

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

FORM 10-K

FOR ANNUAL & TRANSITION REPORTS PURSUANT TO
SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2006

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: 001-33221

A.P. PHARMA, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of incorporation or organization)

94-2875566
(I.R.S. Employer Identification Number)

123 SAGINAW DRIVE, REDWOOD CITY, CALIFORNIA
(Address of principal executive offices)

94063
(Zip Code)

Registrant's telephone number, including area code:
(650) 366-2626

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

COMMON STOCK

THE NASDAQ GLOBAL MARKET

Securities registered pursuant to Section 12(g) of the Act:
NONE

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Exchange Act. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer, as defined in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting stock of the registrant held by non-affiliates of the registrant as of June 30, 2006, was \$39,390,906⁽¹⁾.

As of February 28, 2007, 25,438,662 shares of registrant's Common Stock, \$.01 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document
Definitive Proxy Statement to be used in connection with the 2007 Annual Meeting of Stockholders.

Form 10-K Part
III

⁽¹⁾ Excludes 2,862,191 shares held by directors, officers and shareholders whose ownership exceeds 5% of the outstanding shares at June 30, 2006. Exclusion of such shares should not be construed as indicating that the holders thereof possess the power, directly or indirectly, to direct the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

Table of Contents

TABLE OF CONTENTS

	<u>PART I</u>	
ITEM 1.	Business	3
ITEM 1A.	Risk Factors	19
ITEM 1B.	Unresolved Staff Comments	34
ITEM 2.	Properties	34
ITEM 3.	Legal Proceedings	34
ITEM 4.	Submission of Matters to a Vote of Security Holders	34
	<u>PART II</u>	
ITEM 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	35
ITEM 6.	Selected Financial Data	37
ITEM 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	38
ITEM 7A.	Quantitative and Qualitative Disclosure About Market Risk	46
ITEM 8.	Financial Statements and Supplementary Data	47
ITEM 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	71
ITEM 9A.	Controls and Procedures	71
ITEM 9B.	Other Information	71
	<u>PART III</u>	
ITEM 10.	Directors, Executive Officers, and Corporate Governance	72
ITEM 11.	Executive Compensation	72
ITEM 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	72
ITEM 13.	Certain Relationships and Related Transactions, and Director Independence	72
ITEM 14.	Principal Accountant Fees and Services	72
	<u>PART IV</u>	
ITEM 15.	Exhibits and Financial Statement Schedules	73
	Signatures	76
	Certifications	

[Table of Contents](#)

PART I

ITEM 1. BUSINESS

Introduction-Forward Looking Statements

This Annual Report on Form 10-K contains “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties including uncertainties associated with timely development, approval, launch and acceptance of new products, satisfactory completion of clinical studies, establishment of new corporate alliances, progress in research and development programs and other risks and uncertainties described below under the headings “Our Lead Product Candidate APF530”, “Development Pipeline”, “Our Technology Platform”, “Our Strategy”, “Patents and Trade Secrets”, and “Competition”. Such risks and uncertainties also include the matters discussed under “Risk Factors” below, and under Management’s Discussion and Analysis of Financial Condition and Results of Operations in Item 7 below.

Company Overview

In this Annual Report on Form 10-K, the “Company”, “A.P. Pharma”, “APP”, “we”, “us”, and “our”, refer to A.P. Pharma, Inc.

We are a specialty pharmaceutical company focused on developing pharmaceutical products using our proprietary Biochronomer polymer-based drug delivery technology. Our product development philosophy is based on incorporating approved therapeutics into our proprietary bioerodible drug delivery technology to create controlled release pharmaceuticals to improve treatments for diseases or conditions. Our lead product candidate, APF530, is currently in a pivotal Phase III clinical trial for the prevention of acute and delayed onset chemotherapy-induced nausea and vomiting, or CINV. We expect to complete enrollment of our pivotal Phase III clinical trial in the first half of 2008 and to announce results of that trial in the third quarter of 2008. We expect to file our new drug application, or NDA, for approval of APF530 in the fourth quarter of 2008.

Our primary focus is to advance our proprietary Biochronomer technology, consisting of bioerodible polymers designed to release drugs over a defined period. We have completed over 100 *in vivo* and *in vitro* studies demonstrating that our Biochronomer technology is potentially applicable to a range of therapeutic areas, including pain management, prevention of nausea and vomiting, control of inflammation and treatment of ophthalmic diseases. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are safe and well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to several months.

Our lead product candidate using our proprietary Biochronomer technology is APF530, which contains granisetron, a drug approved for the prevention of CINV. We selected granisetron because it is a potent drug which blocks a specific receptor found in the gut that is responsible for triggering CINV. Additionally, the applicable granisetron patent will expire in the United States on December 29, 2007. APF530 is designed to provide at least five days prevention of CINV. In September 2005, we completed a Phase II human clinical trial of APF530 that achieved all of its primary and secondary endpoints. In May 2006, we initiated our pivotal Phase III clinical trial of APF530. We believe that this clinical trial will lead to regulatory approval of APF530 for the prevention of acute and delayed onset CINV for patients undergoing both moderately and highly emetogenic, or vomit-inducing, chemotherapy.

In addition to our lead drug candidate, we have a pipeline of other product candidates that use our Biochronomer technology. One of these, APF112, incorporates the well-known local anesthetic, mepivacaine. It is designed to provide up to 36 hours of

[Table of Contents](#)

post-surgical pain relief and to minimize the use of morphine-like drugs, or opiates, which are used extensively in post-surgical pain management. Post-surgical pain can be treated with local anesthetics, but the usefulness of these is currently limited by the short duration of their effectiveness. We plan to initiate a Phase IIb clinical trial for APF112 in the first half of 2008.

We have several additional product candidates using our Biochronomer technology in early stages of development. For example, we plan to initiate a Phase I clinical trial of APF580 in 2008 for the controlled delivery of an opiate for pain relief.

Our Lead Product Candidate – APF530

CINV Background

Prevention and control of nausea and vomiting, or emesis, are paramount in the treatment of cancer patients. The majority of patients receiving chemotherapy will experience some degree of emesis if not prevented with an antiemetic. Chemotherapy treatments can be moderately emetogenic, meaning that 30 – 90% of patients experience CINV, or highly emetogenic, meaning that over 90% of patients experience CINV, if left untreated. Acute onset CINV occurs within the first 24 hours following chemotherapy treatment, with the highest risk period occurring within the first four hours. Delayed onset CINV occurs more than 24 hours after treatment and may persist for several days. Prevention of CINV is significant because the distress caused by CINV can severely disrupt patient quality of life and can lead some patients to discontinue chemotherapy. The unmet need is greatest with patients receiving highly emetogenic chemotherapy, particularly delayed onset CINV.

Current Therapy and Market Opportunity

Vomiting is a protective reflex against ingestion of potentially harmful substances, including some chemotherapeutic agents. These chemotherapeutic agents activate or destroy cells in the lining of the gut, releasing a neurotransmitter called serotonin. When serotonin binds to the 5-HT₃ (5-hydroxytryptamine type 3) receptors, the patient experiences nausea and vomiting. By blocking the 5-HT₃ receptors, granisetron and the other 5-HT₃ antagonists prevent serotonin from binding to the 5-HT₃ receptors, thereby inhibiting the vomiting reflex. Physicians may combine these 5-HT₃ antagonists with other agents, such as corticosteroids, to better prevent delayed onset CINV.

Despite evidence that delayed onset CINV affects as many as 50 – 70% of patients, and that more patients experience delayed onset CINV than acute onset CINV, oncology nurses and physicians are likely to underestimate the magnitude of these problems in the patients for whom they care. According to the results of a multi-national study recently published in *Cancer* (April 2004), the discrepancy between the perceived incidence and the actual incidence may, in part, be due to the fact that patients often do not report the side effects they experience at home. In this prospective study, 60% of patients receiving highly emetogenic chemotherapy, who also received antiemetics, still had delayed onset CINV.

Current treatment options for CINV include 5-HT₃ antagonists such as palonosetron (Aloxi), ondansetron (Zofran), dolasetron (Anzemet), and granisetron (Kytril), as well as aprepitant (Emend), an NK1 (neurokinin-1) antagonist, which is always used in combination with a 5-HT₃ antagonist. As shown in the table below, all of the 5-HT₃ antagonists are approved for the prevention of acute onset CINV in patients receiving either moderately or highly emetogenic chemotherapy. Only Aloxi is approved for the prevention of delayed onset CINV in patients receiving moderately emetogenic chemotherapy. None is approved as single agent therapies for the prevention of delayed onset CINV in patients receiving highly emetogenic chemotherapy. Aloxi sales

[Table of Contents](#)

were approximately \$250 million in 2006, and we believe the total addressable U. S. market approaches \$1 billion for use of 5-HT₃ antagonists in the prevention of CINV .

Chemotherapy Regimen	Approved 5-HT ₃ Antagonists for Acute Onset CINV	Approved 5-HT ₃ Antagonists for Delayed Onset CINV
Moderately Emetogenic	Granisetron (Kytril) Ondansetron (Zofran) Dolasetron (Anzemet) Palonosetron (Aloxi)	Palonosetron (Aloxi)
Highly Emetogenic	Granisetron (Kytril) Ondansetron (Zofran) Dolasetron (Anzemet) Palonosetron (Aloxi)	NONE

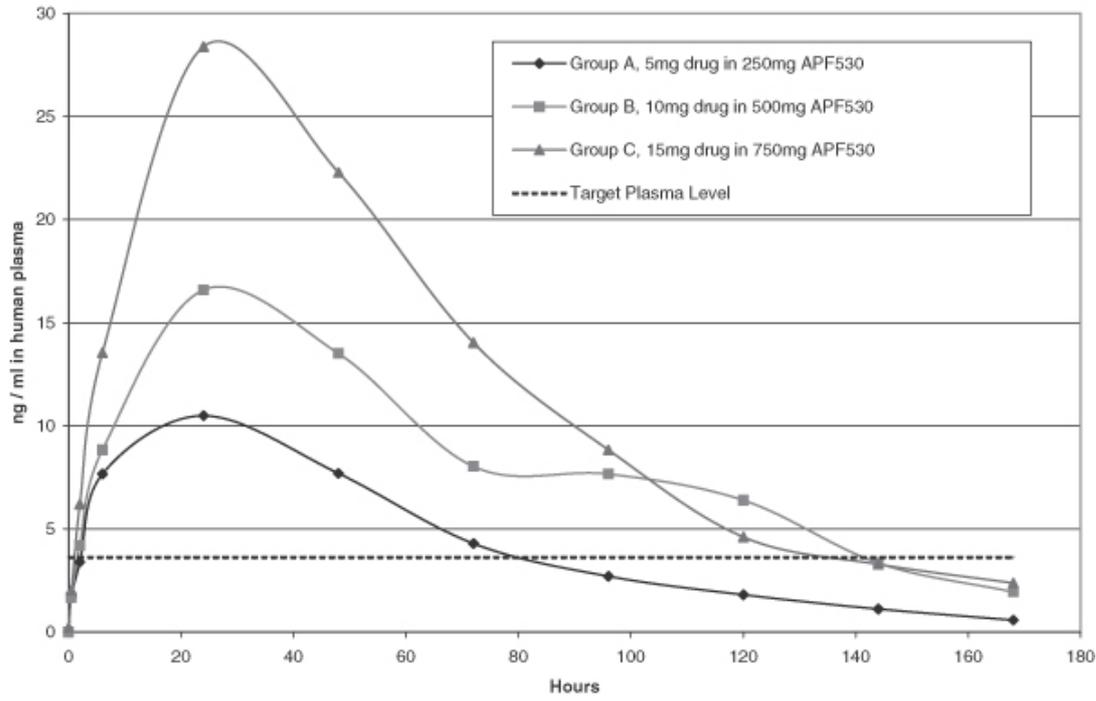
Our Solution – APF530

Our lead product, APF530, is being developed for the prevention of both acute and delayed onset CINV in patients receiving either moderately or highly emetogenic chemotherapy. APF530 contains the 5-HT₃ antagonist, granisetron, delivered by a single subcutaneous injection. Granisetron injections and oral tablets are approved for the prevention of acute onset CINV, but not delayed onset CINV. 5-HT₃ antagonists, as a class, have become the most common antiemetic agents in chemotherapy. However, no 5-HT₃ antagonist formulation is currently approved for the prevention of both acute and delayed onset CINV for both moderately and highly emetogenic chemotherapy. We believe that if APF530 demonstrates in our pivotal Phase III trial that we can deliver therapeutic levels of granisetron over an extended period of time, we will have a unique product with significant commercial potential. Physicians will have the opportunity to provide patients with the broadest efficacious treatment for CINV with a single injection.

Phase II Clinical Trial Results

In September 2005, we completed a Phase II clinical trial for APF530. We evaluated the safety, tolerability and pharmacokinetics of APF530 in cancer patients. In addition, efficacy endpoints were evaluated relating to emetic events and the use of additional medication for CINV. The clinical trial demonstrated that APF530 was well tolerated: there were no serious adverse events attributed to APF530; less than 10% of participating patients had injection site reactions, all of which were mild. As shown in the graph below, the pharmacokinetic evaluation in all three dose groups (250, 500 and 750 mg injection doses corresponding to 5, 10 and 15 mg of granisetron, respectively) demonstrated that the minimum efficacy target plasma levels of granisetron were substantially achieved. The target plasma levels were based on oral doses of granisetron shown to have exhibited efficacy for acute onset CINV.

Granisetron Levels in Patients from Phase II Clinical Trial of APF530

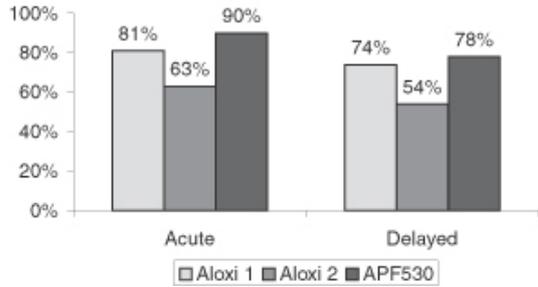


Analysis of the efficacy data from our open-label Phase II trial in which patient groups received either moderately or highly emetogenic chemotherapy was based on complete responders. "Complete response" is defined as an absence of vomiting and no use of additional medication for CINV during the observation period.

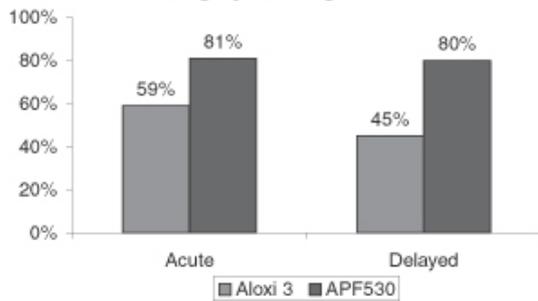
[Table of Contents](#)

Results of APF530's Phase II trial and Aloxi's Phase III trial are presented in the table below. Aloxi's Phase III trials included two trials of 189 patients each for moderately emetogenic chemotherapy and one trial involving 223 patients for highly emetogenic chemotherapy. The two trials evaluating moderately emetogenic chemotherapy indicated that the percentage of complete responders was 81% and 63% in the acute phase and 74% and 54% in the delayed phase, respectively. The study evaluating highly emetogenic chemotherapy indicated that the percentage of complete responders was 59% in the acute phase and 45% in the delayed phase. In comparison, in our APF530 Phase II trial, 20 patients were treated and evaluated for moderately emetogenic chemotherapy; the percentage of complete responders among them was 90% in the acute phase and 78% in the delayed phase. 21 patients were treated and evaluated for highly emetogenic chemotherapy; the percentage of complete responders among them was 81% in the acute phase and 80% in the delayed phase. While these trials measure complete responders, there are inherent differences between the studies for the two products including, for example: phase of study, use of adjunct medications, presence of a control group, number of patients, blinded versus unblinded and study objectives.

Moderately Emetogenic



Highly Emetogenic



Based on the data from the Aloxi Phase III trials and our own Phase II results, we designed our Phase III clinical program to conclusively compare APF530 to Aloxi in a prospective randomized design.

[Table of Contents](#)

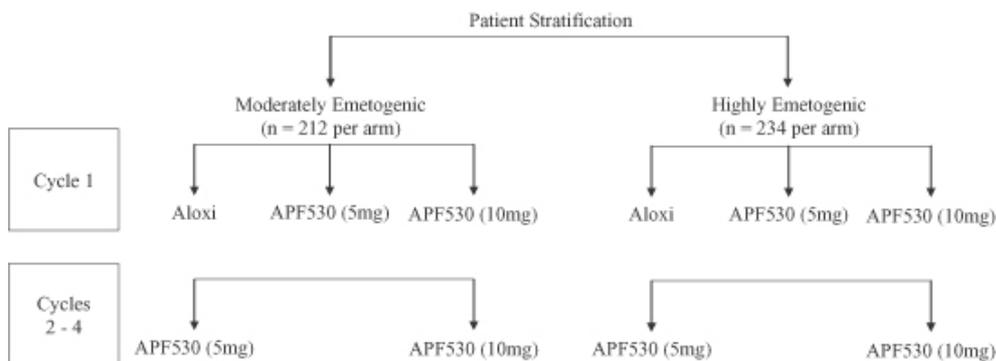
Pivotal Phase III Clinical Trial Design

In December 2005, we held our end-of-Phase-II meeting with the FDA, at which we discussed our regulatory approval strategy and our proposed design for the pivotal Phase III trial. Following this meeting, we designed our pivotal Phase III trial in accordance with FDA input. The trial's primary objectives are to demonstrate:

- non-inferiority of APF530 in comparison to Aloxi for the prevention of acute onset CINV following the administration of either moderately emetogenic or highly emetogenic chemotherapy;
- non-inferiority of APF530 in comparison to Aloxi for the prevention of delayed onset CINV following administration of moderately emetogenic chemotherapy; and
- superiority of APF530 in comparison to Aloxi for the prevention of delayed onset CINV following administration of highly emetogenic chemotherapy.

Based on our discussions with the FDA, we are planning to file our NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) of the FDCA permits the FDA, in its review of an NDA, to rely on previous FDA findings of safety and efficacy of the active ingredient in APF530, granisetron. The 505(b)(2) approval pathway is distinguished from the Abbreviated New Drug Application or generics route by the requirement that drug products approved under this section must have significant difference relative to the reference approved product. The additional information in the 505(b)(2) applications can be provided by literature or reference to past FDA findings of safety and efficacy for approved drugs, or it can be based upon studies conducted by or for the applicant to which it has obtained a right of reference. The majority of 505(b)(2) applications are filed for new formulations of currently approved drugs, so there is an existing understanding—on the part of the FDA, as well as the medical community—of their safety and efficacy.

Our pivotal Phase III clinical trial, initiated in May 2006, is a multicenter, randomized, observer-blind, actively-controlled, double-dummy, parallel group study that will compare the efficacy of APF530 with Aloxi. The trial will include approximately 1,350 patients, stratified in two groups, one receiving moderately and the other receiving highly emetogenic chemotherapeutic agents. In each group, the patients are randomized to receive in the first chemotherapy treatment cycle either APF530 high dose (10 mg), APF530 low dose (5 mg) or the currently approved dose of Aloxi. In subsequent treatment cycles (up to three additional cycles), the patients are re-randomized to either of the two APF530 doses. The diagram below provides further graphical representation of how patients are randomized in our clinical trial.



[Table of Contents](#)

We expect to complete enrollment of our pivotal Phase III clinical trial in the first half of 2008 and to announce results of that trial in the third quarter of 2008. We expect to file our NDA for approval of APF530 in the fourth quarter of 2008.

Market Survey

We commissioned Timely Data Resources, Inc., or TDR, to conduct market research to determine oncologists' and oncology nurses' perceptions of current antiemetics for CINV. This survey, completed in August 2006, was intended to assess the market opportunity for APF530 for the prevention of CINV. TDR interviewed 75 randomly selected medical oncologists and 25 oncology nurses from across the United States. The survey concluded that there is significant unmet need in the treatment of CINV, especially delayed onset CINV. 84% of the surveyed oncologists and oncology nurses currently use Aloxi and continue to have patients who experience CINV, particularly delayed onset CINV.

Development Pipeline

In addition to our lead program, we have a pipeline of other product candidates using our Biochronomer technology:

Product Candidate	Potential Application	Drug	Targeted Duration	Status
APF112	Post-surgical pain relief	Mepivacaine	Up to 36 hours	Phase II
APF580	Pain relief	Undisclosed Opiate	At least seven days	Preclinical
APF328	Local anti-inflammatory (orthopedic surgery)	Meloxicam	Up to two weeks	Preclinical
APF505	Anti-inflammatory (osteoarthritis)	Meloxicam	Up to six weeks	Preclinical

APF112

APF112 utilizes our Biochronomer delivery technology to target post-surgical pain relief. The product is designed to provide up to 36 hours of localized pain relief by delivering mepivacaine directly to the surgical site. Mepivacaine is a well-known, short-acting local anesthetic with an excellent safety profile. APF112 is designed to prolong the anesthetic effect of mepivacaine and thus to minimize or eliminate the use of opiates. Opiates are currently used in the majority of surgical procedures as a means of managing post-operative pain, and while they are powerful and useful drugs, they may have side effects such as addiction, nausea, disorientation, sedation, constipation, vomiting, urinary retention and, in some situations, life-threatening respiratory depression. If efficacy in treating post-surgical pain can be demonstrated, we believe that there will be substantial potential for this product, as there are approximately 20 million surgical procedures performed annually in the United States for which the product could potentially be utilized.

During 2004, our Phase II clinical trial was conducted in surgeries for inguinal hernia repair, which is considered a moderately to severely painful procedure. The results indicated excellent safety and tolerability. The pharmacokinetics of APF112 showed sustained release of mepivacaine systemically over a period of three days (72 hours). No significant difference was shown between the two doses of APF112 and the standard of care (bupivacaine) in terms of pain scores and the amount of additional

[Table of Contents](#)

pain medication used. Mean Visual Analog Scale, or VAS, pain scores in the standard of care group (bupivacaine) were significantly lower in this study when compared with other previously published studies in similar hernia trials. Based on published data, VAS scores for the standard of care in similar inguinal hernia studies ranged from 4.5 to 6.7, whereas in this study the mean score for the bupivacaine arm was 2.9 within the first 24 hours post surgery. We believe that we can demonstrate that APF112 is effective in controlling post surgical pain, however, we were unable to demonstrate this due to the unexpectedly low levels of pain displayed by the control group in this trial. We intend to complete additional preclinical work in 2007 with a revised protocol, followed by initiation of a Phase IIb clinical trial in the first half of 2008. Assuming successful completion of our Phase IIb clinical trial, we plan to explore corporate partnering opportunities to continue the development of APF112.

APF580

APF580 will incorporate an opiate into our Biochronomer technology and is designed to provide analgesia lasting up to seven days by a single injection. It is targeted for situations where the intensity and duration of pain require use of an opiate rather than a local anesthetic. APF580 may find use in acute and chronic pain settings, improve patient compliance and reduce the risk of drug abuse. Our initial animal pharmacokinetic studies completed in 2006 present a promising profile, supporting future product development for post-surgical (inpatient) and chronic pain applications (cancer pain). We plan to supplement our animal studies with additional preclinical data from an ongoing research and development agreement with a major animal health company, which is evaluating the same product for use in cats and dogs. We plan to initiate a Phase I clinical trial of APF580 in 2008.

APF328

APF328 represents a novel formulation in preclinical development for the potential treatment of pain following orthopedic surgery. Our Biochronomer polymer has been designed in this instance to control the local delivery of meloxicam for up to two weeks. Meloxicam is a non-steroidal anti-inflammatory drug that was developed as an oral tablet for the treatment of osteoarthritis of the knee and hip.

APF505

APF505 is an extension of the concept outlined in APF328. This Biochronomer formulation has the potential to deliver meloxicam within the knee joint for up to six weeks and may be appropriate to treat osteoarthritis, a common form of arthritis that occurs in nearly 70% of the U.S. population over the age of 65. For both APF328 and APF505, our objective is to deliver the drug to the site of action, thereby avoiding the side effects associated with oral treatment, namely gastrointestinal disturbances.

Our Technology Platform

We have made significant investments in the development of our bioerodible drug delivery technologies, which have created tangible results. Specifically, we have developed a broad family of polymers with unique attributes, known collectively as poly(ortho esters), under the trade name Biochronomer. This technology has been specifically designed for use in drug delivery applications with a number of technical advantages, such as: ease of manufacturing, flexible delivery times, various physical forms and multiple potential applications due to a neutral pH environment for acid sensitive actives (nucleic acids, proteins, etc.).

[Table of Contents](#)

Due to the inherent versatility of our Biochronomer technology, products can be designed to deliver drugs at a variety of implantation sites including, under the skin, at the site of a surgical procedure, in joints, in the eye, or in muscle tissue. Our Biochronomer technology can provide sustained levels of drugs in systemic circulation for prolonged efficacy.

Ease of Manufacturing. Our Biochronomer technology is formed by the coupling of various monomers into a polymer chain. Our process knowledge underlying the commercial manufacture of our Biochronomers is based on extensive, well-documented, development studies. Commercial manufacturing campaigns to date have demonstrated that our Biochronomers may be produced in a highly reproducible manner. By selecting suitable monomers the resulting polymers will melt at differing temperatures which will allow for different manufacturing techniques, e.g. injection molding, extrusion, compression molding, etc.

Flexible Delivery Times. The Biochronomer "links" or bonds are stable at neutral pH conditions. Upon coming into contact with water-containing media, such as internal body fluids, the water reacts with these bonds. This reaction is known as hydrolysis. During the hydrolysis of the Biochronomer links, acidic elements are produced in a local micro-environment, in a controlled manner, without impacting the overall neutrality of the drug delivery technology. These elements assist in the continued, controlled erosion of the polymer with a simultaneous, controlled release of the active drug contained within the Biochronomer. By varying the amount of the acidic elements in the Biochronomer, different rates of hydrolysis may be effectively realized. In this manner, delivery times ranging from days to weeks to several months can be achieved.

Various Physical Forms. Our Biochronomers can be prepared in a variety of physical forms, ranging from hard, glassy materials to semi-solids that are injectable at room temperature, by proper selection of monomers. A significant advantage of our Biochronomer technology is that drugs can be incorporated by simple mixing procedures allowing the production of formulations in the form of injectable gels, microspheres, coatings, and strands. All of these physical forms can be used in the controlled delivery of drugs without the undesirable incorporation of organic solvents in the final product. .

Multiple Potential Applications. We have completed over 100 *in vivo* and *in vitro* studies demonstrating that our Biochronomer technology is potentially applicable to a range of therapeutic areas, including pain management, prevention of nausea, control of inflammation and treatment of ophthalmic diseases. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are safe and well tolerated.

All of our current development programs utilize the same semi-solid poly(ortho ester) delivery vehicle. Additional applications for the treatment of a number of indications are under development using the same vehicle. The present forms of these products are stored under refrigeration. We are actively developing products that can be stored at room temperature.

Through our experience and continued insight obtained during our research and development, Biochronomer polymers can be extended into novel technologies via the design of additional architectures containing poly(ortho esters). One example of such a technology is our family of polymers called Bioerodimers. These polymers are poly(ethylene glycol) products that have the ability to form micelles in water and can be delivered intravenously. We believe this family of polymers may be safer and better tolerated than more conventional intravenous formulations which employ solvents and surfactants. At least eight patents and patent applications cover this and other aspects of our Bioerodimer technologies. The materials resulting from these inventions have the potential to be exploited in the creation of new drug delivery technologies that can be used to treat more indications via additional delivery routes.

Our Strategy

Our primary objective is to be a leading specialty pharmaceutical company focused on improving the effectiveness of existing pharmaceuticals using our proprietary drug delivery technologies. Key elements include:

Expand product pipeline. We plan to expand our product pipeline by leveraging our existing technology. We intend to develop new products based on our Biochronomer polymer-based drug delivery technology. Our research has indicated that our Biochronomer technology has potential applications across a range of therapeutic areas including pain management, prevention of nausea, control of inflammation and treatment of ophthalmic diseases. With further work on our technology platforms, we may be able to develop products that deliver proteins, peptides, sRNA (soluble RNA) and RNAi (RNA interference).

Minimize product development risk and time-to-market. We are applying our proprietary drug delivery technologies to improve the effectiveness of approved pharmaceutical products. By using our technologies to administer drugs for which clinical efficacy and safety data are available, we will reduce the cost and development risk inherent in traditional pharmaceutical product development.

Maximize the value of our lead product, APF530. We believe that partnering APF530 after successful results from our clinical trial will maximize the value of APF530 for our shareholders. We expect to secure significant upfront license fees, followed by milestone payments and royalties. We also plan to evaluate separate commercial partnerships for the United States and the rest of world.

Enter into strategic partnerships. We believe that selective partnering of our future product development programs can enhance the success of our product development and commercialization efforts, and enable diversification of our product portfolio by having partners fund the major portion of our late stage clinical trials. Additionally, such partnering will enable us to leverage the sales capabilities of our partners to commercialize our products.

Manufacturing and Supply

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our product candidates. We currently rely on a small number of third-party manufacturers to produce our compounds and expect to continue to do so to meet the preclinical and clinical requirements of our potential products and for all of our commercial needs. We do not have long-term agreements with any of these third-parties.

We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce APIs and finished products in accordance with cGMP and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our drug candidates.

With regard to our lead product candidate, APF530, we currently use Sigma Aldrich Fine Chemicals as our primary raw materials and polymer supplier. We currently source granisetron from one supplier and know of at least three other capable suppliers. We currently ship all of our formulation components directly to our contract manufacturer, Hyaluron. We continue to evaluate potential suppliers and manufacturers.

Marketing and Sales

A key part of our business strategy is to form collaborations with pharmaceutical partners. In the past, we have successfully partnered our development stage programs with leading pharmaceutical companies. In general, we grant limited marketing exclusivity in defined markets for defined periods to our partners. However, after development is completed and a partner commercializes a formulated product utilizing our delivery technologies, we can exert only limited influence over the manner and extent of our partner's marketing efforts.

The status of our initial marketing relationships for APF530 are as follows:

- In October 2006, we announced that we had granted an exclusive license to RHEI Pharmaceuticals, Inc. to seek regulatory approval and sell APF530 in China, Taiwan, Hong Kong and Macau. The agreement included an upfront payment to us and includes provisions for milestone payments and royalties on future net sales.
- During the Phase III trial we will continue to seek additional domestic and international partners. Our current belief is that concluding a successful collaboration on mutually acceptable terms may not be possible until the availability of trial results, presently expected in the third quarter of 2008.

Patents and Trade Secrets

As part of our strategy to protect our current products and to provide a foundation for future products, we have filed a number of United States patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. In addition to obtaining patents in a number of foreign countries, we have also filed the United States and foreign patent applications on our polymer technology with the Patent Cooperation Treaty (PCT), the European Patent Office, Australia, Canada, China, Hong Kong, Japan, South Korea, Singapore and Taiwan. We have a total of 21 issued United States patents and an additional 113 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between January 2016 and November 2022.

Although we believe the bases for these patents and patent applications are sound, they are untested, and there is no assurance that they will not be successfully challenged. There can be no assurance that any patent previously issued will be of commercial value, that any patent applications will result in issued patents of commercial value, or that our technology will not be held to infringe patents held by others.

We also rely on unpatented trade secrets and know-how to protect certain aspects of our production technologies. Our employees, consultants, advisors and corporate partners have entered into confidentiality agreements with us. These agreements, however, may not necessarily provide meaningful protection for our trade secrets or proprietary know-how in the event of unauthorized use or disclosure. In addition, others may obtain access to, or independently develop, these trade secrets or know-how.

Competition

There are several companies that are developing new formulations of existing drugs using novel drug delivery technologies. Many of these companies have substantially greater financial, research and development,

manufacturing, sales and marketing and distribution resources and experience than we do. The following are our major competitors:

- Alkermes, Inc.
- Depomed, Inc.
- Durect Corporation
- ProStrakan Group PLC
- SkyePharma PLC

Additionally, APF530 is expected to face competition from MGI Pharma's Aloxi (palonosetron), Roche's Kytril (granisetron), GlaxoSmithKline's Zofran (ondansetron), and Aventis' Anzemet (dolasetron), as well as Hana Biosciences' Zensana (oral ondansetron). We are also aware of several companies developing both generic and new formulations of granisetron. APF112 is expected to face competition from Durect Corporation's Posidur (injectable controlled release bupivacaine) and SkyePharma PLC's recently divested DepoBupivacaine (injectable controlled release bupivacaine).

Government Regulation and Product Approvals

The manufacturing and marketing of our potential products and our ongoing research and development activities are subject to extensive regulation by the FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries.

United States Regulation

Before any of our products can be marketed in the United States, they must secure approval by the FDA. To secure approval, any drug we develop must undergo rigorous preclinical testing and clinical trials that demonstrate the product candidate's safety and effectiveness for each chosen indication for use. This extensive regulatory process controls, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of biopharmaceutical products.

In general, the process required by the FDA before investigational drugs may be marketed in the United States involves the following steps:

- preclinical laboratory and animal tests;
- submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use;

[Table of Contents](#)

- pre-approval inspection of manufacturing facilities and selected clinical investigators; and
- FDA approval of a new drug application, or NDA, or of a NDA supplement (for subsequent indications).

Preclinical Testing

In the United States, drug candidates are tested in animals until adequate proof of safety is established. These preclinical studies generally evaluate the mechanism of action of the product and assess the potential safety and efficacy of the product. Tested compounds must be produced according to applicable current good manufacturing practice (cGMP) requirements and preclinical safety tests must be conducted in compliance with FDA and international regulations regarding good laboratory practices (GLP). The results of the preclinical tests, together with manufacturing information and analytical data, are generally submitted to the FDA as part of an investigational new drug application, or IND, which must become effective before human clinical trials may commence. The IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA requests an extension or raises concerns about the conduct of the clinical trials as outlined in the application. If the FDA has any concerns, the sponsor of the application and the FDA must resolve the concerns before clinical trials can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, and the FDA must grant permission for each clinical trial to start and continue. Regulatory authorities may require additional data before allowing the clinical studies to commence or proceed from one Phase to another, and could demand that the studies be discontinued or suspended at any time if there are significant safety issues. Furthermore, an independent institutional review board, or IRB, for each medical center proposing to participate in the conduct of the clinical trial must review and approve the clinical protocol and patient informed consent before the center commences the study.

Clinical Trials

Clinical trials for new drug candidates are typically conducted in three sequential phases that may overlap. In Phase I, the initial introduction of the drug candidate into human volunteers, the emphasis is on testing for safety or adverse effects, dosage, tolerance, metabolism, distribution, excretion, and clinical pharmacology. Phase II involves studies in a limited patient population to determine the initial efficacy of the drug candidate for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks. Once a compound shows evidence of effectiveness and is found to have an acceptable safety profile in Phase II evaluations, pivotal Phase III trials are undertaken to more fully evaluate clinical outcomes and to establish the overall risk/benefit profile of the drug, and to provide, if appropriate, an adequate basis for product labeling. During all clinical trials, physicians will monitor patients to determine effectiveness of the drug candidate and to observe and report any reactions or safety risks that may result from use of the drug candidate. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk.

The data from the clinical trials, together with preclinical data and other supporting information that establishes a drug candidate's safety, are submitted to the FDA in the form of a new drug application, or NDA, or NDA supplement (for approval of a new indication if the product candidate is already approved for another indication). Under applicable laws and FDA regulations, each NDA submitted for FDA approval is usually given an internal administrative review within 45 to 60 days following submission of the NDA. If deemed complete, the FDA will "file" the NDA, thereby triggering substantive review of the application.

The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established internal substantive review goals of six months for priority NDAs (for drugs addressing serious or life threatening conditions for which there is an unmet medical need) and ten months for regular NDAs. The FDA, however, is not legally required to complete its review within these periods, and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, is not typically an actual approval, but an "action letter" that describes additional work that must be done before the NDA can be approved. The FDA's review of a NDA may involve review and recommendations by an independent FDA advisory committee. The FDA may deny approval of a NDA or NDA supplement if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA or NDA supplement does not satisfy the criteria for approval.

Data Review and Approval

Satisfaction of FDA requirements or similar requirements of state, local, and foreign regulatory agencies typically takes several years and requires the expenditure of substantial financial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit, or prevent regulatory approval at any stage of the process. Accordingly, the actual time and expense required to bring a product to market may vary substantially. We cannot assure you that we will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit, or prevent regulatory approval. Success in early stage clinical trials does not ensure success in later stage clinical trials. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations, and dosages, or have conditions placed on them that restrict the commercial applications, advertising, promotion, or distribution of these products.

Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. The FDA may also request additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after a drug receives approval. The results of Phase IV studies can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA's voluntary adverse drug reaction reporting system. Any products manufactured or distributed by us pursuant to FDA approvals would be subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the good manufacturing practices regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug. Furthermore, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

The FDA closely regulates the marketing and promotion of drugs. Approval may be subject to post-marketing surveillance and other record keeping and reporting obligations, and involve ongoing requirements. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers' communications on the subject of off-label use.

Section 505(b)(2) Applications

Some of our product candidates may be eligible for submission of applications for approval under the FDA's Section 505(b)(2) approval process, which requires less information than the NDAs described above. Section 505(b)(2) applications may be submitted for drug products that represent a modification (e.g., a new indication or new dosage form) of an eligible approved drug and for which investigations other than bioavailability or bioequivalence studies are essential to the drug's approval. Section 505(b)(2) applications may rely on the FDA's previous findings for the safety and effectiveness of the listed drug, scientific literature, and information obtained by the 505(b)(2) applicant needed to support the modification of the listed drug. For this reason, preparing Section 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information from a full set of clinical trials. The law governing Section 505(b)(2) or FDA's current policies may change in such a way as to adversely affect our applications for approval that seek to utilize the Section 505(b)(2) approach. Such changes could result in additional costs associated with additional studies or clinical trials and delays.

The FDCA provides that reviews and/or approvals of applications submitted under Section 505(b)(2) will be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity, during which the FDA will not approve, and may not even review a Section 505(b)(2) application from other sponsors. If the listed drug is claimed by patent that the NDA holder has listed with the FDA, the Section 505(b)(2) applicant must submit a patent certification. If the 505(b)(2) applicant certifies that the patent is invalid, unenforceable, or not infringed by the product that is the subject of the Section 505(b)(2), and the 505(b)(2) applicant is sued within 45 days of its notice to the entity that holds the approval for the listed drug and the patent holder, the FDA will not approve the Section 505(b)(2) application until the earlier of a court decision favorable to the Section 505(b)(2) applicant or the expiration of 30 months. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances.

In addition, both before and after approval is sought, we and our collaborators are required to comply with a number of FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain limitations and other requirements concerning advertising and promotion for our products. Also, quality control and manufacturing procedures must continue to conform to continuing GMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with continuing GMP. In addition, discovery of problems such as safety problems may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

[Table of Contents](#)

Foreign Approvals

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

The policies of the FDA and foreign regulatory authorities may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our investigational drugs or approval of new diseases for our existing products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Legal Proceedings

While the Company is not currently a party to any material pending legal proceedings, from time to time the Company is named as a party to lawsuits in the normal course of its business. Litigation, in general, and intellectual property litigation in particular, can be expensive and disruptive to normal business operations. Moreover, the results of legal proceedings are difficult to predict.

Properties

We lease 26,067 square feet of laboratory, office and warehouse space in Redwood City, California under leases expiring in 2011. The annual rent expense for the Redwood City facility is approximately \$463,000.

We believe our facilities are adequate and suitable for current and anticipated needs.

Employees

As of February 28, 2007, we had 41 full-time employees, six of whom hold Ph.D. degrees. There were 33 employees engaged in research and development and quality control, and eight working in finance, business development, human resources and administration.

We consider our relations with employees to be good. None of our employees is covered by a collective bargaining agreement.

ITEM 1A. RISK FACTORS

Risk Factors

Our business is subject to various risks, including those described below. You should consider carefully these risk factors and all of the other information included in this Form 10-K. Any of these risk factors could materially adversely affect our business, operating results and financial condition.

Going Concern—See “Going Concern” in Note 1 of Notes to Financial Statements, in which we discuss the need to obtain additional financing in 2007.

Risks Related To Our Business

We have a history of losses, we expect to generate losses in the near future, and we may never achieve or maintain profitability.

We have suffered recurring losses and had an accumulated deficit of \$87.8 million as of December 31, 2006. We expect to continue to generate substantial losses over at least the next several years as we:

- expand drug product development efforts;
- conduct preclinical testing and clinical trials; and
- pursue additional applications for our existing delivery technologies.

To achieve and sustain profitability, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, market and sell our products. We will incur substantial expenses in our efforts to develop and commercialize products and we may never generate sufficient revenue to become profitable or to sustain profitability.

We may require additional capital to conduct our operations and to develop our products. Such funding may not be available on commercially favorable terms and may cause dilution to our existing stockholders.

We may require additional capital resources in order to conduct our operations and develop our products. We may not be able to obtain required funding on favorable terms and required funding may cause dilution to our existing stockholders. The timing and degree of any future capital requirements will depend on many factors, including:

- the number of product development programs we pursue and the pace of each program;
- the scope, rate of progress, results and costs of preclinical testing and clinical trials;
- the time and costs involved in seeking regulatory approvals;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;

[Table of Contents](#)

- our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing; and
- market conditions and other factors.

We intend to acquire additional funding through sales of our common stock or other company securities, and/or strategic collaborations, in the form of license fees, research and development fees and milestone payments. If we issue additional equity securities or securities convertible into equity securities to raise funds, our stockholders will suffer dilution of their investment and it may adversely affect the market price of our common stock. In the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize ourselves. If adequate funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our product development programs and reduce personnel-related and other costs, which will have a material adverse effect on our business. See "Going Concern" in Note 1 of Notes to Financial Statements, in which we discuss the need to obtain additional financing in 2007.

We are substantially dependent upon the success of our APF530 product candidate. Clinical trials for this product may not demonstrate efficacy or lead to regulatory approval.

We will not be able to commercialize our lead product candidate, APF530, until we obtain regulatory approval in the United States or foreign countries. To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Our lead product candidate, APF530, is designed to provide at least five days prevention of CINV. In September 2005, we completed a Phase II human clinical trial of APF530 that achieved all of its primary and secondary endpoints. In May 2006, we initiated our pivotal Phase III clinical trial of APF530.

Although, we believe that this clinical trial will lead to regulatory approval of APF530 for the prevention of acute and delayed onset CINV for patients undergoing both moderately and highly emetogenic, or vomit-inducing, chemotherapy, the results of initial preclinical testing and clinical trials to date do not necessarily predict the results that we will get from subsequent or more extensive preclinical testing and clinical trials. Clinical trials of APF530 and our other product candidates may not demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. If we cannot adequately demonstrate through the clinical trial process that the product we are developing is safe and effective, regulatory approval of that product would be delayed or prevented, which would impair our reputation, increase our costs and prevent us from earning revenue.

We may not obtain regulatory approval for our products. Regulatory approval may also be delayed or cancelled or may entail limitations on the indicated uses of a proposed product.

The regulatory process, particularly for biopharmaceutical products like ours, is uncertain, can take many years and requires the expenditure of substantial resources. Any product that we or our collaborative partners develop must receive all relevant regulatory agency approvals or clearances, if any, before it may be marketed in the United States or other countries. In part - -

[Table of Contents](#)

ular, human pharmaceutical therapeutic products are subject to rigorous preclinical and clinical testing and other requirements by the Food and Drug Administration, or FDA, in the United States and similar health authorities in foreign countries. We may not receive necessary regulatory approvals or clearances to market APF530 or any other product candidate.

Data obtained from preclinical and clinical activities is susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals or clearances. For example, the FDA may require additional clinical data to support approval, such as confirmatory studies, carcinogenicity studies and other data or studies to address questions or concerns that may arise during the FDA review process. Delays or rejections also may be encountered as a result of changes in regulatory agency policy during the period of product development and/or the period of review of any application for regulatory agency approval or clearance for a product. Delays in obtaining regulatory agency approvals or clearances could:

- significantly harm the marketing of any products that we or our collaborators develop;
- impose costly procedures upon our activities or the activities of our collaborators;
- diminish any competitive advantages that we or our collaborative partners may attain; or
- adversely affect our ability to receive royalties and generate revenue and profits.

Even though we intend to apply for approval of most of our products in the United States under Section 505(b)(2) of the United States Food, Drug and Cosmetic Act, or FDCA, which applies to reformulations of approved drugs and that may require smaller and shorter safety and efficacy testing than that for entirely new drugs, the approval process will still be costly, time-consuming and uncertain. We plan to file the NDA for APF530 under Section 505(b)(2) of the FDCA, to rely on previous FDA findings of safety and efficacy of the active ingredient in APF530, granisetron. While we believe that Section 505(b)(2) is applicable to APF530, it is possible that the FDA may disagree and require us to submit a "stand-alone" or "full" Section 505(b)(1) NDA, which would require significantly more clinical studies and or other data collection or analysis.

We or our collaborators may not be able to obtain necessary regulatory approvals on a timely basis, if at all, for any of our potential products. Even if granted, regulatory approvals may include significant limitations on the uses for which products may be marketed. Failure to comply with applicable regulatory requirements can, among other things, result in warning letters, imposition of civil penalties or other monetary payments, delay in approving or refusal to approve a product candidate, suspension or withdrawal of regulatory approval, product recall or seizure, operating restrictions, interruption of clinical trials or manufacturing, injunctions and criminal prosecution.

In addition, the marketing and manufacturing of drugs and biological products are subject to continuing FDA review, and later discovery of previously unknown problems with a product, its manufacture or its marketing may result in the FDA requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market.

Clinical trials are expensive and may not result in commercially viable products.

Conducting clinical trials is a lengthy, time-consuming and expensive process. For example, we are incurring significant expenses in developing APF530, and even if approved, it may not result in a commercially viable product. Before obtaining regulatory approvals for the commercial sale of any products, we or our partners must demonstrate through preclinical testing

[Table of Contents](#)

and clinical trials that our product candidates are safe and effective for use in humans. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, preclinical testing and clinical trials.

Our business, results of operations and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials. Factors impacting our ability to generate revenue or become profitable include:

- insufficient funds to continue necessary clinical trials;
- inability to find partners willing to fund some or all of our clinical trial expenditures;
- failure of clinical trials to demonstrate the safety and efficacy of our products to the extent necessary to obtain regulatory approvals;
- failure of preclinical testing and early clinical trials to predict results of later clinical trials;
- delay in completion of clinical trials, resulting in increased costs; and
- inability to obtain regulatory approval of our products following completion of clinical trials, or delays in obtaining such approvals.

Delays in clinical testing could increase our costs and delay our ability to obtain regulatory approval and commercialize our product candidates.

Before we or our collaborators can file for regulatory approval for the commercial sale of our potential products, the FDA will require extensive preclinical safety testing and clinical trials to demonstrate their safety and efficacy. Significant delays in preclinical and clinical testing could materially impact our product development costs and delay regulatory approval of our product candidates. For example, enrollment in the Phase III trial for APF530 has been slower than we expected, resulting in delays in our development timeline and increased costs. Completing clinical trials in a timely manner depends on, among other factors:

- obtaining regulatory approval to commence a trial;
- obtaining clinical materials;
- reaching agreement on acceptable clinical study terms with prospective sites and clinical research organizations;
- obtaining institutional review board approval to conduct a study at a prospective site; and
- recruiting patients to participate in a study.

We rely on third parties to conduct our clinical trials, and their failure to perform their obligations in a timely and competent manner may delay development and commercialization of our product candidates.

We are using a clinical research organization to oversee our ongoing clinical trial of APF530 and we expect to use the same or similar organizations for our future clinical trials. There are numerous alternative sources to provide these services; however, we

[Table of Contents](#)

may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion, or if we are forced to change service providers. If we experience significant delays in the progress of our clinical trials and in our plans to file NDAs, the commercial prospects for product candidates could decrease.

Our polymer-based drug delivery technology is at an early stage of development, and we cannot be certain that such development will be successful.

Our bioerodible drug delivery technology is at an early stage of development. We may not be able to substantiate the capability of our drug delivery technology for a variety of reasons:

- selection of inappropriate therapeutic compound for delivery;
- selection of inappropriate application for the particular product candidate;
- failure to receive regulatory approval on a timely basis or at all; or
- difficulties with manufacturing in commercial quantities at an acceptable cost.

Successful development of delivery technologies will require significant preclinical and clinical testing prior to regulatory approval, if any. Because of these scientific, regulatory and commercial hurdles, any program could be abandoned or otherwise fail, even after significant resources have been expended.

Recent changes in management may be disruptive.

We had significant changes in management during 2006. On October 9, 2006, Michael O'Connell, our President and Chief Executive Officer began a temporary leave of absence for medical reasons. Effective that same date, Gregory Turnbull, formerly an independent director of the Company, began to serve as President and Chief Executive Officer until Mr. O'Connell's return. Effective September 27, 2006, Stephen Whiteford was appointed the Company's Vice President, Finance and Chief Financial Officer to replace our former Chief Financial Officer who left the Company on September 12, 2006 to pursue another opportunity. Additions of new personnel and departures of existing personnel, particularly in key positions, can be disruptive, might lead to additional departures of existing personnel and could have a material adverse effect on our business, operating results and financial condition.

If any products that we or our collaborators may develop do not attain adequate market acceptance by healthcare professionals and patients, our business prospects and results of operations will suffer.

Even if a product candidate receives regulatory approval for commercial sale, the revenue received or to be received from the sale of the product may not be significant and will depend on many factors that are outside of our control. Factors that may affect revenue from our product candidates, if and when approved, include:

- perception of physicians and other members of the health care community of their safety and efficacy relative to that of competing products;

[Table of Contents](#)

- cost-effectiveness;
- patient and physician satisfaction with these products;
- ability to manufacture commercial products successfully and on a timely basis;
- cost and availability of raw materials;
- size of the markets for these products;
- reimbursement policies of government and third-party payors;
- unfavorable publicity concerning these products or similar drugs;
- the introduction, availability and acceptance of competing treatments, including those of our collaborators;
- adverse event information relating to these products;
- product labeling or product insert required by the FDA or regulatory authorities in other countries;
- regulatory developments related to the manufacture or continued use of these products;
- extent and effectiveness of sales and marketing and distribution support for the products; and
- our collaborators' decisions as to the timing of product launches, pricing and discounting.

Our product revenue will be adversely affected if, due to these or other factors, the products we or our collaborators are able to commercialize do not gain significant market acceptance.

We depend on contract manufacturers and collaborators for manufacturing our products; if they do not perform as expected, our revenue and customer relations will suffer.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of any product. We rely on a small number of third-party manufacturers to produce our compounds and expect to continue to do so to meet the preclinical and clinical requirements of our potential products and for all of our commercial needs. We have no long-term agreements with any of these third parties. We may not be able to extend these agreements at satisfactory terms, or at all, and we may not be able to find a replacement contract manufacturer at satisfactory terms or on a timely basis.

Further, our contract manufacturers and our collaborators are required to comply with FDA requirements related to product testing, quality assurance, manufacturing and records and documentation. Our contract manufacturers or our collaborators may not be able to comply with the applicable FDA regulatory requirements, which could result in an enforcement or other action, prevent commercialization of our product candidates and impair our reputation and results of operations.

[Table of Contents](#)

If we fail to comply with continuing federal, state and foreign regulations, we could lose our approvals to market drugs and our business would be seriously harmed.

Following initial regulatory approval of any drugs we may develop, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any post-marketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our contract manufacturers will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we and our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

Additionally, such regulatory review covers a company's activities in the promotion of its drugs, with significant potential penalties and restrictions for promotion of drugs for an unapproved use. Sales and marketing programs are under scrutiny for compliance with various mandated requirements, such as illegal promotions to healthcare professionals. We are also required to submit information on our open and completed clinical trials to public registries and databases; failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

If we are unable to recruit and retain skilled employees, we may not be able to achieve our objectives.

We depend on a small number of key management and technical personnel. Retaining our current employees and recruiting qualified scientific personnel to perform future research and development work will be critical to our success. There is a shortage of skilled personnel in our industry, competition is intense for experienced scientists, and an inability to recruit or retain

[Table of Contents](#)

sufficient skilled personnel could result in delays to product development or approval, loss of sales and diversion of management resources.

We face intense competition from other companies.

We face intense competition from companies that are developing new formulations of existing drugs using novel drug delivery technologies. Many of our competitors have much greater financial, research and development, manufacturing, marketing, sales, distribution and managerial resources and experience than we do. Many of them also have much more experience than we do in preclinical testing and clinical trials of new drugs and in obtaining FDA and foreign regulatory approvals.

The following are our major competitors:

- Alkermes, Inc.
- Depomed, Inc.
- Durect Corporation
- ProStrakan Group PLC
- SkyePharma PLC

Additionally, APF530 is expected to face competition from MGI Pharma's Aloxi, Roche's Kytril, GlaxoSmithKline's Zofran, and Aventis' Anzemet, each of which is currently on the market, as well as Hana Biosciences' Zensana. We are also aware of several companies developing both generic and new formulations of granisetron. APF112 is expected to face competition from Durect's Posidur and SkyePharma's recently divested DepoBupivacaine. Most or all of the products we could develop or commercialize will face competition from different therapeutic agents intended for treatment of the same indications or from other products incorporating drug delivery technologies. The competition potentially includes all of the pharmaceutical and drug delivery companies in the world. To the extent that we develop or market products incorporating drugs that are off-patent, or are being developed by multiple companies, we will face competition from other companies developing and marketing similar products.

Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

Because we or our collaborators must obtain regulatory approval to market our products in the United States and foreign jurisdictions, we cannot predict whether or when we will be permitted to commercialize our products.

Federal, state and local governments in the United States and governments in other countries have significant regulations in place that govern many of our activities. The preclinical testing and clinical trials of the products that we develop ourselves or

[Table of Contents](#)

that our collaborators develop are subject to government regulation and may prevent us from creating commercially viable products from our discoveries. These regulations and their application may change making it more difficult or prohibitive to develop our products. In addition, the sale by us or our collaborators of any commercially viable product will be subject to government regulation from several standpoints, including the processes of:

- manufacturing;
- labeling;
- distributing;
- advertising and promoting; and
- selling and marketing.

We depend on our collaborators to help us complete the process of developing and testing our products.

Our strategy for the development, clinical testing and commercialization of our products requires entering into collaborations with corporate partners, licensors, licensees and others. These collaborations are critical to our success in bringing our products and product candidates to the market and promoting such marketed products profitably. We are dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to our research activities related to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Failure to make or maintain these arrangements or a delay in a collaborative partner's performance or factors that may affect our partner's sales may materially adversely affect our business, results of operations and financial condition.

Under agreements with collaborators, we may rely significantly on them, among other activities, to:

- fund research and development activities with us;
- pay us fees upon the achievement of milestones; and
- market with us any commercial products that result from our collaborations.

Our business strategy includes the entry into additional collaborative agreements. We may not be able to enter into additional collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements.

Our current business strategy includes the entry into additional collaborative agreements for the development and commercialization of our delivery technologies. The negotiation and consummation of these types of agreements typically involve simulta - -

[Table of Contents](#)

neous discussions with multiple potential collaborators and require significant time and resources from our officers, business development, legal and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well as the collaborators' own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may have to consume money more rapidly on our product development efforts, defer development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business.

If we or our collaborators cannot arrange for adequate third-party reimbursement for our products, our revenue will suffer.

In both domestic and foreign markets, sales of our potential products will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services and such pressure may increase in the future. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. If any products we develop do not receive adequate reimbursement, our revenue will be severely limited.

Our inability to obtain specialized materials could slow down our research and development process.

Some of the critical materials and components used in our products in development are sourced from a single supplier. An interruption in supply of a key material could significantly delay our research and development process or increase our expenses.

Specialized materials must often be manufactured for the first time for use in drug delivery technologies, or materials may be used in the technologies in a manner different from their customary commercial uses. The quality of materials can be critical to the performance of a drug delivery technology, so a reliable source of a consistent supply of materials is important. Materials or components needed for our drug delivery technologies may be difficult to obtain on commercially reasonable terms, particularly when relatively small quantities are required, or if the materials traditionally have not been used in pharmaceutical products.

If we are unable to adequately protect or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us.

Our success will depend in part on our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of others. We have filed a number of U. S. patent applications on inventions relating to the composition of a variety of polymers, specific products, product groups and processing technology. In addition to obtaining patents in a number of foreign countries, we have also filed U.S. and foreign patent applications on our polymer technology with the Patent

[Table of Contents](#)

Cooperation Treaty (PCT), the European Patent Office, Australia, Canada, China, Hong Kong, Japan, South Korea, Singapore and Taiwan. We have a total of 21 issued United States patents and an additional 113 issued (or registered) foreign patents. The patents on the bioerodible technologies expire between January 2016 and November 2022. Our existing patents may not cover future products, additional patents may not be issued, and current patents or patents issued in the future may not provide meaningful protection or prove to be of commercial benefit.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications or those that are licensed to us may not issue into patents, and any issued patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as the U. S. law.

We are party to several collaborative agreements. These agreements subject us to obligations which must be fulfilled and require us to manage complex relationships with third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated, our revenue may decrease. Our third-party collaborators have entered into these agreements based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration requiring us to devote management time and resources to such dispute which we would otherwise spend on our business.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference proceedings declared by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

We may infringe on the intellectual property rights of others, and any litigation could force us to stop developing or selling potential products and could be costly, divert management attention and harm our business.

We must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to the composition of a variety of polymers, specific products, product groups and processing technology, it could be difficult for us to use our technologies or develop products without infringing the proprietary rights of others. We may not be able to design around the patented technologies or inventions of others and we may not be able to obtain licenses to use patented technologies on acceptable terms, or at all. If we cannot operate without infringing the proprietary rights of others, we will not earn product revenue.

If we are required to defend ourselves in a lawsuit, we could incur substantial costs and the lawsuit could divert management attention, regardless of the lawsuit's merit or outcome. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process and any license required under any such patent may not be made available to us on acceptable terms, if at all.

Periodically, we review publicly available information regarding the development efforts of others in order to determine whether these efforts may violate our proprietary rights. We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense, regardless of its outcome, and may not be resolved in our favor.

Furthermore, patents already issued to us or our pending patent applications may become subject to dispute, and any disputes could be resolved against us. In addition, because patent applications in the United States are currently maintained in secrecy for a period of time prior to issuance, and patent applications in certain other countries generally are not published until more than 18 months after they are first filed, and because publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by our pending patent applications or that we were the first to file patent applications on such inventions.

We are exposed to risks and increased expenses as a result of laws requiring non-accelerated filers to evaluate internal controls over financial reporting.

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year beginning with the year ending December 31, 2007, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for each fiscal year. Section 404 also requires our independent auditors to attest to, and report on, management's assessment of our internal controls over financial reporting beginning with the year ending December 31, 2008. We have implemented an ongoing program to perform the system and process evaluation and testing we believe to be necessary to comply with these requirements. However, we cannot assure you that we will be successful in our efforts. We expect to incur increased expense and to devote additional management resources to Section 404 compliance. Any failure to implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm

[Table of Contents](#)

our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Legislative actions, potential new accounting pronouncements and higher insurance costs are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenue or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, the Public Company Accounting Oversight Board, pronouncements and The NASDAQ Global Market rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We could be exposed to significant product liability claims that could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage

The testing, manufacture, marketing and sale of our products involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our products, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could also significantly harm our reputation and delay market acceptance of our products.

Our use of hazardous materials could subject us to liabilities, fines and sanctions.

Our laboratory and clinical testing sometimes involve use of hazardous and toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result and such liability could exceed our financial resources. Compliance with environmental and other laws may be expensive and current or future regulations may impair our development or commercialization efforts.

Risks Related To Our Common Stock

The price of our common stock may be volatile.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In addition, the limited trading volume of our stock may contribute to its volatility.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- continuing losses and failure to achieve or maintain profitability;
- lack of availability of additional capital funding on commercial favorable terms to conduct operations and develop products;
- adverse results, lack of success or delays in our clinical trials of our product candidates, including APF530;
- announcements of FDA non-approval of our product candidates, or delays in the FDA review process;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing processes or sales and marketing activities;
- delays in preclinical and clinical testing;
- failure of third parties to perform their clinical trial obligations in a timely or competent manner;
- failure to substantiate the capability of our drug delivery technology;
- failure to attain adequate market acceptance by healthcare professionals and patients;
- failure of our contract manufacturers and collaborators to perform as expected;
- failure to comply with continuing federal, state and foreign regulations;
- announcements of technological innovations or new products by our competitors;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- changes in accounting principles; and
- loss of any of our key scientific or management personnel.

[Table of Contents](#)

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management's attention and our company's resources.

Our common stock may be delisted from The NASDAQ Global Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is listed on The NASDAQ Global Market. The listing standards of The NASDAQ Global Market provide that a company may be delisted if the bid price of its stock drops below \$1.00 for a period of 30 consecutive business days. Additionally, issuers must maintain either (i) stockholders' equity of at least \$10 million or (ii) total assets and total revenue of at least \$50 million, or total market value of listed securities of at least \$50 million. As of the end of the third fiscal quarter of 2005, we failed to meet the \$10 million stockholders' equity requirement, although we regained compliance with that requirement in January 2006. If we fail to comply with all listing standards applicable to issuers listed on The NASDAQ Global Market, our common stock may be delisted from The NASDAQ Global Market. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets, and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from The NASDAQ Global Market could also result in other negative implications, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

Our certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law, our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders; and
- providing for dilutive issuance of preferred stock, commonly referred to as a "poison pill", which can be triggered after a person or a group acquires 20% or more of our common stock.

In addition, Section 203 of Delaware General Corporation Law may discourage, delay or prevent a change in control of our company by prohibiting stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us, unless certain approvals are obtained.

[Table of Contents](#)

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

Available Information

We make available free of charge on or through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission. Our Internet website address is "www.appharma.com." The reference to our Internet website does not constitute incorporation by reference of the information contained on or hyperlinked from our Internet website. We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934. The SEC maintains an Internet site that contains reports, proxy information and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is <http://www.sec.gov>. The materials are also available at the SEC's Public Reference Room, located at 100 F Street, Washington, D.C. 20549. The public may obtain information through the public reference room by calling the SEC at 1-800-SEC-0330.

ITEM 2. PROPERTIES

We lease 26,067 square feet of laboratory, office and warehouse space in Redwood City, California under leases expiring in 2011. The annual rent expense for the Redwood City facility is approximately \$463,000.

We believe our facilities are adequate and suitable for current and anticipated needs.

ITEM 3. LEGAL PROCEEDINGS

None.

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

None.

[Table of Contents](#)

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Shares of the Company's common stock trade on the NASDAQ Global Market, under the symbol APPA. As of February 28, 2007, there were 423 holders of record of the Company's common stock.

The Company has never paid cash dividends and does not anticipate paying cash dividends in the foreseeable future. The following table sets forth for the fiscal periods indicated, the range of high and low sales prices for the Company's common stock on the NASDAQ Global Market (formerly the NASDAQ National Market).

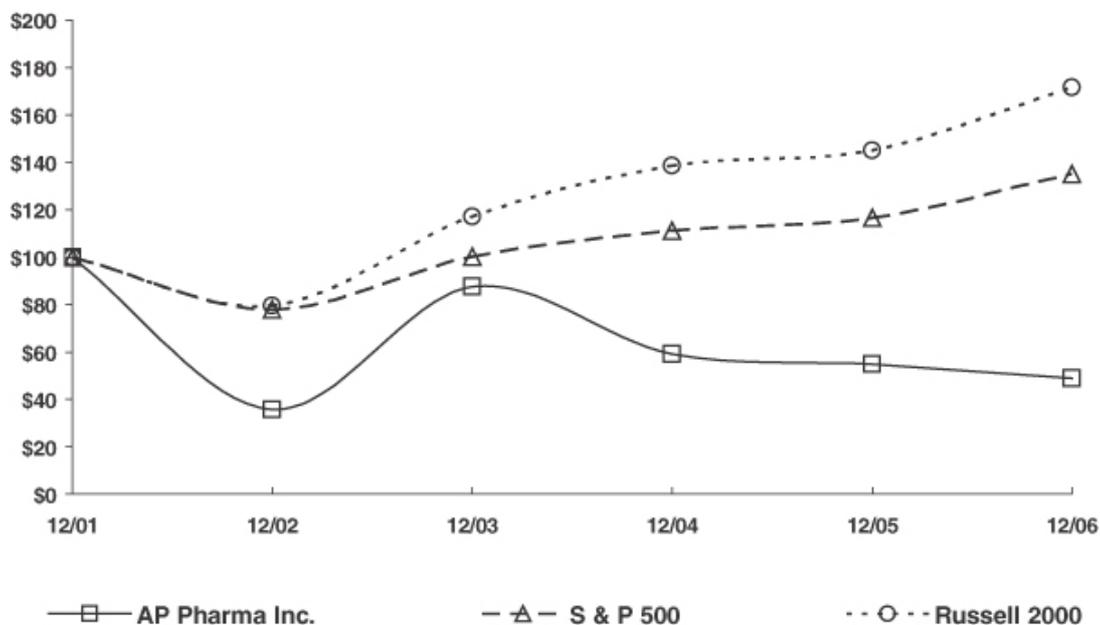
2006	High	Low	2005	High	Low
First Quarter	\$2.32	\$1.44	First Quarter	\$2.73	\$1.41
Second Quarter	2.19	1.33	Second Quarter	1.80	1.37
Third Quarter	1.62	0.84	Third Quarter	2.25	1.47
Fourth Quarter	1.56	1.00	Fourth Quarter	1.88	1.30

Performance Graph

The rules of the SEC require APP to include in this annual report on form 10K a line graph presentation comparing cumulative five year stockholder returns, on a dividend reinvested basis, with a broad based equity index and a published industry index. The Company selected the S&P 500 Stock Index and Russell 2000 for purposes of the comparison which appears below. The graph assumes that \$100 was invested in APP stock and each index on December 31, 2001, with all dividends reinvested. Past stock performance is not necessarily indicative of future results.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among AP Pharma Inc., The S & P 500 Index
And The Russell 2000 Index



* \$100 invested on 12/31/01 in stock or index-including reinvestment of dividends. Fiscal year ending December 31.
Copyright © 2007, Standard & Poor's, a division of The McGraw-Hill Companies, Inc. All rights reserved.
www.researchdatagroup.com/S&P.htm

	12/01	12/02	12/03	12/04	12/05	12/06
A.P. PHARMA, INC.	100	36	88	59	55	49
S&P 500	100	78	100	111	117	135
RUSSELL 2000	100	80	117	139	145	171

[Table of Contents](#)

ITEM 6. SELECTED FINANCIAL DATA
(IN THOUSANDS, EXCEPT PER SHARE DATA)

For the Years Ended and as of December 31,	2006	2005	2004	2003	2002
STATEMENTS OF OPERATIONS DATA					
Royalties	\$ —	\$ 5,247	\$ 4,972	\$ 4,502	\$ 4,026
Contract revenue	—	144	432	346	407
License fees	—	—	—	—	237
Total revenue	—	5,391	5,404	4,848	4,670
Expenses:					
Research and development	15,236	10,299	11,495	8,421	6,414
General and administrative	3,628	3,565	3,225	3,039	3,309
Operating loss	(18,864)	(8,473)	(9,316)	(6,612)	(5,053)
Gain on sale of interest in royalties	23,429	—	—	—	—
Interest and other income, net	952	290	224	404	658
Income (loss) from continuing operations	5,517	(8,183)	(9,092)	(6,208)	(4,395)
Income (loss) from discontinued operations ⁽¹⁾	(188)	(89)	(133)	(57)	401
Gain on disposition of discontinued operations ⁽²⁾	56	62	4	1,902	216
Income (loss) before income taxes	5,385	(8,210)	(9,221)	(4,363)	(3,778)
Income tax expense	119	—	—	—	—
Net income (loss)	\$ 5,266	\$ (8,210)	\$ (9,221)	\$ (4,363)	\$ (3,778)
Diluted income (loss) per common share:					
Income (loss) from continuing operations	\$ 0.22	\$ (0.33)	\$ (0.40)	\$ (0.30)	\$ (0.22)
Net income (loss)	\$ 0.21	\$ (0.33)	\$ (0.40)	\$ (0.21)	\$ (0.19)
Weighted average common shares outstanding used to calculate diluted earnings (loss) per common share	25,434	25,118	22,909	20,553	20,409

(1) Income (loss) from discontinued operations represents the income (loss) attributable to our Analytical Standards division that was sold to GFS Chemicals on February 13, 2003, and the income (loss) attributable to our cosmeceutical and toiletries business that was sold to RP Scherer on July 25, 2000. See Note 10 "Discontinued Operations" in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K.

(2) The gain on disposition of discontinued operations in 2003 represents the gain on sale of our Analytical Standards division to GFS Chemicals on February 13, 2003. See Note 10 "Discontinued Operations" in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K.

[Table of Contents](#)

December 31,	2006	2005	2004	2003	2002
BALANCE SHEET DATA					
Cash, cash equivalents and marketable securities	\$15,522	\$5,809	\$13,596	\$ 9,484	\$14,121
Working capital	12,014	4,882	12,636	9,366	13,989
Total assets	17,521	8,969	17,014	13,155	17,781
Long-term liabilities	1,000	—	—	—	345
Stockholders' equity	12,059	6,203	14,154	11,263	15,459

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

Overview

We are a specialty pharmaceutical company focused on developing pharmaceutical products using our proprietary Biochronomer polymer-based drug delivery technology. Our product development philosophy is based on incorporating approved therapeutics into our proprietary bioerodible drug delivery technology to create controlled release pharmaceuticals to improve treatments for diseases or conditions. Our lead product candidate, APF530, is currently in a pivotal Phase III clinical trial for the prevention of acute and delayed onset chemotherapy-induced nausea and vomiting, or CINV. We expect to complete enrollment of our pivotal Phase III clinical trial in the first half of 2008 and to announce results of that trial in the third quarter of 2008. We expect to file our new drug application, or NDA, for approval of APF530 in the fourth quarter of 2008.

Our primary focus is to advance our proprietary Biochronomer technology, consisting of bioerodible polymers designed to release drugs over a defined period. We have completed over 100 *in vivo* and *in vitro* studies demonstrating that our Biochronomer technology is potentially applicable to a range of therapeutic areas, including pain management, prevention of nausea and vomiting, control of inflammation and treatment of ophthalmic diseases. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are safe and well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to several months.

Our lead product candidate using our proprietary Biochronomer technology is APF530, which contains granisetron, a drug approved for the prevention of CINV. We selected granisetron because it is a potent drug which blocks a specific receptor found in the gut that is responsible for triggering CINV. Additionally, the applicable granisetron patent will expire in the United States on December 29, 2007. APF530 is designed to provide at least five days prevention of CINV. In September 2005, we completed a Phase II human clinical trial of APF530 that achieved all of its primary and secondary endpoints. In May 2006, we initiated our pivotal Phase III clinical trial of APF530. We believe that this clinical trial will lead to regulatory approval of APF530 for the prevention of acute and delayed onset CINV for patients undergoing both moderately and highly emetogenic, or vomit-inducing, chemotherapy.

This Annual Report on Form 10-K contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties including uncertainties associated with timely development, approval, launch and acceptance of new products, satisfactory completion of clinical studies, establishment of new corporate alliances, progress in research and development programs and other risks and uncertainties identified below and in Item 1A "Risk Factors," herein. We caution

investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

Critical Accounting Policies and Estimates

Our accounting policies are more fully described in Note 2 of the Financial Statements. The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires our management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ significantly from those estimates. We believe that the following addresses our most critical accounting policies for fair statement of the financial statements and require our management's subjective and complex judgment in 2006.

• **Revenue Recognition**

Our revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

• **Royalties**

Contractually required minimum royalties are recorded ratably throughout the contractual period. Royalties in excess of minimum royalties are recognized as earned when the related product is shipped to the end customer by our licensees based on information provided to us by our licensees.

• **Contract Revenue**

Generally, contract revenue relates to research and development arrangements that generally provide for our Company to invoice research and development fees based on full-time equivalent hours for each project. Revenue from these arrangements are recognized as the related development services are rendered. These revenue approximate the costs incurred.

• **License Fees**

Licensing agreements generally provide for us to receive periodic minimum payments, royalties, and/or non-refundable license fees. These licensing agreements typically require a non-refundable license fee and allow our partners to sell our proprietary products in a defined field or territory for a defined period. The license agreements provide for us to earn future revenue through royalty payments. These non-refundable license fees are initially reported as deferred revenue and recognized as revenue over the estimated life of the product to which they relate as we have continuing involvement with licensees until the related product is discontinued or the related patents expire, whichever is earlier. Revenue recognized from deferred license fees is classified as license fees in the accompanying statements of operations. License fees received in connection with arrangements where we have no continuing involvement are recognized when the amounts are received or when collectibility is reasonably assured, whichever is earlier.

A milestone payment is a payment made by a third party or corporate partner to us upon the achievement of a predetermined milestone as defined in a legally binding contract. Milestone payments are recognized as license fees when the milestone event has occurred and we have completed all milestone related services such that the milestone payment is currently due and is non-refundable.

• **Clinical Trial Accruals**

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. Since the invoicing related to these services does not always coincide with our financial statement close process, we must estimate the level of services performed and fees incurred in determining the accrued clinical trial costs. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the successful enrollment of patients or achievement of certain events or the completion of portions of the clinical trial or similar conditions. The Phase 3 clinical trials of APF530 will have a significant effect on the Company's research and development expenses. Expenses related to clinical trials generally are accrued based on the level of patient enrollment and services performed by the clinical research organization or related service provider according to the protocol. We monitor patient enrollment levels and related activity to the extent possible and adjust our estimates accordingly. Historically these estimates have been accurate and no material adjustments have had to be made.

• **Stock-Based Compensation**

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" (SFAS 123R). SFAS 123R revised SFAS 123, "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123R requires companies to measure and recognize compensation expense for all employee share-based payments at fair value over the service period underlying the arrangement. Accordingly, we are required to record the grant-date fair value of stock options issued to employees and purchase-date fair value of employee stock purchases. We adopted SFAS 123R using the "modified prospective" method, whereby fair value of all previously-granted employee share-based arrangements remaining unvested at January 1, 2006, based on the grant-date value estimated in accordance with the pro forma provisions of SFAS 123, and all grants made on or after January 1, 2006, based on fair value estimated in accordance with SFAS 123(R), have been included in our determination of share-based compensation expense in 2006. We have not restated our operating results in prior periods to reflect changes for the fair value of share-based arrangements.

Prior to January 1, 2006 we elected to account for stock-based compensation related to employees using the intrinsic value method. Accordingly, except for stock options issued to non-employees and restricted stock awards to employees and directors, no compensation cost was recognized for our stock option plans and stock purchase plan because stock option exercise prices historically equalled the per share fair values of the underlying common stock. Compensation related to options granted to non-employees was periodically remeasured as earned.

[Table of Contents](#)

Results of Operations for the years ended December 31, 2006, 2005 and 2004 (References to Notes herein refer to Notes to Financial Statements, in Item 8, herein)

The following sets forth the statement of operations data and percentage changes as compared to the prior year (dollar amounts are presented in thousands):

	For the Years Ended December 31,			Annual % Change	
	2006	2005	2004	2006/2005	2005/2004
Royalties	\$ —	\$ 5,247	\$ 4,972	(100)%	6 %
Contract revenue	—	144	432	(100)%	(67)%
Total revenue	—	5,391	5,404	(100)%	0 %
Research and development	15,236	10,299	11,495	48 %	(10)%
General and administrative	3,628	3,565	3,225	2 %	(11)%
Interest income	1,006	287	202	*	42 %
Gain on sale of royalty interests	23,400	—	—	*	*
Loss from discontinued operations	(188)	(89)	(133)	*	(33)%
Gain on disposition of discontinued operations, net of taxes	56	62	4	(10)%	*

* Calculation not meaningful.

We had no revenue in 2006, reflecting the sale of our rights to royalties on sales of Retin-A Micro and Carac on January 18, 2006, on which we recorded a gain of \$23.4 million (see Note 13). Royalties increased in 2005 by \$275,000 or 6% to \$5,247,000 from \$4,972,000 in 2004. This increase was due mainly to a 20% increase in royalties on sales of Carac, a topical prescription treatment for actinic keratoses which was sold by our marketing partner, Dermik Laboratories, a sanofi-aventis company. Royalties on sales of Retin-A Micro, a topical prescription treatment for acne which is marketed by Ortho Neutrogena, a Johnson & Johnson company, were essentially flat with the prior year.

Contract revenue decreased in 2006 by \$144,000 or 100% from \$144,000 in 2005 as a result of no collaborative research and development programs as we focused our efforts on the development of APF530 for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting. Contract revenue decreased in 2005 by \$288,000 or 67% to \$144,000 from \$432,000 in 2004 as a result of fewer collaborative research and development programs and our focus on APF530.

Research and development expense in 2006 increased by \$4,937,000 or 48% to \$15,236,000 from \$10,299,000 in 2005 due mainly to our Phase 3 clinical trial for APF530. Research and development expense in 2005 decreased by \$1,196,000 or 10% to \$10,299,000 from \$11,495,000 in 2004. During 2005, we successfully completed a Phase 2 clinical trial in the U.S. involving 45 patients, using APF530 for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting, and began preparations for a Phase 3 study. The decrease in expense from 2004 to 2005 is due to the fact that in 2004 we incurred higher expenses on toxicology studies and performed a Phase 2 study using APF112, our product candidate for post-surgical pain management, as well as a Phase 1 study using APF530. Research and development expenses in 2007 are expected to increase over those incurred in 2006, reflecting the increased number of patients enrolled in our Phase 3 study for APF530.

[Table of Contents](#)

The scope and magnitude of future research and development expenses are difficult to predict given the number of studies that will need to be conducted for any of our potential products. In general, biopharmaceutical development involves a series of steps, beginning with identification of a potential target, and includes proof of concept in animals and Phase 1, 2 and 3 clinical studies in humans. Each step of this process is typically more expensive than the previous one, so success in development results in increasing expenditures. Our research and development expenses currently include costs for scientific personnel, animal studies, human clinical trials, supplies, equipment, consultants, overhead allocation and sponsored research at academic and research institutions.

Products in Development

We have a number of product candidates in various stages of development. The following table sets forth the current opportunities for our own portfolio of product candidates, the compound selected, the delivery time and the status.

Current Opportunities

Product Portfolio	Drug	Delivery Duration	Status
APF530—Anti-nausea (chemo-therapy)	Granisetron	Short-term	Phase III
APF112—Acute pain relief (surgical/orthopedic)	Mepivacaine	Medium-term	Phase II
APF328—Anti-inflammatory (surgical/orthopedic)	Meloxicam	Medium-term	Preclinical
APF505—Anti-inflammatory (osteoarthritis)	Meloxicam	Long-term	Preclinical
APF580—Pain relief	Undisclosed opiate	At least 7 days	Preclinical

The major components of research and development expenses for 2006, 2005 and 2004 were as follows (in thousands):

	2006	2005	2004
Internal research and development costs	\$ 6,455	\$ 5,197	\$ 5,315
External Development Costs:			
APF530	7,305	3,551	2,739
APF112	—	—	2,422
External raw material supplies, polymer manufacturing and scale-up, and miscellaneous costs	1,476	1,551	1,019
	<u>\$15,236</u>	<u>\$10,299</u>	<u>\$11,495</u>

Internal research and development costs consist of employee salaries and benefits, laboratory supplies, depreciation, and allocation of overhead. External polymer development on clinical and preclinical programs includes expenditures on technology and product development, preclinical and clinical evaluations, regulatory and toxicology consultants, and polymer manufacturing, all of which are performed on our behalf by third parties.

General and administrative expense increased by \$63,000 or 2% in 2006 to \$3,628,000 from \$3,565,000 in 2005. General and administrative expense increased by \$340,000 or 11% in 2005 to \$3,565,000 from \$3,225,000 in 2004 due primarily to expenses associated with the financing activities which we completed in January 2006. General and administrative expense

[Table of Contents](#)

consists of salaries and related expenses, professional fees, directors' fees, investor relations costs, insurance expense and the related overhead cost allocation. General and administrative expense for 2007 is expected to remain consistent with 2006.

Interest income consists primarily of income earned on our invested cash, cash equivalents and marketable securities. Interest income increased by \$719,000 in 2006 to \$1,006,000 compared to \$287,000 in 2005 due to a higher level of invested assets and higher interest rates. Interest income increased by \$85,000 or 42% in 2005 to \$287,000 compared with \$202,000 in 2004 due to higher interest rates.

On February 13, 2003, we completed the sale of certain assets of our Analytical Standards division to GFS Chemicals, Inc. ("GFS"), a privately held company based in Columbus, Ohio. In this transaction, we received \$2.1 million on closing, and are entitled to receive royalties on sales of Analytical Standards products for a period of five years following the sale at rates ranging from 15% to 5%. The net present value of the guaranteed minimum royalties is included in the gain on disposition of these assets.

On July 25, 2000, we completed the sale of certain technology rights for our topical pharmaceutical and cosmeceutical product lines and associated assets ("cosmeceutical and toiletry business") to RP Scherer Corporation, a subsidiary of Cardinal Health, Inc. We received \$25 million on closing and were entitled to receive further earnout amounts for the subsequent three years, the amounts of which were dependent on the performance of the business sold.

Under the terms of the agreement with RP Scherer, we guaranteed a minimum gross profit percentage on RP Scherer's combined sales of products to Ortho Neutrogena and Dermik ("Gross Profit Guaranty"). The guaranty period commenced on July 1, 2000 and ends on the earlier of July 1, 2010 or the end of two consecutive guaranty periods where the combined gross profit on sales to Ortho and Dermik equals or exceeds the guaranteed gross profit.

Income (loss) from discontinued operations represents the income (loss) attributable to our Analytical Standards division through the date of sale and the income (loss) attributable to our Analytical Standards division and our cosmeceutical and toiletries business. For the year 2006, the net loss from discontinued operations of \$188,000 primarily related to the gross profit guarantee owed under the RP Scherer agreement compared to \$89,000 in 2005 and \$133,000 in 2004.

The gain on disposition of discontinued operations recorded in 2006 of \$56,000 compared to \$62,000 in 2005 and \$4,000 in 2004 relates to the gain on the sale of our Analytical Standards division.

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities increased by \$9,713,000 to \$15,522,000 at December 31, 2006 from \$5,809,000 at December 31, 2005.

Net cash provided by continuing operating activities for the year ended December 31, 2006 was \$9,157,000. Net cash used in continuing operating activities for the years ended December 31, 2005 and 2004 was \$7,652,000 and \$7,526,000, respectively. Net cash provided by continuing operating activities relates primarily to income from operations, depreciation and changes in accrued expenses and deferred revenue. Net cash used in continuing operating activities relates primarily to funding operations and changes in deferred revenue offset by depreciation. The increase in net cash provided by continuing operating

[Table of Contents](#)

activities in 2006 was primarily due to proceeds of \$25 million received from the sale of our rights to royalties on sales of Retin-A Micro and Carac, partially offset by funding in operations. The increase in net cash used in continuing operating activities in 2005 was primarily due to the timing of payments on toxicology studies and research and development expenses associated with the Phase 2 study on APF530 compared with payments for the cost of the Phase 2 study in 2004 on APF112 for the treatment of post-surgical pain and the Phase 1 clinical trial on APF530.

The cash provided by discontinued operations of \$24,000, \$125,000 and \$99,000 in 2006, 2005 and 2004, respectively, relates to the royalties received from GFS for sales of Analytical Standards products, partially offset by severance payments and payments of the gross profit guarantee to RP Scherer.

Net cash used in investing activities for the year ended December 31, 2006 was \$7,717,000 compared with net cash provided by investing activities for the year ended December 31, 2005 of \$5,088,000 and net cash used in investing activities of \$1,572,000 in the year ended December 31, 2004. The increase in net cash used in investing activities in 2006 compared with net cash provided by investing activities in 2005 was primarily due to increased purchases of marketable securities and decreased maturities of marketable securities. The increase in net cash provided by investing activities in 2005 compared with net cash used in investing activities in 2004 was primarily due to decreased purchases of marketable securities and increased sales of marketable securities.

Our financing activities provided us with \$79,000, \$119,000 and \$12,012,000 for the years ended December 31, 2006, 2005 and 2004, respectively. The net cash provided by financing activities in 2004 primarily relates to the issuance of 4,153,335 shares of common stock at \$3.00 per share in June 2004. The net cash provided by financing activities in 2006 and 2005 was primarily related to proceeds from issuances of shares under the Employee Stock Purchase Plan and stock option plans.

To date, we have financed our operations including technology and product research and development, primarily through royalties received on sales of Retin-A Micro and Carac, income from collaborative research and development fees, the proceeds received from the sales of our Analytical Standards division and our cosmeceutical and toiletry business, the sale of common stock in June 2004, and interest earned on short-term investments. In January 2006, we sold the rights to our interest in the royalty income from Retin-A Micro and Carac for \$25 million plus additional payments totaling \$5 million which we expect will be made based on the satisfaction of certain pre-determined milestones over the next four years. Our existing cash and cash equivalents, marketable securities, together with interest income will not be sufficient to meet our cash needs for the year ending December 31, 2007. We are currently seeking additional financing within this timeline through convertible debt and/or equity financing.

At December 31, 2006, we had federal net operating loss carryforwards of \$67.1 million. Section 382 of the Internal Revenue Code imposes an annual limitation on the utilization of net operating loss carryforwards following a "change of ownership." The amount of the limitation is based on a statutory rate of return and the value of the corporation at the time of the change of ownership. Private placements and other sales of equity securities by the Company could cause a change of ownership either individually or in the aggregate. If a change of ownership occurs and an annual limitation is imposed, a portion of the carryforwards may expire before we could utilize them.

Our capital requirements going forward from 2007 will depend on numerous factors including, among others, our ability to enter into collaborative research and development and licensing agreements; progress of product candidates in preclinical and

[Table of Contents](#)

clinical trials; investment in new research and development programs; time required to gain regulatory approvals; resources that we devote to self-funded products; potential acquisitions of technology, product candidates or businesses; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technology.

There can be no assurance that we will be able to raise sufficient additional capital when we need it or to raise capital on favorable terms. The sale of additional equity or convertible debt securities in the future may be dilutive to our stockholders, and debt financing arrangements may require us to pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to us or our stockholders. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or to obtain funds by entering into financing, supply or collaboration agreements on unattractive terms.

Below is a summary of fixed payments related to certain contractual obligations (in thousands). This table excludes amounts already recorded on our balance sheet as current liabilities at December 31, 2006.

	Total	Less Than 1 year	1-3 years	3-5 years	More Than 5 years
Operating Leases ⁽¹⁾	\$2,243	\$ 511	\$1,061	\$ 671	\$ —
Total	\$2,243	\$ 511	\$1,061	\$ 671	—

⁽¹⁾ See Note 7 "Commitments and Contingencies."

Under the terms of the agreement with RP Scherer, we guaranteed a minimum gross profit percentage on RP Scherer's combined sales of products to Ortho Neutrogena and Dermik ("Gross Profit Guaranty"). The guaranty period commenced on July 1, 2000 and ends on the earlier of July 1, 2010 or the end of two consecutive guaranty periods where the combined gross profit on sales to Ortho and Dermik equals or exceeds the guaranteed gross profit. The Gross Profit Guaranty expense totaled \$729,000 for the first six guaranty years and in those years did not include two consecutive periods where the combined gross profit on sales to Ortho and Dermik equaled or exceeded the guaranteed gross profit. Therefore, we expect the Gross Profit Guaranty payments to range from approximately \$100,000 to \$150,000 per year for the remainder of the guaranty period.

Off-Balance-Sheet Arrangements

As of December 31, 2006, we did not have any off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recent Accounting Pronouncements

Recent accounting pronouncements are disclosed in Note 2.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments. We manage our interest rate risk by maintaining an investment portfolio primarily consisting of debt instruments of high credit quality and relatively short average maturities. The interest rates as of December 31, 2006 and 2005 were 5.1% and 3.78%, respectively. At December 31, 2006 and 2005, respectively, our cash equivalents and marketable securities include corporate and other debt securities as follows: (in thousands)

December 31,	<u>2006</u>	<u>2005</u>
Available-for-sale:		
Due in less than 1 year	14,665	3,997
Due after 1 year but less than 5 years	400	1,478
Total available-for-sale	<u>\$15,065</u>	<u>\$5,475</u>

Notwithstanding our efforts to manage interest rate risks, there can be no assurance that we will be adequately protected against the risks associated with interest rate fluctuations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
A.P. Pharma, Inc.

We have audited the accompanying balance sheet of A.P. Pharma, Inc. as of December 31, 2006 and the related statements of operations, stockholders' equity and cash flows for the year then ended. Our audit also included the 2006 financial data in the financial statement schedule listed in the Index at Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements audited by us present fairly, in all material respects, the financial position of A.P. Pharma, Inc. at December 31, 2006, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for the year ended December 31, 2006, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 2, the Company adopted SFAS No. 123(R) (Revised 2004), Share-Based Payment, applying the modified prospective method effective January 1, 2006.

The accompanying financial statements at December 31, 2006 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and may not have adequate working capital to sustain its future operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plan in regard to these matters is also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ ODENBERG, ULLAKKO, MURANISHI & CO. LLP

San Francisco, California
March 26, 2007

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
A.P. Pharma, Inc.

We have audited the accompanying balance sheet of A.P. Pharma, Inc. as of December 31, 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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 financial position of A.P. Pharma, Inc. at December 31, 2005, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 24, 2006

[Table of Contents](#)

A.P. PHARMA, INC.
BALANCE SHEETS
(in thousands except par value and shares)

December 31,	2006	2005
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 2,333	\$ 790
Marketable securities	13,189	5,019
Accounts receivable	75	1,519
Prepaid expenses and other current assets	609	320
Total current assets	16,206	7,648
Property and equipment, net	958	1,164
Other long-term assets	87	157
Total Assets	<u>\$ 17,251</u>	<u>\$ 8,969</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 772	\$ 614
Accrued expenses	3,085	1,904
Accrued disposition costs	335	248
Total current liabilities	4,192	2,766
Deferred revenue	1,000	—
Total Liabilities	5,192	2,766
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock, 2,500,000 shares authorized; none issued or outstanding at December 31, 2006 and 2005	—	—
Common stock, \$.01 par value, 50,000,000 shares authorized; 25,438,663 and 25,279,970 issued and outstanding at December 31, 2006 and 2005, respectively	254	253
Additional paid-in capital	99,581	98,995
Accumulated other comprehensive loss	(13)	(16)
Accumulated deficit	(87,763)	(93,029)
Total Stockholders' Equity	12,059	6,203
Total Liabilities and Stockholders' Equity	<u>\$ 17,251</u>	<u>\$ 8,969</u>

See accompanying notes to financial statements.

[Table of Contents](#)

A.P. PHARMA, INC.
STATEMENTS OF OPERATIONS
(in thousands except per share amounts)

For the Years Ended December 31,	2006	2005	2004
REVENUE			
Royalties	\$ —	\$ 5,247	\$ 4,972
Contract revenue	—	144	432
Total revenue	—	5,391	5,404
OPERATING EXPENSES			
Research and development	15,236	10,299	11,495
General and administrative	3,628	3,565	3,225
Total operating expenses	18,864	13,864	14,721
Operating loss	(18,864)	(8,473)	(9,316)
Interest income	1,006	287	202
Gain on sale of interest in royalties	23,429	—	—
Other income (loss), net	(54)	3	22
Income (loss) from continuing operations	5,517	(8,183)	(9,092)
Loss from discontinued operations	(188)	(89)	(133)
Gain on disposition of discontinued operations, net of taxes	56	62	4
Income (loss) before income taxes	5,385	(8,210)	(9,221)
Tax provision	(119)	—	—
Net income (loss)	\$ 5,266	\$ (8,210)	\$ (9,221)
Basic income (loss) per share			
Income (loss) from continuing operations	\$ 0.22	\$ (0.33)	\$ (0.40)
Net income (loss)	\$ 0.21	\$ (0.33)	\$ (0.40)
Diluted income (loss) per share			
Income (loss) from continuing operations	\$ 0.22	\$ (0.33)	\$ (0.40)
Net income (loss)	\$ 0.21	\$ (0.33)	\$ (0.40)
Weighted average common shares outstanding—basic	25,262	25,118	22,909
Weighted average common shares outstanding—diluted	25,434	25,118	22,909

See accompanying notes to financial statements.

Table of Contents

A.P. PHARMA, INC. STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands)

For the Years Ended December 31, 2006, 2005 and 2004	Common Stock		Addi- tional Paid-In Capital	Accu- mulated Deficit	Accu- mulated Other Compre- hensive Income (Loss)	Stock- holders' Equity
	Shares	Amount				
BALANCE, DECEMBER 31, 2003	20,642	\$ 206	\$ 86,638	\$ (75,598)	\$ 17	\$ 11,263
Comprehensive loss:						
Net loss	—	—	—	(9,221)	—	(9,221)
Net unrealized loss on marketable securities	—	—	—	—	(33)	(33)
Comprehensive Loss						(9,254)
Common stock issuance, net of issuance costs	4,153	41	11,715	—	—	11,756
Common stock issued upon exercise of stock options	69	1	150	—	—	151
Fair value of stock based compensation issued to directors for services and to employees for restricted stock awards	52	1	116	—	—	117
Expenses associated with stock options granted to non-employees	—	—	16	—	—	16
Common stock issued to employees under the Employee Stock Purchase Plan	118	1	104	—	—	105
BALANCE, DECEMBER 31, 2004	25,034	250	98,739	(84,819)	(16)	14,154
Net loss and comprehensive loss	—	—	—	(8,210)	—	(8,210)
Common stock issued upon exercise of stock options	15	—	22	—	—	22
Fair value of stock based compensation issued to directors for services and to employees for restricted stock awards	145	2	135	—	—	137
Stock based compensation related to stock options granted to non-employees	—	—	4	—	—	4
Common stock issued to employees under the Employee Stock Purchase Plan	86	1	95	—	—	96
BALANCE, DECEMBER 31, 2005	25,280	253	98,995	(93,029)	(16)	6,203
Comprehensive income:						
Net income	—	—	—	5,266	—	5,266
Net unrealized income on marketable securities	—	—	—	—	3	3
Comprehensive income						5,269
Common stock issued upon exercise of stock options	10	—	11	—	—	11
Fair value of stock based compensation issued to directors for services and to employees for restricted stock Awards	84	1	134	—	—	135
Stock based compensation related to stock options granted to non-employees	—	—	2	—	—	2
Common stock issued to employees under the Employee Stock Purchase Plan	65	—	67	—	—	67
SFAS123R stock-based compensation related to stock options and ESPP	—	—	372	—	—	372
BALANCE, DECEMBER 31, 2006	25,439	\$ 254	\$ 99,581	\$ (87,763)	\$ (13)	\$ 12,059

See accompanying notes to financial statements.

Table of Contents

A.P. PHARMA, INC. STATEMENTS OF CASH FLOWS (in thousands)

For the Years Ended December 31,	2006	2005	2004
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	\$ 5,266	\$ (8,210)	\$ (9,221)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Loss from discontinued operations	188	89	133
Gain on disposition of discontinued operations	(56)	(62)	(4)
Loss (gain) on sale of marketable securities	1	4	(2)
Depreciation and amortization	394	387	381
Recovery of note receivable	—	—	(18)
Stock-based compensation	508	140	133
Amortization of premium/discount and accretion of marketable securities	(638)	59	249
Loss on retirements and disposals of fixed assets	—	—	7
Changes in operating assets and liabilities:			
Accounts receivable	1,369	(83)	(287)
Prepaid expenses and other current assets	(289)	74	58
Other long-term assets	75	132	184
Accounts payable	158	(83)	221
Accrued expenses	1,167	(99)	830
Deferred revenue	1,014	—	(190)
Net cash provided by (used in) continuing operating activities	9,157	(7,652)	(7,526)
Cash provided by discontinued operations	24	125	99
Net cash provided by (used in) operating activities	9,181	(7,527)	(7,427)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(187)	(316)	(193)
Purchases of marketable securities	(14,701)	(8,126)	(12,838)
Maturities of marketable securities	1,800	7,935	9,577
Sales of marketable securities	5,371	5,595	1,882
Net cash provided by (used in) investing activities	(7,717)	5,088	(1,572)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of common stock, net of issuance costs	—	—	11,756
Proceeds from the exercise of common stock options	11	22	151
Proceeds from issuance of shares under the Employee Stock Purchase Plan	68	97	105
Net cash provided by financing activities	79	119	12,012
Net increase (decrease) in cash and cash equivalents	1,543	(2,320)	3,013
Cash and cash equivalents at the beginning of the year	790	3,110	97
Cash and cash equivalents at the end of the year	\$ 2,333	\$ 790	\$ 3,110
Supplemental Cash Flow Data:			
Cash paid for interest	\$ 15	\$ 4	\$ 5

See accompanying notes to financial statements.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

NOTE 1 BUSINESS

We are a specialty pharmaceutical company focused on developing pharmaceutical products using our proprietary Biochronomer polymer-based drug delivery technology. Our product development philosophy is based on incorporating approved therapeutics into our proprietary bioerodible drug delivery technology to create controlled release pharmaceuticals to improve treatments for diseases or conditions. Our lead product candidate, APF530, is currently in a pivotal Phase III clinical trial for the prevention of acute onset and delayed onset chemotherapy-induced nausea and vomiting, or CINV. We expect to complete enrollment of our pivotal Phase III clinical trial in the first half of 2008 and to announce results of that trial in the third quarter of 2008. We expect to file our new drug application, or NDA, for approval of APF530 in the fourth quarter of 2008.

Our primary focus is to advance our proprietary Biochronomer technology, consisting of bioerodible polymers designed to release drugs over a defined period. We have completed over 100 in vivo and in vitro studies demonstrating that our Biochronomer technology is potentially applicable to a range of therapeutic areas, including pain management, prevention of nausea, control of inflammation and treatment of ophthalmic diseases. We have also completed comprehensive animal and human toxicology studies that have established that our Biochronomer polymers are safe and well tolerated. Furthermore, our Biochronomer technology can be designed to deliver drugs over periods varying from days to several months.

On July 25, 2000, we completed the sale of certain technology rights for our topical pharmaceutical and cosmeceutical product lines and other assets ("cosmeceutical and toiletry business") to RP Scherer Corporation, a subsidiary of Cardinal Health, Inc. As a result of this transaction, our Statements of Operations reflect the receipt of certain earnout payments and the payment of certain contractual obligations in the gain from disposition of discontinued operations (see Note 10).

On February 13, 2003, we completed the sale of our Analytical Standard division to GFS Chemicals, Inc. ("GFS"), a privately held company based in Columbus, Ohio. In this transaction, we received \$2.1 million and are entitled to receive royalties on sales of Analytical Standards products of 15% for the first year, 10% for the second through fourth years, and 5% for the fifth year. The net present value of the guaranteed minimum royalties is included in the gain on disposition of discontinued operations (see Note 10).

On January 18, 2006 we sold our rights to royalties on sales of Retin-A Micro(R) and Carac (R), effective October 1, 2005, for up to \$30 million. We received \$25 million at closing, and will receive the remaining balance upon the achievement of certain milestones over the next four years. In 2006, we recognized a gain on the sale of the royalty interest of \$23.4 million, net of \$1.6 million related to royalties recognized as revenue in 2005 (see Note 13).

On October 1, 2006, we entered into an agreement with RHEI Pharmaceuticals, Inc. ("RHEI") in which we granted RHEI exclusive license to develop and market APF530 in Greater China. See Note 13.

Going Concern

The accompanying financial statements have been prepared assuming we will continue as a going concern. We have suffered recurring losses and had an accumulated deficit of \$87.8 million as of December 31, 2006.

At December 31, 2006, we had \$15.5 million cash, cash equivalents and marketable securities that we believe will not enable us to fund our operations through fiscal year 2007. We are seeking additional financing to continue our research and development

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

activities. We anticipate that our cash expenditures during fiscal year 2007 will be approximately \$30 million. We expect to meet our cash needs and fund our working capital requirements from additional capital sources, which may include an equity offering. If we are unable to complete an equity offering, or otherwise obtain sufficient financing, we may be required to reduce, defer, or discontinue our research and development activities or may not be able to continue as a going concern entity.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash Equivalents and Marketable Securities

We consider all debt securities that have original maturities, from the date of purchase, of less than three months to be cash equivalents. Investments with maturities of three months and longer from the date of purchase are classified as marketable securities. Investments consist primarily of government obligations, mortgage backed securities, municipal bonds and corporate debt securities. We have classified all our investments in certain debt securities as "available-for-sale", and, therefore, they are recorded at fair value with unrealized gains and losses reported as a separate component of stockholders' equity. If the estimated fair value of a security is below its carrying value, we evaluate whether we have the intent and ability to retain our investment for a period of time sufficient to allow for any anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. Other-than-temporary declines in estimated fair value of all marketable securities are charged to "other income (loss), net." The cost of all securities sold is based on the specific identification method.

Financial Instruments

The carrying values of the Company's financial instruments, including marketable securities, accounts receivable and accrued liabilities, approximate their respective fair values due to their short maturities.

Allowance for Note Receivable

A 100% allowance of \$394,000 was recorded for a note receivable at such time as management determined that collection was not reasonably assured. Interest income under the terms of note receivable agreement is recorded when cash is received or collectibility is reasonably assured. The note receivable, net of the related allowance, is included in prepaid expenses and other current assets in the accompanying balance sheets.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets as follows: equipment and machinery, 3 to 5 years; furniture and fixtures, 5 years; and leasehold improvements, over the shorter of the respective lease terms or the respective useful lives of the leasehold improvements.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

Long-Lived Assets

As circumstances dictate, we evaluate whether changes have occurred that would require us to consider whether those assets have been impaired. Recoverability of assets to be held and used is determined by comparing the undiscounted net cash flows of long-lived assets to their respective carrying values. If such assets are considered to be impaired, the amount of impairment to be recognized is measured based on the projected discounted cash flows using an appropriate discount rate.

Stock-Based Compensation

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" (SFAS 123R). SFAS 123R revised SFAS 123, "Accounting for Stock-Based Compensation" and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123R requires companies to measure and recognize compensation expense for all employee share-based payments at fair value over the service period underlying the arrangement. Accordingly, we are required to record the grant-date fair value of stock options issued to employees and purchase-date fair value of employee stock purchases. We adopted SFAS 123R using the "modified prospective" method, whereby fair value of all previously-granted employee share-based arrangements remaining unvested at January 1, 2006, based on the grant-date value estimated in accordance with the pro forma provisions of SFAS 123, and all grants made on or after January 1, 2006, based on fair value estimated in accordance with SFAS 123(R), have been included in our determination of share-based compensation expense in 2006. We have not restated our operating results in prior periods to reflect changes for the fair value of share-based arrangements.

In November 2005, the FASB issued FASB Staff Position No. SFAS 123(R)-3 "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards" (FSP 123(R)-3). The Company adopted the alternative transition method provided in the FASB Staff Position for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R) in the fourth quarter of fiscal 2006. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects for employee stock-based compensation, and to determine the subsequent impact on the APIC pool and Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123(R). The adoption did not have a material impact on our results of operations and financial condition.

Prior to January 1, 2006 we elected to account for stock-based compensation related to employees using the intrinsic value method. Accordingly, except for stock options issued to non-employees and restricted stock awards to employees and directors, no compensation cost was recognized for our stock option plans and stock purchase plan because stock option exercise prices historically equalled the per share fair values of the underlying common stock. Compensation related to options granted to non-employees was periodically remeasured as earned.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

In accordance with SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure," we have provided, below, the pro forma disclosures of the effect on net loss and net loss per share as if SFAS No. 123 had been applied in measuring compensation expense for the years ended December 31, 2005 and 2004 (in thousands, except for per share amounts) (see Note 8 "Stockholders' Equity"):

	2005	2004
Net loss—as reported	\$(8,210)	\$(9,221)
Add:		
Stock-based employee compensation expense for restricted stock awards	24	—
Deduct:		
Stock-based employee compensation expense determined under SFAS 123	(360)	(400)
Net loss—pro-forma	<u>\$(8,546)</u>	<u>\$(9,621)</u>
Basic and diluted net loss per common share—as reported	\$ (0.33)	\$ (0.40)
Basic and diluted net loss per common share—pro-forma	\$ (0.34)	\$ (0.42)

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates were made relating to useful lives of fixed assets, valuation allowances, impairment of assets accruals, and share-based costs. Actual results could differ materially from those estimates.

Revenue Recognition

Our revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration we receive is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units. Advance payments received in excess of amounts earned are classified as deferred revenue until earned.

Royalties

Royalties from licenses are based on third-party sales of licensed products or technologies and recorded as earned in accordance with contract terms when third-party results can be reliably determined and collectibility is reasonably assured.

Generally, contractually required minimum royalties are recorded ratably throughout the contractual period. Royalties in excess of minimum royalties are recognized as earned when the related product is shipped to the end customer by our licensees based on information provided to us by our licensees.

Contract Revenue

Contract revenue also relate to research and development arrangements that generally provide for the company to invoice research and development fees based on full-time equivalent hours for each project. Revenue from these arrangements are recognized as the related development services are rendered. These revenue approximate the costs incurred.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

License Fees

We have licensing agreements that generally provide for periodic minimum payments, royalties, and/or non-refundable license fees. These licensing agreements typically require a non-refundable license fee and allow our partners to sell our proprietary products in a defined field or territory for a defined period. The license agreements provide for us to earn future revenue through royalty payments. These non-refundable license fees are initially reported as deferred revenue and recognized as revenue over the estimated life of the product to which they relate as we have continuing involvement with licensees until the related product is discontinued or the related patents expire, whichever is earlier. Revenue recognized from deferred license fees is classified as license fees in the accompanying statements of operations. License fees received in connection with arrangements where we have no continuing involvement are recognized as license fees when the amounts are received or when collectibility is reasonably assured, whichever is earlier.

A milestone payment is a payment made by a third party or corporate partner to us upon the achievement of a predetermined milestone as defined in a legally binding contract. Milestone payments are recognized as license fees when the milestone event has occurred and we have completed all milestone related services such that the milestone payment is currently due and is non-refundable. No such fees were recorded during the years ended December 31, 2006, 2005 and 2004.

Research and Development

Research and development consists of costs incurred for Company-sponsored and collaborative research and development expenses. These costs consist primarily of employee salaries and other personnel-related expenses, facility-related expenses, lab consumables, polymer development manufacturing, clinical and pre-clinical related services performed by clinical research organizations, research institutions and other outside service providers.

Expenses related to clinical trials generally are accrued based on the level of patient enrollment and services performed by the clinical research organization or related service provider according to the protocol. The Company monitors patient enrollment levels and related activity to the extent possible and adjusts estimates accordingly.

Research and development expenses under collaborative agreements approximate the revenue recognized, excluding milestone and up-front payments received under such arrangements.

Net Income (Loss) Per Share

Basic income (loss) per share is estimated based on the weighted-average number of common shares outstanding. Diluted earnings per share is calculated using the weighted-average number of common shares outstanding and other dilutive securities. See Note 9.

Concentrations of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash equivalents, short-term investments and trade accounts receivable. We invest excess cash in a variety of high grade short-term, interest-bearing securities. This diversification of risk is consistent with our policy to ensure safety of principal and maintain liquidity.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

Approximately 95% of the accounts receivable were concentrated with two customers in the pharmaceutical industry as of December 31, 2005. As we sold our rights to royalties on sales of Retin-A Micro and Carac on January 18, 2006 (see Note 13), we did not have royalty revenue receivables at December 31, 2006. Approximately 97% and 92% of total revenue were concentrated with two customers for the years ended December 31, 2005 and 2004. To reduce credit risk, we performed ongoing credit evaluations of our customers' financial condition. We do not generally require collateral for customers with accounts receivable balances.

Segment and Geographic Information

Our operations are confined to a single business segment, the design and commercialization of polymer technologies for pharmaceutical and other applications. Substantially all of our revenue are derived from customers within the United States.

Recent Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" ("FIN 48"). This Interpretation clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The evaluation of a tax position in accordance with FIN 48 is a two-step process. The first step is recognition: The Company determines whether it is "more-likely-than-not" that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the "more-likely-than-not" recognition threshold, the company presumes that the position will be examined by the appropriate taxing authority that would have full knowledge of all relevant information. The second step is measurement: A tax position that meets the "more-likely-than-not" recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely to be realized upon ultimate settlement. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company has not yet determined what effect, if any, adoption of FIN 48 will have on its results of operations or financial position.

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is intended to be applied in conjunction with other accounting pronouncements that require or permit fair value measurements. Although SFAS 157 does not require any new fair value measurements, its application may change current practice for some entities. The definition of fair value contained in SFAS 157 retains the exchange price notion inherent in earlier definitions of fair value. SFAS 157 clarifies that the exchange price is the price in an orderly transaction between market participants to sell an asset or transfer a liability in the principal (or most advantageous) market for the asset or liability. Accordingly, the definition focuses on the price that would be received to sell the asset or paid to transfer the liability at the measurement date (an exit price), not the price that would be paid to acquire the asset or received to assume the liability at the measurement date (an entry price). SFAS 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, SFAS 157 prescribes that a fair value measurement be determined based on the assumptions that market participants would use in pricing the asset or liability.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

As a basis for considering market participant assumptions in fair value measurements, SFAS 157 establishes a fair value hierarchy that distinguishes between (1) market assumptions developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) the reporting entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). SFAS 157 clarifies that market participant assumptions include, among other considerations, assumptions about risk, about the effect of a restriction on the sale or use of an asset and about the effect of credit risk (credit standing) on the fair value of a liability. SFAS 157 expands disclosures about the use of fair value to measure assets and liabilities, and particularly the inputs used to measure fair value, in interim and annual periods subsequent to initial recognition. This statement is effective for fiscal years beginning after November 15, 2007. The Company has not yet determined what impact this statement will have on its results of operations or financial position.

NOTE 3 CASH EQUIVALENTS AND MARKETABLE SECURITIES

We consider our investments in debt securities as available-for-sale and, accordingly, we have recorded these investments at fair value. Realized losses totaled \$1,000 and \$4,000 for the years ended December 31, 2006 and 2005, respectively. Realized gains totaled \$2,000 for the year ended December 31, 2004.

At December 31, 2006 and 2005, the amortized cost and estimated market value of investments in debt securities and cash equivalents are set forth in the tables below:

December 31, 2006 (in thousands)	Cost	Unrealized Gains	Unrealized Losses	Estimated Market Value
Available-for-sale:				
Corporate debt securities	\$ 4,293	\$ 1	\$ (4)	\$ 4,290
Asset-backed securities	3,992	—	—	3,992
Government debt securities	4,813	—	(10)	4,803
Other debt securities	1,980	—	—	1,980
Total available-for-sale	\$15,078	\$ 1	\$ (14)	\$ 15,065

December 31, 2005 (in thousands)	Cost	Unrealized Gains	Unrealized Losses	Estimated Market Value
Available-for-sale:				
Corporate debt securities	\$1,809	\$ —	\$ (6)	\$ 1,803
Asset-backed securities	1,484	—	(5)	1,479
Government debt securities	996	—	(4)	992
Other debt securities	1,202	—	(1)	1,201
Total available-for-sale	\$5,491	\$ —	\$ (16)	\$ 5,475

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

The table below summarizes fair value disclosures at December 31 (in thousands):

	2006		2005	
	Cost	Fair Value	Cost	Fair Value
Cash equivalents	\$ 1,875	\$ 1,876	\$ 456	\$ 456
Marketable securities	13,203	13,189	5,035	5,019
Totals	<u>\$15,078</u>	<u>\$15,065</u>	<u>\$5,491</u>	<u>\$5,475</u>

The cost and estimated fair value of available-for-sale debt securities as of December 31, 2006, by contractual maturity, consisted of the following (in thousands):

	Cost	Estimated Market Value
Available-for-sale:		
Due in one year or less	\$14,678	\$ 14,665
Due in more than one year but less than 5 years	400	400
Total available-for sale	<u>\$15,078</u>	<u>\$ 15,065</u>

NOTE 4 PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

December 31, (in thousands)	2006	2005
Leasehold improvements	\$ 1,359	\$ 1,359
Furniture and equipment	2,771	2,641
Total property and equipment	4,130	4,000
Accumulated depreciation and amortization	(3,172)	(2,836)
Property and equipment, net	<u>\$ 958</u>	<u>\$ 1,164</u>

Depreciation expense amounted to \$394,000, \$387,000 and \$381,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

NOTE 5 ACCRUED EXPENSES

Accrued expenses consist of the following:

December 31, (in thousands)	2006	2005
Professional fees	\$ 228	\$ 230
Accrued salaries	294	226
Accrued bonus	250	378
Clinical studies	1,987	892
Deferred Revenue	14	—
Other	312	178
Total	<u>\$ 3,085</u>	<u>\$ 1,904</u>

NOTE 6 LONG-TERM DEBT

In September 1995, we extinguished \$2.5 million of Industrial Revenue Bonds through an “in-substance defeasance” transaction by placing approximately \$2.5 million of United States government securities in an irrevocable trust to fund all future interest and principal payments. In accordance with the agreement, the investments held in the irrevocable trust shall be the exclusive source of all principal and interest payments and we have no liability for any shortfall in payments due. In addition, we have relinquished all rights with respect to the amounts held in the trust. The defeased debt balance outstanding of \$2.5 million as of December 31, 2004 was repaid on January 15, 2005 using the proceeds from the maturities of the United States government securities held in the irrevocable trust. The bond liability and related assets held in trust are not reflected in the accompanying balance sheets.

NOTE 7 COMMITMENTS AND CONTINGENCIES

We lease office, warehouse and laboratory space and certain office equipment under operating lease arrangements which expire in 2011. Our future minimum lease payments under these noncancelable operating leases for facilities and equipment are as follows (in thousands):

Year Ending December 31,	Minimum Payments
2007	\$ 511
2008	523
2009	538
2010	551
2011	120
	<u>\$ 2,243</u>

Total rental expense for facilities and equipment was \$500,000, \$492,000 and \$501,000 for 2006, 2005 and 2004, respectively.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

As part of the sale of our cosmeceutical and toiletry business to RP Scherer Corporation in July 2000, we guaranteed a minimum gross profit percentage on RP Scherer's sales of products to Ortho Neutrogena and Dermik (See Note 10 "Discontinued Operations").

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, we have a director or officer insurance policy that limits our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of December 31, 2006.

In the normal course of business, we provide indemnifications of varying scope under our agreements with other companies, typically our clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, we generally indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with use or testing of our products or product candidates or with any U.S. patent or any copyright or other intellectual property infringement claims by any third party with respect to our products. The term of these indemnification agreements is generally perpetual. The potential future payments we could be required to make under these indemnification agreements is unlimited. Historically, costs related to these indemnification provisions have been immaterial. We also maintain various liability insurance policies that limit our exposure. As a result, we believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of December 31, 2006.

NOTE 8 STOCKHOLDERS' EQUITY

Shareholders' Rights Plan

On December 18, 2006, we entered into a Preferred Shares Rights Agreement. As part of this agreement, preferred stock purchase rights ("the rights") were distributed to stockholders of record as of January 2, 2007, at the rate of one right for each share of common stock held. The rights become exercisable only upon the acquisition, or the acquisition of the right to acquire, by a person or group of affiliated or associated persons, 20% or more of the outstanding shares of the Company's common stock. Once exercisable, each right entitles the holder to purchase, at a price of \$11.00, one one-thousandth of a share of Series A Participating Preferred Stock. For a limited period of time following the announcement of any such acquisition or offer, the rights are redeemable by the Company at a price of \$0.01 per right. If the rights are not redeemed or exchanged, each right will then entitle the holder to receive, upon exercise of such right, a number of shares of the Company's common stock having a then current value equal to two times the purchase price of such right. Similarly, if the rights are not redeemed or exchanged and following the acquisition of 20% or more of the outstanding shares of the Company's common stock by a person or group of affiliated or associated persons, (i) the Company consolidates with or merges into another entity, (ii) another entity consolidates with or merges into the Company or (iii) the Company sells or otherwise transfers 50% or more of its consolidated assets or earning power, each right will then entitle the holder to receive, upon exercise of such right, a number of shares of common stock of the acquiring company having a then current value equal to two times the purchase price. For a limited period of time after the exercisability of the rights, each right, at the discretion of the board of directors, may be exchanged for one share of common stock per right. The Company has initially reserved 200,000 shares of preferred stock pursuant to the exercise of these rights. These rights expire on December 31, 2016.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

Stock-Based Compensation Plans

We have two types of stock-based compensation plans, which consist of a stock purchase plan and two stock option plans.

In 1997, our stockholders approved our 1997 Employee Stock Purchase Plan (the "Plan"). In May 2006 the stockholders authorized the increase in shares reserved for issuance under the Plan by 150,000 to 800,000 to our employees, nearly all of whom are eligible to participate. Under the terms of the Plan, employees can elect to have up to a maximum of 10 percent of their base earnings withheld to purchase our common stock. The purchase price of the stock is 85 percent of the lower of the closing prices for our common stock on: (i) the first trading day in the enrollment period, as defined in the Plan, in which the purchase is made, or (ii) the purchase date. The length of the enrollment period may not exceed a maximum of 24 months. Enrollment dates are the first business day of May and November and the first enrollment date was April 30, 1997. Approximately 40 percent of eligible employees participated in the Plan in 2006. Under the Plan, we issued 64,699 shares in 2006, 86,449 shares in 2005 and 118,062 shares in 2004. The weighted average fair value of purchase rights granted during 2006, 2005 and 2004 was \$0.65, \$0.70 and \$0.51, respectively. The weighted average exercise price of the purchase rights exercised during 2006, 2005 and 2004 was \$1.05, \$1.11 and \$0.89, respectively. We had 223,383, 138,082, and 74,531 shares reserved for issuance under the Plan at December 31, 2006, 2005 and 2004, respectively.

We have two current stock option plans for employees, officers, directors and consultants. We grant stock options under the 2002 Stock Incentive Plan ("2002 Plan") and the Non-Qualified Stock Plan. The Company is authorized to issue up to 1,700,000 shares under the 2002 Plan, 400,000 of which were approved in May 2006, and 250,000 shares under the Non-Qualified Stock Plan. The options to purchase our common stock are granted with an exercise price which equals fair market value of the underlying common stock on the grant dates, and expire no later than ten years from the date of grant. The options are exercisable in accordance with vesting schedules that generally provide for them to be fully vested and exercisable four years after the date of grant. Any shares that are issuable upon exercise of options granted under the 2002 Plan and the Non-Qualified Stock Plan that expire or become unexercisable for any reason without having been exercised in full are available for future grant and issuance under the same stock option plan.

We adopted SFAS 123R "Share-Based Payment" on January 1, 2006. Accordingly, we recorded the grant-date or purchase-date fair value of stock options issued to employees and employee stock purchases. We have also recorded the compensation expense for stock options issued to non-employees and restricted stock awards to employees and directors. The fair value of each employee and director grant of options to purchase common stock is estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants for the year ended December 31, 2006: 1) risk-free interest rate of 4.8% for stock options and 4.90% for employee stock purchase plan; 2) expected dividend yield of 0% for both stock options and employee stock purchase plan; 3) expected holding period of 6.25 years based on the simplified method provided in Staff Accounting Bulletin No. 107 for "plain vanilla options" and expected term of 1.25 years for employee stock purchase plan based on weighted-average purchase period of the plan; 4) expected volatility of 240% for stock options and 82% for employee stock purchase plan based on the Company's historical stock prices; and 5) an estimated forfeiture rate of 3.62% of the options granted based on historical data.

The SFAS 123R share-based compensation expenses recorded for awards granted under the stock option plans and employee stock purchase plan were approximately \$372,000, net of estimated forfeitures, for the year ended December 31, 2006. The share-based compensation expense of \$134,000 and \$238,000 was recorded in research and development

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

expense and general and administrative expense for the year ended December 31, 2006, respectively. No tax benefit was recognized related to share-based compensation expense since we have incurred operating losses and we have established a full valuation allowance to offset all the potential tax benefits associated with our deferred tax assets.

We granted options to purchase common stock to consultants from time to time in exchange for services rendered and these options vest over a period of two to four years. No options were granted to consultants in 2006 or 2005. We recorded compensation expense related to option grants to consultants of approximately \$2,000, \$4,000, and \$16,000 in 2006, 2005 and 2004, respectively, which represents the fair market value of the portion of the awards that vested during 2006, 2005 and 2004. The unvested shares held by consultants have been revalued using the Black-Scholes option pricing model at the end of each accounting period. As of December 31, 2006, all shares held by consultants have been vested.

The following table summarizes option activity for 2006, 2005 and 2004:

	2006				2005		2004	
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value as of December 31, 2006	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	2,165,966	\$ 3.40			2,205,636	\$ 3.60	2,108,605	\$ 3.97
Granted	439,940	1.43			182,000	1.61	383,500	2.04
Exercised	(9,606)	1.16			(15,057)	1.45	(68,448)	2.20
Expired or Forfeited	(407,079)	5.23			(206,613)	4.08	(218,021)	4.93
Outstanding at end of year	<u>2,189,221</u>	2.67	5.71	<u>\$ 97,240</u>	<u>2,165,966</u>	3.40	<u>2,205,636</u>	3.60
Options exercisable at year end	1,662,884		4.68	\$ 43,949	1,828,833		1,712,166	
Shares available for future grant at year end	539,338				538,741		320,961	
Weighted-average fair value of stock options granted during the year	\$ 1.43				\$ 1.05		\$ 1.12	

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

As of December 31, 2006 there was approximately \$558,046 of total unrecognized compensation expense related to nonvested stock options. This expense is expected to be recognized over a weighted-average period of 1.2 years.

The following table summarizes information about stock options outstanding at December 31, 2006:

Range of Exercise Prices	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.89-\$1.44	503,697	7.8 years	\$ 1.19	277,306	\$ 1.23
\$1.49-\$2.00	528,239	7.8	1.70	274,315	1.77
\$2.05-\$2.88	471,785	5.4	2.50	425,763	2.51
\$2.94-\$4.63	450,500	3.7	3.46	450,500	3.46
\$5.88-\$8.00	235,000	1.2	\$ 6.87	235,000	6.87
\$0.89-\$8.00	<u>2,189,221</u>	5.7	\$ 2.67	<u>1,662,884</u>	\$ 3.05

In 2006, we granted 40,000 shares of restricted stock awards under the 2002 Plan to employees and directors. As of December 31, 2006, we had a total of 250,000 shares of restricted stock awards granted to employees and directors. The compensation cost that has been expensed in the statements of operations for the restricted stock awards issued to employees and directors was \$57,000 for 2006. Also in 2006, we granted our non-employee directors 44,000 shares representing directors' fees, and recorded \$77,000 of expense in our statement of operations.

The following table summarizes restricted stock awards activity for the twelve months ended December 31, 2006.

	Shares	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	210,000	\$ 3.77
Awarded	40,000	1.64
Outstanding at end of year	<u>250,000</u>	<u>\$ 3.43</u>

The table regarding the net loss and net loss per share included in Note 2, "Summary of Significant Accounting Policies," prepared in accordance with SFAS 123 has been determined as if we had accounted for our employee stock options and employee stock purchase plan under the fair value method prescribed by SFAS 123.

Fair values of awards granted under the stock option plans and employee stock purchase plan prior to January 1, 2006 were estimated at grant or purchase dates using a Black-Scholes option pricing model. For pro forma disclosure, the estimated fair

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

value of the options is amortized to expense over the vesting period of the options using the straight line method. The multiple option approach is used to value the purchase rights granted under the employee stock purchase plan. We used the following assumptions:

Year Ended December 31,	2005	2004
Expected life in years (from vesting date):		
Stock options	5	5
Employee Stock Purchase Plan	0.5 - 2	1.5 - 2
Risk free rate:		
Stock options	4.0%	3.2%
Employee Stock Purchase Plan	3.15% - 3.63%	1.47% - 2.55%
Volatility		
Stock options	78%	69%
Employee Stock Purchase Plan	94% - 105%	65% - 147%
Expected dividend yield	0%	0%

NOTE 9 NET INCOME (LOSS) PER SHARE

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share computations (in thousands).

	2006
Numerator:	
Net income	\$ 5,266
Denominator:	
Weighted-average shares outstanding used to compute basic earnings per share	25,262
Effect of dilutive stock options, employee stock purchase and restricted stock awards.	172
Weighted-average shares outstanding and dilutive securities used to compute diluted earnings per share	25,434

The following options and restricted stock awards were outstanding as of December 31, 2005 and 2004, but were not included in the computation of diluted net loss per share since inclusion of these potentially dilutive securities would have been anti-dilutive for the periods presented (in thousands):

	2005	2004
Number of options outstanding	2,166	2,206
Number of restricted stock awards outstanding	75	—

NOTE 10 DISCONTINUED OPERATIONS

We completed the sale of certain assets of our Analytical Standards division as well as certain technology rights for our topical pharmaceutical and cosmeceutical product lines and other assets ("cosmeceutical and toiletry business") in February 2003 and July 2000, respectively.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

The Analytical Standards division and cosmeceutical and toiletry business are reported as discontinued operations for all periods presented in the accompanying Statements of Operations.

Loss from discontinued operations represents the loss attributable to changes in estimates of our cosmeceutical and toiletry business that was sold to RP Scherer on July 25, 2000, as follows (in thousands):

For the years ended December 31,	2006	2005	2004
Cosmeceutical and Toiletry Business			
Change in estimates for severance costs and guarantees	\$ (188)	\$ (89)	\$ (133)

Revenue relating to the discontinued operations totaled \$0 for the years ended December 31, 2006, 2005 and 2004.

The following table sets forth the Company's basic and diluted income (loss) per common share from discontinued operations excluding the gain on sale for the years ended December 31, 2006, 2005 and 2004:

For the years ended December 31,	2006	2005	2004
Basic income (loss) per common share from discontinued operations	\$ *	\$ *	\$ (0.01)
Diluted income (loss) per common share from discontinued operations	\$ *	\$ *	\$ (0.01)

* Less than (\$0.00) per share

As of December 31, 2006, liabilities related to the discontinued operations in the amount of \$335,000 include severance costs and accruals for gross profit guarantees. These liabilities are reported as accrued disposition costs in the accompanying balance sheets.

The cash provided by discontinued operations of \$24,000, \$125,000, and \$99,000 in 2006, 2005 and 2004, respectively, relates to the royalties received from GFS from sales of Analytical Standards products, partially offset by severance payments made to former employees who were terminated as a result of the sale of the Analytical Standards division and a payment relating to the Gross Profit Guaranty.

Analytical Standards Division

On February 13, 2003, we completed the sale of our Analytical Standards division to GFS Chemicals, Inc. ("GFS"), a privately held company based in Columbus, Ohio. In this transaction, we received \$2.1 million on closing and are entitled to receive royalties on sales of Analytical Standards products for a period of five years following the sale at rates ranging from 5% to 15%. The net present value of the guaranteed minimum royalties is included in the gain on disposition of discontinued operations.

As a result of the sale of the Analytical Standards division, we recorded severance charges of \$210,000 in the year ended December 31, 2003 as a partial offset to the gain on disposition of the Analytical Standards division. An increase to the estimated severance charges of \$2,000 was recorded in 2006. Approximately \$227,000 of these severance charges has been paid through December 31, 2006.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

Cosmeceutical and Toiletry Business

On July 25, 2000, we completed the sale of certain technology rights for our topical pharmaceutical and cosmeceutical product lines and other assets ("cosmeceutical and toiletry business") to RP Scherer Corporation, a subsidiary of Cardinal Health, Inc.

Under the terms of the agreement with RP Scherer, we guaranteed a minimum gross profit percentage on RP Scherer's combined sales of products to Ortho Neutrogena and Dermik ("Gross Profit Guaranty"). The guaranty period commenced on July 1, 2000 and ends on the earlier of July 1, 2010 or the end of two consecutive guaranty periods where the combined gross profit on sales to Ortho and Dermik equals or exceeds the guaranteed gross profit. The Gross Profit Guaranty expense totaled \$729,000 for the first six guaranty years. We expect the annual Gross Profit Guaranty payments to range from approximately \$100,000 to \$150,000 for the remainder of the guaranty period. As there is no minimum amount of Gross Profit Guaranty due, no accrual for the guaranty is estimable for future years. A liability of \$330,000 related to the current amount due under the gross profit guarantees is included in accrued disposition costs as of December 31, 2006.

NOTE 11 DEFINED CONTRIBUTION PLAN

We have a defined contribution plan covering substantially all of our employees. In the past three calendar years, we made matching cash contributions equal to 50% of each participant's contribution during the plan year up to a maximum amount equal to the lesser of 3% of each participant's annual compensation or \$6,600, \$6,300 and \$6,150 for 2006, 2005 and 2004, respectively, and such amounts were recorded as expense in the corresponding years. We may also contribute additional discretionary amounts to the defined contribution plan as we may determine. For the years ended December 31, 2006, 2005 and 2004, we contributed to the plan approximately \$85,000, \$73,000 and \$86,000, respectively. No discretionary contributions have been made to the plan since its inception.

NOTE 12 INCOME TAXES

In 2006, we had a provision of \$119,000 reflecting alternative minimum tax on the gain on the sale of our right to receive royalties on the sales of Retin A Micro and Carac. See Note 13. There was no provision for income taxes in 2005 or 2004 because we have incurred operating losses. Deferred income taxes reflect the net tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows (in thousands):

December 31,	2006	2005
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 24,000	\$ 26,500
Research credits	2,700	2,300
Capitalized research expenses	100	100
Other	600	400
Total deferred tax assets	27,400	29,300
Valuation allowance	(27,400)	(29,300)
Net deferred tax assets	—	—

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by \$1,900,000 and increased by \$600,000 and \$1,500,000 during 2006, 2005 and 2004, respectively.

Deferred tax assets related to carryforwards at December 31, 2006 include approximately \$2,900,000 associated with stock option activity related to nonqualified stock options for which any subsequently recognized tax benefits will be credited directly to stockholders' equity.

As of December 31, 2006, we had net operating loss carryforwards for federal income tax purposes of approximately \$67,100,000 which expire in the years 2007 through 2026 and federal research and development tax credits of approximately \$1,500,000 which expire in the years 2007 through 2026.

As of December 31, 2006, we had net operating loss carryforwards for state income tax purposes of approximately \$20,300,000 which expire in the years 2012 through 2015 and state research and development tax credits of approximately \$1,800,000 which do not expire.

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

NOTE 13 SIGNIFICANT AGREEMENTS

Paul Royalty Fund

On January 18, 2006 we sold our rights to royalties on sales of Retin-A Micro and Carac effective October 1, 2005 to an affiliate of the Paul Royalty Fund for up to \$30 million. Proceeds of \$25 million were received upon the closing of the transaction and used primarily to fund pivotal clinical development of APF530, our drug candidate for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting. The remaining \$5 million will be paid based on the satisfaction of certain predetermined milestones over the next three years.

RHEI Pharmaceuticals, Inc.

On October 1, 2006, we entered into an agreement with RHEI in which we granted RHEI exclusive license to develop and market APF530 in Greater China. We received a license fee on the signing of the contract, which has been recorded as deferred revenue on the Balance Sheet, and will receive additional milestone payments upon the achievement of certain regulatory approvals. Furthermore, we will receive royalties on future sales of APF530 in Greater China.

[Table of Contents](#)

NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2006, 2005 AND 2004

NOTE 14 QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following table presents summarized unaudited results of operations for each of our quarters in the years ended December 31, 2006 and 2005.

Quarterly Results of Operations (in thousands, except per share data) (unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2006				
Total revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses	4,401	4,790	3,948	5,725
Interest and other, net	23,693	274	195	219
Income (loss) from continuing operations	19,292	(4,516)	(3,753)	(5,506)
Discontinued operations	7	(34)	(64)	(41)
Net income (loss) before income taxes	19,299	(4,550)	(3,817)	(5,547)
Income tax expenses	—	—	—	(119)
Net income (loss)	19,299	(4,550)	(3,817)	(5,666)
Basic income (loss) per common share:				
Income (loss) from continuing operations	0.77	(0.18)	(0.18)	(0.22)
Net income (loss)	0.77	(0.18)	(0.18)	(0.22)
Diluted income (loss) per common share:				
Income (loss) from continuing operations	0.76	(0.18)	(0.18)	(0.22)
Net income (loss)	0.76	(0.18)	(0.18)	(0.22)
Year Ended December 31, 2005				
Total revenue	\$ 1,360	\$ 1,250	\$ 1,337	\$ 1,444
Operating expenses	2,671	3,901	3,174	4,118
Interest income and other income, net	61	87	73	69
Loss from continuing operations	(1,250)	(2,564)	(1,764)	(2,605)
Discontinued operations	(6)	(44)	20	3
Net loss	(1,256)	(2,608)	(1,744)	(2,602)
Basic and diluted loss per common share:				
Loss from continuing operations	(0.05)	(0.10)	(0.07)	(0.10)
Net loss	(0.05)	(0.10)	(0.07)	(0.10)

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures: We carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operations of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15(d)-15(e) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2006 the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that information required to be disclosed in the reports we are required to file with the SEC is accumulated and communicated to members of management, including the CEO and the CFO, as appropriate, to allow timely decisions regarding required disclosure.

(b) Changes in internal controls: During the quarter ended December 31, 2006 there have been no significant changes in our internal control over financial reporting that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

[Table of Contents](#)

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

We have incorporated by reference the information set forth under the captions "Election of Directors", "Executive Officers", "Corporate Governance" and "Compliance with Section 16(a) of the Securities Exchange Act" of the Company's Proxy Statement (the "Proxy Statement") for the 2007 annual meeting of shareholders.

Code of Ethics

We have adopted a Code of Ethics that applies to all of our directors, officers and employees. The Code of Ethics is posted on our website at <http://www.appharma.com> under the caption Investor Relations.

ITEM 11. EXECUTIVE COMPENSATION

We have incorporated by reference the information set forth under the captions "Executive Compensation" and "Director Compensation" of the Proxy Statement.

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

We have incorporated by reference the information set forth under the captions "Common Stock Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" of the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

We have incorporated by reference the information set forth under the captions "Related Party Transactions" and "Corporate Governance" of the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

We have incorporated by reference the information set forth under the captions "Report of the Audit Committee," "Ratification of Independent Registered Public Accountants" and "Auditors Fees & Services" of the Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

The financial statements and supplementary data set forth in Part II of the 10-K Annual Report are included herein.

2. Financial Statement Schedules

Schedule II Valuation Accounts

All other schedules have been omitted because the information is not required or is not so material as to require submission of the schedule, or because the information is included in the financial statements or the notes thereto.

3. Exhibits

2.1-Copy of Asset Purchase Agreement between Registrant and RP Scherer South, Inc. dated June 21, 2000.⁽¹⁾

3-A-Copy of Registrant's Certificate of Incorporation.⁽²⁾

3-B-Copy of Registrant's Bylaws.⁽²⁾

3-C-Copy of Registrant's Certificate of Designation.⁽³⁾

4-A-Copy of Registrant's Preferred Shares Rights Agreement.⁽⁴⁾

4-B-Copy of Registrant's Form of Rights Certificate⁽⁵⁾

10-C-Registrant's 1992 Stock Plan dated August 11, 1992.^{(6)*}

10-D-Registrant's 1997 Employee Stock Purchase Plan dated March 5, 1997.^{(7)*}

10-E-Lease Agreement between Registrant and Metropolitan Life Insurance Company for lease of Registrant's executive offices in Redwood City dated as of November 17, 1997.⁽⁸⁾

10-F-Registrant's 2002 Equity Incentive Plan dated June 13, 2002.^{(9)*}

10-G-Agreement between Registrant and RHEI Pharmaceuticals, Inc. (RHEI) granting exclusive license to RHEI to develop and sell APF530 in Greater China dated October 1, 2006.⁽¹⁰⁾

10-H-Royalty Interest Agreement between Registrant and Paul Royalty Fund dated January 18, 2006.⁽¹¹⁾

10-N-Agreement with Johnson & Johnson dated April 14, 1992.⁽¹²⁾

10-X-Registrant's Non-Qualified Plan dated June 13, 2002.^{(13)*}

23.1-Consent of Independent Registered Public Accounting Firm.

23.2-Consent of Independent Registered Public Accounting Firm.

31.1-Certification of Chief Executive Officer pursuant to Rules 13A-15(e) Promulgated under the Securities Exchange Act of 1934 as amended.

31.2-Certification of Chief Financial Officer pursuant to Rules 13A-15(e) Promulgated under the Securities Exchange Act of 1934 as amended.

32-Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(c) Exhibits

The Company hereby files as part of this Form 10-K the exhibits listed in Item 15(a)3 as set forth above.

- (1) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated July 25, 2000, and incorporated herein by reference.
- (2) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Registration Statement on Form S-1 (Registration No. 33-15429) and incorporated herein by reference.
- (3) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.
- (4) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.
- (5) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.
- (6) Filed as Exhibit No. 28.1 to Registrant's Registration Statement on Form S-8 (Registration No. 33-50640), and incorporated herein by reference.
- (7) Filed as Exhibit No. 99.1 to Registrant's Registration Statement on Form S-8 (Registration No. 333-35151), and incorporated herein by reference.
- (8) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Annual Report on Form 10-K for the year ended December 31, 1997, and incorporated herein by reference.
- (9) Filed as Exhibit No. 99.1 to Registrant's Registration Statement on Form S-8 (Registration No. 333-90428), and incorporated herein by reference.

[Table of Contents](#)

- (10) Filed as Exhibit 99.1 to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.
- (11) Filed on Form 8K dated January 18, 2006.
- (12) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Annual Report on Form 10-K for the year ended December 31, 1992, and incorporated herein by reference.
- (13) Filed as Exhibit No. 99.2 to Registrant's Registration Statement on Form S-8 (Registration No. 333-90428), and incorporated herein by reference.

(d) Financial Statement Schedules

See Item 15(a)2 of this Form 10-K.

* Management contract or compensatory plans.

SIGNATURES

Pursuant to the requirement of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

A.P. PHARMA, INC.

By: /s/ Gregory Turnbull
Gregory Turnbull
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Gregory Turnbull and Stephen C. Whiteford, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Gregory Turnbull</u> Gregory Turnbull	President and Chief Executive Officer (Principal Executive Officer)	March 30, 2007
<u>/s/ Stephen C. Whiteford</u> Stephen C. Whiteford	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2007
<u>/s/ Paul Goddard</u> Paul Goddard	Chairman of the Board of Directors	March 30, 2007
<u>/s/ Michael O'Connell</u> Michael O'Connell	Director	March 30, 2007
<u>/s/ Peter Riepenhausen</u> Peter Riepenhausen	Director	March 30, 2007
<u>/s/ Toby Rosenblatt</u> Toby Rosenblatt	Director	March 30, 2007
<u>/s/ Arthur Taylor</u> Arthur Taylor	Director	March 30, 2007
<u>/s/ Robert Zerbe</u> Robert Zerbe	Director	March 30, 2007

[Table of Contents](#)

SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS (in thousands)

	<u>Beginning Balance</u>	<u>Additions Charged to Cost and Expense</u>	<u>Deductions, Write-Offs and Recoveries</u>	<u>Ending Balance</u>
DECEMBER 31, 2006				
Note receivable, allowance for doubtful note	\$ 394	\$ —	\$ —	\$ 394
DECEMBER 31, 2005				
Note receivable, allowance for doubtful note	\$ 394	\$ —	\$ —	\$ 394
DECEMBER 31, 2004				
Note receivable, allowance for doubtful note	\$ 413	\$ —	\$ 19	\$ 394

[Table of Contents](#)

EXHIBIT INDEX

FORM 10-K ANNUAL REPORT

- 2.1-Copy of Asset Purchase Agreement between Registrant and RP Scherer South, Inc. dated June 21, 2000.⁽¹⁾
- 3-A-Copy of Registrant's Certificate of Incorporation.⁽²⁾
- 3-B-Copy of Registrant's Bylaws.⁽²⁾
- 3-C-Copy of Registrant's Certificate of Designation.⁽³⁾
- 4-A-Copy of Registrant's Preferred Shares Rights Agreement.⁽⁴⁾
- 4-B-Copy of Registrant's Form of Rights Certificate⁽⁵⁾
- 10-C-Registrant's 1992 Stock Plan dated August 11, 1992.^{(6)*}
- 10-D-Registrant's 1997 Employee Stock Purchase Plan dated March 5, 1997.^{(7)*}
- 10-E-Lease Agreement between Registrant and Metropolitan Life Insurance Company for lease of Registrant's executive offices in Redwood City dated as of November 17, 1997.⁽⁸⁾
- 10-F-Registrant's 2002 Equity Incentive Plan dated June 13, 2002.^{(9)*}
- 10-G-Agreement between Registrant and RHEI Pharmaceuticals, Inc. (RHEI) granting exclusive license to RHEI to develop and sell APF530 in Greater China dated October 1, 2006.⁽¹⁰⁾
- 10-H-Royalty Interest Agreement between Registrant and Paul Royalty Fund dated January 18, 2006.⁽¹¹⁾
- 10-N-Agreement with Johnson & Johnson dated April 14, 1992.⁽¹²⁾
- 10-X-Registrant's Non-Qualified Plan dated June, 13, 2002.^{(13)*}
- 23.1-Consent of Independent Registered Public Accounting Firm.
- 23.2-Consent of Independent Registered Public Accounting Firm.
- 31.1-Certification of Chief Executive Officer pursuant to Rules 13A-15(e) Promulgated under the Securities Exchange Act of 1934 as amended.
- 31.2-Certification of Chief Financial Officer pursuant to Rules 13A-15(e) Promulgated under the Securities Exchange Act of 1934 as amended.
- 32-Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated July 25, 2000, and incorporated herein by reference.

(2) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Registration Statement on Form S-1 (Registration No. 33-15429) and incorporated herein by reference.

(3) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.

(4) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.

(5) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.

(6) Filed as Exhibit No. 28.1 to Registrant's Registration Statement on Form S-8 (Registration No. 33-50640), and incorporated herein by reference.

(7) Filed as Exhibit No. 99.1 to Registrant's Registration Statement on Form S-8 (Registration No. 333-35151), and incorporated herein by reference.

[Table of Contents](#)

- (8) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Annual Report on Form 10-K for the year ended December 31, 1997, and incorporated herein by reference.
- (9) Filed as Exhibit No. 99.1 to Registrant's Registration Statement on Form S-8 Registration No. 333-90428, and incorporated herein by reference.
- (10) Filed as Exhibit 99.1 to Registrant's Form 8-K dated December 19, 2006, and incorporated herein by reference.
- (11) Filed on Form 8K dated January 18, 2006.
- (12) Filed as an Exhibit with corresponding Exhibit No. to Registrant's Annual Report on Form 10-K for the year ended December 31, 1992, and incorporated herein by reference.
- (13) Filed as Exhibit No. 99.2 to Registrant's Registration Statement on Form S-8 Registration No. 333-90428, and incorporated herein by reference.
- * Management contract or compensatory plans.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S3 No. 333-115163 of A.P. Pharma, Inc., and the Registration Statements on Form S-8 (Nos. 333-06841, No. 333-60585, 333-35151, 333-90428, 333-118546, 333-127574, and 333-137954), pertaining to the 1992 Stock Plan, the 1997 Employee Stock Purchase Plan, the 2002 Equity Incentive Plan and Non-Qualified Stock Option Plan, the 2002 Equity Incentive Plan and 1997 Employee Stock Purchase Plan of A.P. Pharma, Inc., of our report dated March 1, 2007 with respect to the financial statements and schedule of A.P. Pharma, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2006.

/s/ ODENBERG, ULLAKKO, MURANISHI & CO., LLP

San Francisco, California
March 26, 2007

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

- 1) Registration Statement (Form S-3 No. 333-115163) of A.P. Pharma, Inc.,
- 2) Registration Statement (Form S-8 No. 333-06841) pertaining to the 1992 Stock Plan of A.P. Pharma, Inc.,
- 3) Registration Statement (Form S-8 No. 333-60585) pertaining to the 1992 Stock Plan of A.P. Pharma, Inc.,
- 4) Registration Statement (Form S-8 No. 333-35151) pertaining to the 1997 Employee Stock Purchase Plan of A.P. Pharma, Inc.,
- 5) Registration Statement (Form S-8 No. 333-90428) pertaining to the 2002 Equity Incentive Plan and Non-Qualified Stock Option Plan of A.P. Pharma, Inc.,
- 6) Registration Statement (Form S-8 No. 333-118546) pertaining to the 2002 Equity Incentive Plan and 1997 Employee Stock Purchase Plan of A.P. Pharma, Inc.,
- 7) Registration Statement (Form S-8 No. 333-127574) pertaining to the 2002 Equity Incentive Plan and 1997 Employee Stock Purchase Plan of A.P. Pharma, Inc., and
- 8) Registration Statement (Form S-8 No. 333-137954) pertaining to the 2002 Equity Incentive Plan and 1997 Employee Stock Purchase Plan of A.P. Pharma, Inc.;

of our report dated February 24, 2006, with respect to the financial statements and schedule of A.P. Pharma, Inc. for the year ended December 31, 2005 included in this Annual Report (Form 10-K) for the year ended December 31, 2006.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 26, 2007

CERTIFICATIONS

I, Gregory Turnbull, certify that:

1. I have reviewed this annual report on Form 10-K of A.P. Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonable likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2007

/s/ Gregory Turnbull
 Gregory Turnbull
 Chief Executive Officer

CERTIFICATIONS

I, Stephen C. Whiteford, certify that:

1. I have reviewed this annual report on Form 10-K of A.P. Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonable likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2007

/s/ Stephen C. Whiteford

Stephen C. Whiteford
Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of A.P. Pharma, Inc. (the "Company") on Form 10-K for the year ending December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregory Turnbull, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Gregory Turnbull

Gregory Turnbull,
Chief Executive Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of A.P. Pharma, Inc. (the "Company") on Form 10-K for the year ending December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen C. Whiteford, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Stephen C. Whiteford

Stephen C. Whiteford,
Chief Financial Officer