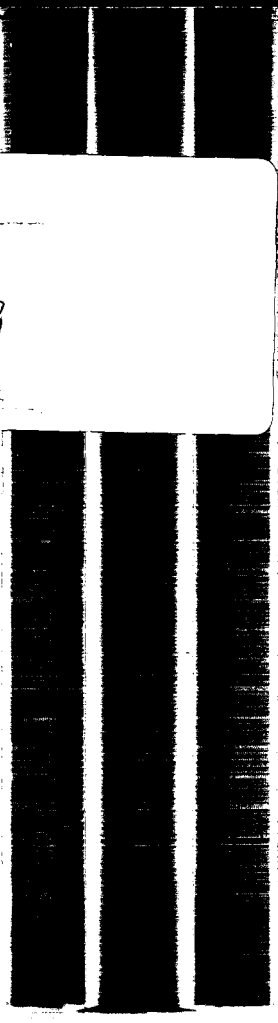
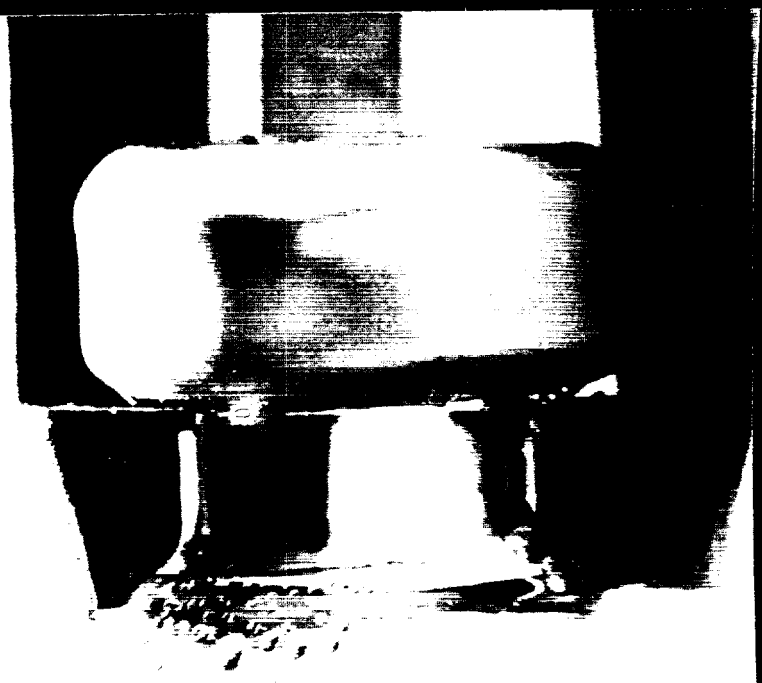


momentum & results

PRAECIS PHARMACEUTICALS INCORPORATED ANNUAL REPORT 2002

PRAECIS



gaining momentum

WITH THE RECENT REFILING OF OUR NDA FOR PLENAXIS, advancements made in other research programs, and significant additions to our senior management team we are accelerating along our path to becoming a product driven, commercial company.

TO OUR STOCKHOLDERS:

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

During 2002 PRAECIS continued to gain momentum and achieve results in our clinical, research and commercial development efforts. We thank all of our stockholders for participating with us in a year during which we obtained clarity from the United States Food and Drug Administration (FDA) with regard to our lead program, Plenaxis™ for prostate cancer, continued our first clinical trial with a novel compound for Alzheimer's disease and brought forward from our research pipeline our next compound for clinical development for the treatment of B-Cell Non-Hodgkin's lymphoma. Based on the results achieved and the momentum created during 2002, we believe PRAECIS is well positioned to transition to a product driven, fully integrated pharmaceutical company.

PLENAXIS FOR PROSTATE CANCER

Result – Working with the FDA, we agreed on a clear regulatory path forward for Plenaxis that could lead to marketing approval.

As I indicated in last year's letter, our goal was to refile our New Drug Application (NDA) for Plenaxis by the end of the first quarter of 2003. This goal was accomplished on February 27, 2003.

We are now seeking approval for Plenaxis for use in a defined sub-population of advanced prostate cancer patients for whom the use of existing hormonal therapies may not be appropriate. The specific sub-population of patients will be determined through additional discussions with the FDA. We expect to receive a response from the FDA during the second half of 2003.

We believe that Plenaxis could provide a valuable therapeutic alternative for the many advanced prostate cancer patients in the United States who may otherwise face the prospect of bilateral orchiectomy (surgical castration). If approved, we intend to market and sell Plenaxis in the United States through our own marketing and sales team.

In Europe, we intend to seek approval to market Plenaxis for a broad population of hormonally responsive advanced prostate cancer patients through a mutual recognition filing. We expect to submit our registration dossier during the second quarter of 2003. We are currently seeking a partner to market and sell Plenaxis outside of the United States.

APAN™ FOR ALZHEIMER'S DISEASE

Result – We continued to enroll subjects in our phase 1a clinical trial and believe we have defined the maximum tolerated dose. We have obtained preliminary results from these studies that are indicative of the drug's mechanism of action.

WE GAINED CLARITY ON OUR REGULATORY PATH FORWARD,

A KEY STEP IN POSITIONING PRAECI

FOR THE FUTURE.

achieving results

DURING 2002 WE ACHIEVED MANY RESULTS. In our lead clinical program, Plenaxis for prostate cancer, we gained clarity on our regulatory path forward. This was a key step toward our NDA refiling which was recently completed in February 2003. In our Apan clinical program, we continued to enroll subjects in our ongoing clinical trial and examined varying dosages of Apan and certain characteristics about its target, beta amyloid. In our endometriosis clinical program, we completed the treatment and observation phases of a pharmacokinetic study. We identified PPI-2458 as our next IND candidate. The first indication for this new drug candidate is B-Cell Non-Hodgkins lymphoma.

The development program for our proprietary compound, Apan, for the treatment of Alzheimer's disease, continues to progress as expected. The phase 1a clinical trial, which began in 2001, has enrolled 76 healthy subjects within 14 distinct dosing groups. Each dosing group enrolled during this period was administered a single dose of Apan the magnitude of which increased with each successive dosing group. Through this ongoing dose escalation study, we have achieved several results. First, we were able to define what we believe to be the maximum tolerated dose for Apan administration in healthy volunteers, which now sets the stage for studying the behavior of the drug in Alzheimer's disease patients. Second, we also were able to quantify Apan in the cerebrospinal fluid (CSF) of the ten subjects whose CSF was tested. This test enabled us to determine that increased clearance of damaging beta-amyloid in Alzheimer's patients may be induced by Apan.

Based on the final results from this phase 1a clinical study and following discussions with the FDA, we intend, during the first half of 2003, to initiate a phase 1b clinical study to evaluate a single dose of Apan in Alzheimer's disease patients. It is then our intent to evaluate in a phase 1c clinical study multiple doses of Apan in Alzheimer's patients.

There is a widely held theory that Alzheimer's disease is the result of the accumulation of beta-amyloid containing plaques in brain tissues. We believe Apan is one of the most advanced therapeutics designed to alter this accumulation and thus alter the course of the disease. Consequently, we believe Apan could be a valuable drug for a large percentage of the population affected by this debilitating disease.

PLENAXIS FOR ENDOMETRIOSIS

Result – We conducted additional clinical studies of Plenaxis for the treatment of endometriosis.

The development program for Plenaxis for the treatment of endometriosis progressed during 2002 with the initiation and conduct of a pharmacokinetic study. This study was designed to better understand both the dose and dosing schedule necessary to maximize the benefit of our drug candidate, as well as to assess attendant bone mineral density loss in women with endometriosis. We have completed the treatment and observation phases of this study and expect to complete our review of the results during the first half of 2003 before deciding upon the next steps for development.

PPI-2458 FOR B-CELL NON-HODGKINS LYMPHOMA

Result – We identified our next IND candidate – PPI-2458.

In my letter last year, I articulated our goal of filing an Investigational New Drug application (IND) during 2002 on our preclinical drug candidate that demonstrated promise in both the rheumatoid arthritis and oncology clinical arenas. During the year we further investigated the utility of PPI-2458 in oncology and, as a result, decided that our first indication for this compound would be in B-Cell Non-Hodgkins lymphoma. We made this determination following the completion of our formal toxicology studies and based upon additional information generated by the National Cancer Institute, which continues to evaluate this compound in certain oncology settings. We expect to file an IND with the FDA in mid 2003 and then begin our first human clinical trials with this compound.

WE ARE A DRUG DISCOVERY AND DEVELOPMENT COMPANY WITH A LEAD PRODUCT CANDIDATE, PLENAXIS FOR THE TREATMENT OF HORMONALLY RESPONSIVE ADVANCED PROSTATE CANCER, AS WELL AS CLINICAL DEVELOPMENT PROGRAMS IN THE THERAPEUTIC AREAS OF ALZHEIMER'S DISEASE AND ENDOMETRIOSIS.

We continue to be optimistic about the utility of PPI-2458 for the treatment of rheumatoid arthritis, and are very encouraged by the continued progress of our research in this area.

In addition, during 2002, we completed development of a cGMP manufacturing process for producing quantities of this compound which will be sufficient for human clinical trials and further, we received a "Notice of Allowance" for a United States composition of matter patent application that we had filed on this compound.

POSITIONING PRAECIS FOR THE FUTURE

Result – Hired William K. Heiden as President and Chief Operating Officer

During 2002 we strengthened our management team at PRAECIS by appointing William K. Heiden as our new President and Chief Operating Officer. Bill has extensive operational experience in the pharmaceutical industry and most recently was the Vice President of the Oncology/Biotechnology business unit of Schering Plough. Bill has directed the marketing launch and sales efforts of numerous products and has successfully managed collaborative business relationships.

William K. Heiden
President and Chief Operating Officer

We are extremely pleased to have Bill join PRAECIS. Bill's influence has been immediate and significant as he drives the daily activity of the Company with a focus on positioning the Company in its marketing and commercialization efforts.

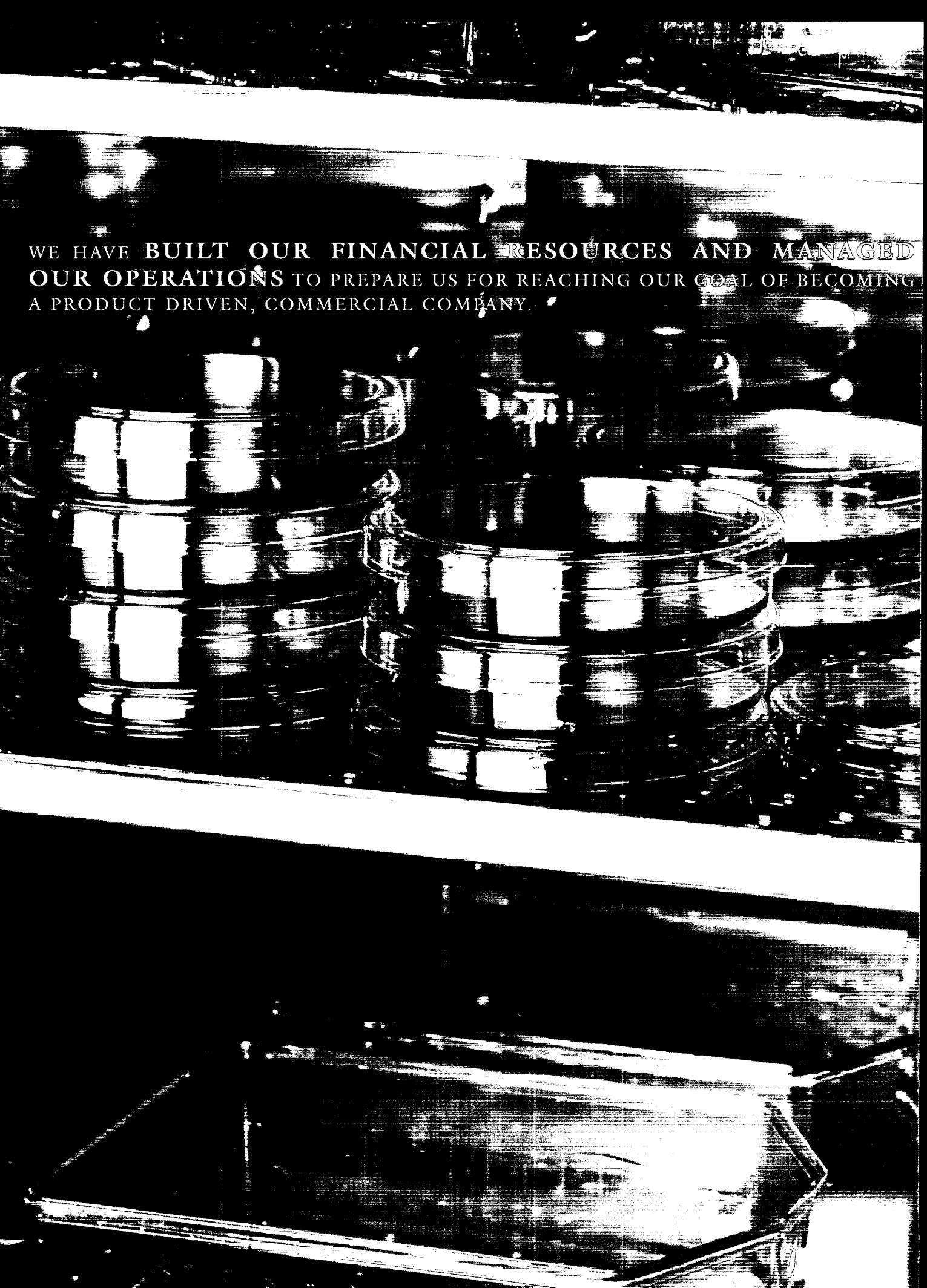
On behalf of our Board of Directors and employees I would like to thank our stockholders for their support during the past year. We believe we have placed the Company in a strong position to move forward with our late stage product, Plenaxis, our compounds in clinical trials, and with our research pipeline. Through these initiatives, we are endeavoring to drive to profitability by 2006. I look forward to updating you on our progress during 2003.

Sincerely,

Malcolm L. Gefter

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

IN ADDITION TO OUR CLINICAL PROGRAMS, WE HAVE NUMEROUS PROGRAMS IN THE RESEARCH OR PRECLINICAL DISCOVERY STAGE. WE INTEND TO FILE BY MID-YEAR 2003 AN INVESTIGATIONAL NEW DRUG APPLICATION FOR OUR MOST ADVANCED PRECLINICAL COMPOUND, PPI-2458.



WE HAVE **BUILT OUR FINANCIAL RESOURCES AND MANAGED OUR OPERATIONS** TO PREPARE US FOR REACHING OUR GOAL OF BECOMING A PRODUCT DRIVEN, COMMERCIAL COMPANY.

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, 2002

or

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

For the transition period from _____ to _____

Commission file number 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. ☒

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☒ No ☐

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 June 28, 2002, was $162,117,195.

The number of shares of common stock, par value $.01 per share, outstanding as of February 28, 2003 was 51,822,475.

Documents Incorporated By Reference

Specified portions of the definitive Proxy Statement with respect to the registrant's 2003 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 Annual 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. We resubmitted our new drug application, or NDA, for Plenaxis to the FDA on February 27, 2003 and expect to receive a response from the FDA regarding our resubmission within six months of that date. In December 2000, we initially submitted the NDA to the FDA seeking marketing approval for Plenaxis for the treatment of hormonally responsive prostate cancer. In June 2001, we received a not-approvable letter from the FDA. Based upon a series of subsequent discussions with the FDA, in our NDA resubmission we are now seeking approval to market Plenaxis in the United States for use in a defined sub-population of advanced prostate cancer patients for whom the use of existing hormonal therapies may not be appropriate. If approved, we intend to market and sell Plenaxis in the United States through our own sales and marketing team. We also intend to submit a registration dossier in Europe during the second quarter of 2003 seeking approval to market Plenaxis for a broad population of hormonally responsive advanced prostate cancer patients.

We are also developing Apan, our drug candidate for the treatment of Alzheimer's disease. 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. Results of our preclinical studies suggest that Apan may be facilitating the clearance of beta-amyloid from the brains of guinea pigs and transgenic mice. We are currently conducting a healthy volunteer, phase Ia dose escalation study of Apan to identify the maximum tolerated dose, or MTD, in healthy volunteers. Assuming favorable FDA review of the study's final results, we intend to move into a phase Ib trial in Alzheimer's disease patients during the first half of 2003. This Ib study will test a single administration of Apan to establish the MTD in patients. Upon completion of the phase Ib study, and assuming favorable FDA review of the study's results, we expect to initiate a phase Ic trial examining multiple administrations of a selected Apan dose in Alzheimer's disease patients.

In addition to our Plenaxis prostate cancer program, 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 of treatment or remain untreated, and that Plenaxis could fulfill a significant unmet need. We completed a phase II study of Plenaxis for the treatment of pain associated with endometriosis in March 2002. Results from this study indicated that we may be able to utilize a lower dose and/or a more prolonged dosing interval in future studies to reduce drug exposure and attendant bone mineral density loss, a known consequence of hormonal therapies that lower estrogen levels. Accordingly, during 2002, we conducted a pharmacokinetic study of Plenaxis for the treatment of endometriosis to examine the appropriate dose and dosing schedule. Upon completion of our review of the results of this study, we will determine the next steps for development.

In addition to our clinical programs, we have numerous programs in the research or preclinical development stage. We intend to file, by mid-year 2003, an investigational new drug application, or IND, for our most advanced preclinical compound, PPI-2458. Assuming favorable FDA review of our IND, we plan initially to conduct clinical trials to study the effectiveness of this compound in the treatment of B-Cell Non-Hodgkin's lymphoma. We also plan to continue preclinical studies of PPI-2458 in other potential indications, including rheumatoid arthritis.

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 efficiently develop 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. We have pending patent applications that cover the essential steps of the LEAP process.

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 patents that cover 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.

PRAECIS™, Plenaxis™, Apan™, LEAP™, Rel-Ease™ and MASTRscreen™ are trademarks or trade names of our company. This Annual Report on Form 10-K also contains trademarks, trade names and service marks of other companies, including but not limited to Casodex®, Lupron Depot® and Zoladex®, all of which are the property of their respective owners.

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 continually evaluate in early research potential candidates for development and are currently focusing our discovery efforts on opportunities in the areas of oncology, inflammation and infectious diseases.

We have outlined our clinical programs and four of our more advanced 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 Resubmitted Q1 2003
Plenaxis	Endometriosis	Phase II
Apan	Alzheimer's Disease	Phase I
PPI-2458	B-Cell Non-Hodgkin's Lymphoma	Preclinical
Androgen Receptor Antagonist	Hormone-Independent Prostate Cancer	Research/Preclinical
Endometriosis Diagnostic	Endometriosis	Research/Preclinical
Antiviral Antagonist	AIDS	Research/Preclinical

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 level of LH causes 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 hormone levels occurs. Due to this surge, current LHRH agonists, such as Lupron Depot, marketed by TAP Pharmaceutical Products Inc., and Zoladex, marketed by AstraZeneca Pharmaceuticals L.P., have precautionary labeling about the hormone-induced flare. The FDA mandates precautionary labeling when appropriate, and the drug labels and packaging for these currently available drugs prominently include 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 clinical program is the development of Plenaxis for the treatment of hormonally responsive advanced prostate cancer. We are also studying Plenaxis for the treatment of endometriosis. In addition, a small, investigator-sponsored clinical study was conducted in which the effects of using Plenaxis to treat hormone refractory prostate cancer were evaluated. We have not begun clinical studies of Plenaxis 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 220,900 new diagnoses of, and 28,900 deaths from, prostate cancer will occur in the United States in 2003. The prostate is a small, walnut-shaped gland located at the base of the male bladder. Prostate cancer cells require hormones, specifically testosterone and its derivatives, for growth. These hormones stimulate the growth of the cancerous cells. The primary goal of treatment is to reduce testosterone to low, or castrate, levels, leading to inhibition of prostate cancer cell growth. Available treatments for prostate cancer patients include hormonal therapies, radiation therapy and surgery. For more advanced, symptomatic patients, for whom the use of existing hormonal therapies may not be appropriate, removal of the testes, known as surgical castration, is often the only treatment alternative.

As discussed above, currently available LHRH agonists induce an initial surge in testosterone. This surge of testosterone may last as long as three weeks before the intended medical effect of reduced testosterone levels takes place. In an attempt to mitigate the potential disease worsening, or flare, that can result from this testosterone surge, 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 diarrhea.

Moreover, some patients with advanced, symptomatic prostate cancer are at higher risk of serious harm resulting from the testosterone surge associated with LHRH agonists. 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. Due to the perceived risks associated with the use of LHRH agonists in these cases, whether alone or in combination with anti-androgens, many advanced, symptomatic prostate cancer patients may be confronted with the option of surgical castration as a potential therapy, both to rapidly reduce testosterone levels and avoid the testosterone surge.

To date, we have focused on the development of Plenaxis as a treatment for hormonally responsive advanced prostate cancer, and are currently seeking approval from the FDA to market Plenaxis in the United States specifically for the treatment of a defined sub-population of advanced prostate cancer patients for whom the use of existing hormonal therapies may not be appropriate. Plenaxis is a proprietary, 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 safety and efficacy 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. In addition, based upon the results of our clinical study in advanced, symptomatic patients, we believe that Plenaxis has the potential to provide a non-surgical alternative to castration for these patients.

Prostate Cancer—Regulatory 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, an open-label study in advanced, symptomatic prostate cancer patients, as well as 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 discussions with the FDA following receipt of the not-approvable letter, the FDA recommended that we analyze the immediate-onset, systemic 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, fluctuations in testosterone levels were observed more frequently in patients treated with Plenaxis than in patients treated with either Lupron Depot or Lupron Depot plus Casodex.

Since learning of these issues, we have proposed various alternatives to the FDA to address them and improve the risk/benefit profile of Plenaxis. Based upon additional discussions with the FDA, we now are seeking approval for Plenaxis for use in a defined sub-population of advanced prostate cancer patients for whom the use of existing hormonal therapies may not be appropriate. The specific sub-population of patients will be determined through additional discussions with the FDA. We resubmitted our NDA on February 27, 2003 seeking approval for this indication and expect to receive a response from the FDA regarding our resubmission within six months of that date. We cannot assure investors that the information included in our NDA resubmission will satisfy FDA concerns that have been or may be raised or that we will be successful in obtaining approval for the commercialization of Plenaxis in the United States for the treatment of a defined sub-population of advanced prostate cancer patients or for any other indication.

We also intend to seek marketing approval for Plenaxis outside of the United States. During 2002, we met with various European experts and, following these meetings, we announced our intention to pursue regulatory approval to market Plenaxis in Europe for a broad population of hormonally responsive advanced prostate cancer patients. We intend to pursue a mutual recognition filing in Europe and have been meeting with potential sponsor countries' regulatory authorities. We expect to make a decision on the country of filing and to submit our registration dossier during the second quarter of 2003. We cannot assure investors that we will be successful in obtaining regulatory approval to market Plenaxis in Europe.

Prostate Cancer Clinical Studies. In support of our initial NDA filing in December 2000, we 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, none 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 plus Casodex. Further, Plenaxis suppressed testosterone levels more rapidly, achieving castration by day eight in 70% of patients compared to none 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, fluctuations in testosterone above castrate levels occurred more frequently than they did in patients treated with either Lupron Depot or Lupron Depot plus Casodex. As stated above, the FDA raised concerns with these results in their response to our initial NDA filing. We have proposed to the FDA that testosterone levels could be monitored by physicians after six months of treatment with Plenaxis as a means of addressing these fluctuations.

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 an open-label clinical trial to evaluate the use of Plenaxis in patients with advanced, symptomatic prostate cancer. This study was completed in September 2000. We submitted preliminary results from this study to the FDA as part of our initial NDA filing. In February 2003, we included as part of our NDA resubmission additional, more detailed analyses of the data from this study to support approval of Plenaxis for the treatment of a defined sub-population of advanced prostate cancer patients for whom the use of existing hormonal therapies may not be appropriate. In this trial, Plenaxis was administered to 72 patients with advanced, symptomatic prostate cancer, defined as the presence of one or more of the following: bone pain from prostate cancer skeletal metastases, ureteral obstruction, impending spinal cord compression, or bladder neck outlet obstruction. Following enrollment and initial evaluation, it was determined that over half of the patients suffered from more than one sign or symptom of advanced prostate cancer. Patients received a 100 mg dose of Plenaxis every four weeks for 24 weeks, with one additional dose administered on day 15. The primary endpoint was the avoidance of surgical castration at four and 12 weeks. This endpoint was selected because these patients, if treated with currently available hormonal therapies, could be required to undergo immediate surgical castration due to disease worsening caused by the testosterone surge associated with those therapies. The primary endpoint was met by 100% of the patients. In addition, no patient required surgical castration during follow-up in another study. These studies had a cumulative duration of 40 weeks and lasted as long as 159 weeks.

The trial also had several secondary endpoints, which included the clinical assessment of improvement in bone pain from prostate cancer skeletal metastases. A subset analysis was performed on those patients with bone pain requiring narcotic analgesic use. Within the first day of treatment with Plenaxis, the median pain score in these patients was reduced from 6.8 to 5.3 on a scale of 0 (no pain) to 10 (worst pain imaginable), and by week one, the median pain score was reduced to 4.4. At week 24, the median pain score was less than 1. In addition, at week 24, 64% of the patients suffering from bone pain had a reduction in the frequency, dose and/or potency of narcotic analgesic use, while the remainder reported no change or an increased need.

A clinical assessment was also made of improvement of urinary symptoms in patients at risk for developing urinary retention. This assessment was based upon several measures, including the patient's American Urological Association, or AUA, Symptom Score and Post Void Residual, or PVR, urine

volume. During the first month of treatment, the majority of at-risk patients showed improvements in their symptoms of urinary obstruction demonstrated by decreased AUA scores and PVR urine volume.

Patients with metastatic prostate cancer were also evaluated for anti-cancer disease response. Disease response in these patients was determined by radiographic and serological parameters, and was measured in accordance with modified National Prostate Cancer Project standards. The results of this evaluation showed that a significant portion, at least 75% of these patients at 12 and 24 weeks, achieved an "overall objective response," classified as either "complete response," "partial response" or "stable disease."

Overall, 90% of the patients studied experienced improvement of one or more of the symptoms associated with their advanced prostate cancer. Due to the advanced stage of disease in the patients enrolled, ten patients developed progressive disease and six patients died during this study.

Our former European collaborator also conducted a one-to-one randomized, open label, multicenter phase III clinical study of 177 patients in Europe comparing the safety and efficacy of Plenaxis to the combination of Zoladex plus Casodex. Available safety data from this study was submitted to the FDA as part of our original NDA submission. We have now received from our former European corporate collaborator the efficacy data from this study, together with additional safety data. The study included a 48-week primary treatment period, followed by an extension of up to 96 weeks. Our study report from the primary study was included as part of our NDA resubmission. We intend to submit to the FDA a report on the extension as soon as it is available.

The primary endpoint of the European study was time to induction of medical castration during the first 12 weeks of treatment. The results demonstrated that the median time to medical castration was significantly shorter for patients treated with Plenaxis (seven days), compared to patients treated with Zoladex plus Casodex (21 days).

The European study also had several secondary endpoints, including the measurement, in a subset of patients, of castration rates at day three. Castration rates at day three were 36% for Plenaxis patients, compared to zero percent for Zoladex plus Casodex patients. In addition, in a subset of patients, avoidance of testosterone surge was evaluated. Testosterone surge was defined as a 10% increase above baseline levels on days one and/or three. In the group evaluated, no patient treated with Plenaxis experienced a testosterone surge. In contrast, 96% of the patients treated with Zoladex plus Casodex experienced a surge.

Another secondary endpoint of the study was maintenance of medical castration. In patients who were castrate by day 84, testosterone fluctuations above castrate levels, defined as greater than 50 ng/dL, were observed more frequently in patients treated with Plenaxis (22%) than in patients in the comparator arm (8%). Most of the fluctuations in both treatment groups occurred on or after day 168. An evaluation was also made of disease progression. The findings indicate that overall disease progression rates were approximately 9% in both treatment groups through one year of treatment.

Finally, prostate specific antigen, or PSA, levels were also monitored throughout this study. The data indicate that treatment with Plenaxis results in a more rapid reduction in PSA values compared to treatment with Zoladex plus Casodex. PSA values were significantly lower on day seven in Plenaxis treated patients. PSA levels were similar in both groups on days 14 and 21, and both treatment therapies achieved a greater than 90% reduction in PSA values from day 56 through the end of the study.

In general, the overall safety profile of Plenaxis in this study was consistent with other clinical studies of Plenaxis. In contrast to our clinical studies conducted in the United States, this study had, in accordance with European regulatory guidance, prospectively defined patient inclusion, exclusion and withdrawal criteria based upon electrocardiographic, or ECG, parameters. This criteria included an evaluation of the QTc interval, which measures a portion of the electrical impulse conduction in the heart. Results of this evaluation indicate that both Plenaxis alone and the combination of Zoladex plus Casodex were associated with findings of QTc prolongation, although Plenaxis was associated with a

smaller QTc increase from baseline than the comparator arm. QTc prolongations can be associated with irregularities of the heart rhythm, which, in rare cases, can lead to sudden death. There were no serious adverse events reported in connection with the QTc prolongations observed in this study. However, one Plenaxis patient and three Zoladex plus Casodex patients were withdrawn for QTc prolongations. No irregularities in heart rhythm were observed in any of the patients who were withdrawn from the study due to QTc prolongations. We cannot assure investors that the FDA will not request additional information regarding these findings that could further delay the review and potential approval of our resubmitted NDA.

There was also one immediate-onset, systemic allergic reaction observed in the Plenaxis arm of the extension of the European study which was not previously reported and which has been included in our discussion of safety below. The inclusion of this reaction will not materially change the per-injection incidence rate of immediate-onset, systemic allergic reactions previously reported by the Company due to the overall increase in the number of Plenaxis injections administered to date.

As previously disclosed, to address questions raised by the FDA, during 2002 we also conducted an open-label clinical study in which patients were treated with Plenaxis for three months and then switched to a commercially available hormonal therapy for an additional two months of treatment. We included Plenaxis data from this study in our NDA resubmission. As agreed upon with the FDA, we will submit to the FDA a final report containing all of the results from this study as soon as it is available.

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

During the clinical studies described above, in which approximately 1,400 patients were treated with Plenaxis, 17 Plenaxis patients experienced allergic reactions that resulted in the discontinuation of trial participation. We observed a similar incidence 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 17 Plenaxis patients, six patients experienced immediate-onset, systemic allergic reactions, consisting of either a drop in blood pressure or temporary syncope (fainting), within ten minutes 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 onset. At the recommendation of the FDA, we conducted additional analyses of the existing samples from these patients to further understand what the potential cause of these reactions may be. Based upon the results of these analyses and upon additional skin tests and other testing, we have concluded that these reactions are likely anaphylactoid in nature, meaning that they are not caused by an antibody driven response. We have included in our proposed Plenaxis product label submitted to the FDA a black-box warning regarding the risk of immediate-onset, systemic allergic reactions. However, we cannot assure investors that this additional information or the proposed label warning will satisfy the FDA or that the FDA will not continue to raise concerns regarding, or delay or deny approval of our NDA resubmission based on, the incidence of immediate-onset, systemic allergic reactions observed in our clinical trials.

Plenaxis—Endometriosis

Background. We are also 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 tissue, regardless of location in the body, responds 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 occur. 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 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 40 patient, phase I/II study of Plenaxis and a 363 patient, phase II study. 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 study compared the safety and efficacy of various doses of Plenaxis to the standard dose of Lupron Depot for treating endometriosis-associated pain. This randomized, double-blind, active-control study included 363 women with surgically confirmed, moderate to severe endometriosis. Three different doses of Plenaxis (30 mg, 60 mg and 120 mg), administered subcutaneously, were compared to the standard dose of Lupron Depot (3.75 mg), administered intramuscularly. Patients were treated once every four weeks over a 24-week period, receiving a total of six doses of drug. Patients were then followed for 48 weeks post-treatment. The primary endpoint was defined as the achievement of all of the following at four and 24 weeks: improvement of pelvic pain, improvement in pelvic tenderness and elimination of dysmenorrhea, which is painful menstruation.

The percentage of patients treated with Plenaxis at any dose who experienced improvement in endometriosis-associated pain was no different than Lupron Depot at four weeks. At 24 weeks, only patients treated with a 60 mg dose of Plenaxis experienced statistically equivalent relief of endometriosis-associated pain compared to patients treated with Lupron Depot. More patients experienced an elimination of dysmenorrhea at four weeks at all doses of Plenaxis (30 mg: 96%; 60 mg: 96%; 120 mg: 97%) compared to patients treated with Lupron Depot (72%).

In addition to the pre-specified endpoints, estrogen levels were also measured at various time points during the study. The data demonstrated that patients treated with Plenaxis experienced a more rapid reduction in estrogen levels compared to patients treated with Lupron Depot.

Patients appear to have generally tolerated treatment well with Plenaxis in these studies. No treatment-related serious adverse events or immediate-onset, systemic allergic reactions were reported in either study. However, as expected, we observed some adverse reactions in both Plenaxis and Lupron Depot patients, including headache, temporary and reversible irritation at the injection site and temporary and reversible elevation of some liver enzymes. In addition, it is well documented that the use of hormonal therapies that lower estrogen levels results in bone mineral density loss. Analysis of the results of our phase II study indicates that patients treated with Plenaxis experienced more bone mineral density loss than those treated with Lupron Depot, and that this loss was dose-related. We are conducting additional analyses of this data to clarify the extent and magnitude of the bone loss.

In order to better understand the bone mineral density loss, during 2002 we also conducted a pharmacokinetic study of Plenaxis for the treatment of endometriosis to determine the appropriate dose and dosing schedule necessary to maximize the benefit of the therapy for patients while minimizing attendant bone mineral density loss. We have completed the treatment and observation phases of this study and expect to complete our review of the results during the first half of 2003 before deciding upon the next steps for development.

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 may be 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. Studies in transgenic mice that develop human Alzheimer's disease plaques in their brains and in guinea pigs suggest that Apan can facilitate the clearance of beta-amyloid from the brain. Alzheimer's disease, with 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 cerebrospinal 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 may be facilitating the clearance of beta-amyloid from the brain.

In March 2001, we began a phase Ia dose escalation study of Apan in healthy volunteers. In this study, we are evaluating the safety and pharmacokinetics of the compound and identifying a MTD in healthy volunteers. As of mid-February 2003, we had enrolled 76 volunteers in 14 dosing groups. Preliminary observations from CSF taken from ten of these healthy volunteers indicate that Apan can be quantified in the CSF. These preliminary CSF results also indicate that Apan may be promoting clearance from the brain of beta-amyloid. This trend in the early data is consistent with the CSF beta-amyloid results we have seen with Apan in animal models.

Assuming favorable FDA review of the study's final results, we intend to move into a phase Ib trial in Alzheimer's patients during the first half of 2003. This phase Ib study will test a single administration of Apan to establish the MTD in patients. Upon completion of the phase Ib study, and assuming favorable FDA review of the study's results, we expect to initiate a phase Ic trial examining multiple administrations of a selected dose of Apan in Alzheimer's disease patients.

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 anti-proliferative and anti-angiogenic activity. These processes are considered to be of critical importance in the growth of aberrant tissues in diseases such as cancer and rheumatoid arthritis. The dose limiting toxicity associated with fumagillin derivatives have largely prevented the clinical development of these compounds. PPI-2458 was designed to maintain potent activity while at the same time improving the toxicity profile relative to other members of the fumagillin class of compounds.

In recent preclinical studies conducted separately by us and the National Cancer Institute, PPI-2458 demonstrated significant anti-tumor activity against certain types of cancerous cells. Based upon encouraging pre-clinical data, we plan to investigate initially the effectiveness of this compound for the treatment of B-Cell Non-Hodgkin's lymphoma. We intend to file by mid-year 2003 an IND for PPI-2458 for a study in this indication. Information from this initial study, combined with on-going preclinical work, will form the basis for next steps in the development of this compound for the treatment of additional indications.

We are also evaluating through preclinical studies the potential utility of PPI-2458 for treating rheumatoid arthritis. These studies have demonstrated the efficacy of PPI-2458 in rodent models of rheumatoid arthritis, 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 rheumatoid arthritis, there remains a significant unmet medical need. We believe that new drugs which could be used alone or in combination with established DMARDs could be successful in treating rheumatoid arthritis.

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 many 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 and are testing ligands that bind to the AR, 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 presence of unique proteins in the serum of disease sufferers. Using the proteomics component of our LEAP technology, we are seeking to identify proteins whose abundance in serum can discriminate between diseased and non-diseased individuals. These proteins could prove useful to diagnose individuals with the disease, as well as enhance understanding of the disease process.

Antiviral Antagonist

Various studies by others have identified groups of individuals who are resistant to HIV infection despite multiple exposures to the 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. Through our collaboration with Human Genome Sciences, we have licensed certain rights to CCR5 as a disease target. We have been using our LEAP technology to search for ligands against CCR5 that may act as inhibitors of HIV entry, but have not yet identified a lead candidate. We are currently preparing a report for review by Human Genome Sciences summarizing the results of our research to date. Following delivery of the report, we intend to meet with Human Genome Sciences to discuss whether further development efforts should be pursued under the collaboration agreement.

We have also independently initiated a separate research program to discover peptide ligands to disrupt the interaction between CCR5 and the HIV protein, gp120. Disruption in the interaction of these proteins by antibodies results in the blockade of HIV entry into cells. We are investigating novel peptide structures that target gp120 and possess antiviral activity. In addition, we have independently expanded our research to include other potential antiviral targets and compounds.

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 millions of molecules in a few months. By contrast, conventional screening and medicinal chemistry permit 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. We have pending patent applications in the United States and abroad that cover the essential steps of the LEAP process.

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 may explore in the future the potential use of our Rel-Ease technology to create improved formulations and sustained release formulations of approved drugs. We hold patents that cover the general application of this technology for a broad range of peptide-based 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. We have pending patent applications in the United States and abroad that cover the essential steps of the MASTRscreen process.

Research and Development

As of December 31, 2002, we had a total of 110 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 $85.9 million in 2000, $59.4 in 2001 and $56.4 in 2002 on research and development activities.

Corporate Collaborations

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. One of these targets has been identified as CCR5, a human protein the HIV virus uses to enter human cells. Under the agreement, we have been using LEAP to attempt to identify drug candidates targeted to these molecules. If we discover a lead clinical drug candidate, we will jointly develop it 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 which case other terms contained in the agreement will apply. 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. With respect to the CCR5 target, we are currently preparing a report for review by Human Genome Sciences summarizing the results of our research to date. Following delivery of the report, we intend to meet with Human Genome Sciences to discuss whether further development efforts should be pursued under the collaboration agreement.

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. In August 2002, we and Amgen entered into a termination agreement with respect to the termination by Amgen of the license agreement. Under the terms of the termination agreement, we paid to Amgen $13.0 million in full and complete satisfaction of all amounts payable under the license agreement and in consideration of the transfer from Amgen to us of title to, and possession of, any existing materials inventory.

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. In December 2002, we and Sanofi-Synthélabo entered into a termination agreement with respect to the termination by Sanofi-Synthélabo of the license agreement.

Technology License

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, 2002, 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, currently 2015. 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. We have long-term contracts for each stage of the manufacturing process for our lead drug candidate, Plenaxis.

We have a development and supply agreement with UCB S.A. under which UCB will supply us with commercial volumes of the Plenaxis drug compound. As of December 31, 2002, we were committed to purchase from UCB approximately $4.4 million of pharmaceutical grade peptide during 2003. This amount represents the outstanding balance of our purchase commitment under the UCB agreement.

We also have a supply agreement with Cambrex Charles City, Inc., formerly Salsbury Chemicals, Inc. Under this supply agreement, Cambrex has agreed to manufacture for us the commercial depot formulations of Plenaxis. We contributed approximately $6.0 million toward Cambrex's construction and outfitting of a dedicated manufacturing facility, to which we will retain manufacturing process rights. During 2002, we paid Cambrex approximately $634,000 toward minimum purchase commitments and facility maintenance. We expect to provide Cambrex with a comparable level of support during 2003.

In December 2002, we entered into a commercial supply agreement with Baxter Pharmaceutical Solutions LLC to provide for the supply of Plenaxis products in finished vials. Under the terms of the Baxter agreement, we are required to purchase a minimum of $375,000 of product from Baxter each calendar year until the first anniversary of the first commercial shipment of Plenaxis, at which time the minimum annual purchase commitment will be adjusted to $650,000. Under our former collaboration agreement with Amgen, Amgen had been performing this stage of the manufacturing process. As a new manufacturer, Baxter may need to undergo a regulatory pre-approval inspection in connection with the FDA's review of our NDA resubmission for Plenaxis, which, if major issues are identified, could be costly and could delay the FDA's review of our resubmission.

In order to meet potential increases in demand in connection with the possible commercial launch of Plenaxis for the treatment of a defined sub-population of advanced prostate cancer patients, we intend to evaluate the need for a second source for each stage of Plenaxis production. However, 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 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, commercialization and sale of Plenaxis products without substantial and costly delays.

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 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 hold 18 United States patents and exclusive licenses to three United States patents. These patents have expiration dates from 2012 through 2016. In addition, we have filed or hold exclusive licenses to 32 United States utility and provisional patent applications, as well as 171 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, consultants and scientific collaborators to execute confidentiality and invention assignment agreements with us to maintain the confidentiality of our trade secrets and proprietary information. These 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, consultancy or collaboration 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. Many of these companies have greater financial resources and more experience than we do in developing drugs, obtaining regulatory approvals, manufacturing and marketing. 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, Zoladex 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 Serono, Inc., and Antagon®, manufactured by Organon, Inc., which are approved GnRH antagonists for use in infertility that are only available as daily injectable formulations.

We are also aware of another GnRH antagonist, Degarelix, being developed by Ferring Pharmaceuticals, which is in late-stage clinical trials for the treatment of prostate cancer. In addition, 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 Corporation 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 2002, Atrix received FDA approval for its one- and three-month depot formulations 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 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. Generally, 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. Due to the termination of our collaboration agreement with Sanofi-Synthélabo, we are relying primarily on third party contractors to assist us with the preparation and submission of our European regulatory filings for Plenaxis for the treatment of hormonally responsive advanced prostate cancer. However, although we have sought qualified experience and assistance in dealing with the foreign regulatory processes and interacting with foreign regulatory authorities, we can not assure investors 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 Plenaxis or any of our other product candidates 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 Plenaxis or any other product candidates 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, 2003, we had 147 full-time employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and potential commercialization 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.

Available Information

We maintain a website with the address www.praecis.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission.

ITEM 2. PROPERTIES.

Our corporate headquarters and principal research facility is 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. In connection with the acquisition of our corporate headquarters and principal research facility, our subsidiary granted a security interest in the facility, together with all fixtures, equipment, improvements and related items, as more fully discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" appearing elsewhere in this report.

We believe that our facility 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, 2002.

PART II

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

Our common stock is traded on The Nasdaq National Market under the symbol "PRCS." 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, 2002:		
First Quarter	$ 5.94	$ 4.24
Second Quarter	5.80	2.71
Third Quarter	3.93	2.60
Fourth Quarter	3.54	2.20
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

As of February 28, 2003, there were approximately 145 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 our 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.

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, 2002, and our balance sheet data at December 31, 2001 and 2002, 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, 1998 and 1999 and the balance sheet data at December 31, 1998, 1999 and 2000 from our audited financial statements, which we do not include in this report.

	Year Ended December 31,				
	1998	1999	2000	2001	2002
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Corporate collaborations	$37,624	$61,514	$ 61,189	$ 9,907	$ 1,029
Contract services	1,943	—	—	—	—
Total revenues	39,567	61,514	61,189	9,907	1,029
Costs and expenses:					
Research and development	33,704	48,764	85,915	59,416	56,383
Sales and marketing	—	2,601	6,444	8,737	1,837
General and administrative	3,605	3,572	5,285	6,961	9,676
Total costs and expenses	37,309	54,937	97,644	75,114	67,896
Operating income (loss)	2,258	6,577	(36,455)	(65,207)	(66,867)
Gain on assignment of leasehold improvements	—	—	—	1,499	—
Gain on termination of collaboration agreement	—	—	—	—	16,020
Interest income, net	3,516	4,473	7,819	9,105	4,772
Income (loss) before income taxes	5,774	11,050	(28,636)	(54,603)	(46,075)
Provision for income taxes	100	1,800	100	—	—
Net income (loss)	$ 5,674	$ 9,250	$(28,736)	$(54,603)	$(46,075)
Net income (loss) per share:					
Basic	$ 0.99	$ 1.51	$ (0.95)	$ (1.10)	$ (0.89)
Diluted	$ 0.16	$ 0.24	$ (0.95)	$ (1.10)	$ (0.89)
Weighted average number of common shares:					
Basic	5,738	6,106	30,259	49,777	51,678
Diluted	35,139	37,849	30,259	49,777	51,678
Pro forma net loss per share:					
Basic and diluted			$ (0.74)		
Pro forma weighted average number of common shares:					
Basic and diluted			38,794		

	December 31,				
	1998	1999	2000	2001	2002
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$85,298	$ 94,525	$132,207	$266,216	$195,035
Working capital	76,626	86,220	115,733	229,028	185,523
Total assets	90,625	140,331	195,571	342,125	268,250
Long-term debt	—	—	24,000	33,000	33,000
Capital lease obligations, net of current portion	59	—	—	—	—
Total stockholders' equity	78,373	87,716	146,531	270,696	224,890

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 certain hormone levels. We are developing Plenaxis for the treatment of hormonally responsive advanced prostate cancer and endometriosis.

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.

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 notified us 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 2002, we entered into an agreement relating to the termination of these collaborations with each of Amgen and Sanofi-Synthélabo.

Since our inception, we have had no revenues from product sales. Prior to 2002, a significant portion of our revenues was received under collaboration agreements through which we converted the potential value underlying our Plenaxis program into a stream of upfront, milestone and expense reimbursement payments from corporate collaborators. In 2001, we regained full ownership of our Plenaxis program from our corporate collaborators and, as a result, our revenues decreased substantially. We do not anticipate receiving any additional revenues under former collaboration agreements. Substantially all of our expenditures to date have been for drug development and commercialization activities and for general and administrative expenses.

Our accumulated deficit as of December 31, 2002 was approximately $130.5 million.

At December 31, 2002, we had 139 full-time employees, 110 of whom were engaged in research and development activities, compared to 127 full-time employees at December 31, 2001, 99 of whom were engaged in research and development activities.

Due to the costs associated with the continued development and potential commercialization of Plenaxis for the treatment of a defined sub-population of advanced prostate cancer patients, as well as other research and development and general and administrative expenses, and our lack of revenues, we had a net operating loss for the year ended December 31, 2002. We expect to have net operating losses for the next several years. We do not expect to generate operating income unless we receive FDA approval to market Plenaxis in the United States for the treatment of a defined sub-population of advanced prostate cancer patients. Assuming that we receive FDA approval by the end of 2003, and that we are able to partner clinical programs at opportune times, we believe that we will begin to generate operating income by 2006.

The termination of our collaboration agreement with Sanofi-Synthélabo became effective as of December 31, 2001 and we received a final reimbursement payment of approximately $1.0 million during the second quarter of 2002. Including this payment, we recognized a total of approximately $24.7 million in non-refundable fees and performance-based payments, and a total of approximately $11.7 million in reimbursement for ongoing development costs under this agreement.

The termination of our collaboration agreement with Amgen became effective as of December 17, 2001. 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 were required to reimburse Amgen for one-half of the costs associated with establishing a sales and marketing infrastructure for Plenaxis products in the United States. Through December 31, 2001, we recognized an aggregate of approximately $121.7 million of revenues under the Amgen agreement. During 2002, we recognized no additional revenues under this agreement.

On August 19, 2002, we executed a termination agreement with Amgen. In accordance with this agreement, we made a final payment to Amgen of $13.0 million. This payment represented full and complete satisfaction of our share of the expenses incurred under the collaboration agreement, as well as consideration for the receipt from Amgen of full title to, and possession of, all materials inventory purchased during the term of the collaboration.

Prior to signing the termination agreement with Amgen, we had provided a $29.1 million accrual representing previously incurred collaboration expenses, our share of purchased materials inventory, and certain other costs associated with finalizing the termination. As a result of our payment of $13.0 million plus certain related legal fees in connection with the termination agreement, we eliminated our accrued liability related to the Amgen agreement and recognized a gain on termination of $16.0 million.

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:

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. The actual payments, and thus our actual results, could differ from our estimates.

Impairment or Disposal of Long-Lived Assets. Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS No. 144, requires that if the sum of the undiscounted future cash flows expected to result from a company's asset, net of interest charges, is less than the reported value of the asset, an asset impairment must be recognized in the financial statements. We evaluate our property, plant and equipment for impairment whenever

indicators of impairment exist. The amount of the impairment to be recognized is calculated by subtracting the fair value of the asset from the reported value of the asset.

We believe that the application of SFAS No. 144 and the method used to determine the impairment of our property, plant and equipment involve critical accounting estimates because they are highly susceptible to change from period to period and because they require management to make assumptions about future cash flows, including residual values. In addition, we believe that had alternative assumptions been used the impact of recognizing an impairment on the assets reported on our balance sheet, as well as our net loss, may have been material.

We reviewed our building for impairment as of December 31, 2002. We have determined that the undiscounted sum of the expected future cash flows from the building exceeded the recorded value of the building. As a result, no impairment allowance was required in accordance with SFAS No. 144.

Management has discussed the development, selection and disclosure of these critical accounting policies with the audit committee of our board of directors.

Results of Operations

Years Ended December 31, 2002 and 2001

Revenues for the year ended December 31, 2002 decreased to approximately $1.0 million, from approximately $9.9 million in 2001. The decrease in revenues was the result of the termination during the fourth quarter of 2001 of our collaboration agreements with Amgen and Sanofi-Synthélabo. During 2001 our revenues were comprised principally of reimbursement revenues under these agreements. During 2002 our revenues were comprised of a final reimbursement payment received in connection with the termination of our agreement with Sanofi-Synthélabo. We will not receive any additional revenues under these agreements. Furthermore, if the FDA does not grant marketing approval for Plenaxis in the United States, or if approval is substantially delayed, such denial or delay is likely to have a materially adverse impact on our future planned revenues.

Research and development expenses for the year ended December 31, 2002 decreased 5% to approximately $56.4 million, from approximately $59.4 million in 2001. The slight decrease in expenses primarily reflects slightly reduced spending in our Plenaxis prostate cancer clinical program and, to a lesser extent, the lack of spending on our clinical program for Latranal, an in-licensed compound that was in development for the treatment of musculoskeletal pain. Development of Latranal was discontinued during the third quarter of 2001. These decreases were partially offset by increased spending on preclinical studies related to our experimental drug candidate PPI-2458. We are unable to predict the precise level of spending on individual clinical programs due to the uncertain nature of clinical development. However, as a result of the resubmission of our NDA during February 2003, we plan to reduce our spending on the clinical development of Plenaxis for the treatment of hormonally responsive advanced prostate cancer during 2003 and thereafter. We also expect spending on our endometriosis program to decline during 2003 pending decisions regarding further development. We plan to increase our development efforts on Apan and future clinical programs during 2003 and thereafter and, accordingly, will increase our spending in these areas. Overall, we expect our research and development expenses to decrease during 2003 and then increase thereafter. In addition, 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.

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 specifically identify all costs related to each of our research and development programs. We estimate that during 2002 and 2001, the majority of our research and development expenses were related to manufacturing costs, clinical trial costs, salaries and lab supplies related to our prostate cancer and endometriosis clinical programs. The remaining research and development costs were incurred primarily in our Alzheimer's disease clinical program, our PPI-2458 preclinical research program and our other 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 prostate cancer. However, the FDA raised concerns over the occurrence of immediate-onset, systemic allergic reactions 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, fluctuations in testosterone levels were observed more frequently in patients treated with Plenaxis than in patients treated with either Lupron Depot or Lupron Depot plus Casodex. We have proposed various alternatives to the FDA to address these issues and improve the risk/benefit profile of Plenaxis. Based upon our discussions with the FDA, we now are seeking approval for Plenaxis for use in a defined sub-population of advanced prostate cancer patients for whom the use of existing hormonal therapies may not be appropriate. The specific sub-population of patients will be determined through additional discussions with the FDA. We resubmitted our NDA on February 27, 2003 seeking approval for this indication and expect a response from the FDA within six months of that date. We also intend to file, during the second quarter of 2003, a registration dossier in Europe seeking approval to market Plenaxis for the treatment of a broad population of hormonally responsive advanced prostate cancer patients. However, we cannot assure investors that we will be successful in obtaining approval in the United States or abroad for the commercialization of Plenaxis for the treatment of any portion of the hormonally responsive advanced prostate cancer patient population or for any other indication.

In 1998, we began our clinical program to develop Plenaxis for the treatment of endometriosis. We completed a phase II study of Plenaxis for the treatment of pain associated with endometriosis in March 2002. Results from this study have suggested that we may be able to utilize a lower dose and/or a more prolonged dosing interval in future studies to reduce drug exposure and attendant bone mineral density loss, a known consequence of hormonal therapies that lower estrogen levels. Accordingly, during 2002, we initiated and completed both the dosing and observation phases of a pharmacokinetic study of Plenaxis for the treatment of endometriosis to examine the appropriate dose and dosing schedule. Upon completion of our review of the results of this study, we will determine the next steps for development.

We began our clinical program for Apan in 2000. We are currently conducting a normal volunteer, phase Ia dose escalation study of Apan to identify the MTD in healthy volunteers. Assuming favorable FDA review of the study's results, we intend to move into a phase Ib trial in Alzheimer's disease patients during the first half of 2003. This Ib study will test a single administration of Apan to establish the MTD in patients. Upon completion of the phase Ib study and, assuming favorable FDA review of the study's results, we expect to initiate a phase Ic trial examining multiple administrations of a selected Apan dose in Alzheimer's disease patients.

Sales and marketing expenses for the year ended December 31, 2002 decreased 79% to approximately $1.8 million, from approximately $8.7 million in 2001. During 2001, we incurred increased sales and marketing expenses in preparation for the potential launch of Plenaxis for the treatment of hormonally responsive advanced prostate cancer. The subsequent decrease in sales and marketing expenses was due to the temporary suspension of the majority of marketing efforts resulting from the repositioning of our prostate cancer program in response to issues raised by the FDA. These expenses are likely to increase during 2003 and thereafter as we again incur costs related to preparing for the possible launch of Plenaxis for the treatment of a defined sub-population of advanced prostate cancer patients. We intend, upon FDA approval of our application, to market and sell Plenaxis in the United States through our own marketing and sales team. Accordingly, assuming FDA approval of

Plenaxis, we expect our sales and marketing expenses to increase during 2003 and thereafter, and to include expenses relating to the building of a marketing infrastructure, the cost of our sales force, commissions to the sales force on Plenaxis sales and promotional and marketing programs.

General and administrative expenses for the year ended December 31, 2002 increased 39% to approximately $9.7 million, from approximately $7.0 million in 2001. This increase was due primarily to higher facility-related expenses. In May 2001, we occupied our new, larger facility and began incurring depreciation expense and increased utilities, maintenance and tax expenses. In addition, higher personnel-related operating costs and increased professional services expenses contributed to the increase in general and administrative expenses. General and administrative expenses for 2002 and going forward now fully reflect these new facility-related expenses. We expect that general and administrative expenses will increase slightly during 2003 and thereafter based on normal hiring of additional administrative personnel to support continued growth of our research, development and commercialization initiatives.

Net interest income for the year ended December 31, 2002 decreased 48% to approximately $4.8 million, from approximately $9.1 million in 2001. The decrease in net interest income was due primarily to lower average cash balances and reduced average interest rates.

The provision for income taxes for the years ended December 31, 2002 and 2001 was zero. We anticipate that we will continue to be in a net operating loss carryforward position for the next several years. Therefore, as in 2001, 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, 2002 and 2001, have been established in each period to reflect these uncertainties.

At December 31, 2002, we had federal net operating loss carryforwards of $129.0 million that will expire in varying amounts through 2022, 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, 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.

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.

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.

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.

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 during 2001 under the loan agreement entered into in connection with the purchase in July 2000 of our corporate headquarters and primary research facility.

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 were in a net operating loss carryforward position during 2001 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, 2002. 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, 2001	June 30, 2001	Sept. 30, 2001	Dec. 31, 2001	Mar. 31, 2002	June 30, 2002	Sept. 30, 2002(1)	Dec. 31, 2002
	(in thousands, except per share data)							
Total revenues	$ 2,582	$ 3,167	$ 2,479	$ 1,679	$ —	$ 1,029	$ —	$ —
Operating loss	(14,321)	(16,000)	(24,052)	(10,834)	(13,890)	(15,506)	(22,585)	(14,886)
Net loss	(11,847)	(12,997)	(22,217)	(7,542)	(12,686)	(14,215)	(5,568)	(13,606)
Basic and diluted net loss per share	$ (0.26)	$ (0.26)	$ (0.44)	$ (0.15)	$ (0.25)	$ (0.27)	$ (0.11)	$ (0.26)

(1) In August 2002, we executed a termination agreement with Amgen and recognized a gain on termination of $16.0 million.

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

To date, our operations and capital requirements have been financed primarily with the proceeds of public and private sales of common stock and preferred stock, research and development partnerships, collaborative agreements and investment income.

At December 31, 2002, we had cash, cash equivalents and marketable securities of approximately $195.0 million and working capital of approximately $185.5 million, compared to approximately $266.2 million and $229.0 million, respectively, at December 31, 2001. During 2003, we expect to use approximately $75.0 million of our current cash and investments in our business. We believe that our existing cash and investments will be sufficient to meet our working capital and capital expenditure needs through approximately the end of 2005. Assuming receipt by the end of 2003 of regulatory approval to market Plenaxis in the United States for a defined sub-population of advanced prostate

cancer patients, partnering of clinical programs at opportune times and continued conservative fiscal management, we believe that we should have sufficient financial resources to execute our operating plan and attain profitability by 2006 without returning to the capital markets.

For the year ended December 31, 2002, net cash of approximately $69.9 million was used in operating activities, compared to approximately $31.6 million used in operating activities during 2001. During the year ended December 31, 2002, our use of cash in operations was due principally to our net loss of approximately $46.1 million, and our payment of $13.0 million in connection with the Amgen termination agreement, partially offset by depreciation and amortization. We expect our cash utilization to increase during 2003 as a result of an overall increase in operating expenses as we prepare for the possible commercial launch of Plenaxis in the United States for the treatment of a defined sub-population of advanced prostate cancer patients, continue with clinical trials for Apan, initiate a new clinical program for PPI-2458 and expand our research and development initiatives. The actual amount of these expenditures will depend on numerous factors, including the timing of expenses and the timing and progress of our research, development, marketing and sales efforts.

Net cash used in investing activities of approximately $10.9 million in 2002 consisted of purchases of property and equipment of approximately $1.8 million, and net purchases of marketable securities of approximately $9.1 million. This represents a decline in net cash used in investing activities of approximately $132.3 million from 2001. Net cash used in investing activities in 2001 consisted of the conversion of cash equivalents held at the end of the prior year and the proceeds from our follow-on public offering into instruments with slightly longer maturities, as well as purchases of property and equipment of approximately $23.9 million. Our financing activities for the year ended December 31, 2002 consisted of approximately $1.0 million of proceeds received from the exercise of common stock options. This contrasts with the approximately $187.3 million in net cash provided by financing activities in 2001, primarily attributable to our follow-on public offering.

In July 2000, in connection with the purchase, through our wholly owned real estate subsidiary, of our 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 facility. As of December 31, 2002, $33.0 million was outstanding under the loan agreement. Advances bear interest at a rate equal to the 30-day LIBOR plus 2.0% (3.38% at December 31, 2002). Interest is payable monthly in arrears. Principal is due and payable in full on July 30, 2003, subject to two one-year extension options. We intend to exercise the option to extend the maturity date until July 30, 2004 and believe that we will be able to satisfy the conditions for this extension set forth in the loan agreement. The loan is secured by the 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, we have spent approximately $38.0 million of our own funds in connection with the build-out and occupancy of this facility. We have occupied this facility since May 2001 and, as planned, are actively seeking to sublease a portion of the facility.

In addition to our long-term debt, we have fixed purchase obligations under various supply agreements. As of December 31, 2002, our long-term debt and fixed purchase obligations were as follows:

		Payments Due By Period			
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	After 5 Years
		(in thousands)			
Long-term debt obligations	$33,000	$ —	$33,000	$ —	$ —
Unconditional purchase obligations	6,269	4,769	750	750	—
Total	$39,269	$4,769	$33,750	$750	$ —

At December 31, 2002, we had provided a valuation allowance of $64.1 million for our deferred tax assets. The valuation allowance represents the value of the deferred tax assets. Due to anticipated operating losses in the future, we believe that it is more likely than not that we will not realize the net deferred tax assets in the future and we have provided an appropriate valuation allowance.

Recent Accounting Pronouncements

On October 20, 2001, the Financial Accounting Standards Board issued SFAS No.144. SFAS No. 144 supersedes Statement of Financial Accounting Standards 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 became effective in the first quarter of 2002. The adoption of SFAS No. 144 did not have any effect on the Company's consolidated results of operations in 2002.

In July 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or SFAS No. 146. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)*. The principal difference between SFAS No. 146 and EITF Issue No. 94-3 relates to SFAS No. 146's requirements for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF Issue No. 94-3, a liability for an exit cost as generally defined in EITF Issue No. 94-3 was recognized at the date of an entity's commitment to an exit plan. Therefore, SFAS No. 146 eliminates the definition and requirements for recognition of exit costs in EITF Issue No. 94-3. SFAS No. 146 also establishes that fair value is the objective for initial measurement of the liability. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company does not anticipate the adoption of SFAS No. 146 to have a material impact on its consolidated financial statements.

On December 31, 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, or SFAS No. 148. SFAS No. 148 amends Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, or SFAS No. 123, to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and Accounting Principles Board Opinion No. 28, *Interim Financial Reporting*, or APB No. 28, to include increased pro-forma disclosure of the effects of stock-based employee compensation on the results of operations. SFAS No. 148 became effective for fiscal years ending after December 15, 2002. The Company has elected to continue to account for employee stock-based compensation using the intrinsic value method as described in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and therefore, the adoption of SFAS No. 148 did not have a material impact on the Company's consolidated results of operations in 2002.

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 attain profitability, 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 and the uncertainty regarding regulatory approval for our lead product candidate, Plenaxis, for the foreseeable future, we do not expect to have any revenues, other than interest income. In addition, we expect to continue to spend significant amounts to develop commercial sales and marketing capabilities, continue clinical studies, seek regulatory approval for our existing product candidates and for further build-out of our facility. 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, 2002, we had an accumulated deficit of approximately $130.5 million. We expect that our operating expenses will increase significantly in the near term due primarily to increased expenses related to the continued development and pre-commercialization activities for Plenaxis, resulting in significant operating losses at least through 2005 and possibly thereafter.

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 and foreign regulatory authorities as to, the safety and efficacy of the product. 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. 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, 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 advanced prostate cancer, in which the FDA indicated that the information presented in the NDA was inadequate for approval. The FDA raised concerns over the occurrence of immediate-onset, systemic allergic reactions 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, fluctuations in testosterone levels were observed more frequently in patients treated with Plenaxis than in patients treated with either Lupron Depot or Lupron Depot plus Casodex. We have proposed various alternatives to the FDA to address these issues and improve the risk/benefit profile of Plenaxis. Based upon our discussions with the FDA, we are now seeking approval for Plenaxis for use in a defined sub-population of advanced prostate cancer patients for whom the use of existing hormonal therapies may not be appropriate. The specific sub-population of patients will be determined through additional discussions with the FDA. In February 2003, we resubmitted to the FDA our NDA seeking approval for this indication. We expect to receive a response from the FDA within six months.

The FDA actions described above 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.

The termination by our corporate collaborators of their agreements with us could adversely affect the development and commercialization of Plenaxis.

We depended upon our former corporate collaborators, Amgen and Sanofi-Synthélabo, to provide substantial financial support for the development and commercialization of Plenaxis. We also relied on them to some extent in seeking regulatory approval in the United States and abroad 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. Accordingly, we have had, and will continue for the foreseeable future, to devote funds and other resources to Plenaxis development and commercialization that we had planned would be available from our collaborators. In addition, we have had, and in the future may have, to enter into new arrangements with third parties to support the Plenaxis program. If we encounter unanticipated expenses or delays in the development and commercialization of Plenaxis for a defined sub-population of advanced prostate cancer patients, we may be required to curtail or terminate one or more of our other drug development programs and/or seek additional funding. We cannot assure investors that we would be able to raise such additional funds.

We may be unable to establish marketing and sales capabilities necessary to successfully commercialize Plenaxis or our other 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. We have announced our intention to independently market and sell Plenaxis in the United States if we receive FDA approval of this compound for use in a defined sub-population of advanced prostate cancer patients. Accordingly, we will need to hire a sales force with expertise in pharmaceutical sales. Recruiting and retaining qualified sales personnel will be critical to our success. Competition for skilled personnel is intense, and we cannot assure you that we will be able to attract and retain a sufficient number of qualified individuals to successfully launch Plenaxis or any other potential product. In addition, establishing the expertise necessary to successfully market and sell Plenaxis, or any other product, will require a substantial capital investment. We cannot assure you that we will have the funds necessary to successfully commercialize Plenaxis for the treatment of a defined sub-population of advanced prostate cancer patients 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.

Even if we receive approval for the marketing and sale of Plenaxis or any of our other 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 Plenaxis or any of our other 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 rate at which Plenaxis or our other product candidates are reimbursed by third-party payors, in particular Medicare;
- 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.

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 Plenaxis or any of 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 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 commercialization of our potential products. Any such delays may lower our revenues and delay or prevent our attaining or maintaining profitability.

If the third-party manufacturers upon which we rely fail to meet our needs for clinical or commercial supply, we may be required to supplement our manufacturing capacity by building our own manufacturing facilities. This would require substantial expenditures. Also, we would need to hire and train significant numbers of employees to staff a new facility. If we are required 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.

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 and was itself performing certain 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 were required to enter into a new agreement with a third party manufacturer to provide for the manufacturing functions that Amgen had been performing. Due to the use of a different manufacturer, we may be required 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 a defined sub-population of advanced prostate cancer patients.

The loss or failure of any of our third-party manufacturers could substantially 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, terrorism, acts of God or insolvency or bankruptcy, could result in substantial delays in, or substantially impair our ability to complete, clinical trials and regulatory submissions or reviews, and could delay or impair substantially our sale or continued sale of Plenaxis products. Such delays or impairment, and the associated costs and expenses, may lower our potential revenues and delay or prevent our attaining 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 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.

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 a defined sub-population of advanced prostate cancer patients, the approval is expected to 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 a defined sub-population of advanced prostate cancer patients, we may not become profitable.

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.

Our potential revenues will diminish if we fail to obtain acceptable prices or adequate reimbursement for Plenaxis or our other product candidates 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 Plenaxis or our other product candidates, physicians may not prescribe them. If we are unable to offer physicians comparable or superior financial motivation to use Plenaxis or our other product candidates, 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 Plenaxis or any of our other 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 drugs. 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 Plenaxis or any of our other products.

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 and to attain and maintain profitability.

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 21 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 or other intellectual property rights 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 patents or other intellectual property rights of third parties. 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, we could be required 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 on acceptable terms or at all. 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.

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 the agreements with them regarding the termination of those collaborations also 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 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 this facility. To date, we have not been able to find suitable sub-tenants to occupy this space. If we are unable to find suitable sub-tenants, we will not be able to offset with rental income any of 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 and Chairman of the Board, and William K. Heiden, our President and Chief Operating Officer. 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 will require the addition of new personnel, including management and marketing and sales personnel, and the development of additional expertise by existing management personnel, in particular in the area of product marketing and sales. The inability to retain these personnel or to develop this expertise

could prevent, or result in delays in, the research, development and commercialization of Plenaxis or our other potential products.

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, which may pose health risks. 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 health and safety and environmental laws and regulations is necessary and expensive. Current or future health and safety and 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. 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 a defined sub-population of advanced prostate cancer patients or any of our other product candidates;
- failure or delay by third-party manufacturers in performing their supply obligations or disputes or litigation regarding those obligations;
- our ability to commercialize, directly or with collaborators, our product candidates and the timing of commercialization;
- the success rate of our discovery efforts and clinical trials;
- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights, including 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 than it would be without these provisions.

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

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. We have not entered into any instruments for trading purposes. 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. An immediate hypothetical 100 basis point increase in interest rates would have resulted in an approximate $0.8 million decrease in the fair value of our investments as of December 31, 2002. The same hypothetical increase in interest rates as of December 31, 2001 would have resulted in an approximate $0.7 million decrease in the fair value of our investments. Due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. As of December 31, 2002, approximately 51% of our total portfolio will mature in one year or less, with the remainder maturing in less than three 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 21, 2003. 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 2002," "Aggregated Option Exercises in Last Fiscal Year and Option Values at December 31, 2002," "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 21, 2003. Such information is incorporated herein by reference.

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

Information required by this Item may be found in the sections captioned "Stock Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" 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 21, 2003. 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 21, 2003. Such information is incorporated herein by reference.

ITEM 14. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures.

Our chief executive officer and chief financial officer have evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended) as of a date within 90 days prior to the filing date of this annual report, referred to as the evaluation date. Based on this evaluation, these officers have concluded that, as of the evaluation date, the Company's disclosure controls and procedures are effective in alerting them on a timely basis to material information relating to the Company required to be included in the Company's reports filed or submitted under the Exchange Act.

(b) Changes in Internal Controls.

Since the evaluation date, there have not been any significant changes in the Company's internal controls or in other factors that could significantly affect these controls. There were no significant deficiencies or material weaknesses, and therefore, there were no corrective actions required or undertaken.

ITEM 15. 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 Certifications of the chief executive officer and chief financial officer, which immediately follow 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	Third 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	Rights Agreement between PRAECIS and American Stock Transfer & Trust Company, as Rights Agent (6)
4.4	Form of Certificate of Designations of Series A Junior Participating Preferred Stock (attached as Exhibit A to the Rights Agreement filed as Exhibit 4.3 hereto) (6)
4.5	Form of Rights Certificate (attached as Exhibit B to the Rights Agreement filed as Exhibit 4.3 hereto) (6)
10.1*	Second Amended and Restated 1995 Stock Plan (3)
10.2*	Amendment No. 1 to the Second Amended and Restated 1995 Stock Plan (8)
10.3*	Executive Management Bonus Plan, as amended and restated as of September 12, 2002 (10)
10.4*	Employee Stock Purchase Plan (4)
10.5*	Amendment No. 1 to the Employee Stock Purchase Plan (7)
10.6*	Management Incentive Program
10.7*	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)
10.8*	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)
10.9*	Letter Agreement dated as of May 9, 2002 between PRAECIS and William K. Heiden (9)
10.10*	Promissory Note dated May 16, 2002 executed by William K. Heiden in favor of PRAECIS (9)
10.11*	Letter Agreement dated as of May 9, 2002 between PRAECIS and Malcolm L. Gefter, Ph.D. (9)
10.12*	Letter Agreement dated as of May 9, 2002 between PRAECIS and Kevin F. McLaughlin (9)
10.13*	Letter Agreement dated as of May 9, 2002 between PRAECIS and Marc B. Garnick, M.D. (9)
10.14†	License Agreement effective as of October 17, 1996 by and between PRAECIS and Indiana University Foundation, as amended as of June 3, 1998 (1)

Exhibit No.	Exhibit
10.15†	Supply Agreement dated as of July 23, 1998 by and between PRAECIS and Salsbury Chemicals, Inc. (1)
10.16†	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) (7)
10.17††	Commercial Supply Agreement dated December 4, 2002 and effective as of June 1, 2002 by and between Baxter Pharmaceutical Solutions LLC and PRAECIS
10.18	Termination Agreement dated as of August 19, 2002 by and between PRAECIS and Amgen Inc. (10)
10.19	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)
10.20	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)
10.21	Guaranty of Costs and Completion dated as of July 11, 2000 (3)
10.22	Guaranty of Non-Recourse Exceptions dated as of July 11, 2000 (3)
10.23	Environmental Compliance and Indemnity Agreement dated as of July 11, 2000 executed by 830 Winter Street LLC and PRAECIS (3)
10.24	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)
99.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 filed with the Securities and Exchange Commission on May 8, 2002.

(8) Incorporated by reference to Registration Statement on Form S-8 (Registration No. 333-90734) filed with the Securities and Exchange Commission on June 18, 2002.

(9) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 filed with the Securities and Exchange Commission on August 12, 2002.

(10) Incorporated by reference to Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 filed with the Securities and Exchange Commission on November 13, 2002.

† 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.

On October 25, 2002, we filed a Current Report on Form 8-K to file under Item 5 (Other Events) a copy of our Press Release dated October 25, 2002.

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 19th day of March, 2003.

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 below by the following persons on behalf of the registrant and in the capacities indicated on March 19, 2003.

Signature	Title
/s/ MALCOLM L. GEFTER, PH.D. Malcolm L. Gefter, Ph.D.	Chairman of the Board and Chief Executive Officer (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

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

CERTIFICATIONS

I, Malcolm L. Gefter, certify that:

1. I have reviewed this annual report on Form 10-K of PRAECIS PHARMACEUTICALS INCORPORATED;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 19, 2003

/s/ MALCOLM L. GEFTER

Malcolm L. Gefter
Chief Executive Officer

I, Kevin F. McLaughlin, certify that:

1. I have reviewed this annual report on Form 10-K of PRAECIS PHARMACEUTICALS INCORPORATED;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 19, 2003

/s/ KEVIN F. MCLAUGHLIN

Kevin F. McLaughlin
Chief Financial Officer

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, 2001 and 2002, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of PRAECIS PHARMACEUTICALS INCORPORATED at December 31, 2001 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
January 22, 2003

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

	December 31, 2001	December 31, 2002
Assets		
Current assets:		
Cash and cash equivalents	$144,685	$64,913
Marketable securities	121,531	130,122
Accounts receivable	458	—
Prepaid expenses and other assets	783	848
Total current assets	267,457	195,883
Property and equipment, net	74,200	71,252
Due from officer	—	933
Other assets	468	182
Total assets	$342,125	$268,250
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$30,721	$3,285
Accrued expenses	7,708	7,075
Total current liabilities	38,429	10,360
Long-term debt	33,000	33,000
Commitments and contingencies		
Stockholders' equity:		
Common Stock, $0.01 par value; 200,000,000 shares authorized; 51,116,135 shares in 2001 and 51,801,423 shares in 2002 issued and outstanding	511	518
Additional paid-in capital	353,887	354,676
Accumulated other comprehensive income	730	203
Accumulated deficit	(84,432)	(130,507)
Total stockholders' equity	270,696	224,890
Total liabilities and stockholders' equity	$342,125	$268,250

See accompanying notes.

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

	Year Ended December 31,		
	2000	2001	2002
Corporate collaboration revenue	$ 61,189	$ 9,907	$ 1,029
Costs and expenses:			
Research and development	85,915	59,416	56,383
Sales and marketing	6,444	8,737	1,837
General and administrative	5,285	6,961	9,676
Total costs and expenses	97,644	75,114	67,896
Operating loss	(36,455)	(65,207)	(66,867)
Interest income	8,195	10,503	6,113
Interest expense	(376)	(1,398)	(1,341)
Gain on assignment of leasehold improvements	—	1,499	—
Gain on termination of collaboration agreement	—	—	16,020
Loss before income taxes	(28,636)	(54,603)	(46,075)
Provision for income taxes	100	—	—
Net loss	$(28,736)	$(54,603)	$(46,075)
Net loss per share:			
Basic and diluted	$ (0.95)	$ (1.10)	$ (0.89)
Weighted average number of common shares:			
Basic and diluted	30,259	49,777	51,678
Unaudited pro forma net loss per share:			
Basic and diluted	$ (0.74)		
Unaudited pro forma weighted average number of common shares:			
Basic and diluted	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, 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										
Net loss										
Unrealized loss on marketable securities										
Total comprehensive loss										
Stock compensation										
Issuance of Common Stock										
Balance at December 31, 2002										

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, 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
Net loss					(46,075)	(46,075)
Unrealized loss on marketable securities				(527)		(527)
Total comprehensive loss						(46,602)
Stock compensation			(185)			(185)
Issuance of Common Stock	685,288	7	974			981
Balance at December 31, 2002	51,801,423	$518	$354,676	$ 203	$(130,507)	$224,890

See accompanying notes.

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

	Year Ended December 31,		
	2000	2001	2002
Operating activities:			
Net loss	$(28,736)	$(54,603)	$(46,075)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	4,745	3,500	4,704
Gain on assignment of leasehold improvements	—	(1,499)	—
Gain on termination of collaboration agreement	—	—	(16,020)
Deferred income taxes	5,575	—	—
Stock compensation	1,391	(265)	(185)
Changes in operating assets and liabilities:			
Accounts receivable	7,042	621	458
Refundable income taxes	(4,853)	4,853	—
Unbilled revenues	2,766	1,493	—
Materials inventory	21,100	—	—
Prepaid expenses and other assets	(1,410)	867	221
Due from officer	—	—	(933)
Accounts payable	2,898	17,887	(11,416)
Accrued expenses	283	566	(633)
Deferred revenue	(4,984)	(5,064)	—
Advance payments	(21,100)	—	—
Income taxes payable	(4,672)	—	—
Net cash used in operating activities	(19,955)	(31,644)	(69,879)
Investing activities:			
Purchase of available-for-sale securities	—	(177,110)	(137,220)
Sales and maturities of available-for-sale securities	—	56,309	128,102
Proceeds from disposition of property and equipment	—	1,499	—
Purchase of property and equipment	(52,523)	(23,879)	(1,756)
Net cash used in investing activities	(52,523)	(143,181)	(10,874)
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	1,895	2,464	981
Repurchase of Common Stock	—	(53)	—
Net cash provided by financing activities	110,160	187,303	981
Increase (decrease) in cash and cash equivalents	37,682	12,478	(79,772)
Cash and cash equivalents at beginning of year	94,525	132,207	144,685
Cash and cash equivalents at end of year	$132,207	$144,685	$64,913

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, 2002, the Company's cash, cash equivalents and marketable securities had a maximum maturity of less than three years with an average maturity of approximately five 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.

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

2. Significant Accounting Policies (Continued)

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.

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 remaining life of the building, whichever is shorter
Laboratory and office equipment	3–7 years or term of lease, 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, 2001 and 2002 was approximately $0.8 million, $0.6 million and zero, 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.

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.

2. Significant Accounting Policies (Continued)

Stock-Based Compensation

The Company has elected to follow Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), in accounting for its stock-based employee compensation plans using the intrinsic value method, 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 No. 25, when the exercise price of options granted to employees under these plans equals the market price of the underlying stock on the date of grant, no compensation expense is required.

The reconciliation of net loss and net loss per share, as reported, to pro forma net loss and net loss per share giving effect to employee stock-based compensation accounted for using the fair value accounting method, is as follows:

	Year Ended December 31,		
	2000	2001	2002
		(in thousands)	
Net loss, as reported	$(28,736)	$(54,603)	$(46,075)
Deduct/(add): Stock compensation cost as computed under APB No. 25	1,391	(265)	(185)
Deduct: Stock based employee compensation cost, net of related tax effects, that would have been included in the determination of net loss as reported if the fair value method had been applied to all awards	(6,127)	(7,847)	(10,792)
Pro forma net loss	$(33,472)	$(62,715)	$(57,052)
Diluted net loss per share, as reported	$ (0.95)	$ (1.10)	$ (0.89)
Diluted net loss per share, pro forma	$ (1.11)	$ (1.26)	$ (1.10)

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:

	2000	2001	2002
Risk-free interest rate	6.2%	4.0%	4.0%
Expected life (years)	5	5	6
Volatility	84%	84%	103%

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.

Accounting Pronouncements

On October 20, 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 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 became effective

2. Significant Accounting Policies (Continued)

in the first quarter of 2002. The adoption of SFAS No. 144 did not have any effect on the Company's consolidated results of operations in 2002.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ("SFAS No. 146"). SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)* ("EITF Issue No. 94-3"). The principal difference between SFAS No. 146 and EITF Issue No. 94-3 relates to SFAS No. 146's requirements for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF Issue No. 94-3, a liability for an exit cost as generally defined in EITF Issue No. 94-3 was recognized at the date of an entity's commitment to an exit plan. Therefore, SFAS No. 146 eliminates the definition and requirements for recognition of exit costs in EITF Issue No. 94-3. SFAS No. 146 also establishes that fair value is the objective for initial measurement of the liability. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company does not anticipate the adoption of SFAS No. 146 to have a material impact on its consolidated financial statements.

On December 31, 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure* ("SFAS No. 148"). SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, *Interim Financial Reporting* ("APB No. 28"), to include increased pro-forma disclosure of the effects of stock-based employee compensation on the results of operations. SFAS No. 148 became effective for fiscal years ending after December 15, 2002. The Company has elected to continue to account for employee stock-based compensation using the intrinsic value method as described in APB No. 25 and therefore, the adoption of SFAS No. 148 did not have a material impact on the Company's consolidated results of operations in 2002.

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 Loss Per Share

Basic net loss per share is based on the weighted average number of shares of common stock, par value $.01 per share ("Common Stock") outstanding. For all years presented, diluted net loss per common share is the same as basic net loss per common share as the inclusion of Common Stock equivalents, including the effect of stock options and warrants, would be antidilutive due to the Company's net loss position for all periods presented.

2. Significant Accounting Policies (Continued)

Pro Forma Net Loss Per Share (Unaudited)

Pro forma net 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.

	Year Ended December 31, 2000 (in thousands)
Pro Forma (unaudited):	
Weighted average number of common shares outstanding used in computing basic and diluted net loss per share	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 basic and diluted net loss per share	38,794

3. Marketable Securities

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

	December 31, 2002			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies:				
Due in one year or less	$ 3,089	$ 10	$ —	$ 3,099
Due in one to three years	33,999	140	(2)	34,137
U.S. corporate securities:				
Due in one year or less	31,153	158	(109)	31,202
Due in one to three years	61,678	54	(48)	61,684
Total marketable securities	$129,919	$362	$(159)	$130,122

	December 31, 2001			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies:				
Due in one year or less	$ 37,558	$208	$(101)	$ 37,665
Due in one to three years	52,311	154	(3)	52,462
U.S. corporate securities:				
Due in one year or less	5,250	—	(11)	5,239
Due in one to three years	25,682	483	—	26,165
Total marketable securities	$120,801	$845	$(115)	$121,531

4. Due from Officer

In May 2002, the Company extended a $1.0 million loan to an officer in connection with the officer's acceptance of employment with the Company. The loan is full recourse, uncollateralized, bears no interest and becomes due and payable in May of 2012. Under the terms of the promissory note (the "Note") executed in connection with the loan, 10% of the original loan principal will be forgiven annually on each anniversary date of the Note, provided that the officer remains an employee of the Company. The Company is not responsible for the personal income tax implications related to the forgiveness of this Note. Upon the officer's voluntary termination of employment with the Company, with certain exceptions, and upon termination by the Company of the officer's employment for cause, the Note becomes immediately due and payable.

5. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2001	2002
	(in thousands)	
Building	$56,314	$56,784
Land	10,500	10,500
Laboratory and office equipment	14,312	15,306
Construction in progress	—	292
	81,126	82,882
Less: accumulated depreciation and amortization	6,926	11,630
	$74,200	$71,252

6. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2001	2002
	(in thousands)	
Clinical trial costs	$4,514	$2,644
Other	3,194	4,431
	$7,708	$7,075

7. 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.

7. Stockholders' Equity (Continued)

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.

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 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. On March 14, 2002, the Board of Directors approved an amendment to the Employee Stock Purchase Plan extending the initial two-year term by one additional year. During 2000, 2001 and 2002, the Company issued 9,497, 35,532 and 53,571 shares of Common Stock, respectively, under the Employee Stock Purchase Plan.

7. Stockholders' Equity (Continued)

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 Company's 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 had a five-year term, was exercisable at a price of $12.88 per share and expired on May 13, 2002.

Stock Option Plan

The Second Amended and Restated 1995 Stock Plan, as amended (the "Plan") allows for the granting of incentive and nonqualified options and awards to purchase shares of Common Stock. Incentive options granted to employees under the Plan 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 under the Plan generally vest over the period of service with the Company. On March 14, 2002, the Board of Directors approved the Plan, as amended to increase by 3,000,000 the number of shares of Common Stock reserved for issuance under the Plan. At December 31, 2002, a total of 14,375,000 shares of Common Stock were approved for issuance under the Plan.

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

	2000		2001		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at January 1,	8,212	$3.35	8,235	$6.74	6,659	$8.54
Granted	1,528	22.99	1,087	11.75	1,779	3.30
Exercised	(997)	1.74	(1,209)	1.74	(632)	1.31
Cancelled	(508)	10.70	(1,454)	6.38	(745)	9.07
Options outstanding at December 31,	8,235	$6.74	6,659	$8.54	7,061	$7.82
Options exercisable at December 31,	3,328	$2.55	3,274	$4.73	3,330	$6.70

The weighted average per share fair value of options granted was $16.64 in 2000, $10.05 in 2001 and $2.75 in 2002. At December 31, 2002, there were 9,992,449 shares of Common Stock reserved for the exercise of stock options and for issuances under the Employee Stock Purchase Plan, including 2,869,608 options available for grant under the Plan.

7. Stockholders' Equity (Continued)

The following table presents weighted average price and weighted average remaining contractual life information about significant option groups outstanding at December 31, 2002 (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	1,230	3.6	$ 0.53	921	$ 0.62
$1.61–$6.38	3,845	7.5	$ 4.46	1,584	$ 4.95
$6.39–$16.25	1,015	7.6	$11.58	514	$11.20
$16.26–$42.00	971	7.8	$26.39	311	$26.21
	7,061			3,330	

On October 3, 2001, an officer of the Company, 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, the officer returned to the Company the 200,000 shares of Common Stock acquired upon the exercise of the option, the Company returned to the officer 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.

8. Income Taxes

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

	Year Ended December 31,		
	2000	2001	2002
	(in thousands)		
Current:			
Federal	$(5,575)	$ —	$ —
State	100	—	—
	(5,475)	—	—
Deferred:			
Federal	5,575	—	—
	5,575	—	—
	$ 100	$ —	$ —

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

	Year Ended December 31,		
	2000	2001	2002
	(in thousands)		
Statutory federal income tax benefit	$(9,736)	$(18,565)	$(15,614)
Increase in valuation allowance	9,631	18,565	15,570
Other	205	—	44
Income tax provision	$ 100	$ —	$ —

8. Income Taxes (Continued)

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

	December 31,	
	2001	2002
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 21,010	$ 51,943
Property and equipment	4,095	2,651
Accrued expenses	12,791	1,813
Research and development tax credits	4,501	7,640
Other	102	74
Total deferred tax assets	42,499	64,121
Valuation allowance	(42,499)	(64,121)
	$ —	$ —

At December 31, 2001 and 2002, the Company has provided a valuation allowance for the value of the deferred tax assets. The valuation allowance increased by $27.5 million in 2001 and $21.6 million in 2002 due primarily to the increase in net operating losses and tax credit carryforwards. The Company has federal net operating loss carryforwards in the amount of approximately $129.0 million, which expire through 2022. Due to anticipated operating losses in the future, the Company believes that it is more likely than not that it will not realize the net deferred tax assets in the future and has provided an appropriate valuation allowance.

Any subsequent recognized tax benefits relating to a reduction in the valuation allowance for deferred tax assets as of December 31, 2002 would be allocated as follows (in thousands):

Reported in the statement of operations	$59,429
Reported in additional paid-in capital	4,692
	$64,121

9. 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. In addition, in connection with the termination of the Sanofi-Synthélabo agreement, the Company received in 2002 a final

9. Corporate Collaborations (Continued)

reimbursement payment from Sanofi-Synthélabo of approximately $1.0 million for collaboration expenses incurred by the Company.

The Company recognized revenues in 2000, 2001 and 2002 of approximately $4.1 million, $2.1 million and $1.0 million, respectively, under the Sanofi-Synthélabo agreement.

Amgen Agreement

In March 1999, the Company entered into a binding agreement in principle (the "License Agreement") with Amgen Inc. ("Amgen") for the development and commercialization of the Company's Plenaxis products. In accordance with the License 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 License 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 License Agreement effective December 17, 2001. As a result of the termination of the License Agreement, all licenses for Plenaxis granted to Amgen under the License Agreement, and all rights of Amgen in the Plenaxis program, have terminated. At that time, the Company accrued an estimate of its potential liability of approximately $29.1 million under the License Agreement.

In January 2002, the Company assumed all of Amgen's rights and obligations under the Development and Supply Agreement with UCB S.A. ("UCB"), including the obligation 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. Approximately $4.4 million related to this agreement was remaining at December 31, 2002 which the Company anticipates paying during the first half of 2003.

In August 2002, the Company and Amgen finalized a termination agreement with respect to the termination by Amgen of the License Agreement (the "Termination Agreement"). Under the terms of the Termination Agreement, the Company paid to Amgen $13.0 million in full and complete satisfaction of all amounts payable under the License Agreement and in consideration of the transfer from Amgen to the Company of title to, and possession of, any existing materials inventory. As a result of the Company's payment of $13.0 million plus certain related legal fees in connection with the Termination Agreement, the Company eliminated the excess of its previously accrued $29.1 million liability related to Amgen and recognized a gain of $16.0 million during the third quarter of 2002.

The Company recognized revenues in 2000, 2001 and 2002 of approximately $57.1 million, $7.8 million and zero, respectively, under the Amgen agreement.

10. Building and Related Mortgage Financing

In July 2000, in connection with the purchase of the Company's corporate headquarters and research facility in Waltham, Massachusetts for approximately $41.3 million, the Company's wholly owned real estate 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 facility. Advances bear interest at a rate equal to the 30-day LIBOR plus 2.0% (3.38% at December 31, 2002). Interest is payable monthly in arrears. Principal is due and payable in full on July 30, 2003, subject to two one-year extension options, exercisable at the Company's option. Since the Company has the ability and intent to exercise the first such option to extend the maturity date until July 30, 2004, the loan has been classified as long-term debt in the accompanying consolidated balance sheet. The loan is secured by the facility, together with all fixtures, equipment, improvements and other related items, and by all rents, income or profits received by the Company's real estate subsidiary. The Company occupied this facility during May 2001 and, as planned, is actively seeking to sublease a portion of the 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, 2002, the notional amount and fair market value under the Interest Rate Cap Agreement were $33.0 million and zero, respectively. Interest paid under the loan agreement approximated interest expense in 2000, 2001 and 2002.

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.

11. 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.

Baxter Pharmaceutical Solutions LLC

On December 4, 2002, the Company signed a five-year commercial supply agreement (the "Baxter Agreement") with Baxter Pharmaceutical Solutions LLC ("Baxter") related to the fill and finish steps of the manufacturing process related to Plenaxis. Under the terms of the Baxter Agreement, the Company is required to purchase a minimum of $375,000 of product from Baxter each calendar year until the first anniversary of the first commercial shipment of Plenaxis, at which time the minimum annual purchase commitment will increase to $650,000. The Company made no payments under the Baxter Agreement during 2002.

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STOCKHOLDER INFORMATION

BOARD OF DIRECTORS

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

EXECUTIVE OFFICERS

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

William K. Heiden
President and
Chief Operating Officer

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

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

CORPORATE HEADQUARTERS

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

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 21, 2003 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, 2002, 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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