with the following assumptions: a risk-free interest rate of 2.81%, volatility of 0.89, and a dividend yield of 0%. The warrants were then transferred to permanent equity, and the change in the value of the warrant liability between March 5, 2004 and March 31, 2004, or $3,616,000, was charged to Change in valuation of derivatives in the accompanying statement of operations.

Warrants

At December 31, 2004, warrants to purchase the following shares of our common stock were outstanding:

Number of Shares	Exercise Price	Issue Date	Expiration Date
1,924,400	$3.00–4.25	2002	2006
551,419	4.00–6.00	2003	2007
1,997,500	5.00	2003	2008
1,135,000	10.00	2004	2009
230,000	10.35	1997	2007
200,000	10.47	2001	2006
100,000	10.47	2003	2007
1,045,000	13.50	1997	2007
7,183,319			

3. Stockholders' Equity (Continued)

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. 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. These warrants expired unexercised in 2004.

In March 2001, we entered into agreements with The Kriegsman Group ("Kriegsman") (also see Notes 6 and 9 below) 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 warrant was fully vested in 2001, and the value of the warrant of $758,000 was charged to Selling, general and administrative expense in 2001. In February 2003, we extended the expiration date of this warrant by three years, and issued the consultant another four-year warrant to purchase 100,000 shares of unregistered common stock at an exercise price of $10.47. We calculated the value of the warrant extension and the new warrant grant at $249,000, using an expected volatility of 0.844, risk-free interest rate of 4.12%, and expected life of two additional years for the extended warrant and four years for the new warrant. The value of our stock on the date of the extension and new grant was $3.00. The value of the warrant extension and new warrant grant was charged to Selling, general and administrative expense in 2003.

Stock Reserved for Future Issuance

At December 31, 2004, we have reserved shares of common stock for future issuance as follows:

Stock options outstanding	6,502,052
Stock options available for grant	870,912
Warrants to purchase common stock	7,183,319
Shares available for Employee Stock Purchase Plan	178,813
	14,735,096

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.

No shares were repurchased during the year ended December 31, 2004. During the year ended December 31, 2003, we repurchased 266,000 shares of our common stock at a cost, net of commissions, of $891,000. Since inception of the stock repurchase plan, we have repurchased 3,299,000 shares of our common stock at a cost, net of commissions, of $19,579,000. All shares repurchased have been retired.

4. Stock Option Plans

We have 10,263,000 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).

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

	Options Outstanding			
	Number of Shares	Weighted Average Exercise Price	Options Exercisable	Weighted Average Fair Value At Grant Date
Balance at January 1, 2002	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	4,535,457	10.28	3,188,761	
Granted at fair value	1,405,450	4.61		3.28
Exercised	(400,488)	3.80		
Forfeited	(214,070)	8.61		
Balance at December 31, 2003	5,326,349	9.34	4,080,995	
Granted at fair value	1,861,050	9.85		6.40
Exercised	(325,801)	4.30		
Forfeited	(359,546)	11.07		
Balance at December 31, 2004	6,502,052	$ 9.64	4,951,378	

Information concerning the options outstanding at December 31, 2004 is as follows:

	Options outstanding			Options exercisable	
Range	Number	Weighted average exercise price	Weighted average remaining contractual life	Number exercisable	Weighted average exercise price
$ 1.75 to $ 4.10	1,198,497	$ 3.19	7.64	1,014,600	$ 3.28
4.12 to 6.10	1,458,785	5.38	5.17	1,313,841	5.37
6.16 to 11.22	1,097,295	8.28	7.31	709,544	8.52
11.27 to 12.63	1,590,635	11.44	8.19	769,345	11.61
12.69 to 68.00	1,156,840	20.51	3.96	1,144,048	20.60
$ 1.75 to $68.00	6,502,052	$ 9.64	6.51	4,951,378	$ 9.88

4. Stock Option Plans (Continued)

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-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:

	Year ended December 31,		
	2004	2003	2002
Risk-free interest rate	2.21%	2.73%	4.17%
Dividend yield	—	—	—
Expected volatility	0.804	0.865	0.834
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.

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 was included as a component of stockholders' equity and was amortized to expense on a straight line basis over four years, the vesting period of the options. During the years ended December 31, 2003 and 2002, we recorded amortization of deferred stock compensation expense of $6,000, and $75,000, respectively. During the year ended December 31, 2003, we reversed $41,000 of deferred compensation, representing the value of unvested stock options forfeited upon the departure of an officer of the Company. We had no similar expenses during the year ended December 31, 2004.

During the years ended December 31, 2004 and 2003, we recorded non cash charges of $654,000 and $1,499,000, respectively for stock compensation related to the modification and acceleration of options associated with the change in status or departure of certain Company management.

5. Convertible Debt Financing Transactions

February 2003 Convertible Debt Transaction

On February 26, 2003 we entered into a Securities Purchase Agreement for the private placement of Senior Exchangeable Convertible Notes ("February Notes") in the principal amount of $21.25 million and related warrants. The February Notes accrued interest at a rate of 4% per year. The principal amount of the February Notes was repayable in four equal quarterly installments beginning nine months after the closing of the transaction. The February Notes were, 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 shares of common stock of AVI that we own (the "AVI Shares") at a fixed exchange price of $5.00 per share.

5. Convertible Debt Financing Transactions (Continued)

June 2003 Convertible Debt Transaction and February Notes Restructuring

On June 24, 2003, we closed a private placement transaction in which we issued Senior Convertible Notes ("June Notes") in the aggregate principal amount of $21.25 million, to the same holders of our outstanding February Notes. The June Notes were payable in four equal quarterly installments which began March 31, 2004, and accrued interest at a rate of 4% per year. Pursuant to the terms of the June Notes, the note holders could elect to convert, at any time prior to maturity, their June Notes into shares of our common stock at a fixed price $6.36, which was calculated based on the trading prices of our common stock for the twenty trading days after issuance of the June Notes.

Concurrent with the issuance of the June Notes, we restructured our outstanding February Notes. Pursuant to the restructuring, the holders of the February Notes converted half of the principal amount into shares of our common stock at the fixed conversion price of $4.25, thereby causing the remaining $10,625,000 principal amount of the outstanding February Notes to have a final maturity date of February 26, 2004. The remaining February Notes were amended to remove the feature permitting the holders to exchange such notes into the AVI Shares at an exchange price of $5.00, and to remove our ability to use the AVI Shares valued at market at the time of repayment to repay the outstanding principal amount. However, in connection with the issuance of the June Notes and the restructuring of the February Notes, we issued to the note holders warrants to purchase the 2,634,211 AVI Shares at an exercise price of $5.00 per share. The warrants represent a derivative under SFAS 133 that must be recorded at fair value. Changes in the fair value of the derivative are recognized in earnings. During years ended December 31, 2004 and 2003, we recorded changes in the value of this derivative of $3,898,000 and $4,557,000, respectively.

While the full amount of the $21,250,000 proceeds from the June Notes was transferred to SuperGen, $10,625,000 of such funds were placed into an interest bearing collateral account, and not available for our use until release. Absent certain defaults by us, $5,312,500 (one-half of the $10,625,000) was to be available to us on March 24, 2004, and the remaining $5,312,500 was to be available on June 24, 2004. In connection with the private placement transaction completed in March 2004 (see Note 3 above), the holders of the June Notes released the entire $10,625,000 plus accrued interest from the collateral account.

In connection with the issuance of the warrants to acquire the 2,634,211 AVI Shares, we pledged the AVI Shares into a collateral account. The fair value of the AVI Shares is included in the accompanying consolidated balance sheet under non-current Restricted cash and investments. We also hold an additional 50,000 shares of AVI, which are included in the accompanying December 31, 2004 balance sheet in Investment in stock of related parties. We continue to hold all of the pledged and unpledged AVI Shares and reflect temporary changes in those share values in accumulated other comprehensive loss. During 2004 we recorded a write-down of $7,851,000 related to an other than temporary decline in the value of our investment in AVI. We had no such write down in 2003.

During the years ended December 31, 2004 and 2003, we issued 4,750,000 and 3,889,000 shares of our common stock, respectively, in payment of principal and interest on the February and June Notes. As of December 31, 2004, all principal from both the February Notes and June Notes was repaid.

In connection with the February and June convertible note transactions, we recorded prepaid financing costs related to the placement agent fees, legal fees, and other cost associated with the transactions. During the years ended December 31, 2004 and 2003, we recorded amortization of the

5. Convertible Debt Financing Transactions (Continued)

prepaid financing costs totaling $1,811,000 and $3,064,000, respectively, to interest expense. At December 31, 2004, all prepaid financing costs had been fully amortized.

Also in connection with the February and June convertible note transactions, we recorded deemed discounts on the convertible debt. During the years ended December 31, 2004 and 2003, we recorded amortization of the deemed discount on convertible debt of $12,657,000 and $13,738,000, respectively.

6. Stock Purchase and License Agreements with MGI PHARMA, Inc.

On August 31, 2004, we entered into three agreements with MGI PHARMA, Inc., a Minnesota corporation ("MGI"): (1) a common stock purchase agreement (the "Stock Purchase Agreement") for the sale of 4,000,000 shares of our common stock at a cash price per share of $10.00; (2) a license agreement relating to Dacogen™ (decitabine) (the "License Agreement"); and (3) an investor rights agreement that obligates us, within the first anniversary of the closing date of the transactions contemplated by the Stock Purchase Agreement, to file with the Securities and Exchange Commission a registration statement registering the common stock for resale, and to use commercially reasonable efforts to cause the registration statement to become effective within such time period. The agreements became effective on September 21, 2004.

Dacogen is our investigational anti-cancer therapeutic which is currently in clinical trials for the treatment of patients with myelodysplastic syndrome ("MDS"). Pursuant to the terms of the License Agreement, MGI received exclusive worldwide rights to the development, commercialization and distribution of Dacogen for all indications. We will continue to pursue regulatory approvals of Dacogen for the treatment of MDS in the United States and Europe, with assistance from MGI, provided that all development of Dacogen will be transitioned to MGI no later than the end of 2005. MGI will assume full development responsibilities following the transition to them. MGI is required to fund further development costs associated with Dacogen at a minimum of $15 million over a three year period. In addition to MDS, MGI will pursue development of Dacogen for other indications. If specified regulatory and commercialization milestones are achieved, MGI will pay us up to $45 million based upon the achievement of such milestones. Subject to certain limitations, MGI will also pay us 50% of certain revenue payable to MGI as a result of MGI sublicensing rights to market, sell, and/or distribute Dacogen, to the extent such revenues are in excess of the milestone payments. We will receive a royalty starting at 20% and escalating to a maximum of 30% on annual worldwide net sales of licensed products.

In accordance with the Stock Purchase Agreement described above, we issued 4,000,000 shares of our common stock to MGI at $10.00 per share, for aggregate proceeds totaling $40,000,000. In connection with this transaction, we paid the placement agent, The Kriegsman Group, $3,200,000 in cash and issued Kriegsman a warrant exercisable for 400,000 shares of our common stock at an exercise price of $10.00 per share. The warrant will be exercisable for a term of five years, and we were obligated to register for resale the common stock issuable upon exercise of the warrant. We calculated the fair value of the warrant issued to Kriegsman at $1,436,000, using the Black-Scholes model with a volatility of 0.83, expected life of five years, dividend yield of 0%, and risk free interest rate of 3.29%. We have allocated the aggregate proceeds and related costs of the placement agent fee and warrant valuation between equity, for the portion attributable to the Stock Purchase Agreement, and deferred revenue, for the portion attributable to the License Agreement. On August 31, 2004, the date that the Stock Purchase Agreement was executed, the fair value of our common stock, based on the closing price on the NASDAQ National Market, was $6.43

6. Stock Purchase and License Agreements with MGI PHARMA, Inc. (Continued)

per share. Therefore, we allocated $23,662,000, the fair value of 4,000,000 shares of our common stock at $6.43 per share, net of related offering costs, to equity, with the remaining $12,625,000 being allocated to deferred revenue. The deferred revenue is being amortized to license revenue over 15 months, which is the period of time in which our development obligations for Dacogen would transfer to MGI. During the year ended December 31, 2004, we recorded amortization of deferred revenue $2,720,000 to Development and license revenue on the accompanying statement of operations.

Under the terms of the License Agreement, MGI is obligated to pay us milestone payments for achievement of certain regulatory and commercialization goals, as well as reimburse us for certain development and allocated overhead costs of Dacogen until we receive marketing authorization. During the year ended December 31, 2004, we recognized development revenue of $12,500,000 for milestone achievement and $3,646,000 relating to the reimbursements under this agreement.

7. 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. These shares are carried as part of Marketable Securities—non-current.

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 milestone or royalty payments have been made 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 Investigational New Drug Application utilizing the licensed patents. During the years ended December 31, 2004 and 2003, we paid the annual license fees of $200,000 to Peregrine in shares of our common stock. We issued Peregrine 18,454 and 61,653 shares of unregistered stock in 2004 and 2003, respectively, which were calculated based on the average price of our common stock during the 30-day period preceding the payment date. During the year ended December 31, 2002, we paid Peregrine $200,000 in cash in connection with this agreement. The annual license fees paid to Peregrine have been charged to Research and development expense.

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™.

During the years ended December 31, 2004, 2003, and 2002, we recorded expenses of $100,000, $100,000, and $274,000, respectively, in connection with the research agreement, which we have charged to Research and development expense.

7. Acquisition Activity (Continued)

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.

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 were 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 $800,000 in 2003 and $1,200,000 in 2002 and had paid Stehlin all of the $9.6 million required for research. During the year ended December 31, 2004, we filed a New Drug Application for Orathecin with the FDA. This triggered a required milestone payment to Stehlin of $500,000. We made the milestone payment through the issuance of 63,969 shares of unregistered common stock, which was calculated based on the average trading price of our stock during the 30-day period preceding the payment date.

8. 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 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. In connection with this termination agreement, we agreed to reimburse Abbott for development work they completed on our behalf and paid Abbott $880,000 in March 2002 and $370,000 in 2003.

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 is included in deferred revenue and was recognized as other revenue through December 2002.

In March 2003, we entered into an agreement with Abbott that allows us to terminate the Nipent distribution agreement, for a stated fee that decreases over time to $1.5 million at March 2005. As part of the agreement, we paid Abbott $500,000 for the right to terminate the Nipent distribution agreement at our option. The $500,000 has been recorded as a reduction of the deferred revenue we initially received

8. Termination of Agreements with Abbott Laboratories (Continued)

from Abbott for the distribution rights, and we stopped amortizing the remaining deferred revenue, which was $1,667,000 at December 31, 2003, to account for the termination fee we may pay to Abbott.

The unamortized balance of $1,667,000 is included in current deferred revenue at December 31, 2004 and non-current deferred revenue at December 31, 2003. In February 2005, we paid Abbott $1,500,000 to terminate the Nipent distribution agreement.

9. 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. 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. During 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 were charged to Selling, general, and administrative expense in 2002. In 2003 and 2004, the results of EuroGen are included in our consolidated operations in Selling, general and administrative expenses. During the years ended December 31, 2004 and 2003, we have recorded expenses of $2,269,000 and $325,000, respectively, related to the EuroGen.

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. ("KineMed"), a start-up biotech company. In March 2003, we made an additional equity investment of $30,000 to acquire an additional 15,000 shares. The president and chief executive officer of KineMed is a former director of SuperGen. Our current president and chief executive officer 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.

In late 2004, we reached an agreement with KineMed whereby we granted them exclusive worldwide rights to the development, manufacture, commercialization and distribution of proprietary property we own relating to etiocholoandeione and etiocholanolone compounds. Under the terms of the license agreement and upon successful commercialization, we could earn future royalty revenue on worldwide sales. In addition, we have termination rights and rights of first refusal on new oncological uses.

9. Related Party Transactions (Continued)

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 former president and chief executive officer of SuperGen was a member of the Board of Directors of AVI through March 2004. 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. 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, 2004.

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 2003 and 2002, we recorded $144,000 and $421,000, respectively, in research and development expenses for Avicine. At December 31, 2004, the sum of these expenses, or $565,000, was still payable and is presented on the balance sheet as Payable to AVI BioPharma, Inc.

Quark Biotech, Inc.

Our current president/chief executive officer and our former president/chief executive officer are directors and stockholders of Quark Biotech, Inc. ("QBI"), a privately-held development stage biotechnology company. 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 January 2002, we subleased a portion of our laboratory space to QBI. During 2003 and 2002, we collected $56,000 and $123,000, respectively, in sublease income from QBI. The initial term of the sublease expired on December 31, 2002, but we continued to sublease the space to QBI on a month-to-month basis until August 2003.

9. 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. On July 25, 2002, our former president/chief executive officer and board member through 2004 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. See Note 3 and 6 for discussion of cash and warrants granted to the Kriegsman Group and the accounting treatment of each transaction. We also paid The Kriegsman Group consulting fees of $220,000 in 2003 and $240,000 in 2002. No other consulting fees were paid to Kriegsman in 2004.

Other

At December 31, 2004, 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. The president of this company and our former president and chief executive officer and board member through 2004 are currently partners in a new business enterprise. We paid this company $150,000 in 2004, $371,000 in 2003, and $360,000 in 2002 for services and supplies. We carry our investment in this company at no value.

At December 31, 2004 and 2003, we have $93,000 and $437,000, respectively, in receivables due from related parties. The receivables consist of advances or loans to employees. $250,000 of the balance at December 31, 2003 related to a loan to an officer that was due on December 31, 2003 under its original terms. The loan was repaid in 2004.

10. 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 and investments. 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 June 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 2005 with an option through June 2006.

10. Commitments and Contingencies (Continued)

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

Year ending December 31,	Minimum rental obligations	Sublease income
2005	$ 2,363	$249
2006	2,281	91
2007	2,213	—
2008	2,297	—
2009 and thereafter	4,513	—
	$13,667	$340

Rent expense was $2,034,000 in 2004, $1,985,000 in 2003, and $1,948,000 in 2002. These amounts were net of sublease income of $323,000 in 2004, $393,000 in 2003, and $450,000 in 2002.

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, 2004.

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, 2004.

11. Income Taxes

For financial reporting purposes, our net loss included the following components:

	Year ended December 31,		
	2004	2003	2002
Net Loss:			
United States	$(44,270)	$(52,922)	$(48,380)
Foreign	(2,590)	(548)	(1,091)
	$(46,860)	$(53,470)	$(49,471)

11. Income Taxes (Continued)

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, 2004	December 31, 2003
Deferred Tax Assets:		
Net operating loss carryforwards	$ 107,237	$ 97,030
Purchased in-process technology	6,477	3,415
Research and development credit carryforwards	8,899	7,971
Capitalized research and development	7,395	6,683
Other	8,054	4,919
	138,062	120,018
Valuation allowance	(138,062)	(114,862)
Deferred tax assets	$ —	$ 5,156
Deferred Tax Liabilities:		
Amortization of Debt Discount	—	5,156
Deferred tax liabilities	$ —	$ 5,156
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 $23,200,000 during 2004, $17,015,000 during 2003, and by $14,668,000 during 2002.

As of December 31, 2004 we have net operating loss carryforwards for federal income tax purposes of approximately $295,015,000 which expire in the years 2005 through 2024, and federal research and development credit carryforwards of approximately $5,532,000, which expire in the years 2008 through 2024.

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.

12. Employee Benefit Plans

We have adopted a 401(k) Profit Sharing Plan (the "401(k) Plan") for all eligible employees with a minimum of two 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 $222,000 in 2004, $300,000 in 2003, and $297,000 in 2002.

In 1998 we established the 1998 Employee Stock Purchase Plan ("ESPP"), and a total of 300,000 shares of Common Stock are reserved for issuance under the plan. Employees participating in the ESPP

12. Employee Benefit Plans (Continued)

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 2004, we issued 31,685 and 29,372 shares through the ESPP at $6.15 and $5.00, respectively. In 2003, we issued 37,065 and 45,746 shares through the ESPP at $3.59 and $3.82, respectively. In 2002, we issued 44,097 and 33,606 shares through the ESPP at $4.46 and $3.48, respectively. As of December 31, 2004, 178,813 shares are reserved for future issuance under the ESPP.

13. Quarterly Financial Data (Unaudited)

Following is a summary of the quarterly results of operations for the years ended December 31, 2004 and 2003:

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(Amounts in thousands, except per share data)			
2004				
Net sales	$ 1,098	$ 2,636	$ 3,909	$ 5,484
Cost of sales	551	1,196	1,168	1,221
Net income (loss)	(18,735)	(21,312)	(12,356)	5,543
Basic net income (loss) per share	(0.48)	(0.48)	(0.27)	0.11
Diluted net income (loss) per share	(0.48)	(0.48)	(0.27)	0.11
2003				
Net sales	$ 2,176	$ 4,096	$ 4,419	$ 746
Cost of sales	754	1,585	1,023	504
Net loss	(11,666)	(12,468)	(10,503)	(18,834)
Basic and diluted net loss per share	(0.35)	(0.38)	(0.30)	(0.52)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on this 16th day of March 2005.

SUPERGEN, INC.

By: /s/ JAMES S. J. MANUSO
James S.J. Manuso
Chief Executive Officer, President and Director

POWER OF ATTORNEY

We, the undersigned officers and directors of SuperGen, Inc. hereby constitute and appoint James S.J. Manuso and Michael Molkentin, and each of them individually, our true and lawful attorney-in-fact, with full power of substitution, to sign for us and in our names in the capacities indicated below any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or their substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ JAMES S.J. MANUSO (James S.J. Manuso)	Chief Executive Officer, President and Director (Principal Executive Officer)	March 16, 2005
/s/ MICHAEL MOLKENTIN (Michael Molkentin)	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2005
/s/ CHARLES CASAMENTO (Charles Casamento)	Director	March 16, 2005
/s/ THOMAS V. GIRARDI (Thomas V. Girardi)	Director	March 16, 2005
_____ (Allan R. Goldberg)	Director	March 16, 2005
/s/ WALTER J. LACK (Walter J. Lack)	Director	March 16, 2005
/s/ MICHAEL YOUNG (Michael Young)	Director	March 16, 2005

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1) 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
2) Form S-8 (Registration No. 333-58303) pertaining to the 1993 Stock Option Plan, and 1998 Employee Stock Purchase Plan
3) 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
4) Form S-8 (Registration No. 333-86644) pertaining to the 1996 Directors' Stock Option Plan and 1998 Employee Stock Purchase Plan
5) 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
6) Form S-3 (Registration No. 333-88051) for the registration of 2,014,036 shares of common stock
7) Form S-3 (Registration No. 333-52326) for the registration of 697,533 shares of common stock
8) Form S-3 (Registration No. 333-95177) for the registration of 136,130 shares of common stock
9) Form S-3 (Registration No. 333-100707) for the registration of 3,930,800 shares of common stock
10) Form S-3 (Registration No. 333-104255) for the registration of 11,549,219 shares of common stock
11) Form S-3 (Registration No. 333-107301) for the registration of 5,004,000 shares of common stock
12) Form S-8 (Registration No. 333-110152) pertaining to the 2003 Stock Plan and related prospectuses
13) Form S-3 (Registration No. 333-113858) for the registration of 6,153,454 shares of common stock
14) Form S-3 (Registration No. 333-120502) for the registration of 4,400,000 shares of common stock, and
15) Form S-8 (Registration No. 333-120505) pertaining to the 1998 Employee Stock Purchase Plan,

of our report dated March 15, 2005, with respect to the consolidated financial statements of SuperGen, Inc., SuperGen, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of SuperGen, Inc., included in the Annual Report on Form 10-K for the year ended December 31, 2004.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 15, 2005

EXHIBIT 31.1

Certification of CEO Pursuant to Rule 13a-14(a) of the Exchange Act

I, James S.J. Manuso, certify that:

1. I have reviewed this annual report on Form 10-K of SuperGen, Inc.;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, 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 and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

By: /s/ JAMES S.J. MANUSO
James S.J. Manuso
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification of CFO Pursuant to Rule 13a-14(a) of the Exchange Act

I, Michael Molkentin, certify that:

1. I have reviewed this annual report on Form 10-K of SuperGen, Inc.;

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, 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 and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

By: /s/ MICHAEL MOLKENTIN
Michael Molkentin
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

I, James S.J. Manuso, 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, 2004 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.

Dated: March 16, 2005

By: /s/ JAMES S.J. MANUSO
Name: James S.J. Manuso
Title: President and Chief Executive Officer

I, Michael Molkentin, 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, 2004 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.

Dated: March 16, 2005

By: /s/ MICHAEL MOLKENTIN
Name: Michael Molkentin
Title: Chief Financial Officer

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934, each as amended, (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

STOCKHOLDER INFORMATION

BOARD OF DIRECTORS

James S. J. Manuso, Ph.D.
Chairman, President and Chief Executive Officer
SuperGen, Inc.

Charles J. Casamento
Chief Executive Officer
Osteologix, Inc.

Thomas V. Girardi
Senior Partner
Girardi & Keese

Alan R. Goldberg, Ph.D.
Managing Partner
The Channel Group LLC

Walter J. Lack
Managing Partner
Engstrom, Lipscomb & Lack

Michael D. Young, M.D., Ph.D.
Chairman and Chief Scientific Officer
Strategic Healthcare Development, LLC

SENIOR MANAGEMENT TEAM

James S. J. Manuso, Ph.D.
President and Chief Executive Officer

Edward L. Jacobs
Chief Operating Officer

Michael Molkentin
Chief Financial Officer and Corporate Secretary

Audrey Jakubowski, Ph.D.
Chief Regulatory and Quality Affairs Officer

Wayne Davis, Ph.D.
Vice President, Clinical Operations

Timothy L. Enns
Senior Vice President, Corporate Communications and Business Development

Larry Johnson
President and Chief Executive Officer, EuroGen Pharmaceuticals Limited (United Kingdom)

Robert Marshall
Vice President, Sales

Michael V. McCullar, Ph.D.
Vice President, Strategic Planning and Development

[illegible] Kinomoto, Pharm.D.
Vice President, Medical Affairs

Sanjeev Redkar, Ph.D.
Vice President, Manufacturing and Preclinical Development

CORPORATE HEADQUARTERS

SuperGen, Inc.
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Suite 200
Dublin, CA 94568
925.560.0100 Tel
925.560.0101 Fax

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[illegible] 1TA
United Kingdom
Phone: +44 (0) 1242-703646

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young
Building 1, Suite 200
1001 Page Mill Road
Palo Alto, CA 94304

LEGAL COUNSEL

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
650.493.9300 Tel

TRANSFER AGENT

Mellon Investor Services, LLC
Overpeck Center
85 Challenger Road
Ridgefield Park, NJ 07660
800.[illegible] Tel
www.melloninvestor.com

ANNUAL MEETING

The annual meeting of stockholders will be held May 12 at 2 p.m. at SuperGen's corporate headquarters.

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.


SuperGen®