THE FUTURE IN DRUG DEVELOPMENT

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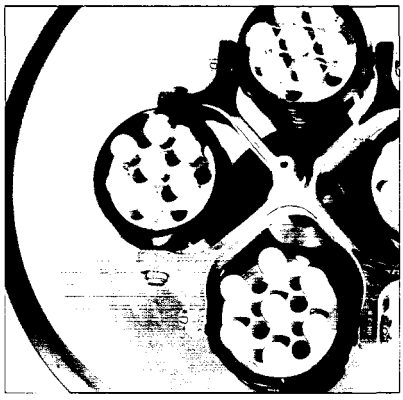
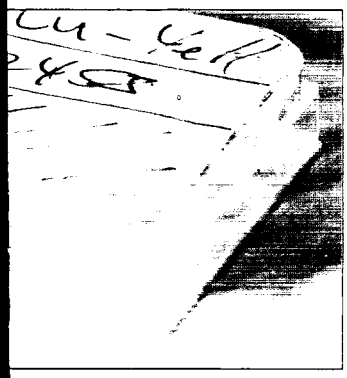
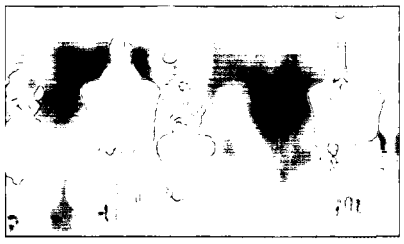
PRAECIS

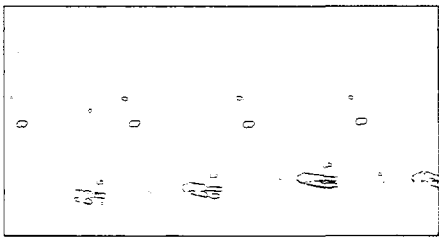
PRAECIS
PHARMACEUTICALS
INCORPORATED

ANNUAL REPORT 2001



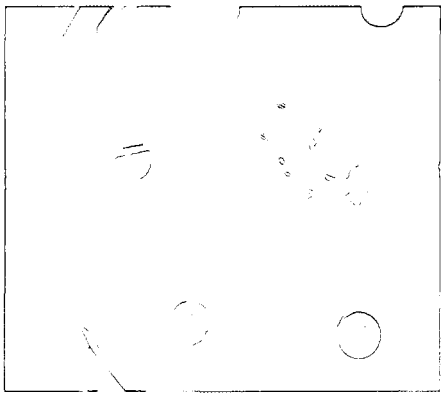






PRAECIS

MAINTAINING FOCUS TO MEET COMPANY OBJECTIVES



PRAECIS' mission is to discover and develop innovative pharmaceutical solutions to improve the lives of people.

We will focus our Company resources on discovering, developing, marketing and/or acquiring drugs to treat unmet medical needs in oncology, inflammation, and aging. The growth of the Company will be in proportion to our revenue and profits.

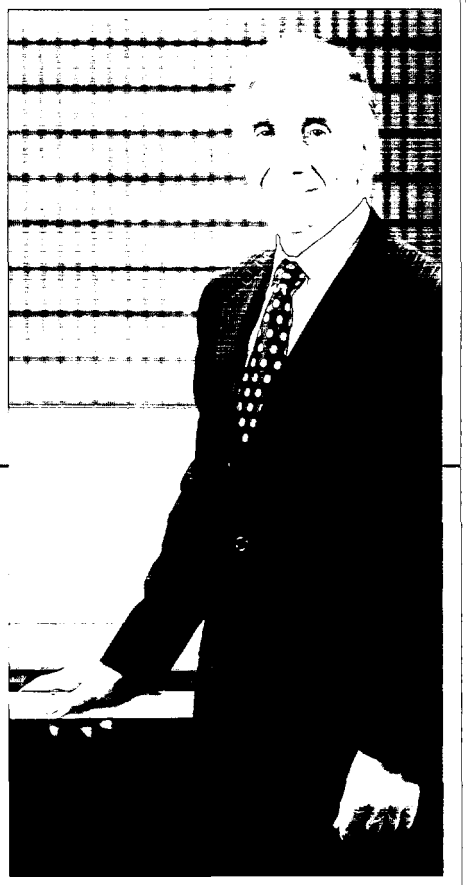
We value meeting the needs of our most important asset, our employees, by providing opportunities to contribute to the growth of the Company and for personal development. We will strive to meet the expectations of our customers and stockholders and to be an excellent corporate citizen within the communities in which we do business.

TO OUR STOCKHOLDERS

DURING 2001, PRAECIS FACED MANY CHALLENGES.

On behalf of all of the employees of PRAECIS, I want to thank you for your support and interest.

PRAECIS was founded with the mission of employing innovative technologies for the discovery and development of pharmaceutical products. Our commitment to this mission remains strong, and our accomplishments to date speak well of our ability to succeed. Our employees are enthusiastic and dedicated to our mission. We have encountered bumps along the road to success, but that is the nature of the drug development business. Drugs are not delivered to the marketplace by genius, desire or hard work alone. Experimentation, by its nature, has uncertain outcomes. To be successful requires planning for the uncertainties and finding creative ways around impediments. PRAECIS, in my opinion, is well positioned to succeed.



MALCOLM L. GEFTER, PH.D.
CHAIRMAN OF THE BOARD,
CHIEF EXECUTIVE OFFICER
AND PRESIDENT

PROSTATE CANCER

In June 2001, the progress of our lead program, the development of Plenaxis™ for the treatment of hormonally responsive advanced prostate cancer, was delayed. A letter from the United States Food and Drug Administration (FDA) related to our New Drug Application (NDA) indicated that the application was inadequate for approval. The FDA raised concerns regarding the long-term efficacy of Plenaxis and certain rare allergic reactions that were observed during our clinical trials. Since receipt of the FDA letter, as before, our top priority has remained unchanged – obtaining marketing approval for this drug candidate. By year end, we were able to submit to the FDA a revised clinical plan in an effort to address some of the issues raised by the FDA. During the first quarter of 2002, we initiated a relatively short-term clinical trial. We also are conducting additional analyses of existing data and samples to further evaluate the allergic reactions. Our goal, assuming positive results in this clinical trial, is to submit additional data to the FDA by the end of the first quarter of 2003.

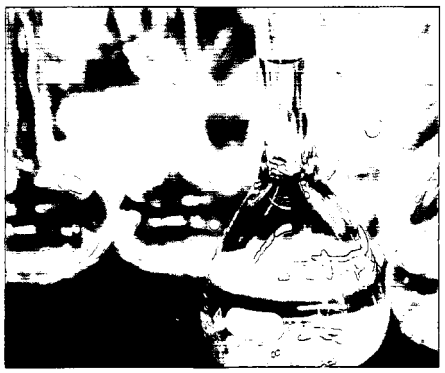
RESEARCH ADVANCEMENTS KEPT IN MOTION

IT'S ONLY FROM
PASSION THAT WE
REACH COMMITMENT

In the Fall of 2001, following the unwinding of existing corporate collaborations, we regained the worldwide rights to develop and commercialize Plenaxis for all indications. In light of the stage of the Plenaxis program, we view this as a tremendous opportunity.

In addition to our lead clinical program, we have two other clinical programs in endometriosis and Alzheimer's disease.

ENDOMETRIOSIS



In connection with the unwinding of our existing corporate collaborations, we regained control over the Investigational New Drug application (IND) for Plenaxis for the treatment of endometriosis. As we advance through 2002, we look forward to moving this program forward. Currently, we are concluding a phase II/III clinical trial. We intend to evaluate the results from this trial during the second quarter of 2002 and submit the results to the FDA. We plan to request a meeting with the FDA mid-year to review the key study results and discuss the initiation of additional clinical trials.

THROUGH COMMITMENT
WE REACH SUCCESS

ALZHEIMER'S DISEASE

Our third clinical program, the development of Apan™ for the treatment of Alzheimer's disease, continues to progress in the clinic. During 2001, we initiated a phase I clinical trial for this drug candidate. This is a dose escalation safety study in normal subjects. Progress has continued as expected and we anticipate that the results from this study will be available in late 2002. Following analysis of the study results and review with the FDA, we expect that a second phase I clinical trial, in which we will test the safety and pharmacokinetics of Apan in Alzheimer's disease patients, will be initiated during the first half of 2003. We believe that our program represents the only compound in clinical development that inhibits the aggregation of beta-amyloid into toxic fibers, which many hypothesize to be the underlying mechanism of this devastating disease.

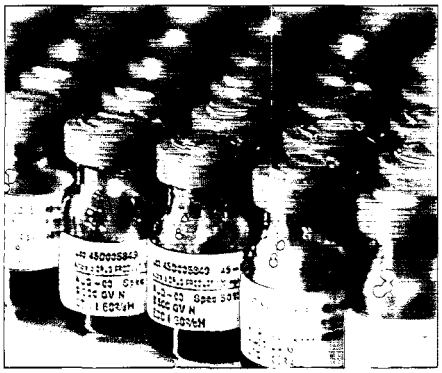
INNOVATIVE THERAPIES TO IMPROVE LIVES

MAINTAINING LEVELS OF ACHIEVEMENT AND SUCCESS

Our research and development pipeline contains promising, innovative prospects targeted to address unmet medical needs in inflammation, oncology and aging.

RHEUMATOID ARTHRITIS

We are making progress in our development of a drug candidate for the treatment of rheumatoid arthritis. This compound has also shown promise as an anti-cancer drug, and we are examining these opportunities as well. We anticipate that, if we continue to meet the goals of our preclinical experiments, we will be able to file an IND for this compound during the third quarter of 2002.



ALZHEIMER'S DISEASE (ADVANCED STAGE)

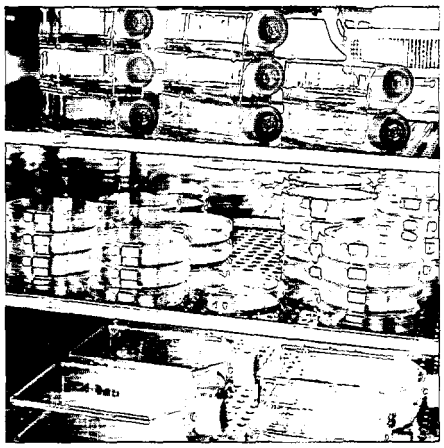
In addition to our ongoing Alzheimer's disease clinical program, we have a second compound in research that we refer to as Apan-CH™. The goal of the Apan-CH program is to develop a compound which reduces the amyloid plaque load in individuals with severe and advanced disease. We are encouraged by the results we have seen in animal models, and intend to continue advancing this program during 2002.

ANDROGEN RECEPTOR ANTAGONIST

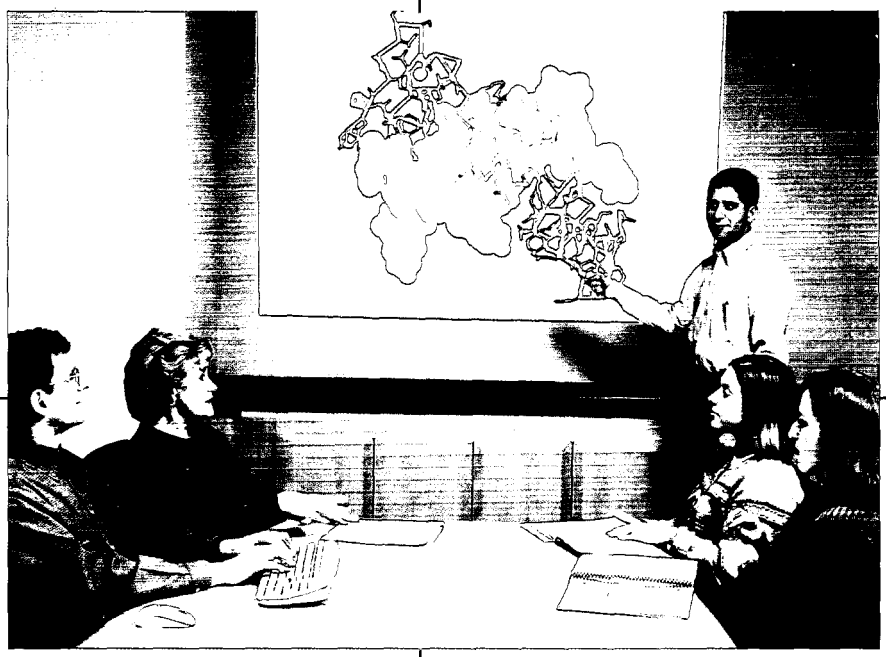
Leveraging our expertise in the area of prostate cancer, we are conducting research to develop a compound for prostate cancer patients who no longer benefit from hormonal therapies. These are generally late stage patients who become hormonally refractory, or resistant to the benefits of testosterone suppression. Our goal is to bring forward a lead compound during 2002 and proceed with appropriate preclinical testing.

ENDOMETRIOSIS DIAGNOSTIC

One of the problems for women afflicted with endometriosis is obtaining a simple and accurate diagnosis of the disease. Current diagnosis involves a relatively painful and expensive invasive procedure called laparoscopy. We believe that a diagnostic that avoids this procedure would be welcomed by medical practitioners and well accepted by patients. Our involvement in this area through our Plenaxis endometriosis program has given us a substantial knowledge base which we hope to combine with our proteomics expertise to identify suitable disease markers.

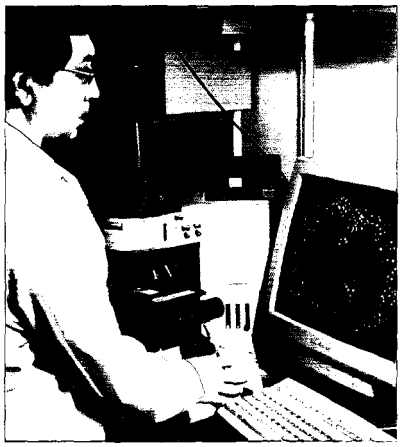


DEDICATION TO RESEARCH AND DEVELOPMENT TO IMPROVE DIAGNOSIS AND THERAPY



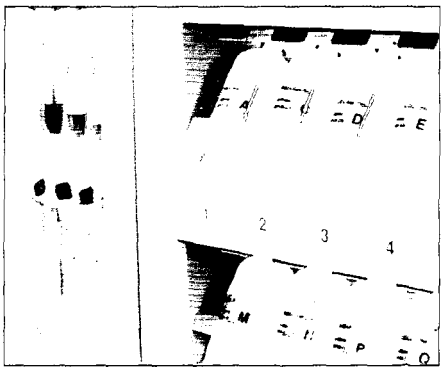
BUILDING SOLID FOUNDATIONS TO ADDRESS CHALLENGES

WE ARE IN A POSITION OF STRENGTH



Our proprietary technology positions us well to achieve and maintain a robust drug pipeline in the future.

Developing drugs is a complex and difficult task. Billions of dollars are spent each year in the hope of discovering and developing innovative and beneficial compounds. PRAECIS is a small company with novel compounds in various therapeutic areas. We believe that we have a discovery platform that is not bounded to any therapeutic area and is a cost-effective mechanism for bringing potential compounds to the clinic.



Our core technology, LEAP™ (Ligand Evolution to Active Pharmaceuticals), is the backbone of our discovery engine. LEAP was instrumental in the development of Plenaxis and Apan, and we are utilizing this technology in our Apan-CH and Androgen Receptor programs as well.

We have built a solid financial and operational foundation from which we can address our current challenges, as well as the future challenges that await us.

As we begin 2002 with approximately $266 million in cash, we are in a position of strength. This is a valuable resource and, through judicious management of our spending, we will be prepared and will strive to overcome the challenges we may encounter.

During 2001, we consolidated our operations into our new corporate headquarters and research facilities in Waltham, Massachusetts. This facility houses state-of-the-art laboratories to meet our current demands and offers the opportunity for expansion if and when needed, providing us with a platform to grow and vigorously pursue innovative pharmaceutical solutions.

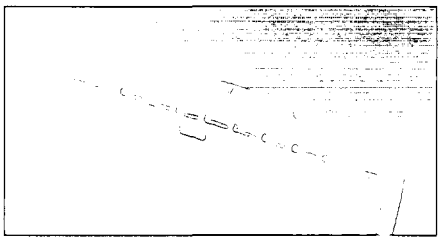
On behalf of our Board of Directors and employees, I would again like to thank our stockholders for their continued support during this challenging time. I believe we have positioned the Company well, both operationally and financially, to realize the potential of our research and clinical endeavors. I look forward to updating you on our progress during 2002.

Sincerely,

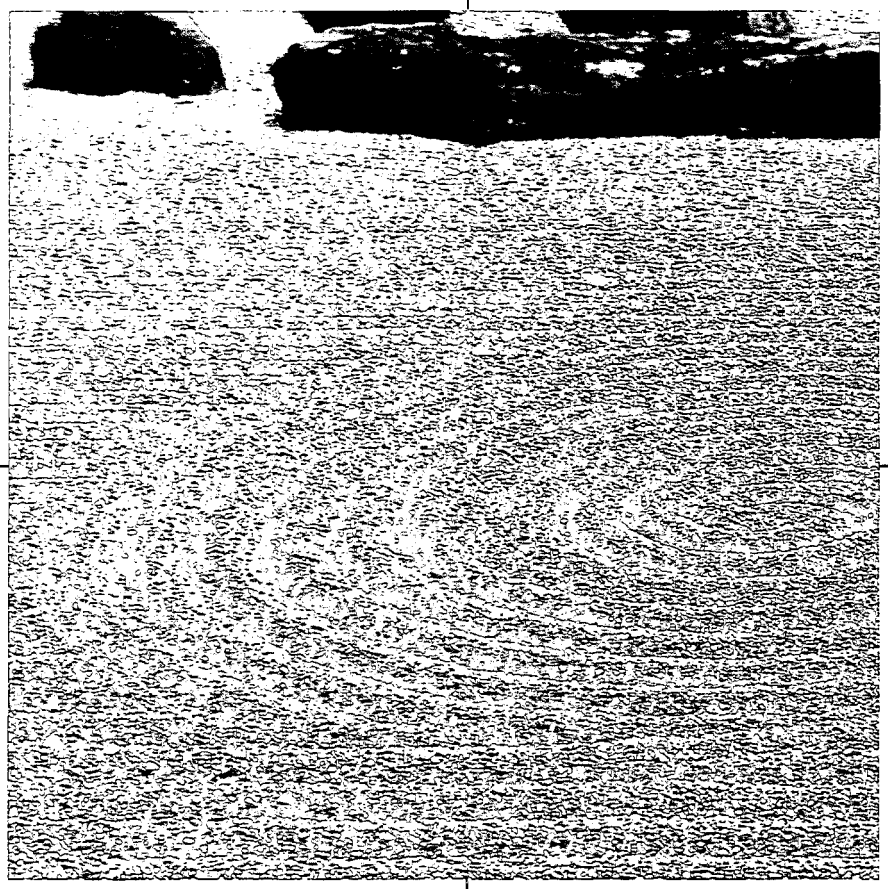
Malcolm L. Gefter

Malcolm L. Gefter, Ph.D.
Chairman of the Board, Chief Executive Officer and President

REALIZING POTENTIAL
IN ALL OF
OUR RESEARCH



COMMITTED TO IMPROVING MEDICAL TREATMENTS



"It's only from passion that we reach commitment, and through commitment we ultimately reach success. PRAECIS is deeply committed to delivering novel and innovative therapies that provide the medical community with new treatment options. It is devotion that keeps the advancement of our research in motion."

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2001

or

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

For the transition period from _____ to _____

Commission file number 000-30289

PRAECIS PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	**04-3200305**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
830 Winter Street **Waltham, Massachusetts**	**02451-1420**
(Address of principal executive offices)	(Zip code)

(781) 795-4100

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

(Title of Class)

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $.01 per share

(Title of Class)

Preferred Stock Purchase Rights

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

The aggregate market value of voting and non-voting stock held by non-affiliates of the registrant, based upon the last sale price of the common stock, par value $.01 per share, reported on the Nasdaq National Market on February 28, 2002, was $207,959,729.

The number of shares of common stock, par value $.01 per share, outstanding as of February 28, 2002 was 51,528,024.

Documents Incorporated By Reference

Specified portions of the definitive Proxy Statement with respect to the registrant's 2002 Annual Meeting of Stockholders to be filed by the registrant with the Securities and Exchange Commission are incorporated by reference into Part III of this Report on Form 10-K.

Factors That May Affect Future Results

The Company's prospects are subject to certain uncertainties and risks. This Annual Report on Form 10-K also contains certain forward-looking statements within the meaning of the federal securities laws. The Company's future results may differ materially from its current results and actual results could differ materially from those projected in the forward-looking statements as a result of certain risk factors. READERS SHOULD PAY PARTICULAR ATTENTION TO THE CONSIDERATIONS DESCRIBED IN THE SECTION OF THIS REPORT ENTITLED "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS—RISK FACTORS THAT MAY AFFECT FUTURE RESULTS." Readers should also carefully review the risk factors described in the other documents the Company files from time to time with the Securities and Exchange Commission.

PRAECIS PHARMACEUTICALS INCORPORATED

ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1. BUSINESS.

Overview

We are a drug discovery and development company with a lead product candidate, Plenaxis™ (abarelix for injectable suspension), for the treatment of hormonally responsive advanced prostate cancer. In December 2000, we submitted to the FDA a new drug application, or NDA, for Plenaxis for the treatment of hormonally responsive advanced prostate cancer. In response to concerns raised by the FDA in June 2001, we recently initiated an additional clinical trial to study the effects of using currently available hormonal therapies in prostate cancer patients following treatment with Plenaxis. We are also evaluating the rare allergic reactions that occurred in our clinical trials. Assuming positive results, we expect to submit to the FDA additional data by the end of the first quarter of 2003.

We are also developing Plenaxis for the treatment of endometriosis, a disease that responds to a reduction of the female hormone estrogen. We believe that patients suffering from endometriosis are not well served by current methods or remain untreated, and that Plenaxis could fulfill a significant unmet need. Endometriosis is a long-lasting, often painful condition affecting an estimated 5.5 million females in the United States and Canada. Patients recently concluded the final stages of follow-up in a phase II/III clinical study of Plenaxis for the treatment of endometriosis. We anticipate meeting with the FDA during mid-year 2002 to discuss the results of this study and the initiation of additional clinical trials.

We are also developing Apan™, our drug candidate for the treatment of Alzheimer's disease, a condition that affects more than four million Americans. Apan is designed to treat what we and others believe to be the underlying cause of Alzheimer's disease, rather than the symptoms. A hallmark of Alzheimer's disease is the accumulation of plaque-like deposits in brain tissue. A major component of this plaque is a small peptide called beta-amyloid. We have demonstrated in preclinical studies that Apan is able to mobilize beta-amyloid in the brains of guinea pigs and transgenic mice, and, based on these studies, we believe that Apan may be facilitating the clearance of beta-amyloid. We are conducting a phase I dose escalation study of Apan in which we are evaluating the safety and pharmacokinetics of the compound in normal human subjects. We anticipate that this study will be completed during the second half of 2002. We expect to initiate a second phase I study in the first half of 2003 in which we intend to further evaluate the safety and pharmacokinetics of Apan in individuals suffering from Alzheimer's disease.

Our proprietary drug discovery technology called Ligand Evolution to Active Pharmaceuticals, or LEAP™, has been valuable in the development of our pipeline of product candidates. Because LEAP technology uses biological molecules as ligands, we believe it can be used to develop efficiently new drugs against a variety of other disease targets. LEAP was instrumental in the development of Plenaxis and Apan, and we are using it against targets in other disease areas, as well.

Our technology platform also includes a proprietary drug delivery system known as Rel-Ease™. Plenaxis is formulated in Rel-Ease, which allows it to be administered to prostate cancer patients once every four weeks. We have demonstrated that Rel-Ease is useful for formulating Plenaxis and various other molecules in sustained release formulations. We hold a patent that covers the general application of this technology for a broad range of peptide-based drugs.

We were incorporated in Delaware in July 1993 under the name Pharmaceutical Peptides, Inc. In June 1997, we changed our name to PRAECIS PHARMACEUTICALS INCORPORATED.

Product Pipeline

We focus our drug development efforts on conditions or diseases where there are unmet needs creating a potential for significant product revenues. We have three programs that have moved beyond the research phase into clinical testing, as well as various research and preclinical programs. We have

outlined our clinical programs and five of our programs in the research or preclinical development stage, along with the clinical indications they address, in the following table:

Product Candidates	Clinical Indication	Status
Plenaxis	Hormonally Responsive Advanced Prostate Cancer	NDA Submitted Q4 2000; additional Study and Analyses ongoing
Plenaxis	Endometriosis	Phase II/III
Apan	Alzheimer's Disease	Phase I
PPI-2458	Rheumatoid Arthritis/Cancer	Research/Preclinical
Apan-CH	Alzheimer's Disease	Research/Preclinical
CCR5 Antagonist*	AIDS	Research/Preclinical
Androgen Receptor Antagonist	Hormone-Independent Prostate Cancer	Research/Preclinical
Endometriosis Diagnostic	Endometriosis	Research/Preclinical

* In collaboration with Human Genome Sciences, Inc. Subject to GlaxoSmithKline option, if exercised, to assume development and commercialization with Human Genome Sciences, Inc.

Plenaxis™ Program

Plenaxis (abarelix for injectable suspension) has potential use in treating diseases that respond to the reduction of testosterone, a male hormone, and estrogen, a female hormone. Examples of these diseases include prostate cancer, endometriosis, benign prostatic hypertrophy, uterine fibroids, breast cancer, polycystic ovarian disease, infertility and precocious puberty. Treatments that reduce testosterone or estrogen through the use of drugs, known as hormonal therapy, can result in a therapeutic benefit to patients suffering from these diseases.

Currently available hormonal therapies, known as LHRH agonists, act by overstimulating the GnRH receptor, located on the pituitary gland, a small gland in the center of the brain. Overstimulation of the pituitary GnRH receptor causes the GnRH receptor to become non-responsive after approximately three weeks. However, this overstimulation first leads to increased production of two hormones, luteinizing hormone, or LH, and follicle stimulating hormone, or FSH. The increased levels of LH cause an initial surge of testosterone from the testes in males and a surge of estrogen from the ovaries in females. The temporary surge in hormone levels may result in a worsening, or flare, of the disease for which the patient takes the therapy. Only after several weeks following administration of these hormonal therapies does the GnRH receptor become non-responsive and the desired reduction of hormonal levels occur. Due to this surge, current LHRH agonists, such as Lupron Depot®, marketed by TAP Pharmaceuticals Inc., and Zoladex®, marketed by AstraZeneca Pharmaceuticals, have precautionary labeling about the hormone-induced flare. The FDA mandates this precautionary labeling, and the drug labels and packaging for these currently available drugs must prominently include the precautionary labeling to protect patients and avoid the use of the drugs in patients who are at risk for developing life-threatening conditions as a result of the disease flare.

In contrast, Plenaxis has a blocking, or antagonist, effect on the GnRH receptor. Plenaxis rapidly shuts off the production of LH and FSH and, consequently, rapidly reduces the patient's levels of testosterone or estrogen. With Plenaxis, unlike commercially available LHRH agonists, there is no increase in hormone levels before achieving the desired hormone level reduction.

Our most advanced programs involve the development of Plenaxis for the treatment of hormonally responsive advanced prostate cancer and for endometriosis. In addition, a small, investigator-sponsored study is underway in which the effects of using Plenaxis to treat hormonally refractory prostate cancer are being evaluated. We have not begun studies for any of the other potential indications identified above.

Plenaxis—Prostate Cancer

Background. Prostate cancer is one of the most commonly diagnosed cancers in men. The American Cancer Society estimates that approximately 189,000 new diagnoses of, and 30,200 deaths from, prostate cancer will occur in the United States in 2002. In nearly all newly diagnosed prostate cancer patients, the cancerous cells require the androgen testosterone, and its derivatives, for growth. Androgens stimulate the growth of the cancerous cells. Since androgens stimulate the growth of the cancerous cells, this stage of prostate cancer is commonly referred to as hormonally responsive prostate cancer. The goal of hormonal therapies is to reduce testosterone to low, or castrate, levels, leading to inhibition of prostate cancer cell growth.

To date, we have focused on the development of Plenaxis as a treatment for hormonally responsive prostate cancer. Plenaxis is a sustained release depot formulation that enables the drug to be administered once every four weeks. During the first four weeks of administration, an additional injection is given on day 15, resulting in two injections during that time period. Our pivotal phase III studies demonstrate that Plenaxis reduces the time required to achieve therapeutically low testosterone levels compared to currently available LHRH agonists and completely avoids the testosterone surge associated with these therapies.

The surge of testosterone associated with available hormonal therapies may last as long as three weeks before the intended medical effect of reduced testosterone levels takes place. In an attempt to mitigate the flare, many practicing physicians prescribe additional drugs, known as anti-androgens. Anti-androgens, such as Casodex®, marketed by AstraZeneca Pharmaceuticals, are oral drugs given one-to-three times a day. Anti-androgens function by interfering with the effect of testosterone at the cellular level, but do not reduce circulating testosterone levels or the initial surge in hormone levels associated with currently available LHRH agonists. This additional therapy may be only partially effective in reducing some of the undesirable effects of the flare. In addition, anti-androgen therapy may cause various side effects, including liver damage, breast enlargement, lung dysfunction and gastrointestinal distress. Finally, Medicare generally does not reimburse the costs of anti-androgens. This means that patients who pay out-of-pocket for medications not covered by Medicare may not fill their prescriptions and, thus, may not receive the potential benefit of anti-androgens.

In our pivotal phase III safety and efficacy studies of over 500 patients, none of the patients treated with Plenaxis experienced a testosterone surge. In contrast, more than 80% of patients treated with Lupron Depot alone or in combination with Casodex experienced a testosterone surge. A major reason for using anti-androgens in clinical practice is to mitigate the effects of the surge and thereby avoid the resultant flare. We believe that the results of our clinical studies may lessen the perceived need to use anti-androgens because the use of Plenaxis alone avoids the surge.

Some patients with advanced-stage hormonally responsive prostate cancer are at higher risk of serious harm resulting from the testosterone surge. In these patients, the testosterone surge may lead to urinary blockage, worsening pain, kidney failure, paralysis and nerve damage due to spinal cord compression, and even death. FDA mandated drug product labels specifically warn against the use of available LHRH agonists in patients with the potential for developing worsening neurologic function, including paralysis, due to spinal metastases, worsening of kidney and urinary function, and worsening of bone pain due to secondary bone metastases. In these cases, patients may require immediate surgical removal of the testes, known as castration, both to rapidly reduce testosterone levels and avoid the testosterone surge. Based upon our analysis of our clinical studies, we believe that Plenaxis may have the potential to provide a non-surgical alternative to castration for these patients. A significant portion of patients who do not have radiographically confirmed epidural or spinal metastases or kidney obstruction are still at risk for developing life-threatening conditions as a result of the disease flare induced by the testosterone surge. We believe that both physicians and patients will prefer a treatment option that eliminates the potential risks of a clinical flare response.

Prostate Cancer—NDA Status. We submitted to the FDA an NDA comprised of comprehensive safety and efficacy data in December 2000 to support marketing approval of Plenaxis for the treatment of hormonally responsive prostate cancer. Our submission included data from two pivotal phase III safety and efficacy studies, one pivotal phase III safety study, a phase II/III study in advanced metastatic prostate cancer patients, as well as previously completed phase I and phase I/II pharmacokinetics studies.

In January 2001, the FDA informed us that it had accepted and filed the NDA and had granted the filing priority review. In June 2001, we received a letter from the FDA in which the FDA indicated that the information presented in the NDA was inadequate for approval. In September 2001, we met with the FDA in an effort to clarify the various deficiencies cited in the FDA's letter, and to discuss what further steps needed to be taken before the application could be approved. The FDA recommended that we analyze the allergic reactions that occurred in a small subset of clinical trial patients. In addition, the FDA expressed concern that, in a subset of patients treated beyond the three-month pivotal study time frame, testosterone suppression was not maintained at a comparable level to that of patients treated with either Lupron Depot or Lupron Depot plus Casodex. The FDA also indicated that the nature of the testosterone surge, if any, associated with treating patients with Plenaxis and then switching them to a currently available therapy should be understood.

We considered various alternatives to address these issues, and in December 2001 the FDA indicated that we could proceed with our clinical plans to study the effects of using currently available hormonal therapies in prostate cancer patients following treatment with Plenaxis. The FDA also indicated that our plan to further evaluate the rare allergic reactions that occurred in our clinical trials was acceptable. We recently initiated an additional clinical trial in accordance with our clinical plan. This trial is summarized below.

Following further review of the proposed protocol for our additional clinical study, the FDA requested that we extend the treatment period for an additional month, which will delay our previously announced timeline. Assuming positive results, we now expect to submit additional data to the FDA by the end of the first quarter of 2003. However, we can give no assurance that our additional clinical studies will yield positive results or that the results, even if positive, will satisfy FDA concerns that have been or may be raised. We cannot assure investors that we will be successful in obtaining approval for the commercialization of Plenaxis for the treatment of hormonally responsive advanced prostate cancer or any other indication.

As discussed above, we have initiated an open-label clinical trial to study the effects of using currently available hormonal therapies in prostate cancer patients following treatment with Plenaxis. We intend to enroll up to 140 patients suffering from prostate cancer in this trial. In this study, in which we have begun patient accrual, patients will receive a three-month treatment of Plenaxis followed by a two-month treatment of either Lupron Depot or Zoladex. The goal is to study the nature and magnitude, if any, of the testosterone surge typically caused by currently available LHRH agonists if patients are initially treated with Plenaxis and then switched to Lupron Depot or Zoladex.

Prostate Cancer Clinical Studies. In support of our NDA, we previously submitted data from two pivotal phase III clinical trials of Plenaxis for the treatment of hormonally responsive prostate cancer. The first phase III clinical trial was a 269 patient study comparing Plenaxis to Lupron Depot. This study compared the safety of both drugs and the ability of both drugs to avoid the testosterone surge, reduce testosterone levels and achieve and maintain therapeutically low levels of testosterone. The second phase III clinical trial was a 251 patient study comparing the safety and efficacy of Plenaxis to the combination therapy of Lupron Depot plus Casodex.

In these clinical trials, zero percent of the patients treated with Plenaxis experienced a testosterone surge compared to more than 80% of patients treated with Lupron Depot, or a combination of Lupron Depot and Casodex. Further, Plenaxis suppressed testosterone levels more rapidly, achieving suppression by day 8 in 70% of patients compared to zero percent of patients treated with either Lupron Depot, or Lupron Depot plus Casodex. Each treatment therapy studied achieved and

maintained therapeutically low testosterone levels from day 29 through day 85 in more than 90% of patients.

All of the patients enrolled in these studies were to continue treatment beyond the three-month pivotal study timeframe for a total of six months. In addition, physicians could continue to administer treatment to patients for up to one year. We observed that in a subset of patients treated with Plenaxis for over six months, testosterone suppression was not maintained at a comparable level to that of patients treated with either Lupron Depot or Lupron Depot plus Casodex. As stated above, the FDA raised concerns with these results and, therefore, we are exploring possible additional studies that could be undertaken to address this issue and eventually expand the potential treatment time for Plenaxis.

In further support of the safety of Plenaxis, we included results in our NDA from a separate pivotal phase III safety study comparing Plenaxis to Lupron Depot in 582 patients. The primary objective of this study was to gain more patient exposure to confirm the safety of Plenaxis over a six-month course of therapy. The results of this safety study were consistent with previous studies and supplement existing patient drug exposure data.

In addition, we conducted a phase II/III clinical trial to evaluate the use of Plenaxis in patients with advanced prostate cancer where the use of current LHRH agonists could result in a life-threatening disease flare. The results of this study indicated that Plenaxis could provide a medical alternative to immediate surgical removal of the testes for this high risk population.

Our former European collaborator also conducted a 176 patient study in Europe comparing the safety and efficacy of Plenaxis to Zoladex plus Casodex. Based upon our initial analysis, we believe the results of this study are consistent with the safety and efficacy results we observed in our two pivotal phase III studies described above. We intend to use the results of this study to support a regulatory filing for Plenaxis in Europe.

From a safety perspective, patients have generally tolerated treatment with Plenaxis well to date. However, a small number of patients in our Plenaxis studies had adverse reactions, including relatively mild allergic reactions and temporary and reversible elevation of some liver enzymes. We expected these types of relatively non-severe reactions and observed them with similar frequency in patients taking Lupron Depot and Lupron Depot plus Casodex in our clinical studies.

During the clinical studies described above, in which approximately 1,200 patients were treated, 15 patients treated with Plenaxis experienced allergic reactions that resulted in the discontinuation of trial participation. We observed a similar frequency of allergic reactions resulting in the discontinuation of trial participation in patients treated with Lupron Depot, Lupron Depot plus Casodex or Zoladex plus Casodex. However, of these 15 patients, five patients, or approximately 0.4% of the total patient population, experienced severe allergic reactions, consisting of either a drop in blood pressure or temporary syncope (fainting), following the administration of Plenaxis. None of the patients in these studies treated with Lupron Depot, Lupron Depot plus Casodex or Zoladex plus Casodex, experienced an allergic reaction of similar severity. At the recommendation of the FDA, we are conducting additional analyses of the existing data and samples from these patients to further characterize these reactions.

Plenaxis—Endometriosis

Background. We also are developing Plenaxis for the treatment of endometriosis. Endometriosis is a condition where endometrial tissue grows beyond the uterine lining, most often on the surfaces of organs in the pelvic cavity. Endometrial tissues, regardless of location in the body, respond to the normal menstrual cycling of women. When the location of the endometrial tissue prevents the appropriate sloughing of tissue that normally occurs during menstruation, inflammation, gastrointestinal symptoms and internal scarring occurs. This causes, among other things, pain, fatigue, heavy menstrual bleeding, painful sexual intercourse and infertility. Each year in the United States, approximately 300,000 females are diagnosed with endometriosis. In addition, an estimated 5.5 million females in the

United States and Canada suffer from endometriosis. As a result of increased awareness of female health, we believe that the number of patients diagnosed with and treated for endometriosis will increase.

Existing treatments for endometriosis include the use of pain management medications, birth control pills and hormonal therapies, of which Lupron Depot and Zoladex are the most commonly used. The use of available hormonal therapies to suppress estrogen production causes an initial estrogen surge in women. Lupron Depot, Zoladex and other drugs that act in a similar way include FDA mandated drug product labels warning against the adverse effects associated with an estrogen surge. These labels can include warnings for the worsening in the signs and symptoms of endometriosis, which include pain, cramping and excessive bleeding, the risk of tumor flare in breast cancer and the development of ovarian cysts. Our initial studies show that Plenaxis causes a more rapid reduction of estrogen levels and associated relief of menstrual-related pain compared to Lupron Depot. In addition, in these initial studies, there has been no initial estrogen increase associated with the use of Plenaxis.

Endometriosis Clinical Studies. To date, we have completed a phase I/II study of 40 women with confirmed endometriosis using Plenaxis, and we recently completed the follow-up phase of a 363 patient, phase II/III study. In both of these studies, we administered an injection of Plenaxis once every four weeks for 24 weeks.

In the phase I/II study, we compared various doses of Plenaxis to the standard dose of Lupron Depot. Patients receiving Lupron Depot therapy experienced initial estrogen increases, and therapeutically low estrogen levels were not achieved for several weeks. Patients treated with Plenaxis experienced a rapid reduction of estrogen levels without the initial increase seen with LHRH agonist therapy.

Our phase II/III study compares the safety and efficacy of various doses of Plenaxis to the standard dose of Lupron Depot with respect to pain relief. The study also seeks to confirm the ability of Plenaxis to rapidly suppress estrogen, which we initially demonstrated in our phase I/II study. The phase II/III study includes a 24-week treatment period and a 48-week follow-up period. Patients recently completed the final stages of follow-up and, following data analyses and conclusion of this study, we anticipate meeting with the FDA to discuss the results of the phase II/III study and the initiation of additional clinical trials in endometriosis.

Patients appear to have generally tolerated treatment with Plenaxis in these studies. As expected, we observed some adverse reactions in patients during our studies of Plenaxis and Lupron Depot, including temporary and reversible irritation at the injection site and temporary and reversible elevation of some liver enzymes. In addition, the use of hormonal therapies that lower estrogen levels, including Plenaxis, results in bone mineral density loss. Preliminary review of the data from our clinical studies indicates that patients treated with Plenaxis experienced dose-related levels of bone mineral density loss. We are further evaluating this data in an effort to clarify the extent and magnitude of this loss. We did not observe any severe allergic reactions in our endometriosis trials similar to those observed in our prostate cancer trials described above.

Apan

We are developing Apan for the treatment of Alzheimer's disease. Alzheimer's disease affects an estimated four million people in the United States, according to a 1998 report issued by the National Institute of Aging. According to the Alzheimer's Association, Alzheimer's disease is expected to become increasingly prevalent as the population ages. Current therapies provide temporary relief for the symptoms of Alzheimer's disease in some patients, but do not affect the progression of the disease itself.

A hallmark of Alzheimer's disease is the accumulation of plaque-like deposits in brain tissue. A major component of this plaque is a small peptide called beta-amyloid. Over the past several years, a large body of clinical, biochemical and genetic evidence has emerged suggesting that the aggregation of

beta-amyloid peptide is the underlying cause of Alzheimer's disease. This body of evidence has led to the widely held theory that when single beta-amyloid molecules aggregate they become toxic to nerve cells, and that this toxicity leads to the development and progression of Alzheimer's disease. We used our LEAP technology to select Apan to interfere with this aggregation process.

We have shown in *in vitro* experiments that Apan specifically inhibits the aggregation of beta-amyloid and prevents the associated nerve cell toxicity. In addition, we have shown in rats and mice that Apan reaches the brain in quantities that we believe may be sufficient to block the aggregation of beta-amyloid molecules and alter the course of the disease. Recent studies in guinea pigs and transgenic mice that develop human Alzheimer's disease plaques in their brains suggest that Apan can mobilize beta-amyloid. Alzheimer's disease, and the associated accumulation of beta-amyloid in the brain, is often thought of as a defect in the ability to clear excess beta-amyloid from the brain to the cerebro-spinal fluid, or CSF. Both humans and transgenic mice with Alzheimer's disease-like plaques show increased levels of beta-amyloid in the brain and decreased levels in the CSF as the disease progresses. In contrast, transgenic mice treated with Apan show significant increases in beta-amyloid levels in the CSF, suggesting that Apan is able to mobilize beta-amyloid in the brain and may be facilitating its clearance.

In March 2001, we began a phase I dose escalation study of Apan in normal subjects. In this study, we are evaluating the safety and pharmacokinetics of the compound. To date, we have treated approximately 52 subjects in 12 dosing groups. We anticipate that this study will be completed during the second half of 2002. We expect to initiate a second phase I study in the first half of 2003 in which we intend to further evaluate the safety and pharmacokinetics of Apan in individuals suffering from Alzheimer's disease.

PPI-2458

PPI-2458 is a novel, proprietary molecule that is based on the fumagillin class of compounds that have been shown to have potent activity in preventing excessive growth and the formation of new blood vessels. The dose limiting toxicity associated with fumagillin derivatives have largely prevented the clinical development of these compounds. PPI-2458 was designed to maintain the potent anti-growth activity while at the same time improving the toxicity profile relative to other members of the fumagillin class of compounds. Therapeutic targets for PPI-2458 include diseases whose underlying pathology is dependent on inappropriate cell growth and/or new blood vessel formation, such as rheumatoid arthritis, or RA, and certain types of cancers.

Preclinical studies have demonstrated the efficacy of PPI-2458 in a rodent model of RA, when administered either by injection or orally. Despite the availability of several new effective disease-modifying anti-rheumatic drugs, also known as DMARDs, for the treatment of RA, there remains significant unmet medical need. We believe that new drugs which could be used alone or in combination with established DMARDs could be successful.

We are also evaluating through preclinical studies the potential utility of PPI-2458 for treating certain types of cancer.

We anticipate that, if we continue to meet the goals of our preclinical pharmacology and toxicology studies of PPI-2458, we would be in the position to file an investigational new drug application, or IND, for a phase I study of PPI-2458 during the third quarter of 2002.

Apan-CH

While our preclinical studies suggest that Apan can mobilize beta-amyloid and potentially prevent its initial accumulation in the brain, we are also pursuing a complementary therapeutic strategy aimed at removing existing plaque and aggregated beta-amyloid molecules from the Alzheimer's disease-affected brain. Recent published studies using a transgenic mouse model of Alzheimer's disease show that stimulating an autoimmune response to beta-amyloid through vaccination can effect the removal of Alzheimer's disease plaques from the brains of these mice. These studies indicate that cells of the immune system can function to take up and remove plaques in the brain. Using natural peptide ligands that bind to Alzheimer's disease plaques, we have created proprietary fusion proteins between these ligands and sequences from proteins of the immune system. We have shown that these fusion proteins, that we refer to as Apan-CH, bind to Alzheimer's disease plaques with high specificity and affinity, and mediate the uptake of aggregated forms of beta-amyloid in *ex vivo* systems. Studies are ongoing to determine if Apan-CH plays a role in the removal of amyloid plaque-like deposits in rodent models of Alzheimer's disease.

CCR5 Antagonist

Various studies by others have identified groups of individuals who are resistant to HIV infection despite multiple exposures to the AIDS virus. Genetic characterization of these individuals revealed that they have mutations in the CCR5 gene which prevents the expression of the functional CCR5 protein, yet they remain healthy. The HIV virus uses the CCR5 protein as a point of entry into macrophages and T cells, which are cells in the human immune system that are commonly infected by HIV. Taken together, these studies identify CCR5 as an ideal drug target for anti-HIV therapy, as CCR5 is necessary for HIV infection, but appears not to be required for human health. Through our collaboration with Human Genome Sciences, we have licensed certain rights to CCR5 as a disease target. We are using our LEAP technology to discover ligands against CCR5 that may act as inhibitors of HIV entry into T cells.

Androgen Receptor Antagonist

Because testosterone and other hormones are growth factors for prostate cancer cells, hormone-lowering therapy can be a safe and effective treatment for patients with hormone-dependent prostate cancer. However, most patients eventually progress to a condition known as hormone-independent prostate cancer, where the prostate cancer cells no longer need testosterone and other hormones to grow and, as a consequence, hormone-lowering therapies are ineffective. Genetic studies in these patients reveal that most of them have accumulated mutations in the gene encoding the Androgen Receptor, or AR, allowing it to function in the absence of testosterone. These studies indicate that the AR is central to the growth of prostate cancer cells. Using our LEAP technology, we have discovered ligands that bind to the AR and prevent it from functioning as a growth stimulatory protein in prostate tumor cells, which could provide the basis for a new class of drugs to treat hormone-independent prostate cancer. If successful, the use of these drugs could be expanded to treat prostate cancer at all stages.

Endometriosis Diagnostic

Considering that an estimated 5.5 million females in the United States and Canada suffer from endometriosis, and that only approximately 300,000 females in the United States and an unknown number in Canada are actually diagnosed with the disease, we believe a diagnostic test is critical to better identify, assess and treat those who suffer from the disease. Currently, endometriosis is diagnosed by a relatively painful and expensive invasive procedure called laparoscopy. We are developing a simple, non-invasive endometriosis diagnostic test based on the immune response of disease sufferers. Significant differences in immune responses have been observed in women with endometriosis, and these differences are thought to be the underlying cause of the disease. Using the proteomics component of our LEAP technology, we are seeking to identify proteins that underlie the

differences in immune responses between diseased and non-diseased individuals. These proteins could prove useful to diagnose individuals with the disease and identify candidates for treatment with Plenaxis, as well as assisting in the further understanding of the disease process.

Technology

LEAP

Our proprietary method for discovering drugs is based on a unique system that combines the power and diversity of biological selection to identify compounds with potentially favorable drug-like properties with an ability to enhance and optimize these compounds using medicinal chemistry. We call this process Ligand Evolution to Active Pharmaceuticals, or LEAP. We believe LEAP is superior to traditional methods of drug discovery that are limited by the number of compounds that the traditional methods can synthesize and test manually. In a typical LEAP selection process, we can examine more than a trillion molecules in a few months. By contrast, conventional screening and medicinal chemistry permits the examination of fewer than one million molecules with equivalent resources and requires more time.

In the case of Plenaxis, LEAP allowed us to take a peptide ligand encoded in the human genome and convert that peptide into a drug. GnRH is a natural peptide ligand that binds to the GnRH receptor on the pituitary gland triggering the production of LH, which, in turn, triggers the production of testosterone. We used LEAP to evolve GnRH into Plenaxis, a drug that binds to the same receptor target, but blocks the production of LH.

If a ligand from the human genome is not available, we can select one encoded in a synthetic gene library using a process we call biological evolution. This process involves the natural selection of the best ligand from a pool containing billions of natural peptides in a biological system. We can carry out this process in repeated cycles, selecting ligands based on their functions. We then modify the selected ligand using a unique process that we call chemical evolution. Chemical evolution is powerful because we can make pools of thousands of diverse molecules based on the structure of the selected ligand and composed of synthetic building blocks. We then select the best molecules from these pools and identify them through our unique application of proteomics technology and the technology called mass spectrometry. These molecules can behave like drugs, because they bind to their target like natural peptides and have the characteristics of an effective drug.

Rel-Ease

We can further enhance the potential clinical utility of our drug candidates by formulating the drugs with our proprietary sustained release technology, Rel-Ease. For example, using Rel-Ease technology, we are able to formulate Plenaxis in such a way that a physician only needs to administer it to prostate cancer patients once every four weeks because Rel-Ease continuously releases the drug in the body over that period of time. In many cases, infrequent injections of a drug in a sustained release formulation are more desirable than oral administration due to patient compliance, convenience or reimbursement issues. We have formulated a variety of molecules with Rel-Ease technology and believe that Rel-Ease may be useful for formulating drug candidates we discover and develop using our LEAP technology. We also intend to explore the use of our Rel-Ease technology to create improved formulations and sustained release formulations of approved drugs.

MASTRscreen

MASTRscreen is our proprietary screening procedure that rapidly identifies and evaluates ligands for the most successful class of drug targets, known as G-protein coupled receptors. The GnRH receptor is a member of this class of receptors. We developed MASTRscreen in connection with our Plenaxis program, and it was instrumental in the selection of Plenaxis from pools of modified peptides. MASTRscreen is useful because of its sensitivity to low concentrations of screened material, easily measurable endpoints and adaptability to various screening systems.

Research and Development

As of December 31, 2001, we had a total of 104 employees dedicated to research and development for Plenaxis and our other product candidates. We have spent substantial funds over the past three years to develop Plenaxis and our other potential drug candidates and expect to continue to do so in the future. We spent approximately $48.8 million in 1999, $85.9 million in 2000 and $59.4 in 2001 on research and development activities.

Corporate Collaborations

Amgen Inc.

Effective March 1999, we entered into an agreement with Amgen for the research, development and commercialization of Plenaxis products in the United States, Canada, Japan and certain other countries. In September 2001, Amgen notified us that it was terminating its agreement with us pursuant to the terms of the agreement. The termination was effective in December 2001. As a result of the termination, all licenses for Plenaxis granted to Amgen under the agreement, and all of Amgen's rights in the Plenaxis program, have terminated.

Sanofi-Synthélabo S.A.

In May 1997, we entered into a license agreement with Sanofi-Synthélabo for the development and commercialization of Plenaxis products in specific territories including Europe, Latin America, the Middle East and various countries in Africa. In October 2001, Sanofi-Synthélabo notified us that it was terminating its license agreement with us pursuant to the terms of the agreement. The termination was effective in December 2001. As a result of the termination, all licenses for Plenaxis granted to Sanofi-Synthélabo under the agreement, and all of Sanofi-Synthélabo's rights in the Plenaxis program, have terminated.

Human Genome Sciences, Inc.

In January 2000, we entered into an agreement with Human Genome Sciences for the discovery, development and commercialization of compounds targeted to two proprietary genomic targets that Human Genome Sciences has identified. The first of these targets is CCR5, a human protein the HIV virus uses to enter human cells. Under the agreement, we will use LEAP to make drugs targeted to these molecules. We will jointly develop clinical drug candidates with Human Genome Sciences on an equal cost and profit sharing basis, unless a pre-existing option that Human Genome Sciences granted to GlaxoSmithKline applies to the drug candidate and GlaxoSmithKline exercises the option. In that case, or if we so elect as to a drug candidate as to which the GlaxoSmithKline option does not apply or has not been exercised, we will have no obligation to participate in any development costs, and we will be entitled to royalties and performance-based payments instead of a profit share. If, instead of an equal share of profits, we are entitled to royalties and performance-based payments, the performance-based payments would be payable upon occurrence of specified regulatory approval-related events; the obligation to pay us royalties would terminate on a country-by-country and product-by-product basis on the later of the expiration of the last applicable licensed patent in that country or ten years after the first country-wide launch of the product in that country. We cannot assure you as to whether or when any drug candidate will be identified and successfully developed and commercialized under the agreement and, accordingly, we cannot predict the potential value, if any, of the agreement to us.

Technology License

Indiana University Foundation

In October 1996, we entered into a license agreement with Indiana University Foundation. The license agreement was amended in June 1998, and Indiana University Foundation assigned it to Indiana University's Advanced Research and Technology Institute, Inc. Under the agreement, we have an

exclusive worldwide license under patent applications, future patents and technology of Indiana University Foundation relating to GnRH antagonist compounds, including Plenaxis and methods of use for Plenaxis. Through December 31, 2001, we have paid non-refundable fees of $305,000 and performance-based payments of $750,000 under this agreement. We have agreed to make performance-based payments of up to an additional $3.5 million, and to pay royalties on our net sales of products covered by the license. The license agreement remains in effect until the last licensed patent expires. Expiration of the license will not preclude us from continuing to develop and market the licensed products and use the licensed technology, provided we obtain the consent of Advanced Research and Technology Institute to extend the license term past the expiration date. Advanced Research and Technology Institute may not unreasonably withhold its consent to our request for such an extension. We can terminate the agreement at any time upon 90 days notice. Advanced Research and Technology Institute may terminate upon 90 days notice if we materially breach the agreement or fail to make required payments.

Manufacturing

We generally manufacture in-house the drug supply required to support our early preclinical studies. External contractors provide all of our later-stage preclinical and clinical supplies and manufacture them in accordance with FDA and European regulations. Under our collaboration agreement with Amgen, Amgen had control over certain phases of the manufacturing process for Plenaxis. Accordingly, Amgen had either entered into or assumed from us agreements with third parties to perform, or was itself performing, these manufacturing processes. Due to the termination of our collaboration agreement with Amgen, to assure an adequate supply of drug product for continued clinical studies and, if Plenaxis is approved for marketing, for commercial sale, we would necessarily need to assume these manufacturing contracts from Amgen, enter into new agreements with third party manufacturers or act as manufacturer ourselves.

In January 2002, we assumed all of Amgen's rights and obligations under its development and supply agreement with UCB S.A. Under this agreement, UCB will supply us with commercial volumes of the Plenaxis drug compound. We are committed to purchase from UCB approximately $16.1 million of pharmaceutical grade peptide during 2002.

We also have a supply agreement with Salsbury Chemicals, Inc. Under this supply agreement, Salsbury has agreed to manufacture for us the commercial depot formulations of Plenaxis. We contributed approximately $6.0 million toward Salsbury's construction and outfitting of a dedicated manufacturing facility, to which we will retain manufacturing process rights. We are obligated to pay Salsbury approximately $634,000 during 2002 towards minimum purchase commitments and facility maintenance.

We are currently negotiating an agreement with a third-party manufacturer to provide for the supply of Plenaxis products in finished vials. We cannot assure you that we will be able to finalize this agreement on reasonable terms or in a timely manner. In addition, the manufacturer will need to undergo regulatory review and compliance procedures which could be costly and could further delay regulatory review and approval, and thus potential commercialization, of Plenaxis for the treatment of hormonally responsive advanced prostate cancer.

In order to meet potential increases in demand in connection with the possible commercial launch of Plenaxis for the treatment of hormonally responsive advanced prostate cancer, we intend to evaluate the need for a second source for each stage of Plenaxis production.

Patents and Proprietary Rights

Proprietary protection for our products, technology and processes is essential to our business. We seek proprietary protection predominantly in the form of patents on our products and the processes which we use to discover them. With respect to a particular product, we generally seek patent protection on the compound itself, its commercial formulation, its range of applications and its

production. Where possible, we also seek patent coverage that could prevent the marketing of, or restrict the commercial threat of, competitive products.

We currently have 16 United States patents and exclusive licenses to two United States patents. These patents have expiration dates from 2012 through 2016. In addition, as of December 31, 2001, we had filed or held exclusive licenses to 32 United States utility and provisional patent applications, as well as 152 related foreign patent applications, including both Patent Cooperation Treaty filings and national filings. We also have non-exclusive licenses to four United States patents directed to technologies embodied in LEAP.

In particular, we have United States patents that cover both the Plenaxis compound and the sustained release formulation enabling its once-per-month administration. We also have patents covering the use of Plenaxis and any other GnRH antagonist in a variety of therapeutic settings, including in combination with surgery or radiation therapy. We intend to file additional United States and foreign patent applications, where appropriate, relating to new product discoveries or improvements.

We also rely on trade secrets, know-how and continuing technological advances to protect various aspects of our core technology. We require our employees and consultants to execute confidentiality and invention assignment agreements with us to maintain the confidentiality of our trade secrets and proprietary information. Our confidentiality agreements generally provide that the employee, consultant or scientific collaborator will not disclose our confidential information to third parties, compete with us or solicit our employees during the course of their employment with us. When appropriate, these agreements also provide that inventions conceived by the employee, consultant or scientific collaborator in the course of working for us will be our exclusive property. Additionally, our employees agree not to solicit our employees for one year following termination of their employment with us.

Competition

A biotechnology company such as ours faces intense competition. Many companies, both public and private, including large pharmaceutical companies, chemical companies and biotechnology companies, develop products or technologies competitive with our products or technologies. In addition, academic, government and industry-based research is intense, resulting in considerable competition in obtaining qualified research personnel, submitting patent filings for protection of intellectual property rights and establishing strategic corporate alliances.

Each of our potential products in research or development will face competition from other products. For example, if approved for marketing and sale, our Plenaxis products will compete with numerous established or newly introduced products on the market, including:

- Lupron Depot, marketed by TAP Pharmaceuticals, Inc., Zoladex, marketed by AstraZeneca Pharmaceuticals, and other pharmaceuticals approved and marketed for the treatment of hormonally responsive prostate cancer or endometriosis in the United States and Europe; and
- Cetrotide®, manufactured by ASTA Medica, and Antagon®, manufactured by Organon, approved GnRH antagonists for use in infertility that are only available as daily injectable formulations.

For each of our product candidates, we will face increasing competition from generic formulations of existing drugs whose active components are no longer covered by patents. Specifically, we are aware of various formulations of leuprorelin, the active ingredient of Lupron Depot, including Viadur™, marketed by Bayer as a 12-month hormone therapy implant, and Eligard™, which is being developed in one, three and four month subcutaneous injections by Atrix Laboratories, Inc. In January 2002, Atrix received FDA approval for its one-month depot of Eligard for the treatment of advanced prostate cancer.

We believe that our product candidates will compete favorably in the market with these and other products, although no assurance can be given in this regard.

Government Regulation

The manufacture and marketing of pharmaceutical products and our ongoing research and development activities in the United States require the approval of numerous governmental authorities, including the FDA. We also must obtain similar approvals from comparable agencies in most foreign countries. The FDA has established mandatory procedures and safety standards which apply to the preclinical testing and clinical trials, as well as to the manufacture and marketing, of pharmaceutical products. State, local and other authorities also regulate pharmaceutical manufacturing facilities.

As an initial step in the FDA regulatory approval process, an applicant typically conducts preclinical studies in animals to assess a drug's efficacy and to identify potential safety problems. An applicant must conduct specified preclinical laboratory and animal studies in compliance with the FDA's good laboratory practice regulations. An applicant must submit the results of these studies to the FDA as part of an IND. Proposed clinical testing can only begin if the FDA raises no objections to the IND. We can give no assurance that any submission of an IND to the FDA relating to our product candidates will result in the commencement of a clinical trial.

Clinical testing must meet requirements for Institutional Review Board oversight and informed consent, as well as FDA prior review, oversight and good clinical practice requirements. Typically, clinical testing involves a three-phase process. Phase I clinical trials involve a small number of subjects and are designed to provide information about both product safety and the expected dose of the drug. Phase II clinical trials generally provide additional information on dosing and safety in a limited patient population. Occasionally, phase II trials may provide preliminary evidence of product efficacy. Phase III clinical trials are large-scale, well-controlled studies. The goal of phase III clinical trials generally is to provide statistically valid proof of efficacy, as well as safety, in the target patient population. The company performing the preclinical testing and clinical trials of a pharmaceutical product then submits the results to the FDA in the form of an NDA, for approval to commence commercial sales. Preparing NDA applications involves considerable data collection, verification, analysis and expense. In responding to an NDA, the FDA may grant marketing approval for a specific indication, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. In addition, after approval for an initial indication, further clinical trials would be necessary to gain approval to promote the use of the product for any additional indication.

Among the conditions for NDA approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform on an ongoing basis with good manufacturing practices. In complying with good manufacturing practices, manufacturers must continue to spend time, money and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing facilities are subject to periodic inspections by the FDA.

The FDA must grant approval of our products, which includes a review of the manufacturing processes and facilities used to produce these products before we can market these products in the United States. The process of obtaining approvals from the FDA can be costly, time consuming and subject to unanticipated delays. The FDA may refuse to approve an application if it believes the product does not meet applicable regulatory criteria. The FDA also may require additional testing for safety and efficacy of the drug. If the FDA grants approval of a drug product, the approval will be limited to specific indications.

The FDA has considerable discretion in determining whether to grant marketing approval for a drug, and may delay or deny approval even in circumstances where the applicant's clinical trials have proceeded in compliance with FDA procedures and regulations and have met the established end-points of the trials. Challenges to FDA determinations are generally time-consuming and costly. We can give no assurance that we will obtain marketing approval for Plenaxis or any of our other product candidates.

If we receive marketing approval, we must comply with FDA requirements for manufacturing, labeling, advertising, record keeping and reporting of adverse experiences and other information. In

addition, we must comply with federal and state anti-kickback and other health care fraud and abuse laws that pertain to the marketing of drugs. For all drugs, failure to comply with applicable regulatory requirements after obtaining regulatory approval could, among other things, result in suspension of regulatory approval, as well as possible recalls, product seizures, injunctions and civil and criminal sanctions.

In addition to regulations enforced by the FDA, we also are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we cannot assure you that accidental contamination or injury from these materials will not occur. Compliance with laws and regulations relating to the protection of the environment has not had a material effect on our capital expenditures or our competitive position. However, we cannot accurately predict the extent of government regulation, and the cost and effect thereof on our competitive position, which might result from any legislative or administrative action.

Additionally, we may have to obtain approval of a product from comparable regulatory authorities in foreign countries prior to the commencement of marketing of the product in those countries. The approval procedure varies among countries, may involve additional testing and the time required may differ from that required for FDA approval. Although there is now a centralized European Union approval mechanism in place, each European country may nonetheless impose its own procedures and requirements, many of which could be time-consuming and expensive. Thus, substantial delays could occur in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. We expect to rely primarily on corporate partners or licensees to obtain governmental approval in foreign countries for our products. Due to the termination of our collaboration agreement with Sanofi-Synthélabo, we must either contract with another third party to pursue foreign regulatory approvals for Plenaxis for the treatment of hormonally responsive advanced prostate cancer or perform this function ourselves. We cannot assure you that we will be able to establish new arrangements for this function on reasonable terms or in a timely manner, if at all. Moreover, even after seeking qualified experience and assistance in dealing with the foreign regulatory processes and interacting with foreign regulatory authorities, we can not assure you that we will be successful in filing and obtaining the necessary governmental approvals for Plenaxis or any of our other product candidates in Europe or any other foreign country.

Product Liability Insurance

We maintain product liability insurance for clinical trials in the amount of $15.0 million per occurrence and $15.0 million in the aggregate. We intend to expand our product liability insurance coverage to include the manufacture, marketing and sale of commercial products if marketing approval for any of our products for which marketing approval is obtained. However, insurance coverage is becoming increasingly expensive, and we may be unable to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. In addition, we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. A successful product liability claim or series of claims brought against us could result in substantial setbacks for our business.

Employees

As of February 28, 2002, we had 127 full-time employees. We also utilize consultants and independent contractors on a regular basis to assist in the development of our products. None of our employees are party to a collective bargaining agreement. We consider our employee relations to be good. We believe that our future success is dependent in part on our ability to attract and retain skilled scientific, sales and marketing, and senior management personnel. Competition in our industry is intense and we cannot assure you that we will be able to attract and retain these personnel.

ITEM 2. PROPERTIES.

Our corporate headquarters and principal research facilities are located in Waltham, Massachusetts, where we own, through our wholly owned real estate subsidiary, land and a building of approximately 175,000 square feet. We have entered into a 15-year lease for this facility with our subsidiary. We currently occupy approximately 100,000 square feet of this facility and are attempting to sublease a portion of the remaining space for up to the next five years, although we have not yet found a tenant.

We believe that our facilities will be adequate for at least the next seven years and that we will be able to obtain additional space as needed on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS.

We are not currently a party to any material legal proceedings.

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

No matters were submitted to a vote of security holders of the company during the last quarter of the fiscal year ended December 31, 2001.

PART II

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

(a) Our common stock is traded on the Nasdaq National Market under the symbol "PRCS." Public trading of our common stock commenced on April 27, 2000. The following table shows the range of high and low per share sale prices of our common stock as reported on the Nasdaq National Market for the periods indicated.

	Common Stock Price	
	High	Low
Year Ended December 31, 2001:		
First Quarter	$33.13	$13.50
Second Quarter	31.11	12.75
Third Quarter	15.41	3.00
Fourth Quarter	6.10	3.37
Year Ended December 31, 2000:		
Second Quarter (from April 27, 2000)	$32.50	$10.06
Third Quarter	47.94	24.63
Fourth Quarter	44.13	18.50

As of February 28, 2002, there were approximately 156 holders of record of our common stock registered with our transfer agent, American Stock Transfer & Trust Company.

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on the common stock in the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Our board of directors will determine future dividends, if any, based upon our financial condition, results of operations, capital requirements and other factors that the board deems relevant. Therefore, you will not receive any funds without selling your shares.

(b) On February 8, 2000, we filed a Registration Statement on Form S-1 (Registration No. 333-96351) with the Securities and Exchange Commission to register under the Securities Act 8,000,000 shares of our common stock (plus an additional 1,200,000 shares subject to an over-allotment option granted to the underwriters). The Registration Statement was declared effective by the Securities and Exchange Commission on April 26, 2000.

From April 26, 2000 through December 31, 2001, we used approximately $38.0 million of the net proceeds from our initial public offering for the purchase and build-out of our new facility. Due to increased construction costs, the total amount of net proceeds from our initial public offering that was used for the purchase and build-out of our new facility exceeded our original estimates by approximately $8.0 million. Pending use of the remaining net proceeds of our initial public offering, we have invested these funds in short-term, interest-bearing, investment-grade securities. Our management will continue to have broad discretion over the actual use of these proceeds.

ITEM 6. SELECTED FINANCIAL DATA.

You should read the following selected financial data in conjunction with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this report. We have derived our statement of operations data for each of the three years in the period ended December 31, 2001, and our balance sheet data at December 31, 2000 and 2001, from our financial statements that have been audited by Ernst & Young LLP, independent auditors, and which we include elsewhere in this report. We have derived the statement of operations data for the years ended December 31, 1997 and 1998 and the balance sheet data at December 31, 1997, 1998 and 1999 from our audited financial statements, which we do not include in this report.

	Year Ended December 31,				
	1997	1998	1999	2000	2001
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Corporate collaborations	$15,118	$37,624	$61,514	$ 61,189	$ 9,907
Contract services	2,615	1,943	—	—	—
Total revenues	17,733	39,567	61,514	61,189	9,907
Costs and expenses:					
Research and development	15,013	33,704	48,764	85,915	59,416
Sales and marketing	—	—	2,601	6,444	8,737
General and administrative	3,780	3,605	3,572	5,285	6,961
Total costs and expenses	18,793	37,309	54,937	97,644	75,114
Operating income (loss)	(1,060)	2,258	6,577	(36,455)	(65,207)
Gain on assignment of leasehold improvements	—	—	—	—	1,499
Interest income (net)	1,364	3,516	4,473	7,819	9,105
Income (loss) before income taxes	304	5,774	11,050	(28,636)	(54,603)
Provision for income taxes	100	100	1,800	100	—
Net income (loss)	$ 204	$ 5,674	$ 9,250	$(28,736)	$(54,603)
Net income (loss) per share:					
Basic	$ 0.05	$ 0.99	$ 1.51	$ (0.95)	$ (1.10)
Diluted	$ 0.01	$ 0.16	$ 0.24	$ (0.95)	$ (1.10)
Weighted average number of common shares:					
Basic	4,446	5,738	6,106	30,259	49,777
Diluted	28,270	35,139	37,849	30,259	49,777
Pro forma net income (loss) per share:					
Basic			$ 0.29	$ (0.74)	
Diluted			$ 0.24	$ (0.74)	
Pro forma weighted average number of common shares:					
Basic			31,714	38,794	
Diluted			37,849	38,794	

	December 31,				
	1997	1998	1999	2000	2001
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$40,190	$85,298	$94,525	$132,207	$266,216
Working capital	31,802	76,626	86,220	115,733	229,028
Total assets	47,361	90,625	140,331	195,571	342,125
Long-term debt	—	—	—	24,000	33,000
Capital lease obligations, net of current portion	249	59	—	—	—
Total stockholders' equity	34,907	78,373	87,716	146,531	270,696

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

General

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and notes thereto appearing elsewhere in this report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ substantially from those anticipated in these forward-looking statements.

Overview

Since our inception, we have been engaged in developing drugs for the treatment of a variety of human diseases. Our lead program is the development of Plenaxis™ (abarelix for injectable suspension), a drug for the treatment of diseases that respond to the lowering of hormone levels. We are developing Plenaxis for the treatment of hormonally responsive advanced prostate cancer and endometriosis.

We had entered into collaborations with Amgen and Sanofi-Synthélabo to develop and commercialize our Plenaxis products. In September 2001, Amgen notified us that it was terminating its agreement with us. In October 2001, Sanofi-Synthélabo gave us notice that it was terminating its agreement with us. Both terminations were effective in December 2001. As a result, all of the licenses for Plenaxis granted to Amgen and Sanofi-Synthélabo under these agreements, and all rights of Amgen and Sanofi-Synthélabo in the Plenaxis program, have terminated. In this connection we are finalizing agreements with Amgen and Sanofi-Synthélabo in an effort to assure a successful transition of the rights and responsibilities for the continued development and commercialization of Plenaxis and to provide for, among other things, final cash payments and mutual releases.

We are also conducting clinical trials of Apan, our proprietary drug candidate for the treatment of Alzheimer's disease. In addition, we have a number of other product candidates in the research or preclinical development stage.

In September 2001, we decided not to proceed with additional clinical trials of Latranal, our in-licensed drug candidate being developed for the relief of musculoskeletal pain, due to the lack of efficacy observed in a phase II clinical trial.

Since our inception, we have had no revenues from product sales. We have received revenues in the form of signing, performance-based, cost sharing and contract services payments from corporate collaborations. We will receive no additional revenues under the Amgen and Sanofi-Synthélabo agreements, other than a potential final reimbursement payment from Sanofi-Synthélabo. Accordingly, for the foreseeable future, we do not expect to have any revenues other than interest income and the potential payment from Sanofi-Synthélabo.

Our accumulated deficit as of December 31, 2001 was approximately $84.4 million.

At December 31, 2001, we had 127 full-time employees, 99 of whom were engaged in research and development activities, compared to 120 full-time employees at December 31, 2000, 93 of whom were engaged in research and development activities. Substantially all of our expenditures to date have been for drug development and commercialization activities and for general and administrative expenses.

Due to the high costs associated with continued development, and preparing for the possible commercial launch, of Plenaxis for the treatment of hormonally responsive advanced prostate cancer, as well as other research and development and general and administrative expenses, we had a net operating loss for 2001. We expect to have net operating losses for the next several years, due, in part, to our assumption of all Plenaxis program costs as of the effective dates of the Amgen and Sanofi-Synthélabo terminations. We do not expect to generate operating income unless, and not until several years after, we receive FDA approval to market Plenaxis for the treatment of hormonally responsive

advanced prostate cancer. We will need to receive regulatory approval to market all of our future products.

Through December 31, 2001, we have recognized an aggregate of approximately $24.7 million in non-refundable fees and performance-based payments, and approximately $10.7 million in reimbursement for ongoing development costs, under the Sanofi-Synthélabo agreement. Of this amount, we recognized the $4.7 million initial non-refundable signing fee payment through December 31, 2001, the effective date of termination of the Sanofi-Synthélabo agreement, which was the period during which we were obligated under the agreement to participate on a continuing and substantial basis in the research, development and manufacturing process development of Plenaxis products. As noted above, we are finalizing an agreement with Sanofi-Synthélabo regarding the termination of its license agreement, which we expect will be executed during the second quarter of 2002.

In addition, through December 31, 2001, we have recognized an aggregate of approximately $121.7 million of revenues under the Amgen agreement. We received a $10.0 million signing fee under the Amgen agreement which we recognized as revenue through December 17, 2001, the effective date of termination of the Amgen agreement, which was the period during which we were obligated under the agreement to participate on a continuing and substantial basis in the research, development and manufacturing process development of Plenaxis products.

Under the Amgen agreement, Amgen paid the first $175.0 million of all authorized costs and expenses associated with the research, development and commercialization of Plenaxis products in the United States. Amgen's initial $175.0 million funding commitment was fulfilled during the third quarter of 2000. Following Amgen's completion of this funding, we became responsible for one-half of all subsequent United States research and development costs for Plenaxis products. Additionally, the agreement provided that following Amgen's completion of its $175.0 million funding commitment, we must reimburse Amgen for one-half of the costs associated with establishing a sales and marketing infrastructure for Plenaxis products in the United States. As noted above, we are finalizing an agreement with Amgen regarding the termination of its agreement with us, which we expect will be executed during the second quarter of 2002.

Critical Accounting Policies

In December 2001, the Securities and Exchange Commission requested that all registrants discuss their most "critical accounting policies" in Management's Discussion and Analysis of Financial Condition and Results of Operations. The Commission indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this report, we believe the following accounting policies to be critical:

Revenue Recognition. We have previously entered into corporate collaborations with other pharmaceutical companies. These agreements provided for the partitioning of the development, manufacturing and commercialization responsibilities related to potential drug candidates. Under these arrangements, we were obligated to participate in several aspects of the remaining development and manufacturing of our drug candidate, Plenaxis. Our collaborations generally have provided for our partners to make up-front payments and additional payments upon the achievement of specific research and product development milestones, share in the costs of development and/or pay royalties, and in some cases, profit-sharing payments to us based upon any product sales resulting from the collaboration.

We recognize revenue in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements.* Under this accounting method, we recognize revenue when it is earned, that is when all of the following have occurred: all of our obligations relating to the revenue have been met

and the earning process is complete; the monies received or receivable are not refundable irrespective of research results; and there are neither future obligations nor future milestones to be met by us with respect to such revenue. In general, collaboration revenues are earned based upon research expenses incurred and milestones achieved. Non-refundable payments upon initiation of contracts are deferred and amortized over the period in which we are obligated to participate on a continuing and substantial basis in the research and development activities outlined in each contract. We continually review these estimates, which could result in a change in the deferral period. Amounts received in advance of reimbursable expenses are deferred and only recognized when the related expenses have been incurred. Milestone payments are recognized as revenue in the period in which the parties agree that the milestone has been achieved and it is deemed that no further obligations exist.

Use of Estimates. We prepare our financial statements in accordance with accounting principles generally accepted in the United States. These principles require that we make estimates and use assumptions that affect the reporting of our assets and our liabilities as well as the disclosures that we make regarding assets and liabilities and income and expense that are contingent upon uncertain factors as of the reporting date. As discussed in Note 8 to our consolidated financial statements, we have accrued an estimate of our potential liability as of December 31, 2001 under our agreement with Amgen which has been terminated. The actual payments, and thus our actual results, could differ from our estimates.

Results of Operations

Years Ended December 31, 2001 and 2000

Revenues for the year ended December 31, 2001 decreased 84% to approximately $9.9 million, from approximately $61.2 million in 2000. The decrease in revenues was the result of decreases in both the amount and rate of reimbursement of Plenaxis expenses from our former collaborators, as well as the one-time sale of materials inventory to Amgen during the fourth quarter of 2000. We will receive no additional revenues under the Amgen or Sanofi-Synthélabo agreements, other than a possible final reimbursement payment from Sanofi-Synthélabo.

Research and development expenses for the year ended December 31, 2001 decreased 31% to approximately $59.4 million, from approximately $85.9 million in 2000. This decrease in expenses was due primarily to the one-time sale of materials inventory to Amgen during the fourth quarter of 2000 combined with reduced clinical spending during the second half of 2001 as we repositioned the Plenaxis program in response to issues raised by the FDA in June 2001. As we initiate new clinical trials for Plenaxis for the treatment of hormonally responsive advanced prostate cancer and endometriosis, continue our Apan clinical program and add new clinical programs, we expect our research and development expenses will increase during 2002 and thereafter.

Members of our research and development team typically work on a number of projects concurrently. In addition, a substantial amount of our fixed costs such as facility depreciation, utilities and maintenance are shared by our various programs. Accordingly, we have not and do not plan to separately track the costs for each of our research and development programs. During 2001 and 2000, we estimate that the majority of our research and development expense was related to clinical trial costs, manufacturing and materials inventory costs, salaries and lab supplies related to our prostate cancer and endometriosis clinical programs. The remaining research and development costs were incurred in our Apan clinical program, as well as our preclinical research programs.

We began our clinical program to develop Plenaxis for the treatment of prostate cancer during 1996. In December 2000, we submitted an NDA to the FDA for Plenaxis for the treatment of hormonally responsive advanced prostate cancer. However, the FDA raised certain concerns over the results of the data submitted to them and, therefore, we recently initiated an additional clinical trial in an effort to respond to those concerns. In 1998, we began our clinical program to develop Plenaxis for the treatment of endometriosis. We recently completed the follow-up phase of a phase II/III study in this program.

We expect to submit additional data to the FDA for Plenaxis for the treatment of hormonally responsive advanced prostate cancer by the end of the first quarter of 2003. With respect to our endometriosis program, we expect to meet with the FDA mid-year 2002 to discuss the results of our phase II/III study and the timing and scope of additional clinical trials.

We began our clinical program for Apan in 2000. We are currently conducting a phase I study of Apan which we anticipate will be completed during the second half of 2002. We expect to initiate a second phase I study in the first half of 2003 in which we intend to evaluate the safety and pharmacokinetics of Apan in individuals suffering from Alzheimer's disease.

We anticipate that the substantial majority of our research and development costs over the next few years will be focused on the development of Plenaxis for the treatment of hormonally responsive advanced prostate cancer and endometriosis. In addition, as discussed above, we currently have several other ongoing research and development programs. Using industry estimates, typical drug development programs may last for ten or more years and may cost hundreds of millions of dollars to complete. As our programs progress, we will assess the possibility of entering into corporate collaborations to offset a portion of development costs. The ultimate success of our research and development programs and the impact of these programs on our operations and financial results cannot be accurately predicted and will depend, in large part, upon the outcome and timing of many variables outside of our control.

Sales and marketing expenses for the year ended December 31, 2001 increased 36% to approximately $8.7 million, from approximately $6.4 million in 2000. The increase in expenses was primarily the result of our obligation under our agreement with Amgen, beginning in the third quarter of 2000, to pay one-half of all subsequent costs associated with establishing a sales and marketing infrastructure in the United States for Plenaxis through the launch period. These increases were partially offset by decreased spending on marketing and sales for the Plenaxis program during the second half of 2001. In response to issues raised by the FDA. Due to the termination of the Amgen and Sanofi-Synthélabo agreements, which provided for the sharing of the costs associated with commercialization, our sales and marketing expenses may increase as we incur costs related to preparing for the possible launch of Plenaxis for the treatment of hormonally responsive advanced prostate cancer.

General and administrative expenses for the year ended December 31, 2001 increased 32% to approximately $7.0 million, from approximately $5.3 million in 2000. The increase was due to an increase in personnel-related operating costs and increased use of professional services. We expect that general and administrative expenses will continue to increase as we hire additional administrative personnel to support continued growth of our research, development and pre-commercialization initiatives and incur increased operating costs related to our new facility.

Net interest income for the year ended December 31, 2001 increased 16% to approximately $9.1 million, from approximately $7.8 million in 2000. The increase in interest income was due to increased cash and investment balances from our follow-on public offering in February 2001, offset by lower interest rates. The increase in interest expense was due to a higher average principal balance outstanding for a full year under our loan agreement during 2001.

The provision for income taxes for the years ended December 31, 2001 and 2000 was zero and $0.1 million, respectively. The provision for income taxes during 2000 was primarily for state income taxes. We anticipate that we will continue to be in a net operating loss carryforward position during 2001 and for several years thereafter. Therefore, as in 2000, no benefit from our operating losses has been recognized. We account for income taxes under Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*. Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2001 and 2000, have been established in each period to reflect these uncertainties.

At December 31, 2001, we had federal net operating loss carryforwards of $51.6 million that will expire in varying amounts through 2021, if not utilized. Utilization of net operating loss and tax credit carryforwards will be subject to substantial annual limitations under the Internal Revenue Code of 1986, as amended. The annual limitations may result in the expiration of the net operating loss and tax credit carryforwards before full utilization.

Years Ended December 31, 2000 and 1999

Revenues for the year ended December 31, 2000 decreased 1% to approximately $61.2 million, from approximately $61.5 million in 1999. The decrease in revenues was the result of a decrease in reimbursable Plenaxis expenses, offset by the one-time sale of materials inventory to Amgen during the fourth quarter of 2000.

Research and development expenses for the year ended December 31, 2000 increased 76% to approximately $85.9 million, from approximately $48.8 million in 1999. The increase in expenses was primarily attributable to the cost of the inventory associated with the one-time sale of materials inventory to Amgen during the fourth quarter of 2000, combined with increased expenses related to our Plenaxis clinical development program for hormonally responsive advanced prostate cancer. This increase also was partially due to increased spending related to our Plenaxis clinical development program for endometriosis, our Latranal and Apan clinical development programs, and discovery research initiatives. Amgen's initial funding commitment was completed during the third quarter of 2000, after which we became responsible for one-half of all subsequent United States research and development costs for Plenaxis products through the launch period.

Sales and marketing expenses for the year ended December 31, 2000 increased 148% to approximately $6.4 million, from approximately $2.6 million in 1999. Following the completion of Amgen's initial funding commitment, we became responsible for one-half of all subsequent costs associated with establishing a sales and marketing infrastructure in the United States for Plenaxis through the launch period.

General and administrative expenses for the year ended December 31, 2000 increased 48% to approximately $5.3 million, from approximately $3.6 million in 1999. The increase was due to an increase in personnel and compensation costs, an increased use of professional services and other costs associated with being a public company.

Net interest income for the year ended December 31, 2000 increased 75% to approximately $7.8 million, from approximately $4.5 million in 1999. The increase in interest income was due to increased cash and investment balances from our initial public offering in May 2000 and an increase in interest rates from the same period in the prior year.

The provision for income taxes for the years ended December 31, 2000 and 1999 was $0.1 million and $1.8 million, respectively. Our effective tax rate was approximately 16.3% during 1999. The provision for income taxes during 2000 was primarily for state income taxes. We were in a net operating loss carryforward position in 2000 and, therefore, no benefit from our operating losses was recognized.

Selected Quarterly Operating Results

The following table sets forth our unaudited statement of operations data for the eight quarters ended December 31, 2001. This information has been derived from our unaudited financial statements. The unaudited financial statements have been prepared on the same basis as the audited financial statements appearing in this report and include all adjustments, consisting only of normal recurring accruals, that we consider necessary for a fair presentation of such information when read in

conjunction with our annual audited financial statements and notes thereto appearing elsewhere in this report. You should not draw any conclusions from the operating results for any quarter.

	Quarter Ended							
	Mar. 31, 2000	June 30, 2000	Sept. 30, 2000	Dec. 31, 2000	Mar. 31, 2001	June 30, 2001	Sept. 30, 2001	Dec. 31, 2001
	(in thousands, except per share data)							
Total revenues	$9,001	$9,972	$7,334	$34,882	$ 2,582	$ 3,167	$ 2,479	$ 1,679
Operating loss	(3,669)	(4,200)	(9,387)	(19,199)	(14,321)	(16,000)	(24,052)	(10,834)
Net loss	(2,475)	(2,052)	(7,132)	(17,077)	(11,847)	(12,997)	(22,217)	(7,542)
Basic and diluted net loss per share	$(0.36)	$(0.07)	$(0.17)	$ (0.41)	$ (0.26)	$ (0.26)	$ (0.44)	$ (0.15)

We expect to experience significant fluctuations in our quarterly operating results in the future, and, therefore, we will continue to have difficulty providing an accurate forecast of our quarterly revenues and operating results. We believe that period-to-period comparisons of our operating results may not be meaningful, and you should not rely upon them as any indication of future performance. It is likely that our operating results in one or more future quarters may be below the expectations of securities analysts and investors. In that event, the trading price of our common stock would almost certainly decline.

Liquidity and Capital Resources

We have financed our operations since inception principally through private placements of equity securities and the proceeds from our public offerings. Prior to our initial public offering, we had received aggregate net proceeds of approximately $88.5 million from various private placements of our securities. In May 2000, we completed our initial public offering in which we sold a total of 9,200,000 shares of common stock at a price of $10 per share, raising a total of approximately $84.3 million, net of underwriting discounts and commissions and offering expenses. In February 2001, we completed a follow-on public offering in which we sold a total of 7,587,500 shares of common stock at a price of $24.5625 per share, raising a total of approximately $175.9 million, net of underwriting discounts and commissions and offering expenses.

Additionally, we have received a total of approximately $185.0 million from one-time signing payments and performance-based payments, cost reimbursements and contract service payments under our collaboration agreements. We have also received approximately $29.8 million from interest on invested cash balances, and paid approximately $2.6 million in interest associated with building and equipment financing.

At December 31, 2001, we had cash, cash equivalents and marketable securities of approximately $266.2 million and working capital of approximately $229.0 million, compared to approximately $132.2 million and $115.7 million, respectively, at December 31, 2000. During 2002, we expect to spend in the range of approximately $40,000,000 to $45,000,000 on operations and approximately $45,000,000 to $55,000,000 on development programs. We believe that our existing cash and investments will be sufficient to meet our working capital and capital expenditure needs for approximately the next three years.

For the year ended December 31, 2001, net cash of approximately $31.6 million was used in operating activities, compared to approximately $20.0 million used in operating activities during 2000. During the year ended December 31, 2001, our use of cash in operations was due principally to our net loss, partially offset by an increase in accounts payable consisting principally of our share of accrued Plenaxis program expenses pursuant to the Amgen agreement. Our investing activities during the year ended December 31, 2001 consisted of the purchase, sale and maturity of marketable securities, as well as $23.9 million of additional spending toward the build-out of our new corporate headquarters and other fixed asset additions. Our financing activities for the year ended December 31, 2001 consisted principally of the $175.9 million of proceeds from our follow-on public offering and $2.4 million of

proceeds received from the exercise of common stock options, as well as advances of $9.0 million under an acquisition and construction loan agreement.

In July 2000, in connection with the purchase, through our wholly owned real estate subsidiary, of our new corporate headquarters and research facility in Waltham, Massachusetts, the subsidiary entered into an acquisition and construction loan agreement providing for up to $33.0 million in financing for the acquisition of, and improvements to, the new facility. As of December 31, 2001, $33.0 million was outstanding under the loan agreement. Advances bear interest at a rate equal to the 30-day LIBOR plus 2.0% (3.87% at December 31, 2001). Interest is payable monthly in arrears. Principal is due and payable in full on July 30, 2003, subject to two one-year extension options. The loan is secured by the new facility, together with all fixtures, equipment, improvements and other related items, and by all rents, income or profits received by our real estate subsidiary, and is unconditionally guaranteed by us. In addition to this financing, as of December 31, 2001, we had spent approximately $38.0 million of our own funds in connection with the build-out and occupancy of our new facility. We occupied the new facility during May 2001 and as planned, are actively seeking to sublease a portion of this facility. We do not believe that there is any impairment issue at this time. We terminated the lease for our Cambridge, Massachusetts facility effective as of September 1, 2001. In addition, in connection with our move to the new facility, we consolidated our Provid Research division with our Massachusetts operations and, effective October 31, 2001, have assigned to a third party all of our right, title and interest in and to the lease for the New Jersey facility and the third party has assumed all of our obligations thereunder.

In addition to our long-term debt, we have fixed contractual obligations under various supply agreements. These fixed contractual obligations were comprised of the following as of December 31, 2001:

		Payments Due By Period		
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	After 3 Years
		(in thousands)		
Long-term debt	$33,000	$ —	$33,000	$ —
Unconditional purchase obligations	634	634	—	—
Total contractual cash obligations	$33,634	$ 634	$33,000	$ —

In January 2002, we assumed all of Amgen's rights and obligations under a development and supply agreement with UCB. Under the terms of this agreement, we are committed to pay UCB approximately $16.1 million for the supply of clinical and commercial volumes of pharmaceutical peptide to be delivered by the end of 2002.

We expect our funding requirements to increase over the next several years as we prepare for the possible commercial launch of Plenaxis for the treatment of hormonally responsive advanced prostate cancer, continue with current prostate cancer and endometriosis clinical trials for Plenaxis and clinical trials for Apan, initiate preclinical trials for additional product candidates, continue to improve our facility and expand our research and development initiatives. The amount of these expenditures will depend on numerous factors, including:

- the cost, timing and outcomes of FDA and other regulatory reviews;
- decisions relating to the Plenaxis program made by us;
- the effect of the termination of our Plenaxis corporate collaborations and our ability to assume the responsibilities under these agreements or contract with other third parties to do so;
- the development of sales and marketing resources by us;
- the establishment, continuation or termination of third-party manufacturing or sales and marketing arrangements for Plenaxis or our other potential products;

- the establishment of additional strategic or licensing arrangements with, or acquisitions of, other companies;
- the progress of our research and development activities;
- the scope and results of preclinical testing and clinical trials;
- the rate of technological advances;
- determinations as to the commercial potential of our product candidates under development;
- the status of competitive products;
- our ability to defend and enforce our intellectual property rights;
- our ability to sublease a portion of our new facility; and
- the availability of additional financing.

At December 31, 2001, we had provided a valuation allowance of $42.5 million for our deferred tax assets. The valuation allowance represents the excess of the deferred tax asset over the benefit from future losses that could be carried back if, and when, they occur. Due to anticipated operating losses in the future, we believe that it is more likely than not that we will not realize a portion of the net deferred tax assets in the future and we have provided an appropriate valuation allowance.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities*, or SFAS No. 133, which became effective for fiscal year 2001. SFAS No. 133 requires all derivatives to be carried on the balance sheet as assets or liabilities at fair value. The accounting for changes in fair value would depend on the hedging relationship and would be reported in the income statement or as a component of comprehensive income. The adoption of SFAS No. 133 did not have a material impact on our consolidated financial position or consolidated results of operations.

In June 2001, the Financial Accounting Standards Board issued SFAS No. 141, *Business Combinations*, and SFAS No. 142, *Goodwill and Other Intangible Assets*, effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill will no longer be amortized but will be subject to annual impairment tests in accordance with the statements. Other intangible assets will continue to be amortized over their useful lives. We will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. Application of the provisions of these statements is not expected to have a material effect on our consolidated financial position or consolidated results of operations since we do not have any goodwill or intangibles at this time.

On October 20, 2001, the Financial Accounting Standards Board issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS No.144. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, however it retains the fundamental provision of that statement related to the recognition and measurement of the impairment of long-lived assets to be held and used. In addition, SFAS No. 144 provides additional guidance on estimating cash flows when performing a recoverability test, requiring that a long-lived asset to be disposed of other than by sale be classified as an asset held for sale until it is disposed of, and establishes more restrictive criteria to classify an asset as held for sale. SFAS No. 144 will be effective in 2002. Application of SFAS No. 144 is not expected to have any effect on our consolidated financial position or consolidated results of operations since we do not believe that we have any impairments at this time.

Risk Factors that May Affect Future Results

Because we have not yet marketed or sold any products and anticipate significant increases in our operating expenses over the next several years, we may not be profitable in the future.

We cannot assure you that we will be profitable in the future or, if we are profitable, that it will be sustainable. All of our potential products are in the research or development stage. We have not yet marketed or sold any products, and we may not succeed in developing and marketing any product in the future. To date, we have derived substantially all of our revenues from payments under corporate collaboration and license agreements. Due to the termination of the Amgen and Sanofi-Synthélabo agreements, for the foreseeable future, we do not expect to have any revenues, other than interest income and any final reimbursement payment from Sanofi-Synthélabo. In addition, we expect to continue to spend significant amounts to continue clinical studies, seek regulatory approval for our existing product candidates, develop commercial capabilities and expand our facilities. We also intend to spend substantial amounts to fund additional research and development for other potential products, enhance our core technologies, and for general and administrative purposes. As of December 31, 2001, we had an accumulated deficit of approximately $84.4 million. We expect that our operating expenses will increase significantly in the near term, primarily due to the termination of the Amgen and Sanofi-Synthélabo agreements, resulting in significant operating losses for 2002 and the next several years.

If our clinical trials are not successful, or if we are otherwise unable to obtain and maintain the regulatory approval required to market and sell our potential products, we would incur additional operating losses.

The development and sale of our product candidates are subject to extensive regulation by governmental authorities. Obtaining and maintaining regulatory approval typically is costly and takes many years. Regulatory authorities, most importantly, the FDA, have substantial discretion to terminate clinical trials, delay or withhold registration and marketing approval in the United States, and mandate product recalls. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions as to our potential products or against us. Outside the United States, we can market a product only if we receive marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process includes all of risks associated with the FDA approval process, and may include additional risks.

To gain regulatory approval from the FDA and foreign regulatory authorities for the commercial sale of any product, we must demonstrate in clinical trials, and satisfy the FDA as to, the safety and efficacy of the product in clinical trials. If we develop a product to treat a long-lasting disease, such as cancer or Alzheimer's disease, we must gather data over an extended period of time. There are many risks associated with our clinical trials. For example, we may be unable to achieve the same level of success in later trials as we did in earlier ones. Additionally, data we obtain from preclinical and clinical activities are susceptible to varying interpretations that could impede regulatory approval. Further, some patients in our prostate cancer and Alzheimer's disease programs have a high risk of death, age-related disease or other adverse medical events that may not be related to our products. These events may affect the statistical analysis of the safety and efficacy of our products. If we obtain regulatory approval for a product, the approval will be limited to those diseases for which our clinical trials demonstrate the product is safe and effective.

In addition, many factors could delay or result in termination of our ongoing or future clinical trials. For example, a clinical trial may experience slow patient enrollment or lack of sufficient drug supplies. Patients may experience adverse medical events or side effects, and there may be a real or perceived lack of effectiveness of, or of safety issues associated with, the drug we are testing. Future governmental action or existing or changes in FDA policies or precedents, may also result in delays or rejection of an application for marketing approval. Accordingly, we may not be able to obtain product registration or marketing approval for Plenaxis, our drug candidate for the treatment of hormonally

responsive advanced prostate cancer and endometriosis, or for any of our other product candidates, or regulatory approval may be conditioned upon significant labeling requirements which could adversely affect the marketability or value of the product.

To date, none of our product candidates has received regulatory approval for commercial sale. In June 2001, we received a letter from the FDA with respect to our NDA for Plenaxis for the treatment of hormonally responsive prostate cancer, which was submitted in December 2000. The FDA indicated that the information presented in the NDA was inadequate for approval. In September 2001, we met with the FDA in an effort to clarify the various deficiencies cited in the FDA's letter, and to discuss what further steps needed to be taken before the application could be approved. The FDA recommended that we analyze the allergic reactions that occurred in a small subset of clinical trial patients. We are conducting this analysis utilizing existing data and samples. In addition, the FDA expressed concern that, in a subset of patients treated beyond the three-month pivotal study time frame, testosterone suppression was not maintained at a comparable level to that of patients treated with either Lupron Depot or Lupron Depot plus Casodex. The FDA also indicated that the nature of the testosterone surge, if any, associated with treating patients with Plenaxis and then switching them to a currently available therapy should be understood. We considered various alternatives to address these issues, and in December 2001 the FDA indicated that we could proceed with our clinical plans to study the effects of using currently available hormonal therapies in prostate cancer patients following treatment with Plenaxis. The FDA also indicated that our plan to further evaluate the rare allergic reactions that occurred in our clinical trials was acceptable. We can give no assurance that our additional clinical studies will yield positive results or that the results, even if positive, will satisfy FDA concerns that have been or may be raised. We cannot assure investors that we will be successful in obtaining approval for the commercialization of Plenaxis for the treatment of hormonally responsive advanced prostate cancer or any other indication.

These FDA actions have delayed, and otherwise adversely affected, our obtaining regulatory approval to market Plenaxis for the treatment of hormonally responsive advanced prostate cancer. Moreover, there could be further delays due to FDA review or action, and the FDA could deny approval altogether. If we are further delayed in obtaining or are unable to obtain this regulatory approval, or regulatory approval to market our other potential products, we may exhaust our available resources significantly sooner than we had planned, particularly given the termination of the Amgen and Sanofi-Synthélabo agreements. If this were to happen, we would need to either raise additional funds or seek alternative partners to complete development and commercialization of Plenaxis and continue our currently planned research and development programs. We cannot assure you that we would be able to raise the necessary funds or negotiate additional corporate collaborations on acceptable terms, if at all.

Due to the termination by our corporate collaborators of their agreements with us, we may be unable to successfully develop, market, distribute or sell our product candidates.

We depended upon our corporate collaborators, Amgen and Sanofi-Synthélabo, to provide substantial financial support for the development and commercialization of Plenaxis. We relied on them to some extent in seeking regulatory approval for Plenaxis for the treatment of hormonally responsive advanced prostate cancer. In addition, under our agreement with Amgen, they had assumed principal responsibility for the manufacture of Plenaxis, and under our agreements with Amgen and Sanofi-Synthélabo, those parties were responsible for the marketing, distribution and sale of Plenaxis in their respective licensed territories.

The termination of our agreements with Amgen and Sanofi-Synthélabo may delay or otherwise adversely affect or prevent the development or commercialization of Plenaxis for the treatment of hormonally responsive advanced prostate cancer and endometriosis. We will likely need to devote funds and other resources to Plenaxis development and commercialization that we had planned would be available from our collaborators. This could require us to curtail or terminate one or more of our other drug development programs. Also, due to increased operating costs, lost revenue and a likely final

payment to Amgen associated with the termination of our agreements with them, we could have to seek additional funding to meet our capital requirements. In addition, we may have to seek alternative partners to support the continued development and commercialization of Plenaxis. We cannot assure you that we would be able to raise the necessary funds or negotiate additional corporate collaborations on acceptable terms, if at all, and in that event we might have to curtail or cease operations.

Even if we receive approval for the marketing and sale of our product candidates, they may fail to achieve market acceptance and, accordingly, may never be commercially successful.

Many factors may affect the market acceptance and commercial success of any of our potential products, including:

- the scope of the patient population and the indications for which Plenaxis or our other product candidates are approved;
- the effectiveness of Plenaxis or any of our other product candidates, including any potential side effects, as compared to alternative treatment methods;
- the extent and success of our marketing and sales efforts relating to the marketing and sales of Plenaxis or other potential products;
- the product labeling or product insert required by the FDA for Plenaxis and each of our other product candidates;
- the timing of market entry as compared to competitive products;
- the rate of adoption of Plenaxis or our other product candidates by doctors and nurses and acceptance by the target patient population;
- the competitive features of our products as compared to other products, including the frequency of administration of Plenaxis as compared to other products, and doctor and patient acceptance of these features;
- the cost-effectiveness of Plenaxis or our other product candidates and the availability of insurance or other third-party reimbursement, in particular Medicare, for patients using our products; and
- unfavorable publicity concerning Plenaxis or any of our other product candidates or any similar products.

If our products are not commercially successful, we may never become profitable.

We may be unable to establish marketing and sales capabilities necessary to successfully commercialize our potential products.

We have no experience in marketing or selling pharmaceutical products and have very limited marketing and sales resources. To achieve commercial success for any approved product, we must either develop a marketing and sales force, as well as the infrastructure to support it, or enter into arrangements with others to market and sell our products. We may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our potential products. If we decide to market and sell our potential products, including Plenaxis, independently, we would need to hire a sales force with expertise in pharmaceutical sales. In that event, recruiting and retaining qualified sales personnel would be critical to our success. Competition for skilled personnel is intense, and we cannot assure you that we would be able to attract and retain a sufficient number of qualified individuals to successfully launch any potential product. In addition, establishing the expertise necessary to successfully market and sell any product would require a substantial capital investment. We cannot assure you that we would have the funds necessary to successfully commercialize Plenaxis for the treatment of hormonally responsive advanced prostate cancer or any other potential product.

In the event that we decide to contract with third parties to provide sales force capabilities to meet our needs for Plenaxis or any other product candidates, we cannot assure you that we will be able to enter into such agreements on acceptable terms, if at all. In addition, co-promotion or other marketing arrangements with third parties to commercialize potential products could significantly limit the revenues we derive from these potential products, and these third parties may fail to commercialize our potential products successfully. To the extent we enter into any such agreements, the parties to those agreements may also market products that compete with our products, further limiting our potential revenue from product sales.

If we fail to develop and maintain our relationships with third-party manufacturers, or if these manufacturers fail to perform adequately, we may be unable to commercialize our product candidates.

Our ability to conduct, or continue to conduct, clinical trials and commercialize our product candidates, including Plenaxis, will depend in part on our ability to manufacture, or arrange for third-party manufacture of, our products on a large scale, at a competitive cost and in accordance with regulatory requirements. We must establish and maintain a commercial scale formulation and manufacturing process for each of our potential products for which we seek marketing approval. We or third-party manufacturers may encounter difficulties with these processes at any time that could result in delays in clinical trials, regulatory submissions or in the commercialization of potential products.

We have no experience in large-scale product manufacturing, nor do we have the resources or facilities to manufacture products on a commercial scale. We will continue to rely upon contract manufacturers to produce Plenaxis and other compounds for later-stage preclinical, clinical and commercial purposes for a significant period of time. Third-party manufacturers may not be able to meet our needs as to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby preventing or delaying the submission of product candidates for, or the granting of, regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

We may increase our manufacturing capacity in part by building our own manufacturing facilities. This activity would require substantial expenditures, and we would need to hire and train significant numbers of employees to staff a new facility. If we decide to build our own facility, we may not be able to develop sufficient manufacturing capacity to produce drug materials for clinical trials or commercial use.

In addition, we and the third-party manufacturers that we use must continually adhere to current Good Manufacturing Practice regulations enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, the FDA pre-market approval of our product candidates will not be granted. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort in production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory sanctions.

If we make changes in our manufacturing processes, the FDA and corresponding foreign authorities may require us to demonstrate that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced. Also, we may want to rely on results of prior preclinical studies and clinical trials performed using the previously produced drug material. Depending on the type and degree of differences between the newer and older drug material, we may be required to conduct additional animal studies or human clinical trials to demonstrate that the newly produced drug material is sufficiently similar to the previously produced drug material.

Any of these factors could prevent, or cause delays in, obtaining regulatory approvals for, and the manufacturing, marketing or selling of, our potential products, including Plenaxis, and could also result in significantly higher operating expenses.

Under our collaboration agreement with Amgen, Amgen had control over certain phases of the manufacturing process for Plenaxis. Accordingly, Amgen had either entered into or assumed from us agreements with third parties to perform, or was itself performing, these manufacturing processes. Due to the termination of our collaboration agreement with Amgen, to assure an adequate supply of drug product for continued clinical studies and, if Plenaxis is approved for marketing, for commercial sale, we will need to assume these manufacturing contracts from Amgen, enter into new agreements with third party manufacturers or act as manufacturer ourselves. We may elect not to, or may not be able to, assume the existing contracts from Amgen, and we may be unable to make necessary alternative arrangements in a timely manner or on favorable terms, if at all. Moreover, to the extent we must make alternative supply arrangements, even if we are able to establish these arrangements in a timely manner, the use of a different manufacturer or the establishment of our own facility will require us to undergo additional regulatory review and compliance procedures which could result in additional expenses and further delay the regulatory review and potential commercialization of Plenaxis for the treatment of hormonally responsive advanced prostate cancer. Also, the establishment of our own facility could itself be costly thereby increasing our operating costs.

The loss or failure of any of our third-party manufacturers could delay or impair our development, or our sale or continued sale, of Plenaxis products.

For each stage of Plenaxis production we have relied, and expect in the near term to continue to rely, on a separate third-party manufacturer, and we currently have not contracted, and in the near term do not expect to contract, with second-source suppliers for any of these production stages. Accordingly, the loss of one or more of these suppliers for any reason, including as a result of fire, acts of God or insolvency or bankruptcy, could result in delays in, or impair our ability to complete, clinical trials and regulatory submissions or reviews, and could delay or impair our sale or continued sale of Plenaxis products. Such delays or impairment, and the associated costs and expenses, may lower our potential revenues and profitability. While we intend to evaluate the possibility of a second source of supply at each stage of Plenaxis production, the number of qualified alternative suppliers is limited, and we cannot assure investors that we will be able to locate alternative suppliers or negotiate second supply agreements on reasonable terms. Furthermore, the process of engineering a new supplier's facility for the production of Plenaxis and obtaining the necessary FDA approval of the facility would require a substantial lead-time and could be extremely costly. We cannot assure investors that we will not lose one or more of our suppliers, or that in such event we would be readily able to continue the development and commercialization and sale of Plenaxis products without substantial and costly delays.

Because we depend on third parties to conduct laboratory testing and human clinical studies and assist us with regulatory compliance, we may encounter delays in product development and commercialization.

We have contracts with a limited number of research organizations to design and conduct our laboratory testing and human clinical studies. If we cannot contract for testing activities on acceptable terms, or at all, we may not complete our product development efforts in a timely manner. To the extent we rely on third parties for laboratory testing and human clinical studies, we may lose some control over these activities. For example, third parties may not complete testing activities on schedule or when we request them to do so. In addition, these third parties may conduct our clinical trials in a manner inconsistent with regulatory requirements or otherwise in a manner that yields misleading or unreliable data. This, or other failures of these third parties to carry out their duties, could result in significant additional costs and expenses and could delay or prevent the development and commercialization of our product candidates.

Alternative treatments are available which may impair our ability to capture market share for our potential products.

Alternative products exist or are under development to treat the diseases for which we are developing drugs. For example, the FDA has approved several drugs for the treatment of prostate cancer that responds to changes in hormone levels. Even if the FDA approves Plenaxis for commercialization for the treatment of hormonally responsive advanced prostate cancer, the approval could be limited to a particular group of patients or to administration over a limited period of time, and Plenaxis may not compete favorably with existing treatments that already have an established market share. If Plenaxis does not achieve broad market acceptance as a drug for the treatment of hormonally responsive advanced prostate cancer, we may not become profitable.

Many of our competitors have substantially greater resources than we do and may be able to develop and commercialize products that make our potential products and technologies obsolete or non-competitive.

A biotechnology company such as ours must keep pace with rapid technological change and faces intense competition. We compete with biotechnology and pharmaceutical companies for funding, access to new technology, research personnel and in product research and development. Many of these companies have greater financial resources and more experience than we do in developing drugs, obtaining regulatory approvals, manufacturing and marketing. We also face competition from academic and research institutions and government agencies pursuing alternatives to our products and technologies. We expect that all of our products under development will face intense competition from existing or future drugs. In addition, for each of our product candidates, we may face increasing competition from generic formulations or existing drugs whose active components are no longer covered by patents.

Our competitors may:

- successfully identify drug candidates or develop products earlier than we do;
- obtain approvals from the FDA or foreign regulatory bodies more rapidly than we do;
- develop products that are more effective, have fewer side effects or cost less than our products; or
- successfully market products that compete with our products.

The success of our competitors in any of these efforts would adversely affect our ability to develop, commercialize and market our product candidates.

If we are unable to obtain and enforce valid patents, we could lose any competitive advantage we may have.

Our success will depend in part on our ability to obtain patents and maintain adequate protection of our technologies and potential products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode any competitive advantage we may have. For example, if we lose our patent protection for Plenaxis, another party could produce and market the compound in direct competition with us. Some foreign countries lack rules and methods for defending intellectual property rights and do not protect proprietary rights to the same extent as the United States. Many companies have had difficulty protecting their proprietary rights in foreign countries.

Patent positions are sometimes uncertain and usually involve complex legal and factual questions. We can protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We currently own or have exclusively licensed 18 issued United States patents. We have applied, and will continue to apply, for patents covering both our technologies and products as we deem appropriate. Others may challenge our patent applications or our patent applications may not

result in issued patents. Moreover, any issued patents on our own inventions, or those licensed from third parties, may not provide us with adequate protection, or others may challenge the validity of, or seek to narrow or circumvent, these patents. Third-party patents may impair or block our ability to conduct our business. Additionally, third parties may independently develop products similar to our products, duplicate our unpatented products, or design around any patented products we develop.

If we are unable to protect our trade secrets and proprietary information, we could lose any competitive advantage we may have.

In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential and proprietary information. These measures may not adequately protect our trade secrets or other proprietary information. If these measures do not adequately protect our rights, third parties could use our technology, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques, which could impair any competitive advantage we may have.

If our technologies, processes or potential products conflict with the patents of competitors, universities or others, we could have to engage in costly litigation and be unable to commercialize those products.

Our technologies, processes or potential products may give rise to claims that they infringe other patents. A third party could force us to pay damages, stop our use of these technologies or processes, or stop our manufacturing or marketing of the affected products by bringing a legal action against us for infringement. In addition, a third party could require us to obtain a license to continue to use the technologies or processes or manufacture or market the affected products, and we may not be able to do so. We believe that significant litigation will continue in our industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume a substantial portion of our resources. Even if legal actions were meritless, defending a lawsuit could take significant time, be expensive and divert management's attention from other business concerns.

If third parties terminate our licenses, we could experience delays or be unable to complete the development and commercialization of our potential products.

We license some of our technology from third parties. Termination of our licenses could force us to delay or discontinue some of our development and commercialization programs. For example, if Advanced Research and Technology Institute, the assignee of Indiana University Foundation, terminated our license with them, we could have to discontinue development and commercialization of our Plenaxis products. We cannot assure you that we would be able to license substitute technology in the future. Our inability to do so could impair our ability to conduct our business because we may lack the technology, or the necessary rights to technology, required to develop and commercialize our potential products.

Our potential revenues will diminish if we fail to obtain acceptable prices or adequate reimbursement for our products from third-party payors.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payors do not provide adequate coverage and reimbursement for our products, physicians may not prescribe them. If we are unable to offer physicians comparable or superior financial motivation to use our products, we may not be able to generate significant revenues. In some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we receive for any

products in the future. Further, cost control initiatives could impair or diminish our ability or incentive, or the ability or incentive of potential partners, to commercialize our products, and our ability to earn revenues from this commercialization.

Our ability to commercialize pharmaceutical products, alone or with collaborators, may depend in part on the availability of reimbursement for our products from:

- government and health administration authorities;
- private health insurers; and
- other third party payors, including Medicare and Medicaid.

We cannot predict the availability of reimbursement for newly approved health care products. Third-party payors, including Medicare, are increasingly challenging the prices charged for medical products and services. Government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for new drugs and, in some cases, refusing to provide coverage for a patient's use of an approved drug for purposes not approved by the FDA. Third-party insurance coverage may not be available to patients for any of our products.

We may be unable to find suitable tenants for a portion of our facility.

In May 2001, we moved to a new 175,000 square foot facility in Waltham, Massachusetts. We are currently seeking to sublease a portion of our new facility to third parties. We may not be able to find suitable sub-tenants to occupy this space in a timely manner, if at all. If we are unable to find suitable sub-tenants in a timely manner, we may not be able to partially offset with rental income the substantial mortgage payments and other operating expenses associated with our facility.

If we lose our key personnel or are unable to attract and retain additional skilled personnel, we may be unable to pursue our product development and commercialization efforts.

We depend substantially on the principal members of our management and scientific staff, including Malcolm L. Gefter, Ph.D., our Chief Executive Officer, President and Chairman of the Board. We do not have employment agreements with any of our executive officers. Any officer or employee can terminate his or her relationship with us at any time and work for one of our competitors. The loss of these key individuals could result in competitive harm because we could experience delays in our product research, development and commercialization efforts without their expertise.

Recruiting and retaining qualified scientific personnel to perform future research and development work also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We compete with numerous companies and academic and other research institutions for experienced scientists. This competition may limit our ability to recruit and retain qualified personnel on acceptable terms. Failure to attract and retain qualified personnel would prevent us from continuing to develop our potential products, enhancing our technologies and launching our products commercially. Our planned activities may require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. The inability to retain these personnel or to develop this expertise could prevent, or result in delays in, the research, development and commercialization of our potential products.

We may have substantial exposure to product liability claims and may not have adequate insurance to cover those claims.

We may be held liable if any product we develop, or any product made by others using our technologies, causes injury. We have only limited product liability insurance coverage for our potential products in clinical trials. We intend to expand our product liability insurance coverage for any of our products for which we obtain marketing approval. However, this insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Our collaboration agreements with Amgen and Sanofi-Synthélabo included, and we anticipate that the agreements we are finalizing with them regarding the termination of those collaborations will include, an indemnification of them for liabilities associated with the development and commercialization of Plenaxis. If a third party, including a former collaborator, sues us for any injury, or for indemnification for losses, arising out of products made by us or using our technologies, our liability could exceed our total assets.

We use hazardous chemicals and radioactive and biological materials in our business and any claims relating to the handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. For example, the health risks associated with accidental exposure to Plenaxis include temporary impotence or infertility and harmful effects on pregnant women. Our operations also produce hazardous waste products. We cannot completely eliminate the risk of accidental contamination or discharge from hazardous materials and any resultant injury. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. Compliance with environmental laws and regulations is necessary and expensive. Current or future environmental regulations may impair our research, development or production efforts. We may be required to pay fines, penalties or damages in the event of noncompliance or the exposure of individuals to hazardous materials.

From time to time, third-parties have also worked with hazardous materials in connection with our agreements with them. We have agreed to indemnify our present and former collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

If we engage in an acquisition, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.

If appropriate opportunities become available, we may attempt to acquire businesses, or acquire or in-license products or technologies, that we believe are a strategic fit with our business. We currently have no commitments or agreements for any acquisitions, nor are there any negotiations as to any specific transaction. If we do undertake any transaction of this sort, the process of integrating an acquired business, or an acquired or in-licensed product or technology, may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. Moreover, we may fail to realize the anticipated benefits of any transaction of this sort. To the extent we issue stock in a transaction, the ownership interest of our stockholders will be diluted. Transactions of this kind could also cause us to incur debt, expose us to future liabilities and result in amortization expenses related to goodwill and other intangible assets.

The market price of our common stock may experience extreme price and volume fluctuations.

The market price of our common stock may fluctuate substantially due to a variety of factors, including, but not limited to:

- announcement of FDA approval or disapproval of Plenaxis for the treatment of hormonally responsive advanced prostate cancer or any of our other product candidates;
- failure or delay by former or future corporate collaborators in performing their obligations, or disputes or litigation regarding those obligations;
- failure or delay by third-party manufacturers in performing their supply obligations or disputes or litigation regarding those obligations;
- the success rate of our discovery efforts and clinical trials;
- our ability or the ability of third parties to commercialize our product candidates and the timing of commercialization;
- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights, including announcements of claims of infringement, interference or litigation against us or our licensors;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industry in general;
- public concerns as to the safety of our products or our competitors' products;
- changes in government regulation of the pharmaceutical or medical industry;
- changes in the reimbursement policies of third-party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In addition, the stock market has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology companies, particularly companies like ours without current product revenues and earnings, have been highly volatile, and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources.

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline.

Our quarterly operating results have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our stock price to decline. Some of the factors that could cause our operating results to fluctuate include:

- the timing and level of expenses related to the development and commercialization of our Plenaxis products leading to revenues from product sales;
- the timing and level of expenses related to our other research and development programs; and

- the timing of our commercialization of other products resulting in revenues.

Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance.

Anti-takeover provisions in our charter and by-laws, our rights agreement and certain provisions of Delaware law may make an acquisition of us more difficult, even if an acquisition would be beneficial to our stockholders.

Provisions in our certificate of incorporation and by-laws may delay or prevent an acquisition of us or a change in our management. Also, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit or delay large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. In addition, the rights issued under our rights agreement may be a substantial deterrent to a person acquiring 10% or more of our common stock without the approval of our board of directors. These provisions in our charter and by-laws, rights agreement and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower that it would be without these provisions.

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

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that an increase in prevailing interest rates may cause the principal amount of the investment to decrease. To minimize this risk in the future, we maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds and government and non-government debt securities. A hypothetical 100 basis point increase in interest rates would result in an approximate $0.7 million decrease in the fair value of our investments as of December 31, 2001. Due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. As of December 31, 2001, approximately 84% of our total portfolio will mature in one year or less, with the remainder maturing in less than two years.

In connection with the purchase of our new facility in July 2000, our wholly owned real estate subsidiary executed an acquisition and construction loan agreement that provides for up to $33.0 million in borrowings at a floating interest rate indexed to 30-day LIBOR. Concurrent with that transaction, the subsidiary also entered into an interest rate cap agreement which limits exposure to interest rate increases above a certain threshold. Due to the decrease in interest rates since we entered into this interest rate cap, we currently do not believe that there is material interest rate risk exposure with respect to the loan agreement. In addition, we believe that we have mitigated our risk relating to significant adverse fluctuations in interest rates with respect to borrowings under the loan agreement, and we do not believe that a 10% change in interest rates would have a material impact on our results of operations or cash flows.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements required by this Item are included on pages F-1 through F-19 of this report. The supplementary financial information required by this Item is included in the section of this report captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations," under the heading "Selected Quarterly Operating Results."

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

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information required by this Item with respect to directors, executive officers and compliance with Section 16(a) of the Securities Act of 1934, as amended, may be found in the sections captioned "Nominees for Election to the Board of Directors," "Executive Officers Who Are Not Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 22, 2002. Such information is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

Information required by this Item may be found in the sections captioned "Director Compensation," "Summary Compensation Table," "Option Grants in Fiscal 2001," "Aggregated Option Exercises in Last Fiscal Year and Option Values at December 31, 2001," "Employment Agreements/ Change of Control Arrangements" and "Compensation Committee Interlocks and Insider Participation" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 22, 2002. Such information is incorporated herein by reference.

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

Information required by this Item may be found in the sections captioned "Stock Ownership of Certain Beneficial Owners and Management" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 22, 2002. Such information is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Information required by this Item may be found in the section captioned "Certain Relationships and Related Transactions" appearing in our definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders expected to be held on May 22, 2002. Such information is incorporated herein by reference.

PART IV

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

(a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Consolidated Financial Statements located on page F-1, immediately following the signature page of this report.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

3. Exhibits

Exhibit No.	Exhibit
3.1	Amended and Restated Certificate of Incorporation (2)
3.2	Second Amended and Restated By-Laws
4.1	Specimen certificate representing shares of common stock (1)
4.2	Specimen certificate representing shares of common stock (including Rights Agreement Legend) (5)
4.3	Warrant to purchase Common Stock dated as of May 13, 1997 (1)
4.4	Amendment dated as of January 30, 2001 between PRAECIS and Sanofi-Synthélabo Inc. (formerly Sylamerica, Inc.) to the Warrant for the Purchase of Shares of Common Stock issued by PRAECIS to Sylamerica, Inc. (5)
4.5	Rights Agreement between PRAECIS and American Stock Transfer & Trust Company, as Rights Agent (6)
4.6	Form of Certificate of Designations of Series A Junior Participating Preferred Stock (attached as Exhibit A to the Rights Agreement filed as Exhibit 4.5 hereto) (6)
4.7	Form of Rights Certificate (attached as Exhibit B to the Rights Agreement filed as Exhibit 4.5 hereto) (6)
10.1*	Second Amended and Restated 1995 Stock Plan (3)
10.2*	Executive Management Bonus Plan, as amended and restated as of January 30, 2001 (7)
10.3*	Employee Stock Purchase Plan (4)
10.4	Amended and Restated Stockholders Agreement dated as of April 30, 1998 by and among PRAECIS and certain stockholders referred to therein, as amended by Amendment No. 1 dated as of May 14, 1998, Amendment No. 2 dated as of July 21, 1998 and Amendment No. 3 dated as of January 31, 2000 (1)
10.5	Amendment No. 4 dated as of September 1, 2000 to Amended and Restated Stockholders Agreement dated as of April 30, 1998 by and among PRAECIS and certain stockholders referred to therein, as amended (4)
10.6	Stock and Warrant Purchase Agreement dated as of May 13, 1997 by and between Sylamerica, Inc. and PRAECIS (1)
10.7	Waiver and Amendment dated as of January 26, 2001 between PRAECIS and Sanofi-Synthélabo Inc. (formerly Sylamerica, Inc.) to the Stock and Warrant Purchase Agreement dated as of May 13, 1997 by and between Sylamerica, Inc. and PRAECIS (5)
10.8†	Collaboration Agreement dated as of January 31, 2000 by and between Human Genome Sciences, Inc. and PRAECIS (1)
10.9†	License Agreement effective as of October 17, 1996 by and between PRAECIS and Indiana University Foundation, as amended as of June 3, 1998 (1)
10.10†	Supply Agreement dated as of July 23, 1998 by and between PRAECIS and Salsbury Chemicals, Inc. (1)

Exhibit No.	Exhibit
10.11††	Development and Supply Agreement effective as of June 21, 2000 by and between UCB S.A. and Amgen Inc., as amended by Amendment No. 1 thereto dated as of March 26, 2002 (together with the Assignment of Development and Supply Agreement entered into January 18, 2002 and effective as of December 17, 2001 by and between Amgen Inc. and PRAECIS)
10.12	Contract of Sale dated as of January 14, 2000 by and between Best Property Fund, L.P. and PRAECIS, as amended as of February 7, 2000 (1)
10.13	Acquisition and Construction Loan Agreement dated as of July 11, 2000 between 830 Winter Street LLC and Anglo Irish Bank Corporation plc and related Loan and Security Agreements (3)
10.14	Guaranty of Costs and Completion dated as of July 11, 2000 (3)
10.15	Guaranty of Non-Recourse Exceptions dated as of July 11, 2000 (3)
10.16	Environmental Compliance and Indemnity Agreement dated as of July 11, 2000 executed by 830 Winter Street LLC and PRAECIS (3)
10.17	Lease Agreement dated as of July 11, 2000 between 830 Winter Street LLC, as landlord, and PRAECIS, as tenant (3)
21.1	List of Subsidiaries of PRAECIS (5)
23.1	Consent of Ernst & Young LLP, Independent Auditors
24.1	Power of Attorney (included on the signature page of this Report on Form 10-K)

* Represents a management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Registration Statement on Form S-1 (Registration No. 333-96351) initially filed with the Securities and Exchange Commission on February 8, 2000 and declared effective on April 26, 2000.

(2) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended March 31, 2000 filed with the Securities and Exchange Commission on June 7, 2000.

(3) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2000 filed with the Securities and Exchange Commission on August 14, 2000.

(4) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 filed with the Securities and Exchange Commission on November 13, 2000.

(5) Incorporated by reference to Registration Statement on Form S-1 (Registration No. 333-54342) initially filed with the Securities and Exchange Commission on January 26, 2001 and declared effective on February 14, 2001.

(6) Incorporated by reference to Registration Statement on Form 8-A filed with the Securities and Exchange Commission on January 26, 2001.

(7) Incorporated by reference to Annual Report on Form 10-K for the year ended December 31, 2000 filed with the Securities and Exchange Commission on March 29, 2001.

† Confidential treatment has been granted for certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

†† Confidential treatment has been requested for certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(b) Reports on Form 8-K. The Registrant did not file any reports on Form 8-K during the quarter ended December 31, 2001.

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on this 1st day of April, 2002.

PRAECIS PHARMACEUTICALS INCORPORATED

By: /s/ KEVIN F. MCLAUGHLIN
Kevin F. McLaughlin
Chief Financial Officer, Senior Vice President, Treasurer and Secretary

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Malcolm L. Gefter and Kevin F. McLaughlin and each of them, as such person's true and lawful attorney-in-fact and agent with full power of substitution and revocation for such person and in such person's name, place and stead, in any and all capacities, to execute any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed by the following persons in the capacities indicated on April 1, 2002.

Signature	Title
/s/ MALCOLM L. GEFTER, PH.D. Malcolm L. Gefter, Ph.D.	Chairman of the Board, Chief Executive Officer and President (Principal Executive Officer)
/s/ KEVIN F. MCLAUGHLIN Kevin F. McLaughlin	Chief Financial Officer, Senior Vice President, Treasurer and Secretary (Principal Financial and Accounting Officer)
/s/ G. LEONARD BAKER, JR. G. Leonard Baker, Jr.	Director
/s/ HENRY F. MCCANCE Henry F. McCance	Director
/s/ WILLIAM R. RINGO William R. Ringo	Director

Signature	Title
/s/ DAVID B. SHARROCK David B. Sharrock	Director
/s/ PATRICK J. ZENNER Patrick J. Zenner	Director
/s/ ALBERT L. ZESIGER Albert L. Zesiger	Director

PRAECIS PHARMACEUTICALS INCORPORATED
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Auditors

Board of Directors and Stockholders
PRAECIS PHARMACEUTICALS INCORPORATED

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

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

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

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
January 24, 2002

PRAECIS PHARMACEUTICALS INCORPORATED
Consolidated Balance Sheets
(In thousands, except share data)

	December 31, 2000	December 31, 2001
Assets		
Current assets:		
Cash and cash equivalents	$132,207	$144,685
Marketable securities	—	121,531
Accounts receivable	1,079	458
Refundable income taxes	4,853	—
Unbilled revenue	1,493	—
Prepaid expenses and other assets	786	783
Total current assets	140,418	267,457
Property and equipment, net	53,821	74,200
Other assets	1,332	468
Total assets	$195,571	$342,125
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,834	$ 30,721
Accrued expenses	7,142	7,708
Deferred revenue	4,709	—
Total current liabilities	24,685	38,429
Deferred revenue	355	—
Long-term debt	24,000	33,000
Commitments and contingencies		
Stockholders' equity:		
Common Stock, $0.01 par value; 200,000,000 shares authorized; 42,284,199 shares in 2000 and 51,116,135 shares in 2001 issued and outstanding	423	511
Additional paid-in capital	175,937	353,887
Accumulated other comprehensive income	—	730
Accumulated deficit	(29,829)	(84,432)
Total stockholders' equity	146,531	270,696
Total liabilities and stockholders' equity	$195,571	$342,125

See accompanying notes.

PRAECIS PHARMACEUTICALS INCORPORATED
Consolidated Statements of Operations
(In thousands, except per share data)

	Year Ended December 31,		
	1999	2000	2001
Corporate collaboration revenue	$61,514	$ 61,189	$ 9,907
Costs and expenses:			
Research and development	48,764	85,915	59,416
Sales and marketing	2,601	6,444	8,737
General and administrative	3,572	5,285	6,961
Total costs and expenses	54,937	97,644	75,114
Operating income (loss)	6,577	(36,455)	(65,207)
Interest income	4,484	8,195	10,503
Interest expense	(11)	(376)	(1,398)
Gain on assignment of leasehold improvements	—	—	1,499
Income (loss) before income taxes	11,050	(28,636)	(54,603)
Provision for income taxes	1,800	100	—
Net income (loss)	$ 9,250	$(28,736)	$(54,603)
Net income (loss) per share:			
Basic	$ 1.51	$ (0.95)	$ (1.10)
Diluted	$ 0.24	$ (0.95)	$ (1.10)
Weighted average number of common shares:			
Basic	6,106	30,259	49,777
Diluted	37,849	30,259	49,777
Unaudited pro forma net income (loss) per share:			
Basic	$ 0.29	$ (0.74)	
Diluted	$ 0.24	$ (0.74)	
Unaudited pro forma weighted average number of common shares:			
Basic	31,714	38,794	
Diluted	37,849	38,794	

See accompanying notes.

PRAECIS PHARMACEUTICALS INCORPORATED

Consolidated Statements of Stockholders' Equity

(In thousands, except share data)

	Preferred Stock									
	Series A		Series B		Series C		Series D		Series E	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance at December 31, 1998	1,041,166	10	63,700	1	1,052,632	11	359,324	4	900,478	9
Common Stock issued upon exercise of stock options										
Net income										
Balance at December 31, 1999	1,041,166	10	63,700	1	1,052,632	11	359,324	4	900,478	9
Common Stock issued upon initial public offering (net of $7,735 in offering costs)										
Conversion of Preferred Stock on initial public offering	(1,041,166)	(10)	(63,700)	(1)	(1,052,632)	(11)	(359,324)	(4)	(900,478)	(9)
Stock compensation										
Issuance of Common Stock										
Common Stock issued upon stock grants										
Common Stock issued upon warrant exercises										
Net loss										
Balance at December 31, 2000										
Net loss										
Unrealized gain on marketable securities										
Total comprehensive loss										
Common Stock issued upon follow-on public offering (net of $10,476 in offering costs)										
Stock compensation										
Repurchase of Common Stock										
Issuance of Common Stock										
Balance at December 31, 2001										

See accompanying notes.

PRAECIS PHARMACEUTICALS INCORPORATED

Consolidated Statements of Stockholders' Equity (Continued)

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 1998	5,920,174	$ 59	$ 88,622		$(10,343)	$ 78,373
Common Stock issued upon exercise of stock options	438,510	5	88			93
Net income					9,250	9,250
Balance at December 31, 1999	6,358,684	64	88,710		(1,093)	87,716
Common Stock issued upon initial public offering (net of $7,735 in offering costs)	9,200,000	92	84,173			84,265
Conversion of Preferred Stock on initial public offering	25,607,850	256	(221)			
Stock compensation			1,325			1,325
Issuance of Common Stock	1,006,787	10	1,884			1,894
Common Stock issued upon stock grants	4,250		66			66
Common Stock issued upon warrant exercises	106,628	1				1
Net loss					(28,736)	(28,736)
Balance at December 31, 2000	42,284,199	423	175,937		(29,829)	146,531
Net loss					(54,603)	(54,603)
Unrealized gain on marketable securities				730		730
Total comprehensive loss						(53,873)
Common Stock issued upon follow-on public offering (net of $10,476 in offering costs)	7,587,500	76	175,816			175,892
Stock compensation			(265)			(265)
Repurchase of Common Stock	(200,000)	(2)	(51)			(53)
Issuance of Common Stock	1,444,436	14	2,450			2,464
Balance at December 31, 2001	51,116,135	$511	$353,887	$ 730	$(84,432)	$270,696

See accompanying notes.

PRAECIS PHARMACEUTICALS INCORPORATED
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	1999	2000	2001
Operating activities:			
Net income (loss)	$ 9,250	$(28,736)	$(54,603)
Adjustments to reconcile net income (loss) to cash provided by (used in) operating activities:			
Depreciation and amortization	1,354	4,745	3,500
Gain on assignment of leasehold improvements	—	—	(1,499)
Deferred income taxes	(5,295)	5,575	—
Stock compensation	—	1,391	(265)
Changes in operating assets and liabilities:			
Accounts receivable	(7,441)	7,042	621
Refundable income taxes	—	(4,853)	4,853
Unbilled revenues	(4,259)	2,766	1,493
Materials inventory	(21,100)	21,100	—
Prepaid expenses and other assets	(182)	(1,410)	867
Accounts payable	8,672	2,898	17,887
Accrued expenses	(372)	283	566
Deferred revenue	6,711	(4,984)	(5,064)
Advance payments	21,100	(21,100)	—
Income taxes payable	4,442	(4,672)	—
Net cash provided by (used in) operating activities	12,880	(19,955)	(31,644)
Investing activities:			
Purchase of available-for-sale securities	—	—	(177,110)
Sales and maturities of available-for-sale securities	—	—	56,309
Proceeds from disposition of property and equipment	—	—	1,499
Purchase of property and equipment	(3,556)	(52,523)	(23,879)
Net cash used in investing activities	(3,556)	(52,523)	(143,181)
Financing activities:			
Follow-on public offering proceeds	—	—	175,892
Initial public offering proceeds	—	84,265	—
Proceeds from debt issuance	—	24,000	9,000
Proceeds from the issuance of Common Stock, options and warrants	93	1,895	2,464
Repurchase of Common Stock	—	—	(53)
Principal repayments of capital lease obligations	(190)	—	—
Net cash (used in) provided by financing activities	(97)	110,160	187,303
Increase in cash and cash equivalents	9,227	37,682	12,478
Cash and cash equivalents at beginning of year	85,298	94,525	132,207
Cash and cash equivalents at end of year	$ 94,525	$132,207	$144,685

See accompanying notes.

1. Basis of Presentation

The Company

PRAECIS PHARMACEUTICALS INCORPORATED (the "Company") was incorporated in July 1993 under the laws of the State of Delaware. The Company is a drug discovery and development company engaged in the development of drugs for the treatment of human diseases.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include the Company's accounts and the accounts of its wholly owned real estate subsidiary. All significant intercompany account balances and transactions between the companies have been eliminated.

2. Significant Accounting Policies

Cash Equivalents

Cash equivalents consist principally of money market funds and other investments with original maturities of three months or less at the date of purchase.

Marketable Securities

The Company invests in marketable securities of highly rated financial institutions and investment-grade debt instruments and limits the amount of credit exposure with any one entity. The Company has classified its marketable securities as "available-for-sale" and, accordingly, carries such securities at aggregate fair value. Unrealized gains and losses, if any, are reported as other comprehensive income in stockholders' equity. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses on available-for-sale securities are included in interest income and expense. The cost of securities sold is based on the specific identification method. Interest and dividends are included in interest income. At December 31, 2001, the Company's marketable securities had a maximum maturity of less than two years with an average of approximately 11 months.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with high credit quality financial institutions and, by policy, limits its credit exposure to any one financial instrument, sovereignty or issuer.

2. Significant Accounting Policies (Continued)

Unbilled Revenue

Unbilled revenue represents reimbursable costs incurred by the Company but not yet billed under corporate collaboration agreements. Billings are prepared monthly upon receipt of reimbursable cost documentation.

Inventory

Materials inventory is carried at the lower of actual cost or market (net realizable value) on a first-in, first-out basis.

Derivatives and Hedging

In June 1998, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 133, *Accounting for Derivative Instruments and Hedging Activities* ("SFAS No. 133"), and its amendments SFAS No. 137 and No. 138, in June 1999 and June 2000, respectively. SFAS No. 133 requires the Company to recognize all derivatives on the balance sheet at fair value.

Derivatives that are not hedges must be adjusted to fair value through income. If the derivative is a hedge, depending on the nature of the hedge, changes in the fair value of derivatives are either offset against the change in fair value of assets, liabilities, or firm commitments through earnings or recognized in other comprehensive income until the hedged item is recognized in earnings. The ineffective portion of a derivative's change in fair value will be immediately recognized in earnings. The adoption of SFAS No. 133 did not have a material impact on the Company's consolidated results of operations in 2001.

Property and Equipment

Property and equipment are recorded at cost. Depreciation and amortization are calculated using the straight-line method over the estimated useful life of the asset as follows:

Building	30 years
Building improvements	30 years or the life of the building, whichever is shorter
Laboratory and office equipment	3-7 years or term of lease, whichever is shorter
Leasehold improvements	Term of the lease or remaining useful life, whichever is shorter

Interest capitalized in connection with facilities is recorded as part of the asset to which it relates and is amortized over the asset's estimated useful life. Interest capitalized into construction in progress during 2000 and 2001 was approximately $0.8 million and $0.6 million, respectively.

Revenue Recognition

Revenue is deemed earned when all of the following have occurred: all obligations of the Company relating to the revenue have been met and the earning process is complete; the monies received or receivable are not refundable irrespective of research results; and there are neither future obligations nor future milestones to be met by the Company with respect to such revenue.

2. Significant Accounting Policies (Continued)

Corporate collaborations. Revenues are earned based upon research expenses incurred and milestones achieved. Non-refundable payments upon initiation of contracts are deferred and amortized over the period in which the Company is obligated to participate on a continuing and substantial basis in the research and development activities outlined in each contract. Amounts received in advance of reimbursable expenses are recorded as deferred revenue until the related expenses are incurred. Milestone payments are recognized as revenue in the period in which the parties agree that the milestone has been achieved and it is deemed that no further obligations exist.

Income Taxes

The Company provides for income taxes under SFAS No. 109, *Accounting for Income Taxes.* Under this method, deferred taxes are recognized using the liability method, whereby tax rates are applied to cumulative temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes based on when and how they are expected to affect the tax return.

Research and Development

Research and development costs, including those associated with technology, licenses and patents, are expensed as incurred. Research and development costs include primarily costs related to ongoing clinical programs, manufacturing and materials inventory costs, salaries, lab supplies and other fixed facility costs used in the Company's research and development operations.

Stock-Based Compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), in accounting for its stock-based employee compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123"), as SFAS No. 123 requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, when the exercise price of options granted under these plans equals the market price of the underlying stock on the date of grant, no compensation expense is required.

Accounting Pronouncements

In June 2001, the FASB issued SFAS No. 141, *Business Combinations*, and SFAS No. 142, *Goodwill and Other Intangible Assets*, effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill will no longer be amortized but will be subject to annual impairment tests in accordance with the statements. Other intangible assets will continue to be amortized over their useful lives. The Company will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. Application of the provisions of these statements is not expected to have a material effect on the Company's consolidated financial position or consolidated results of operations since the Company does not have any goodwill or intangibles at this time.

In October 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ("SFAS No. 144"). SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of;* however, it retains the fundamental provision of that statement related to the recognition and measurement of the impairment of long-lived assets to be held and used. In addition, SFAS No. 144 provides additional guidance on estimating cash flows when performing a recoverability test, requiring that a long-lived asset to be

2. Significant Accounting Policies (Continued)

disposed of other than by sale be classified as an asset held for sale until it is disposed of, and establishes more restrictive criteria to classify an asset as held for sale. SFAS No. 144 is effective for the Company starting in 2002. Application of SFAS No. 144 is not expected to have any effect on the Company's consolidated financial position or consolidated results of operations since it does not believe that there are any impairment indicators at this time.

Comprehensive Loss

Comprehensive loss consists of net loss and unrealized gains or losses on marketable securities and is reflected in the consolidated statements of stockholders' equity.

Net Income (Loss) Per Share

Basic net income (loss) per share represents net income (loss) divided by the weighted average shares of common stock, par value $.01 per share ("Common Stock"), outstanding during the period. Diluted net income (loss) per share includes the effect of all dilutive, potentially issuable common shares using the treasury stock method. The difference between basic and diluted shares used in the computation of net income (loss) per share is as follows:

	Year Ended December 31,		
	1999	2000	2001
	(in thousands)		
Historical:			
Weighted average number of common shares outstanding used in computing basic net income (loss) per share	6,106	30,259	49,777
Effect of dilutive securities:			
Convertible Preferred Stock	25,608	—	—
Stock options	5,989	—	—
Warrants	146	—	—
Weighted average number of common shares used in computing diluted net income (loss) per share	37,849	30,259	49,777

Pro Forma Net Income (Loss) Per Share (Unaudited)

Pro forma net income (loss) per share is computed using the historical basic and diluted weighted average number of outstanding shares of Common Stock assuming conversion of the outstanding shares of Series A, B, C, D and E convertible preferred stock, par value $.01 per share ("Convertible Preferred Stock") into a total of 25,607,850 shares of Common Stock as of their original dates of issuance.

2. **Significant Accounting Policies (Continued)**

	Year Ended December 31,	
	1999	2000
	(in thousands)	
Pro Forma (unaudited):		
Weighted average number of common shares outstanding used in computing basic net income (loss) per share	6,106	30,259
Adjustment to reflect the effect of the assumed conversion of preferred stock from the date of issuance	25,608	8,535
Weighted average number of common shares outstanding used in computing pro forma basic net income (loss) per share	31,714	38,794
Weighted average number of common shares outstanding used in computing diluted net income (loss) per share	37,849	30,259
Adjustment to reflect the effect of the assumed conversion of preferred stock from the date of issuance	—	8,535
Weighted average number of common shares outstanding used in computing pro forma diluted net income (loss) per share	37,849	38,794

3. **Marketable Securities**

The Company's marketable securities, which are classified as available-for-sale, as of December 31, 2001 are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies	$ 89,869	$361	$(103)	$ 90,127
Commercial paper	30,932	484	(12)	31,404
Total marketable securities	$120,801	$845	$(115)	$121,531

4. **Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2000	2001
	(in thousands)	
Building	$ —	$56,314
Land	—	10,500
Laboratory and office equipment	7,711	14,312
Leasehold improvements	1,610	—
Construction in progress	50,540	—
	59,861	81,126
Less accumulated depreciation and amortization	6,040	6,926
	$53,821	$74,200

5. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2000	2001
	(in thousands)	
Clinical trial costs	$3,497	$4,514
Other	3,645	3,194
	$7,142	$7,708

6. Stockholders' Equity

Public Offerings

In May 2000, the Company completed an initial public offering of 9,200,000 shares of Common Stock resulting in net proceeds to the Company of approximately $84.3 million.

In February 2001, the Company completed a follow-on public offering of its Common Stock. The Company sold 7,587,500 shares of Common Stock resulting in net proceeds to the Company of approximately $175.9 million.

Convertible Preferred Stock

Upon the closing of the Company's initial public offering, all of the outstanding shares of the Company's Convertible Preferred Stock automatically converted into 25,607,850 shares of Common Stock. Immediately following the automatic conversion of the Convertible Preferred Stock, the Company filed an amended and restated certificate of incorporation. Under the amended and restated certificate of incorporation, the Company is authorized to issue 200,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, par value $.01 per share ("Preferred Stock"). The Preferred Stock is issuable in one or more classes or series, each of such classes or series to have such rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as may be determined by the Board of Directors. No shares of Preferred Stock have been issued.

Rights Plan

In January 2001, the Company adopted a Rights Agreement (the "Rights Agreement"), commonly known as a "poison pill." Under the Rights Agreement, the Company distributed certain rights to acquire shares of the Company's Series A junior participating preferred stock (the "Rights") as a dividend for each share of Common Stock held of record as of February 5, 2001. Each share of Common Stock issued after the February 5, 2001 record date has an attached Right. Under certain conditions involving an acquisition by any person or group of 10% or more of the Common Stock, each Right permits the holder (other than the 10% holder) to purchase Common Stock having a value equal to twice the exercise price of the Right, upon payment of the exercise price of the Right. In addition, in the event of certain business combinations after an acquisition by a person or group of 10% or more of the Common Stock, each Right entitles the holder (other than the 10% holder) to receive, upon payment of the exercise price, Common Stock having a value equal to twice the exercise price of the Right. The Rights have no voting privileges and, unless and until they become exercisable, are attached to, and automatically trade with, the Company's Common Stock. The Rights will terminate upon the earlier of the date of their redemption or ten years from the date of issuance.

6. Stockholders' Equity (Continued)

Employee Stock Purchase Plan

On February 2, 2000, the Board of Directors adopted, effective as of July 3, 2000, an Employee Stock Purchase Plan and authorized the reservation of 160,000 shares of Common Stock for issuance thereunder. Under the Employee Stock Purchase Plan, eligible employees may purchase shares of Common Stock at a price per share equal to 85% of the lower of the fair market value per share of the Common Stock at the beginning or the end of each six month period during the two-year term of the Employee Stock Purchase Plan. Participation is limited to the lesser of 10% of the employee's compensation or $25,000 in any calendar year. During 2000 and 2001, the Company issued 9,497 and 35,532 shares of Common Stock, respectively, under the Employee Stock Purchase Plan.

Warrants

In connection with its lease financing arrangement entered into on March 29, 1995, the Company agreed to issue warrants to purchase 14,925 shares of Series A Convertible Preferred Stock at $10.085 per share, which, pursuant to the terms thereof, converted into warrants to purchase 111,495 shares of Common Stock at $1.35 per share upon the completion of the initial public offering in May 2000. The fair value of the warrants, when issued periodically over the two year period from March 1995 through March 1997, was not material. Between August and November of 2000, all of the warrants were exercised in three separate net issuance exercises. As a result, the Company issued 106,628 shares of Common Stock.

In May 1997, Sanofi-Synthélabo Inc. (formerly Sylamerica, Inc.), a wholly owned subsidiary of Sanofi-Synthélabo S.A. (formerly Synthélabo S.A.) purchased 1,617,772 shares of Common Stock and a warrant to purchase 404,445 shares of Common Stock, for an aggregate purchase price of $10.0 million. The warrant has a five-year term, expires on May 13, 2002 and is exercisable at a price of $12.88 per share. The Company allocated $0.5 million to the value of the warrant. This value was estimated using the Black-Scholes valuation model using assumptions that are substantially consistent with those used in valuing the Company's Common Stock options under SFAS No. 123 (See "Stock Option Plan" below). As of December 31, 2001, warrants to purchase 404,445 shares of Common Stock were outstanding.

Stock Option Plan

The Second Amended and Restated 1995 Stock Plan (the "Plan") allows for the granting of incentive and nonqualified options and awards to purchase shares of Common Stock. At December 31, 2001, the Plan provided for the issuance of up to 11,375,000 shares of Common Stock. Incentive options granted to employees generally vest at 20% on the first anniversary of the date of grant, with the remaining shares vesting equally over four years following such anniversary date. Nonqualified options issued to consultants generally vest over the period of service with the Company.

6. Stockholders' Equity (Continued)

Information regarding options under the Plan is summarized below (in thousands, except per share data):

	1999		2000		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at January 1,	6,738	$2.03	8,212	$3.35	8,235	$6.74
Granted	2,230	6.47	1,528	22.99	1,087	11.75
Exercised	(438)	0.21	(997)	1.74	(1,209)	1.74
Cancelled	(318)	1.50	(508)	10.70	(1,454)	6.38
Options outstanding at December 31,	8,212	$3.35	8,235	$6.74	6,659	$8.54
Options exercisable at December 31,	2,777	$1.61	3,328	$2.55	3,274	$4.73

The weighted average per share fair value of options granted was $4.07 in 1999, $16.64 in 2000 and $10.05 in 2001. At December 31, 2001, there were 8,082,182 shares of Common Stock reserved for the exercise of stock options and warrants and for issuances under the Employee Stock Purchase Plan, including 903,354 options available for grant under the Plan.

The following table presents weighted average price and weighted average remaining contractual life information about significant option groups outstanding at December 31, 2001 (option amounts in thousands):

Exercise Price	Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price
$0.13-$1.60	1,746	4.1	$ 0.53	1,270	$ 0.63
$3.71-$6.38	2,772	6.2	$ 5.39	1,596	$ 4.90
$7.00-$16.25	1,079	8.7	$11.55	265	$10.99
$23.13-$42.00	1,062	8.9	$26.88	143	$27.66
	6,659			3,274	

Pursuant to the requirements of SFAS No. 123, the following is the pro forma net income (loss) for each year as if the compensation cost for the Plan had been determined based on the fair value at the grant date for grants for each year:

	1999		2000		2001	
	As Reported	Pro Forma	As Reported	Pro Forma	As Reported	Pro Forma
	(in thousands, except per share data)					
Net income (loss)	$9,250	$6,547	$(28,736)	$(34,863)	$(54,603)	$(62,450)
Diluted net income (loss) per common share	$ 0.24	$ 0.17	$ (0.95)	$ (1.15)	$ (1.10)	$ (1.25)

6. Stockholders' Equity (Continued)

The fair value of the stock options at the date of grant was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	1999	2000	2001
Risk-free interest rate	6.0%	6.2%	4.0%
Expected life (years)	5	5	5
Volatility	70%	84%	84%

The Company has never declared or paid any cash dividends on any of its capital stock and does not expect to do so in the foreseeable future.

The effects on pro forma net income (loss) of expensing the fair value of stock options are not necessarily representative of the effects on reported results of operations for future years as the periods presented include only two, three and four years, respectively, of option grants under the Plan.

On October 3, 2001, Dr. Malcolm Gefter, the Company's Chairman, Chief Executive Officer and President, exercised an option to purchase 200,000 shares of Common Stock at an exercise price of $0.27 per share. On November 30, 2001, this option exercise was rescinded, and accordingly, Dr. Gefter returned to the Company the 200,000 shares of Common Stock acquired upon the exercise of the option, the Company returned to Dr. Gefter the option exercise price and the option to purchase 200,000 shares of Common Stock was restored. During 2001, the Company recognized approximately $256,000 in compensation expense related to this transaction.

7. Income Taxes

The Company's provision for income taxes is as follows:

	Year Ended December 31,		
	1999	2000	2001
	(in thousands)		
Current:			
Federal	$ 5,295	$(5,575)	$ —
State	1,800	100	—
	7,095	(5,475)	—
Deferred:			
Federal	(5,295)	5,575	—
State	—	—	—
	(5,295)	5,575	—
	$ 1,800	$ 100	$ —

A reconciliation of the Company's income tax provision to the statutory federal provision is as follows:

	Year Ended December 31,		
	1999	2000	2001
	(in thousands)		
Statutory federal income tax provision (benefit)	$3,868	$(9,736)	$(18,565)
State income taxes	620	—	—
Increase (decrease) in valuation allowance	(2,688)	9,631	18,565
Other	—	205	—
Income tax provision	$1,800	$ 100	$ —

7. Income Taxes (Continued)

In 1998, the Company utilized approximately $10.3 million of net operating loss carryforwards to offset taxable income. Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2000	2001
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 8,761	$ 21,010
Deferred revenue	1,812	—
Property and equipment	1,524	4,095
Accrued expenses	810	12,791
Research and development tax credit carryforwards	1,821	4,501
Other	231	102
Total deferred tax assets	14,959	42,499
Valuation allowance	(14,959)	(42,499)
	$ —	$ —

At December 31, 2000 and 2001, the Company has provided a valuation allowance for the excess of the deferred tax asset over the benefit from future losses that could be carried back if, and when, they occur. The valuation allowance increased by $11.3 million in 2000 and $27.5 million in 2001 due primarily to the increase in net operating losses, accruals and tax credit carryforwards. The Company has net operating loss carryforwards in the amount of approximately $51.6 million, which expire through 2021. Due to anticipated operating losses in the future, the Company believes that it is more likely than not that it will not realize a portion of the net deferred tax assets in the future and has provided an appropriate valuation allowance.

Income tax payments amounted to approximately $4.0 million in 2000 and zero in 2001.

8. Corporate Collaborations

Sanofi-Synthélabo Agreement

In May 1997, the Company entered into a license agreement with Synthélabo S.A., which subsequently merged with Sanofi S.A. forming Sanofi-Synthélabo S.A. ("Sanofi-Synthélabo"), for the development and commercialization of the Company's Plenaxis products. Upon initiation, the Company received a one-time, non-refundable payment of $4.7 million. This initiation fee was recognized into revenue through 2001, which was the period during which the Company was obligated under the agreement to participate on a continuing and substantial basis in the research, development and manufacturing process development activities.

In October 2001, Sanofi-Synthélabo notified the Company that it was terminating the Sanofi-Synthélabo agreement effective December 31, 2001. As a result of the termination of the Sanofi-Synthélabo agreement, all licenses for Plenaxis granted to Sanofi-Synthélabo under the agreement, and all rights of Sanofi-Synthélabo in the Plenaxis program, have terminated.

The Company recognized revenues of approximately $4.7 million in 1999, $4.1 million in 2000 and $2.1 million in 2001 under the Sanofi-Synthélabo agreement.

8. Corporate Collaborations (Continued)

Amgen Agreement

In March 1999, the Company entered into a binding agreement in principle with Amgen Inc. ("Amgen") for the development and commercialization of the Company's Plenaxis products. In accordance with the agreement, the Company received from Amgen a $10.0 million, one-time, non-refundable payment upon initiation. This initiation fee was recognized into revenue through 2001, which was the period during which the Company was obligated under the Amgen agreement to participate on a continuing and substantial basis in the research, development and manufacturing process development activities. In addition to the signing payment, Amgen paid the first $175.0 million of all authorized costs and expenses associated with the development and commercialization of Plenaxis products, including the cost of materials, in the United States.

Following Amgen's completion of this funding during the third quarter of 2000, the Company became responsible for one-half of all subsequent United States research and development costs for Plenaxis products through the launch period. Additionally, the Company was to reimburse Amgen for one-half of the costs associated with establishing a sales and marketing infrastructure for Plenaxis products in the United States.

In September 2001, Amgen notified the Company that it was terminating the Amgen agreement effective December 17, 2001. As a result of the termination of the Amgen agreement, all licenses for Plenaxis granted to Amgen under the agreement, and all rights of Amgen in the Plenaxis program, have terminated. As of December 31, 2001, the Company has accrued an estimate of its potential liability of approximately $29.1 million under its agreement with Amgen.

In January 2002, the Company assumed all of Amgen's rights and obligations under the Development and Supply Agreement with UCB S.A. ("UCB"). Under the terms of this agreement, the Company is committed to pay UCB approximately $16.1 million for the supply of clinical and commercial volumes of pharmaceutical peptide to be delivered by the end of 2002.

The Company recognized revenues in 1999, 2000 and 2001 of approximately $56.8 million, $57.1 million and $7.8 million, respectively, under the Amgen agreement.

Human Genome Sciences Agreement

In January 2000, the Company entered into an agreement with Human Genome Sciences Inc. ("HGS") for the discovery, development and commercialization of compounds targeted to two proprietary molecules identified by HGS. Under the terms of the agreement, the Company will apply its technology to these molecules and any clinical drug candidates will be jointly developed by the parties on an equal cost and profit sharing basis.

9. Building and Related Mortgage Financing

On July 11, 2000, the Company purchased, for approximately $41.3 million, through its wholly owned real estate subsidiary, land and a building to be used as its principal headquarters and research facility. In connection with obtaining first mortgage financing to purchase this facility, the Company formed its real estate subsidiary and assigned to it all of the rights and obligations under the related Purchase and Sale Agreement (the "Purchase and Sale Agreement").

At that time, the Company's real estate subsidiary executed an Acquisition and Construction Loan Agreement (the "Loan Agreement") providing for up to $33.0 million in first mortgage financing. Under the terms of the Loan Agreement, advances are available primarily to pay for the acquisition of,

9. Building and Related Mortgage Financing (Continued)

and improvements to, the Company's new facility. The Company has entered into an interest rate cap agreement (the "Interest Rate Cap Agreement") in order to reduce the potential impact of interest rate increases on future income. At December 31, 2001, the notional amount and fair market value under the Interest Rate Cap Agreement are $33.0 million and $5,000, respectively.

An initial advance of $24.0 million was made in July 2000, a second advance of $2.9 million in February 2001 and a final advance of $6.1 million was made in April 2001. Advances bear interest at a rate equal to the 30-day LIBOR plus 2.0% (3.87% at December 31, 2001). Interest is payable monthly in arrears. Principal is due and payable in full on July 30, 2003, subject to two one-year extension options. The loan is secured by the facility, together with all fixtures, equipment, improvements and other items related thereto, and by all rents, income or profits received by the Company's real estate subsidiary. The Company occupied the facility during the May 2001 and is currently seeking to sublease a portion of the facility.

Interest paid under the Loan Agreement approximated interest expense in 2000 and 2001.

During September 2001, the Company terminated the lease for, and all future obligations with respect to, its Cambridge, Massachusetts facility. In October 2001, the Company assigned to a third party the Company's right, title and interest in and to the Company's lease for the New Jersey facility and the third party has assumed all obligations thereunder.

10. Commitments

Indiana University Foundation ("IUF") License Agreement

The Company has a license agreement with IUF, which was assigned by IUF to IUF's Advanced Research and Technology Institute, Inc., with respect to rights to Plenaxis and certain related technology. In exchange for the license, the Company agreed to pay (a) fees of $0.3 million, (b) up to an additional $4.3 million upon achievement of specific milestones and (c) a royalty percentage of net sales of licensed products, if any. The Company made milestone payments of $500,000 in 2000 under the IUF agreement.

Salsbury Supply Agreement

In July 1998, the Company entered into a seven-year agreement with Salsbury Chemicals, Inc. ("Salsbury") for the development and supply of clinical and commercial depot formulation of Plenaxis. Under the agreement, in 1998 and 1999, the Company contributed approximately $1.7 million and $4.3 million, respectively, towards construction of the manufacturing facility which it has expensed as manufacturing start up costs. The Company has an obligation with Salsbury to pay approximately $634,000 during 2002 towards minimum purchase commitments and facility maintenance.

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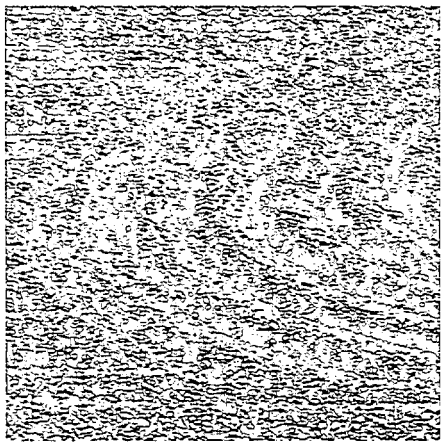
STOCKHOLDER INFORMATION



CORPORATE HEADQUARTERS
830 Winter Street
Waltham, Massachusetts 02451-1420
781.795.4100, fax: 781.890.7471
info@praecis.com
www.praecis.com

EXECUTIVE OFFICERS

Malcolm L. Gefter, Ph.D.
Chairman, Chief Executive Officer and President

Kevin F. McLaughlin
Senior Vice President, Chief Financial Officer, Treasurer and Secretary

Marc B. Garnick, M.D.
Executive Vice President and Chief Medical Officer

James E. Vath, Ph.D.
Senior Vice President, Research

BOARD OF DIRECTORS

Malcolm L. Gefter, Ph.D.
Chairman, Chief Executive Officer and President, PRAECIS

G. Leonard Baker, Jr.
Managing Director, Sutter Hill Ventures, a venture capital firm

Henry F. McCance
Chairman and President, Greylock Management Corporation, a venture capital firm

William R. Ringo
Consultant, retired President, Oncology and Critical Care, Eli Lilly and Company, a global pharmaceutical company

David B. Sharrock
Consultant, retired Executive Vice President and Chief Operating Officer, Marion Merrell Dow Inc., a global pharmaceutical company

Patrick J. Zenner
Retired President and Chief Executive Officer, Hoffmann-LaRoche Inc., North America, a global pharmaceutical company

Albert L. Zesiger
Managing Director, Zesiger Capital Group LLC, a global investment advisory firm

INDEPENDENT AUDITORS
Ernst & Young LLP
Boston, Massachusetts

CORPORATE COUNSEL
Skadden, Arps, Slate, Meagher & Flom LLP
Boston, Massachusetts

INVESTOR RELATIONS
PRAECIS invites stockholders, security analysts, representatives of portfolio management firms and other interested parties to contact:

Kevin F. McLaughlin
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
PRAECIS PHARMACEUTICALS INCORPORATED
830 Winter Street
Waltham, Massachusetts 02451-1420
781.795.4100

TRANSFER AGENT AND REGISTRAR
The transfer agent is responsible, among other things, for handling stockholder questions regarding lost stock certificates, address changes, including duplicate mailings, and changes in ownership or name in which shares are held. These requests may be directed to the transfer agent at the following address:

American Stock Transfer & Trust Company
59 Maiden Lane, Plaza Level
New York, New York 10038
800.937.5449
www.amstock.com

ANNUAL MEETING
The Annual Meeting of Stockholders will be held at 10:00 a.m. on Wednesday, May 22, 2002 at:

PRAECIS PHARMACEUTICALS INCORPORATED
830 Winter Street
Waltham, Massachusetts 02451-1420

FORM 10-K
A copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, including the financial statements, and excluding exhibits, is included as part of this Annual Report. Copies of the Form 10-K, exclusive of exhibits, are available without charge by contacting Investor Relations at 781.795.4100, sending an e-mail message to info@praecis.com, or sending a written request to:

Investor Relations
PRAECIS PHARMACEUTICALS INCORPORATED
830 Winter Street
Waltham, Massachusetts 02451-1420

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