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targeting the surgical market...

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21 million surgical procedures  
in the U.S. could potentially benefit.



Most surgical patients require some form of follow-on drug therapy.





Post-operative pain is one of the most prevalent issues facing patients and their surgeons. In an attempt to reduce potential problems, many doctors administer local anesthetics at the surgical site. The trouble is that currently used drugs provide only short-term benefit. Patients often require more potent pain therapy, including opioids, which can have serious side effects. Today, inadequately treated pain remains a leading cause of delayed discharge from the hospital and unanticipated hospital re-admissions following same-day or outpatient surgery. And among those patients who recuperate at home, an estimated 30% to 40% suffer from moderate to severe pain during the first two days following surgery. Clearly, better pain management is needed.

Our innovative pain reliever begins  
its work in the operating room.



A.P. Pharma's lead product candidate, APF112, is an extended-release formulation of the widely used anesthetic mepivacaine. Administered via a needleless syringe, it is applied at the surgical site just prior to suturing the wound and is designed to deliver pain medication when and where it is needed most – locally for 24 to 36 hours.

#### PHASE 2 CLINICAL TRIALS

Our initial target for APF112 is pain management among patients who have undergone inguinal hernia surgery. The current Phase 2 trial is a two-part study expected to involve approximately 100 patients. The completed first part is an open-label safety assessment to ensure that APF112 does not interfere with the surgical procedure or affect wound healing. The second part, now in progress, is a blinded study comparing two doses of APF112 with current standard care for post-surgical pain relief.

#### IMPORTANT CLINICAL ENDPOINTS

The goal of this program is to achieve prolonged, effective pain relief that increases the patient's comfort following surgery and minimizes or eliminates the use of post-surgical opioid (morphine-like) medication.

#### SIZABLE MARKET OPPORTUNITIES

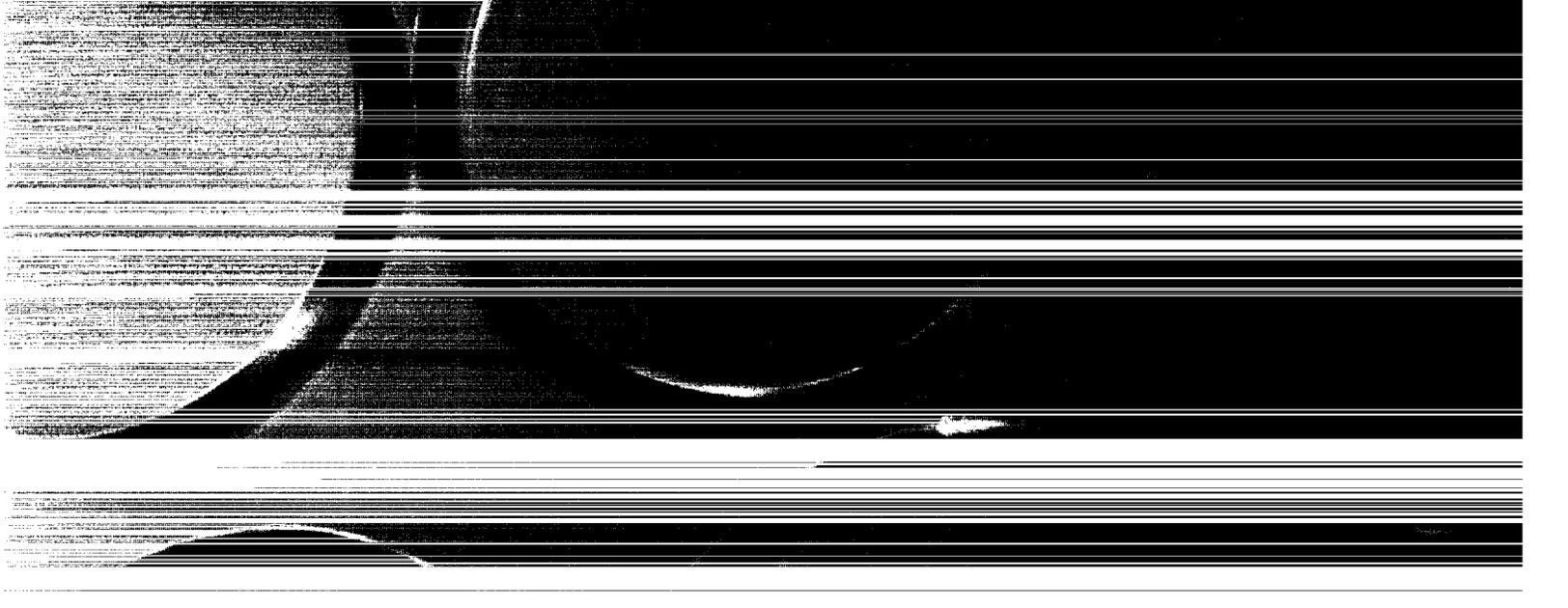
Over time, we expect to evaluate a number of pain management applications for APF112. This product is designed to address major unmet needs in a \$2 billion market for post-surgical pain. The fastest growing segment is pain relief for outpatients and those who undergo same-day in/out surgery. Among them, pain management following abdominal surgery and musculoskeletal surgery is our initial focus, with U.S. patient populations estimated at 5.3 million and 5 million, respectively, in 2003 alone.

#### BEYOND APF112

Pre-IND studies of additional product candidates are under way for the treatment of nausea and vomiting, post-surgical inflammation and osteoarthritis inflammation.



Our objective is straightforward:  
make existing therapies better.



**Leading the way is our Biochronomer™ technology. Designed specifically for use as injectable or implantable products, Biochronomer systems provide control over both the rate and the duration of therapy. Product formulations offer key advantages over their conventional counterparts:**

- **Greater therapeutic efficacy**
- **Minimal drug-related side effects**
- **One-time administration that minimizes concerns about patient compliance**
- **Controlled drug release that avoids the blood-level spikes of conventional drugs**
- **Extended therapy, potentially lasting for hours, days, weeks or months**
- **Multiple types of drug delivery vehicles, including coatings, films, strands, microspheres and gels**
- **Complete bioerosion of the delivery vehicle concurrent with drug release**

We are leveraging our R&D expertise to build our own product portfolio.



A.P. Pharma has a proven track record of developing products that meet market needs. Commercialization agreements have provided us with long-term royalty streams. In the future, we intend to retain certain rights and a significant portion of profits on product sales.

#### STRATEGICALLY POSITIONED

We have made important progress since A.P. Pharma's transformation into a specialty pharmaceuticals company just three years ago. Product candidates based on our Biochronomer™ systems enable us to address a broader spectrum of medical needs and potentially capture opportunities in large markets that far exceed the prospects for our previous products.

Our business focus is on developing the company's own product portfolio for surgical/orthopedic applications and maintaining control and management of Biochronomer-based product candidates through the early phases of clinical development. As clinical studies progress, we expect to establish corporate partnerships to complete the development process and commercialize successful drugs. Our ultimate goal is to retain rights in the U.S., while partners handle sales and distribution in international markets.

#### FUNDING SOURCES

Products developed for A.P. Pharma's own product portfolio have been funded through royalties from our Microsponge®-based topical products (marketed by Johnson & Johnson and Aventis companies), proceeds from the divestitures of our cosmeceutical and analytical standards product lines, and project fees from collaborative research.

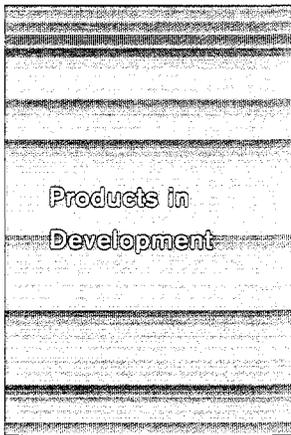
#### LICENSING OPPORTUNITIES

While our primary emphasis is on our own portfolio, we are also conducting feasibility studies of new product concepts based on our Biochronomer technology for other pharmaceutical and biotechnology companies. Those that prove promising could be out-licensed or partnered through product development and commercialization agreements.

# To Our Shareholders

People from all walks of life are concerned about the need for improved healthcare. Although the most vocal complaints center on the costs of care, there remain substantial medical challenges. Some of the more costly problems, including severe post-surgical pain, are not adequately addressed today. The solution frequently may not be new drugs but better use of existing drugs. This is why A.P. Pharma is focused on the application of novel drug delivery technologies for certain established drug therapies – therapies which have proven effective but could, and should, be better. We believe that our patented polymer-based systems offer outstanding potential for improving not only the safety and efficacy but also the value of existing and emerging medical treatments. In our quest for improved healthcare, we have achieved several important milestones in 2003 and early 2004:

- Phase 2 human clinical trials are progressing with APF112 for the treatment of pain following inguinal hernia surgery, and initial findings are very gratifying.
- A second Biochronomer™ drug candidate, APF530 for prevention of nausea and vomiting, has been selected for entry into human clinical trials during the second quarter of 2004.
- Follow-on product candidates are continuing to advance in preclinical testing to address other major therapeutic opportunities.
- Results from a collaborative study at MIT indicate that a Biochronomer formulation could advance DNA vaccine usage against viral infections and cancers.
- Feasibility studies on behalf of other pharmaceutical and biotechnology companies continue to demonstrate the potential for our technology in additional fields.
- Royalty income, which substantially funds our R&D programs, continues to increase and was up 12% in 2003, driven primarily by the sales growth of Retin-A Micro.®
- We continue to maintain tight control over finances, holding our burn rate to approximately \$4.6 million in 2003.



PRODUCT PORTFOLIO	DRUG	MARKET SIZE	DELIVERY DURATION	STATUS
APF112 - Acute pain relief (surgical/orthopedic)	Mepivacaine	\$2 billion	Short-term	Phase 2
APF530 - Anti-nausea (chemotherapy/surgical)	Granisetron	\$2 billion	Short-term	Pre-IND
APF328 - Anti-inflammatory (surgical/orthopedic)	Meloxicam	\$1.5 billion	Medium-term	Pre-IND
APF505 - Anti-inflammatory (osteoarthritis)	Meloxicam	\$3.5 billion	Long-term	Pre-IND

### APF112 for Post-Surgical Pain Management

Our lead product candidate, APF112, entered Phase 2 clinical trials during the fourth quarter of 2003, targeting the first of what we expect to be a series of pain management applications. The two-part study is being conducted at several medical centers and involves 100 patients undergoing surgical repair of an inguinal hernia. APF112 incorporates mepivacaine, a well-established anesthetic/analgesic approved by the FDA for infiltration into surgical wounds. Mepivacaine provides good-quality but short-term pain relief. Our goal is to extend the benefits of mepivacaine and thereby minimize the need for morphine-like drugs (opioids) following surgery. Opioids are associated with a wide range of side effects, such as nausea, sedation, dizziness, constipation, vomiting, urinary retention and even life-threatening respiratory depression – problems that localized mepivacaine does not cause.

The first part of the trial, a 10-patient open-label safety assessment study, provided both preliminary safety and pharmacokinetic data. As reported on March 12, 2004, the patients were followed over a 30-day period, and wound healing in all patients was observed to be normal. No severe or serious adverse events were reported. The pharmacokinetic measurements in these patients demonstrated meaningful levels of mepivacaine over a three-day period consistent with observations made in preclinical studies with APF112. Most important, both patients and physicians reported good to very good quality of pain control. We should stress, however, that this was an open-label study with no control group.

Based on this positive data, we proceeded with part two of the study, a 90-patient blinded trial comparing two doses of APF112 with standard treatment for managing post-operative pain. The endpoints for this trial will include a visual analog score of pain intensity, the standard means of measuring pain, and reduction in opioid-type pain medication such as Vicodin.™ Preliminary Phase 2 clinical data are anticipated by mid-year. In the meantime, we are discussing potential partnerships to support pivotal clinical studies and the commercialization of this promising non-narcotic pain therapy.

### **Compelling Need for Improved Post-Surgical Therapies**

Pain management is a particularly important therapeutic area. Currently, morphine and other potent narcotics are the pain relievers of choice following major surgery, despite the uncomfortable and sometimes serious side effects. Problems are tolerated because there are few acceptable alternatives and patients often fear post-surgical pain even more than the surgery itself. Nevertheless many people, especially the elderly, choose to endure pain in silence rather than experience incapacitating opioid-related side effects. The result is a potentially substantial delay in their discharge from medical care and a corresponding increase in costs. Equally disturbing, the potential for problems is increasing as same-day and outpatient surgical procedures become more commonplace. Patients need non-narcotic pain relief that enables them to get out of the clinic quickly and to recuperate at home.

### **APF530, APF328 and APF505 Product Opportunities**

Beyond APF112, three new product candidates are being evaluated, and we expect the first of these, APF530, to enter human clinical trials in the second quarter of 2004. APF530 is our controlled-release Biochronomer-based formulation of granisetron, a serotonin 5-HT<sub>3</sub> antagonist proven to prevent nausea and vomiting following chemotherapy and surgery. APF328 and APF505 are both Biochronomer product candidates incorporating meloxicam, a proven anti-inflammatory compound. They are designed to be administered directly at the treatment site, either to reduce inflammation following arthroscopic knee surgery or to treat crippling osteoarthritis. We expect these drug formulations to provide therapeutic effect for two and six weeks, respectively, while avoiding systemic side effects. Both product candidates should enter preclinical development during 2004.

### **Feasibility Studies for Other Technology Applications**

While we believe that our own product programs will generate the most value for our company and shareholders, we hope to expand the range of Biochronomer applications through corporate licensing agreements. The technology benefits are well recognized, and we have successfully performed a substantial number of feasibility studies in a variety of therapeutic areas on behalf of others. These studies have demonstrated the potential of our polymer-based delivery systems, especially for use in ophthalmic therapies, medical device coatings and DNA delivery. We have now tightened



PRODUCT	PARTNER	TOPICAL APPLICATIONS	TERRITORY	STATUS
Retin-A Micro (0.1%)	Ortho Neutrogena (J&J)	Acne	U.S	Launched Q1, 1997
Retin-A Micro (0.1%)	Ortho Neutrogena (J&J)	Acne	Canada	Launched Q3, 2001
Retin-A Micro (0.04%)	Ortho Neutrogena (J&J)	Acne	U.S	Launched Q3, 2002
Carac	Dermik (Aventis)	Actinic keratoses	U.S	Launched Q1, 2001

criteria for initiating feasibility studies, in order to improve our prospects for establishing product development agreements that would provide milestone payments and royalties. A number of active feasibility studies are under way, and three have progressed to animal studies.

### Proven Ability to Partner with Big Pharma

Our history of success with earlier prescription pharmaceuticals should serve A.P. Pharma well in the years ahead. FDA-approved products based on our first drug delivery platform, the Microsponge® system, have maintained a strong market presence and enabled us to report a 12% increase in royalty income for 2003 compared with 2002. This revenue stream has no associated costs and helps to fund our current product development and research programs. Most notable is the 21% increase in royalties from Retin-A Micro, which is now in its eighth year of sales for the topical treatment of acne. Available in two formulations, Retin-A Micro continues to gain market share through the efforts of Ortho Neutrogena, a Johnson & Johnson company. Another Microsponge-based pharmaceutical, Carac,™ holds a 25% share of its U.S. market. This extended-release topical chemotherapeutic drug is approved for the treatment of actinic keratoses, a precancerous skin condition caused by over-exposure to the sun. It is marketed by Dermik Laboratories, an Aventis company.

### Financial Results for 2003 Meet Expectations

For the year ended December 31, 2003, we reported revenues of \$4.85 million, research and development expenses of \$8.66 million (reflecting the entry of APF112 into our Phase 2 clinical trial) and a loss from continuing operations of \$6.2 million or \$0.30 per share – all within our expectations. Royalty income from commercial products, contract reimbursements from research partners and proceeds from the divestitures of earlier product lines were used to fund our product development efforts. Over time, as we establish corporate partnerships for new products under development, we expect revenue sources to also include licensing fees, milestone payments and R&D fees. Among our long-term goals is maintaining a low cash burn rate. Reflecting our adherence to this plan, our net burn in 2003 was \$4.6 million, and we ended the year with approximately \$10 million in cash.



### **Cost-Effective, Low-Risk Business Model**

Our financial strategy is to take full advantage of widely available outside resources in all areas of our business. Rather than maintain a sizable staff and incur significant capital expenses, we have structured A.P. Pharma to access the resources available through contract research and manufacturing organizations as well as through our corporate partners and academic associates. A.P. Pharma's in-house competencies are focused on our unique drug delivery technologies, innovative research capabilities and product development expertise. External resources are directed toward conducting pharmacology, toxicology, manufacturing and clinical development on our behalf. We believe that this strategy will enable us to enter larger and more profitable pharmaceutical and biotechnology markets while keeping costs under control.

### **Looking Ahead to a Year of Progress**

During 2004, our priorities are to complete the two-part Phase 2 clinical study using APF112 for pain relief in inguinal hernia surgery and to advance APF530 into human clinical trials for the treatment of nausea and vomiting. We are in discussions with potential partners to complete the development of APF112 and set the stage for commercialization. In addition, we are preparing to initiate new feasibility studies for other companies interested in our technology.

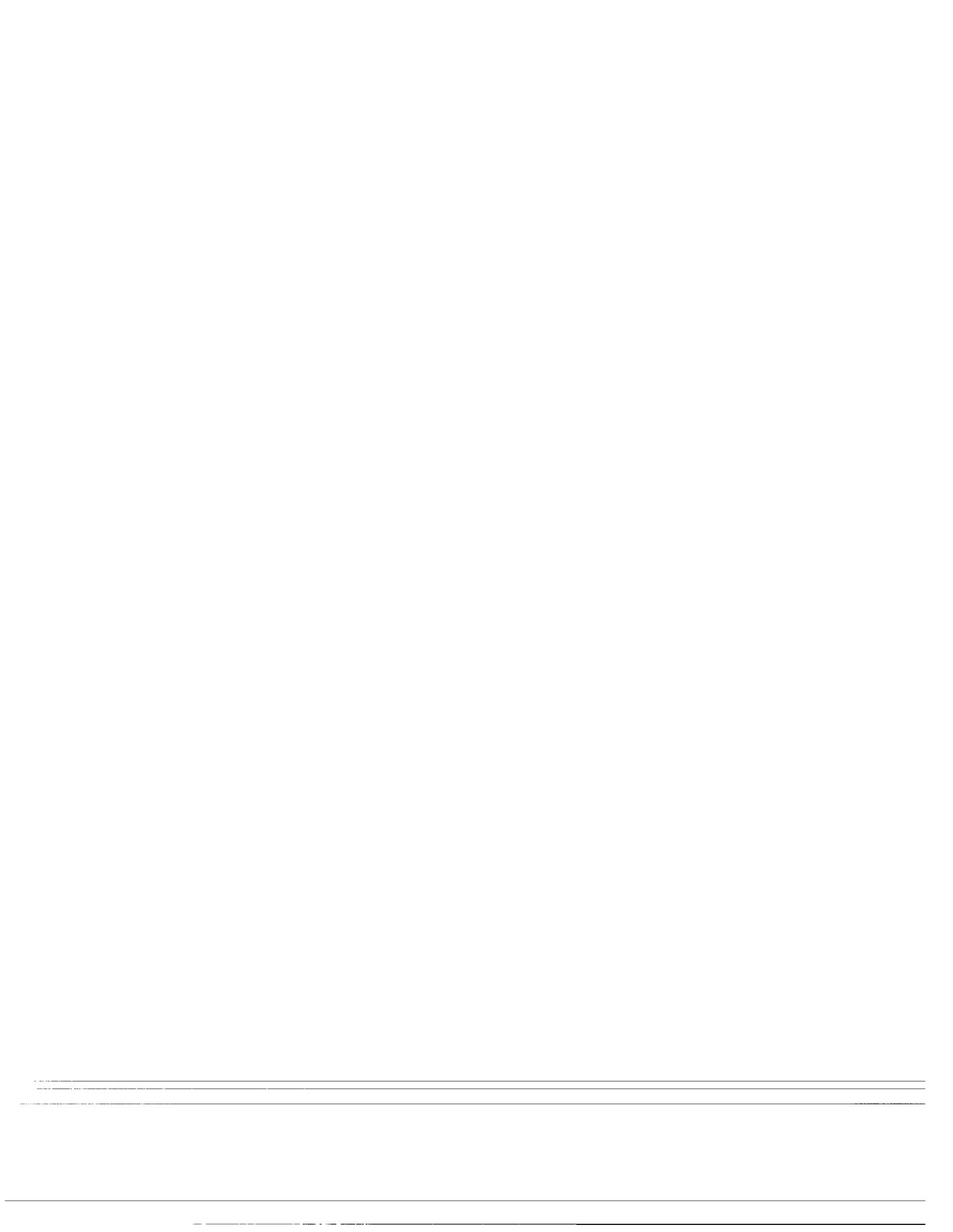
As we proceed, it is important to keep in mind that the development of new therapies is complicated, time-consuming and costly. We believe that A.P. Pharma's focus on improving existing products minimizes these issues and increases our potential for success. At the same time, we have exceptional drug delivery technologies, a strong patent portfolio that includes 132 issued and pending patents worldwide, exciting product candidates and a wide range of commercial opportunities. We are proud of our accomplishments to date and appreciate your continued support.

Paul Goddard, Ph.D.  
Chairman of the Board

Michael O'Connell  
President and  
Chief Executive Officer

March 15, 2004

# Form 10-K



**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, 2003

or

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File Number: 0-16109**

**A.P. PHARMA, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**123 Saginaw Drive, Redwood City, California**  
(Address of principal executive offices)

**94-2875566**

(I.R.S. Employer Identification Number)

**94063**

(Zip Code)

Registrant's telephone number, including area code:

**(650) 366-2626**

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

**None**

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

**Common Stock (\$.01 par value)**

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 an accelerated filer (as defined in Rule 12b-2 of the 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, 2003, was \$25,311,335.<sup>1</sup>

As of February 29, 2004, 20,641,924 shares of registrant's Common Stock, \$.01 par value, were outstanding.

<sup>1</sup> Excludes 5,401,377 shares held by directors, officers and shareholders whose ownership exceeds 5% of the outstanding shares at June 30, 2003. 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.

**DOCUMENTS INCORPORATED BY REFERENCE**

**Document**

Definitive Proxy Statement to be used in connection with the 2004 Annual Meeting of Stockholders .....

**Form  
10-K  
Part**

**III**

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- ITEM 2. Properties
- ITEM 3. Legal Proceedings
- ITEM 4. Submission of Matters to a Vote of Security Holders

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PART IV

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## ITEM 1. BUSINESS

### Introduction-Forward Looking Statements

Except for statements of historical fact, the statements herein are forward-looking and are subject to a number of risks and uncertainties that could cause actual results to differ materially from the statements made. These include, among others, uncertainty associated with progress in research and development programs, timely development, approval, launch and acceptance of new products, establishment of new corporate alliances and other factors described below under the headings "APP Technology", "Products", "Marketing", "Government Regulation", "Patents and Trade Secrets" and "Competition". In addition, such risks and uncertainties also include the matters discussed 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 the development of pharmaceutical products utilizing our proprietary polymer-based drug delivery systems. Our focus is the development and commercialization of bioerodible injectable and implantable systems under the trade name Biochronomer<sup>™</sup>. Our business strategy is twofold:

- to develop selected proprietary products, funding them through the preliminary phases of regulatory review before entering into partnerships to share costs and to earn a share of future profits; and
- to license our proprietary technologies to corporate partners after the successful completion of reimbursed feasibility studies to earn research and development fees, licensing fees, milestone payments and royalties.

Initial targeted areas of application for our drug delivery technologies include pain management; anti-nausea, anti-inflammatory, anti-infective, oncology and ophthalmology applications; device coatings and DNA delivery. Product development programs are primarily funded by royalties from topical prescription products currently marketed by our pharmaceutical partners, Johnson & Johnson and Aventis, proceeds from the divestiture of our cosmeceutical and toiletry product lines in July 2000, fees we receive from collaborative partners, and proceeds from the sale of our Analytical Standards business in February 2003.

Bioerodible polymers are of increasing interest within the pharmaceutical and biotechnology community for use in both drug delivery applications and as devices. We have made substantial progress in developing bioerodible polymers that potentially represent a significant improvement over existing drug delivery systems. A major point of difference with other delivery systems is that our polymers have been specifically designed as drug delivery systems and are versatile. Over one hundred in vivo and in vitro studies have been completed to advance understanding of this innovative drug delivery technology. Importantly, the initial toxicology data indicate that the technology is safe for use in humans. Studies demonstrate complete and controlled bioerosion of the polymers. Erosion times can be varied from hours to days, weeks or months and mechanical properties can be adjusted to produce materials as diverse as injectable gels, coatings, strands, wafers, films or microspheres. In addition, the manufacturing is reproducible, has been scaled up and the polymers are stable, provided they are stored under appropriate anhydrous conditions. In studies, the polymers were observed to erode to completion and, once the drug was released, no polymer remained. In addition, the polymers bioerode with low acidity, thus potentially allowing the delivery of sensitive proteins and DNA.

Our first Biochronomer product candidate is APF112 for the treatment of post-surgical pain. APF112 incorporates the well-known analgesic mepivacaine in our Biochronomer system. It is designed to provide 24 to 36 hours of post-surgical pain relief and to minimize the use of morphine-like drugs (opioids) which are used extensively in post-surgical pain management. Opioids are associated with a wide range of side effects, such as nausea, sedation, dizziness, constipation, vomiting, urinary retention, and in some situations, life-threatening respiratory depression. We completed Phase 1 human clinical trials for APF112 in 2002. However, the U.S. Food and Drug Administration (FDA) expressed concerns

about mild-to-moderate irritation observed during preclinical studies. After discussions with FDA officials, we modified our formulation to minimize the potential for irritation and then initiated more extensive preclinical studies to demonstrate that any irritation is reversible. In August 2003, we announced that the FDA had given us clearance to initiate Phase 2 clinical trials. Our initial target is pain management following inguinal hernia repair. The first part of the trial was an open-label study which was successfully completed. Results of the Part 1 study indicate that the pharmacokinetic measurements demonstrated meaningful levels of mepivacaine over a three day period consistent with observations made in preclinical studies with APF112. No severe or serious adverse events were reported and wound healing in all patients was observed to be normal over a 30-day follow-up period. The second part of the Phase 2 trial is a blinded study involving 90 patients and compares two doses of APF112 with the current standard treatment for post-surgical pain. The endpoints for the trial will include a visual analog score of pain intensity, the standard means of measuring pain, and patient reduction in opioid pain medication. We believe that more than 20 million surgical procedures are performed annually in the U.S. which could benefit from this product.

Our second product candidate is APF530 for the prevention of nausea and vomiting following chemotherapy or surgery. We expect to commence human clinical trials in the second quarter of 2004.

We have also entered into fee-paying feasibility studies with several companies to develop a variety of products using our Biochronomer™ delivery systems. These products are being developed in the areas of vaccines, ophthalmology, device coatings and DNA delivery. In general, these research and development arrangements provide for us to receive research and development fees from our collaborators. Three of these development programs have moved into in vivo testing and, if they are concluded successfully, could lead to licensing agreements under which a partner would pay for development costs and we would receive a license fee, research and development fees, milestone payments and a royalty upon a product's marketing clearance and commercialization.

In February 1997, we received FDA marketing clearance for our first pharmaceutical product based on the original patented Microsponge® technology, Retin-A Micro®, which was licensed to Ortho Neutrogena, a member of the Johnson & Johnson family of companies. This product was launched in the United States in March 1997. Retin-A Micro was also launched in Canada in the third quarter of 2001 and Phase 3 clinical trials were completed in Europe in 2002. In May 2002, the FDA granted marketing clearance for a new low-dose formulation of Retin-A Micro, which was launched in the U.S. in July 2002.

We licensed to Dermik Laboratories, an Aventis company, a Microsponge-based formulation incorporating 5-fluorouracil (5-FU) for the treatment of actinic keratoses, a precancerous skin condition. The product was launched in the first quarter of 2001 under the brand name Carac™. This product has a number of advantages over other topical therapies, including less irritation with shorter duration of therapy and reduced dosage frequency.

Until July 2000, we engaged in the development, manufacturing, and out-licensing of the aforementioned topical pharmaceutical products as well as a variety of cosmeceutical and toiletry products. In July 2000, we sold our cosmeceutical and toiletry product lines, together with certain technology rights to topical pharmaceuticals, to RP Scherer, a subsidiary of Cardinal Health. We received \$25 million at closing and were entitled to receive further annual earnout amounts for the subsequent three years, the amounts of which were dependent on the performance of the product lines sold. We recorded approximately \$3 million at the end of the first earnout period ending June 30, 2001, which represents earnout payments received of \$3.6 million less reserves for certain indemnification claims allowable under the sale agreement, and approximately \$200,000 for the second earnout period ending June 30, 2002. No earnout income was received for the third and final earnout period. Under the sale agreement, we retained the rights to our topical prescription products, which are marketed by our corporate partners, Johnson & Johnson and Aventis, and on which we continue to receive royalties.

In February 2003, we sold the assets of our wholly-owned subsidiary, APS Analytical Standards, Inc., to GFS Chemicals of Columbus, Ohio, for \$2.1 million in cash and the right to receive royalties for the next five years.

The Company, founded in February 1983 as a California corporation under the name AMCO Polymerics, Inc., changed its name to Advanced Polymer Systems, Inc. in 1984 and was reincorporated in Delaware in 1987. The name was changed to A.P. Pharma, Inc. in May 2001 to reflect the new pharmaceutical focus of the Company.

## **APP Technology**

We have made significant investment and progress in the development of bioerodible drug delivery systems. Specifically, we have developed two families of polymers, each with unique attributes. The first family is known collectively as poly(ortho esters) under the trade name Biochronomer™; polymers in the second family are known collectively as block copolymers of poly(ortho esters) and poly(ethylene glycol) under the trade name Bioerodimer™. The two polymer families are covered by US patent 5,968,543, issued October 19, 1999 and US patent 5,939,453, issued August 17, 1999. Both are broad composition of matter patents. A number of other patent applications have been filed.

The Biochronomer polymer is a poly(ortho ester) whose production is highly reproducible and kilo quantities of polymer have been produced according to Good Manufacturing Practices (GMP).

Current product development work takes advantage of the versatility of these materials, and is exemplified by forms that range from injectable gels into which drugs can be incorporated by a simple mixing procedure, to solid devices that can be fabricated at temperatures low enough to allow the incorporation of materials such as proteins that require mild fabrication conditions.

Our primary focus has been on advancing our Biochronomer technology, which is designed to release drugs at selected implantation sites such as at the site of a surgical procedure, under the skin, in joints, in the eye, or in muscle tissue. Key benefits of this technology include the ability to fabricate the poly(ortho ester) polymers into a variety of drug delivery forms as diverse as wafers, strands, microspheres and injectable gels to enable various means of administration into the body. Also under development are device applications. Because both mechanical properties and erosion rates can be controlled, these polymers are emerging as promising materials for device coatings that could be useful in cardiovascular applications such as stent coatings.

## **Products**

### **Ethical Pharmaceutical Products**

We define ethical pharmaceutical products as prescription products that are promoted primarily through the medical profession. We are developing several pharmaceutical product candidates that will require marketing clearance from the FDA before they can be sold in the United States. We believe that the benefits offered by our delivery systems will create valuable product differentiation and commercial advantages in large, profitable markets. Results from various preclinical and initial clinical studies reaffirm that this technology offers the potential to maintain or improve therapeutic efficacy and to reduce adverse drug side effects.

The following ethical dermatological products incorporating the Microsponge technology have already been developed and commercialized:

*Retin-A Micro:* In February 1997, we received FDA marketing clearance for Microsponge-entrapped tretinoin for improved acne treatment. Tretinoin has been marketed in the United States by Ortho Neutrogena (formerly Ortho Dermatological), a Johnson & Johnson ("J&J") subsidiary, under the brand name RETIN-A® since 1971. It has proven to be a highly effective topical acne medication. However, skin irritation among sensitive individuals can limit patient compliance with the prescribed therapy. We developed a new formulation of Retin-A containing Microsponge-entrapped tretinoin for acne treatment which was licensed to J&J. This patent-protected approach to drug delivery reduces the potentially irritating side effects of tretinoin. Ortho Dermatological began marketing this product in March 1997 under

the brand name Retin-A Micro®. Additionally, Ortho received FDA marketing clearance in the United States for a second Retin-A Micro formulation, a low-dose version, and launched the product in July 2002. Our formulation patents on these products continue until 2016.

Ortho launched this product in Canada during 2001 and has completed Phase 3 clinical trials in Europe.

*Carac*: In the fourth quarter of 2000, Dermik Laboratories, an Aventis company, received U.S. marketing clearance for an APP-developed formulation containing Microsponge-entrapped 5-fluorouracil (5-FU) for the treatment of actinic keratoses. This product was launched under the trade name Carac™ in the first quarter of 2001. We receive royalties based on the sales of this product over the life of the applicable patents. In September 2003, a new formulation patent was issued by the U.S. Patent and Trademark office (USPTO) extending patent coverage for this use of our Microsponge formulation until 2021.

### **Products Under Development**

Our efforts in pharmaceutical markets include additional applications using our Biochronomer technology that are under development, as noted below.

The first product candidate that incorporates the Biochronomer™ delivery system targets the management of pain in patients following surgery. Initial clinical studies are being conducted in surgeries for inguinal hernia repair. Upon demonstration of efficacy in treating post-surgical pain, we believe that there will be substantial potential for this product, as there are approximately 20 million surgical procedures performed annually in the U.S. for which the product could potentially be utilized.

The treatment goal is to provide 24 to 36 hours of localized post-surgical pain relief by delivering the drug mepivacaine directly to the surgical site. Mepivacaine is a well-known drug for localized pain relief, and it has an extensive safety protocol. APF112 is designed to prolong the anesthetic effect of mepivacaine and thus to minimize or eliminate the use of opioids (morphine-like drugs) which are currently used in the majority of surgical procedures as a means of managing post-operative pain despite unpleasant side effects - nausea, disorientation, sedation, constipation, vomiting, urinary retention and, in some situations, life-threatening respiratory depression.

### **Other Products**

*Analytical Standards*. We initially developed microspheres (precursors to the Microsponge system) for use as a testing standard for gauging the purity of municipal drinking water.

In February 2003, we announced the sale of the assets of this subsidiary to GFS Chemicals, Inc. of Columbus, Ohio for \$2.1 million in cash and the right to receive royalties for five years at rates ranging from 5% to 15% of sales of analytical standards products.

### **Marketing**

A key part of our business strategy is to form collaborations with pharmaceutical partners. We have therefore negotiated fee-paying feasibility agreements with several pharmaceutical and biotechnology companies for the development of prescription products incorporating the Biochronomer delivery system.

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 systems, we can exert only limited influence over the manner and extent of our partner's marketing efforts.

Our key marketing relationships currently involve only the Microsponge delivery system for prescription products and are as follows:

*Johnson & Johnson Inc.* In May 1992, we entered into a development and license agreement with Ortho-McNeil Pharmaceutical Corporation, (a subsidiary of J&J (“Ortho”) related to tretinoin-based products incorporating our Microsponge technology. As part of the agreement, certain license fees and milestone payments were paid to us by Ortho. The license fees provided Ortho with exclusive distribution or license rights for all Ortho tretinoin products utilizing our Microsponge system. Ortho’s exclusivity will continue as long as annual minimum royalty payments are made, governed by the life of the applicable patents owned by us through 2016.

In February 1997, we received FDA marketing clearance for the first product covered by this agreement, Microsponge-entrapped tretinoin. This product has been marketed by Ortho since March 1997 as Retin-A Micro®. We received a payment of \$3,000,000 from Ortho upon receipt of the FDA approval, of which half is a milestone payment that was recognized as revenue in 1997 and half as prepaid royalties which were recorded as deferred revenues. Ortho pays us a royalty on product sales. In accordance with the licensing agreement, 25% of the royalties we earn is applied against deferred revenues after certain annual minimum royalty payments are met. Should these minimums not be achieved, Ortho would lose its exclusivity and we would regain marketing rights to the retinoid products.

*Dermik.* In March 1992, we restructured our 1989 joint venture agreement with Dermik, an Aventis company. As part of the agreement Aventis received certain exclusive marketing rights for the U.S. Product applications include a 5-FU treatment for actinic keratoses (precancerous skin lesions). In the fourth quarter of 1999, Dermik filed an NDA for this product and expanded its agreement with us to cover two additional indications, in return for milestone payments and royalties upon successful development. We received \$500,000 on execution of this amendment representing a milestone payment of \$250,000 and prepaid royalties of \$250,000. In the fourth quarter of 2000 Dermik received FDA marketing clearance for the product, which was launched under the trade name Carac™ in the first quarter of 2001 and we received a milestone payment of \$50,000. In 2002, we recognized the prepaid royalties as revenues because Dermik decided not to pursue the two additional applications covered by the 1999 amendment and the rights reverted to us. Dermik’s exclusivity relating to Carac will continue as long as annual minimum royalty payments are made, governed by the life of the applicable patents. In September 2003, we received a notice of allowance from the USPTO extending patent coverage for this use of our Microsponge formulation until 2021.

## **Government Regulation**

### **Ethical Products**

In order to clinically test, produce and sell products for human therapeutic use, mandatory procedures and safety evaluations established by the FDA and comparable agencies in foreign countries must be followed. The procedure for seeking and obtaining the required governmental clearances for a new therapeutic product includes preclinical animal testing to determine safety and efficacy, followed by human clinical testing. This can take many years and require substantial expenditures. In the case of third party agreements, we expect that our corporate partners will partially fund the testing and the approval process with guidance from us. We intend to seek the necessary regulatory approvals for our proprietary products as they are being developed.

### **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 specific products, product groups, and processing technology. We have also filed foreign patent applications on our polymer technology with the European Union, Japan, Australia, South Africa, Canada, Korea and Taiwan. We have a total of 15 issued United States patents and an additional 88 issued foreign patents. Currently, we have 29 pending patent applications worldwide. The patents on the Microsponge® system expire between October 2009 and September 2021. The patents on the bioerodible systems expire between January 2016 and November 2021.

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 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**

In the development of bioerodible poly(ortho esters) for implantation applications, there is competition from a number of other bioerodible systems, especially polymers based on lactic and glycolic acid and to a lesser extent, polyanhydrides. We believe that our proprietary bioerodible Biochronomer™ polymers have a number of important advantages. Among these are ease of manufacturing, ability to control both erosion times and mechanical properties, the simultaneous drug delivery and erosion process, resulting in complete polymer disappearance when all the drug has been delivered. Also, the polymer bioerodes with low acidity, thus potentially allowing the delivery of sensitive proteins and DNA.

The attribute of the second family of bioerodible polymers, the block copolymers of poly(ortho esters) and poly(ethylene glycols), named Bioerodimer, is that a hydrophobic (water-repelling) bioerodible segment can be connected to a water-soluble segment. There are other such polymers, but we believe that our proprietary material is superior because the hydrophobic poly(ortho ester) segment can greatly increase the efficiency of drug entrapment making transport to tumors much more effective.

### **Human Resources**

As of February 29, 2004, we had 36 full-time employees, 6 of whom hold PhDs. There were 27 employees engaged in research and development and quality control, and 9 working in finance, business development, human resources and administration.

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

### **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".

## **ITEM 2. PROPERTIES**

We lease 26,067 square feet of laboratory, office and warehouse space in Redwood City, California. The annual rent expense for the Redwood City facility is approximately \$641,000.

We occupied a production facility and warehouse in Lafayette, Louisiana that was sold to RP Scherer in July 2000. The construction of the facility in 1986 was financed primarily by 15-year, tax-exempt industrial development bonds. In 1995, we extinguished the bond liability through an "in-substance defeasance" transaction by placing United States government securities in an irrevocable trust to fund all future interest and principal payments. The defeased debt balance outstanding of \$2,500,000 as of December 31, 2003 will be repaid on January 25, 2005 using the proceeds from the maturities of the United States government securities held in the irrevocable trust.

Our existing research and development and administrative facilities are not yet being used at full capacity and management believes that these facilities are adequate and suitable for current and anticipated needs.

### **ITEM 3. LEGAL PROCEEDINGS**

On October 22, 2003, Tristrata Technology, Inc. (Tristrata) filed an amended complaint joining A.P. Pharma, Inc. and other companies as defendants in Tristrata's action first filed July 12, 2002 against Cardinal Health, Inc. and others in the Federal District Court of Delaware. Tristrata's complaint alleges infringement of patents pertaining to alpha-hydroxyacids used in cosmetics. A.P. Pharma answered Tristrata's amended complaint on December 22, 2003. A.P. Pharma is vigorously defending this action. At this early stage of the proceedings we cannot state the amount, if any, which might be recovered by Tristrata from A.P. Pharma, Inc. In our opinion, this litigation should not have a material effect on our results of operations or financial condition.

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

None.

**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 National Market, under the symbol APPA. As of February 29, 2004, there were 453 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 National Market System.

2003	High	Low	2002	High	Low
First Quarter	\$1.18	\$0.84	First Quarter	\$2.90	\$2.08
Second Quarter	1.96	1.00	Second Quarter	2.65	1.93
Third Quarter	2.45	1.38	Third Quarter	2.20	1.15
Fourth Quarter	3.15	2.02	Fourth Quarter	1.50	0.61

**ITEM 6. SELECTED FINANCIAL DATA**  
(in thousands, except per share data)

	For the Years Ended and as of December 31,				
	2003	2002	2001	2000	1999
<b>Consolidated Statements of Operations Data</b>					
Royalties	\$ 4,502	\$ 4,026	\$ 3,227	\$ 2,081	\$ 2,025
Contract revenues	346	407	38	122	362
License fees	-	237	-	-	1,100
Total revenues	<u>4,848</u>	<u>4,670</u>	<u>3,265</u>	<u>2,203</u>	<u>3,487</u>
<b>Expenses</b>					
Research and development	8,660	6,699	7,348	3,713	2,471
General and administrative	2,800	3,024	3,247	2,869	2,946
Interest and other income and expense, net	404	658	1,192	546	(371)
Loss from continuing operations	(6,208)	(4,395)	(6,138)	(3,833)	(2,301)
Income (loss) from discontinued operations <sup>1</sup>	(57)	401	624	1,238	4,673
Gain on disposition of discontinued operations <sup>2</sup>	1,902	216	3,000	11,147	-
Net income (loss)	<u>\$ (4,363)</u>	<u>\$ (3,778)</u>	<u>\$ (2,514)</u>	<u>\$ 8,552</u>	<u>\$ 2,372</u>
Basic income (loss) per common share:					
Loss from continuing operations	\$ (0.30)	\$ (0.22)	\$ (0.30)	\$ (0.19)	\$ (0.11)
Net income (loss)	\$ (0.21)	\$ (0.19)	\$ (0.12)	\$ 0.42	\$ 0.12
Diluted income (loss) per common share:					
Loss from continuing operations	\$ (0.30)	\$ (0.22)	\$ (0.30)	\$ (0.19)	\$ (0.11)
Net income (loss)	\$ (0.21)	\$ (0.19)	\$ (0.12)	\$ 0.42	\$ 0.12
Weighted average common shares outstanding—basic	20,553	20,409	20,276	20,179	20,079
Weighted average common shares outstanding—diluted	20,553	20,409	20,276	20,213	20,252

## Consolidated Balance Sheet Data

	December 31,				
	2003	2002	2001	2000	1999
Working capital	\$ 9,366	\$13,989	\$18,092	\$20,111	\$13,221
Total assets	13,155	17,781	23,483	26,964	19,265
Long-term debt, excluding current portion	–	–	–	–	2,409
Stockholders' equity	11,263	15,459	19,173	21,159	12,036

<sup>1</sup> 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.

<sup>2</sup> Gain on disposition of discontinued operations in 2000 represents the gain on the sale of our cosmeceutical and toiletries business to RP Scherer on July 25, 2000, and in 2001 and 2002 represents the annual earnout income received from RP Scherer based on the performance of the business sold. 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.

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

Except for statements of historical fact, the statements herein are forward-looking and are subject to a number of risks and uncertainties that could cause actual results to differ materially from the statements made. These include, among others, uncertainty associated with timely development, approval, launch and acceptance of new products, establishment of new corporate alliances, progress in research and development programs, and other risks described below or identified from time to time in our Securities and Exchange Commission filings.

### Critical Accounting Policies and Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates including those related to the useful lives of fixed assets, valuation allowances, impairment of assets, accrued clinical and preclinical expenses and contingencies. Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

### 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 customer by our licensees based on information that we receive from our licensees.

- **License Fees**

We have licensing agreements that 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 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 revenues and recognized as revenues 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 consolidated 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 assured, whichever is earlier.

A milestone payment is a payment made to us by a third party or corporate partner 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.

- **Contract Revenues**

Generally, contract revenues relate 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. Revenues from these arrangements are recognized as the related development costs are incurred. These revenues approximate the costs incurred.

### **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. Expenses related to clinical trials generally are accrued based on the level of patient enrollment and activity according to the protocol. We monitor patient enrollment levels and related activity to the extent possible and adjust our estimates accordingly. Over the next year our clinical trials on APF112 could significantly increase our research and development expenditures.

### **Results of Operations for the years ended December 31, 2003, 2002 and 2001**

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

	For the Year Ended December 31,			Annual % Change	
	2003	2002	2001	03/02	02/01
Royalties	\$4,502	\$4,026	\$3,227	12%	25%
Contract revenues	346	407	38	(15%)	971%
License fees	—	237	—	(100%)	N/A
Total revenues	4,848	4,670	3,265	4%	43%
Expenses					
Research and development	8,660	6,699	7,348	29%	(9%)
General and administrative	2,800	3,024	3,247	(7%)	(7%)

Our revenues are derived principally from royalties, contract revenues and to a lesser extent, license fees. Under strategic alliance arrangements entered into with certain corporations, we may receive non-refundable upfront fees, milestone payments and royalties based on third party product sales.

The increase in royalties in 2003 from 2002 of \$476,000 or 12%, to \$4,502,000 related to a 21% increase in royalties earned on sales of Retin-A Micro® by Ortho Neutrogena, a Johnson and Johnson company, partially offset by a decrease in royalties earned on sales of Carac™ a topical prescription treatment for actinic keratoses that was launched in the first quarter of 2001 by our marketing partner, Dermik Laboratories, an Aventis company. The increase in sales of Retin-A Micro was due primarily to the launch of a new low-dose formulation in July 2002 after FDA marketing clearance. Royalties increased in 2002 from 2001 by \$799,000 or 25% due to a 29% increase in royalties earned on sales of Carac by Dermik Laboratories. Also, royalties on sales of Retin-A Micro® by Ortho Neutrogena, increased by 23% in 2002 over the prior year following the launch of the new low-dose formulation in July 2002. Royalty income is expected to increase in 2004 assuming that sales for both underlying product lines increase and that prices are not eroded.

Contract revenues decreased by \$61,000 or 15% in 2003 compared with 2002 as a result of fewer collaborative research and development arrangements. Additionally, our feasibility studies frequently experience a period of inactivity while initial results are being evaluated by our collaborators. Contract revenues increased in 2002 by \$369,000 from 2001 due to the initiation of new feasibility studies with corporate collaborators during 2002.

License fees recognized in 2002 are attributed to the forfeiture by a partner of certain rights to proprietary Microsponge® formulation which resulted in the full recognition of the related unamortized deferred revenue balance of \$237,000. No license fees were recognized in either 2003 or 2001.

Research and development expense increased in 2003 compared to 2002 by \$1,961,000, or 29% to \$8,660,000 due mainly to the initiation of Phase 2 clinical trials of APF112, our product candidate for post-surgical pain management which incorporates our Biochronomer™ drug delivery system. In addition, costs associated with the manufacturing of GMP product for human clinical trials was incurred during 2003. Research and development expense for 2002 compared to 2001 decreased by \$649,000, or 9% to \$6,699,000, due mainly to the delayed entry into Phase 2 clinical trials of APF112. This compares with higher expenses incurred in the prior year related to preparation for the filing of an Investigational New Drug Application (IND), together with the costs associated with the manufacture of GMP materials for use in clinical trials. Research and development expense is expected to increase in 2004 as we complete Phase 2 clinical trials for APF112 and initiate human clinical testing on APF530.

The scope and magnitude of future research and development expenses are difficult to predict at this time 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, patent filings, 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. Assuming successful completion of Phase 2 studies, the Company contemplates entering into development and marketing agreements for these product candidates.

## Current Opportunities

<u>Product Portfolio</u>	<u>Drug</u>	<u>Market Size</u>	<u>Delivery Duration</u>	<u>Status</u>
APF112 - Acute pain relief (surgical/orthopedic)	Mepivacaine	\$2 billion	Short-term	Phase 2
APF530 - Anti-nausea (chemotherapy/surgical)	Granisetron	\$2 billion	Short-term	Pre-IND
APF328 - Anti-inflammatory (surgical/orthopedic)	Meloxicam	\$1.5 billion	Medium-term	Pre-IND
APF505 - Anti-inflammatory (osteoarthritis)	Meloxicam	\$3.5 billion	Long-term	Pre-IND

In addition, several feasibility studies are ongoing with corporate collaborators in the areas of ophthalmology, device coating and immune stimulation.

The major components of research and development expenses for 2003, 2002 and 2001 were as follows (in thousands):

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Internal research and development costs	\$5,108	\$4,827	\$4,167
External polymer development, clinical and preclinical programs	<u>3,552</u>	<u>1,872</u>	<u>3,181</u>
	<u>\$8,660</u>	<u>\$6,699</u>	<u>\$7,348</u>

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

General and administrative expense decreased in 2003 by \$224,000 or 7% from 2002 due mainly to decreased investor relations, depreciation and travel and entertainment expense, partially offset by higher professional fees. General and administrative expense includes salaries and related expenses, professional fees, directors' fees, investor relations costs, insurance expense and overhead allocation. General and administrative expense decreased in 2002 by \$223,000 or 7% from 2001 due mainly to decreased professional fees and a provision for a doubtful note receivable recorded in 2001 partially offset by higher investor relations expenses. General and administrative expense is expected to remain constant in 2004.

General and administrative expenses in 2001 included an allowance for doubtful accounts of \$417,000 relating to a note receivable arising from our sale of certain proprietary rights to a consumer product in 1999. As payments on the note were not received on a timely basis and we determined collectibility was no longer assured, an allowance was recorded against the note. In 2002, an additional allowance of \$20,000 was recorded on the remaining outstanding balance.

Interest and other income and expense consist primarily of income earned on cash, cash equivalents and marketable securities. Interest income decreased in 2003 by \$339,000 compared to 2002 and decreased in 2002 by \$515,000 compared to 2001 due mainly to reduced interest rates on reduced cash balances.

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 at rates ranging from 15% to 5%. The net present value of the guaranteed minimum royalties is included in the gain on disposition of discontinued operations.

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 up to a maximum of \$26.5 million, the amounts of which were dependent on the performance of the business sold.

Income (loss) from discontinued operations represents the income attributable to our Analytical Standards division through the date of sale and the net contribution (loss) attributable to our cosmeceutical and toiletries product lines which were sold in July 2000. For the year 2003, the net loss from discontinued operations relating to changes in estimates totaled \$65,000, compared with the net income from discontinued operations relating to changes in estimates of \$172,000 in 2002 and \$415,000 in 2001.

The gain on disposition of discontinued operations recorded in 2003 of \$1,902,000 relates to the gain on the sale of our Analytical Standards division compared with \$216,000 and \$3,000,000 in 2002 and 2001, respectively, which relate to the net earnout income resulting from the sale of our cosmeceutical product lines in 2000.

### **Capital Resources and Liquidity**

Cash, cash equivalents and marketable securities decreased by \$4,637,000 to \$9,484,000 at December 31, 2003 from \$14,121,000 at December 31, 2002.

Net cash used in operating activities for the years ended December 31, 2003, 2002 and 2001 was \$6,525,000, \$5,134,000 and \$6,495,000, respectively. Net cash used in operating activities relates primarily to funding net losses excluding the gain on disposition of discontinued operations and changes in deferred revenue offset by depreciation. The increase in net cash used in operating activities for 2003 was primarily due to increased research and development expenses resulting from the initiation of the Phase 2 human clinical studies for APF112, our product candidate for the treatment of post-surgical pain.

Net cash provided by investing activities for the years ended December 31, 2003, 2002 and 2001 was \$3,257,000, \$4,723,000 and \$3,554,000. The proceeds received in 2003 of \$2,142,000 related to the sale of our Analytical Standards division compared to proceeds of \$216,000 and \$3,602,000 in 2002 and 2001, respectively, which relate primarily to the earnout income received from RP Scherer.

Our financing activities provided us with \$83,000, \$75,000 and \$66,000 for the years ended December 31, 2003, 2002 and 2001, respectively. The net cash provided by financing activities in 2003, 2002 and 2001 was primarily related to proceeds from issuances of shares under the Employee Stock Purchase Plan.

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, and interest earned on short-term investments. Our existing cash and cash equivalents, marketable securities, collections of accounts receivable, together with interest income and other revenue-producing activities including royalties, license and option fees and research and development fees, are expected to be sufficient to meet our cash needs for at least the next year. It is possible that we will seek additional financing within this timeline through debt or equity financing, the sale of certain assets and technology rights, collaborative arrangements or other arrangements.

Our future capital requirements will depend on numerous factors including, among others, royalties from sales of products of third party licensees; our ability to enter into collaborative research and development and licensing agreements; progress of product candidates in preclinical and 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.

If our capital resources are unable to meet our capital requirements, we will have to raise additional funds. We may be unable to raise sufficient additional capital when we need it or to raise capital on favorable terms. The sale of 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, 2003.

	<u>Total</u>	<u>1 year</u>	<u>2 years</u>	<u>3 years</u>
Operating Leases <sup>1</sup>	<u>\$621</u>	<u>\$602</u>	<u>\$12</u>	<u>\$7</u>
Total	<u>\$621</u>	<u>\$602</u>	<u>\$12</u>	<u>\$7</u>

<sup>1</sup> See Note 7 "Commitments" in the Notes to Consolidated Financial Statement of Part II, Item 8 of this Form 10-K for more information.

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. Combined payments for the Gross Profit Guaranty totaled \$404,000 for the first three 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.

#### **Reclassifications**

Certain reclassifications have been made to the prior year financial statements to conform with the presentation in 2003. The operations and related assets of the Analytical Standards division were reclassified to discontinued operations and assets held for sale, respectively, in the statements of operations and cash flows for the years ended December 31, 2002, and 2001 and in the balance sheets as of December 31, 2002.

#### **Off-Balance-Sheet Arrangements**

As of December 31, 2003, we did not have any off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

#### **Recent Accounting Pronouncements**

In November 2002, the FASB issued Interpretation No. 45 (or FIN 45), "Guarantor's Accounting and Disclosure requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of the disclosure requirements in November 2002 and the recognition requirements in January 2003 of FIN 45 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued Emerging Issues Task Force (EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. EITF Issue No. 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF Issue No. 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. Finally, EITF Issue No. 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting for an arrangement. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. These provisions which we adopted on July 1, 2003 did not have a material impact on our results of operations and financial position.

In January 2003, the FASB issued Interpretation No. 46 (or FIN 46), "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. The provisions of FIN 46 apply immediately to variable interest entities created before January 31, 2003 and no later than the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. We do not have variable interest entities and as such the adoption of FIN 46 did not have a material impact on our results of operations and financial position.

#### **Factors That May Affect Future Results**

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

#### **Our Bioerodible Drug Delivery System Business is at an Early Stage of Development.**

Our bioerodible drug delivery system business is at an early stage of development. Our ability to produce bioerodible drug delivery systems that progress to and through clinical trials is subject to, among other things:

- success with our research and development efforts;
- selection of appropriate therapeutic compounds for delivery;
- the required regulatory approval.

Successful development of delivery systems will require significant preclinical and clinical testing prior to regulatory approval in the United States and elsewhere. In addition, we will need to determine whether any potential products can be manufactured in commercial quantities at an acceptable cost. Our efforts may not result in a product that can be marketed. Because of the significant scientific, regulatory and commercial milestones that must be reached for any of our research programs to be successful, any program may be abandoned, even after significant resources have been expended.

#### **We Will Need Additional Capital to Conduct Our Operations and to Develop Our Products and Our Ability to Obtain The Necessary Funding on Favorable Terms in The Future is Uncertain.**

We will require additional capital resources in order to conduct our operations and develop our products. While we estimate that our existing capital resources, royalty income and interest income will be sufficient to fund our current level

of operations for at least the next year based on current business plans, we cannot guarantee that this will be the case. The timing and degree of any future capital requirements will depend on many factors, including:

- continued scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- our ability to establish and maintain strategic collaborations or partnerships for research, development, clinical testing, manufacturing and marketing;
- our progress with preclinical and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

We intend to acquire additional funding through strategic collaborations, in the form of license fees, research and development fees and milestone payments. 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 sufficient funding is not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, each of which could have a material adverse effect on our business.

#### **If We are Unable to Recruit and Retain Skilled Employees, We May Not be Able to Achieve Our Objectives.**

Retaining our current employees and recruiting qualified scientific personnel to perform future research and development work will be critical to our success. Competition is intense for experienced scientists, and we may not be able to retain or recruit sufficient skilled personnel to allow us to pursue collaborations and develop our products and core technologies to the extent otherwise possible.

#### **We are Reliant on Single Source Third Party Contractors for The Manufacture and Production of Raw Materials and Product Candidates.**

We currently, and for the foreseeable future will, rely upon outside contractors to manufacture, supply and package for us key intermediates, active pharmaceutical ingredients and formulated drug product for our product candidates. Our current dependence upon others for the manufacture of our raw materials and product candidates and our anticipated dependence upon others for the manufacture of any products that we may develop, may adversely affect our ability to develop our product candidates in a timely manner and may adversely affect future profit margins and our ability to commercialize any products that we may develop on a timely and competitive basis.

#### **Entry Into Clinical Trials With One or More Products May Not Result in Any Commercially Viable Products.**

We do not expect to generate any significant revenues from product sales for a period of several years. We may never generate revenues from product sales or become profitable because of a variety of risks inherent in our business, including risks that:

- clinical trials may not demonstrate the safety and efficacy of our products;
- completion of clinical trials may be delayed, or costs of clinical trials may exceed anticipated amounts;
- we may not be able to obtain regulatory approval of our products, or may experience delays in obtaining such approvals;
- we and our licensees may not be able to successfully market our products.

**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 that our collaborators develop are subject to government regulation and may prevent us from creating commercially viable products from our discoveries. 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;
- advertising and promoting;
- selling and marketing;
- labeling; and
- distributing.

We may not obtain regulatory approval for the products we develop and our collaborators may not obtain regulatory approval for the products they develop. Regulatory approval may also 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 particular, human pharmaceutical therapeutic products are subject to rigorous preclinical and clinical testing and other requirements by the Food and Drug Administration in the United States and similar health authorities in foreign countries. The regulatory process, which includes extensive preclinical testing and clinical trials of each product in order to establish its safety and efficacy, is uncertain, can take many years and requires the expenditure of substantial resources.

Data obtained from preclinical and clinical activities is susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals or clearances. In addition, delays or rejections 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 revenues and profits.

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.

**We Depend on Our Collaborators to Help Us Complete The Process of Developing and Testing Our Products and Our Ability to Develop and Commercialize Products May be Impaired or Delayed if Our Collaborative Partnerships are Unsuccessful.**

Our strategy for the development, clinical testing and commercialization of our products requires entering into collaborations with corporate partners, licensors, licensees and others. 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.

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 Reliance on The Research Activities of Our Non-employee Scientific Advisors and Other Research Institutions, Whose Activities are Not Wholly Within Our Control, May Lead to Delays in Technological Developments.**

We have relationships with scientific advisors at academic and other institutions, some of whom conduct research at our request. These scientific advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these advisors and, except as otherwise required by our collaboration and consulting agreements, can expect only limited amounts of their time to be dedicated to our activities. If our scientific advisors are unable or refuse to contribute to the development of any of our potential discoveries, our ability to generate significant advances in our technologies will be significantly harmed.

**The Loss of Key Personnel Could Slow Our Ability to Conduct Research and Develop Products.**

Our future success depends to a significant extent on the skills, experience and efforts of our executive officers and key members of our scientific staff. We may be unable to retain our current personnel or attract or assimilate other highly qualified management and scientific personnel in the future. The loss of any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives.

**We Face Intense Competition From Other Companies.**

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 companies in the world. Many of these pharmaceutical companies have more financial resources, technical staff and manufacturing and marketing capabilities than we do. 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.

Pharmaceutical companies are increasingly using advertising, including direct-to-consumer advertising, in marketing their products. The costs of such advertising are very high and are increasing. It may be difficult for our company to compete with larger companies investing greater resources in these marketing activities.

Other pharmaceutical companies are aggressively seeking to obtain new products by licensing products or technology from other companies. We will be competing to license or acquire products or technology with companies with far greater financial and other resources.

**Inability to Obtain Special Materials Could Slow Down Our Research and Development Process.**

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

Special materials must often be manufactured for the first time for use in drug delivery systems, or materials may be used in the systems in a manner different from their customary commercial uses. The quality of materials can be critical to the performance of a drug delivery system, so a reliable source of a consistent supply of materials is important. Materials or components needed for our drug delivery systems 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.

**Patents and Other Intellectual Property Protection May be Difficult to Obtain or Ineffective.**

Patent protection generally has been important in the pharmaceutical industry. 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.

In the United States, patents are granted for specified periods of time. Some of our earlier patents have expired, or will expire, over the next several years.

Other companies may successfully challenge our patents in the future. Others may also challenge the validity or enforceability of our patents in litigation. If any challenge is successful, other companies may then be able to use the invention covered by the patent without payment. In addition, if other companies are able to obtain patents that cover any of our technologies or products, we may be subject to liability for damages and our activities could be blocked by legal action unless we can obtain licenses to those patents.

In addition, we utilize significant unpatented proprietary technology and rely on unpatented trade secrets and proprietary know-how to protect certain aspects of our products and technologies and the methods used to manufacture them. Other companies have or may develop similar technology which will compete with our technology.

**Our Royalty Revenues Could Decline.**

Our royalty revenues in future periods could vary significantly. Major factors which could have an effect on our royalty revenues include, but are not limited to:

- our partners' decisions about amounts and timing of advertising support for Retin-A Micro and Carac.
- our partners' decisions about other promotion and marketing support for Retin-A Micro and Carac.
- the timing of approvals for new product applications both in the United States and abroad.
- the expiration or invalidation of patents.
- decreases in licensees' sales of product due to competition, manufacturing difficulties or other factors that affect sales of product, including regulatory restrictions on the advertising of pharmaceutical products.

## 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. We also manage our interest rate risk by maintaining sufficient cash and cash equivalents such that we are typically able to hold our investments to maturity. At December 31, 2003 and 2002, respectively, our cash equivalents and marketable securities include corporate and other debt securities as follows: (in thousands)

	December 31,	
	<u>2003</u>	<u>2002</u>
Available-for-sale:		
Effective maturity of less than 3 months	\$ 14	\$ 2,826
Due after 3 months and less than 1 year	8,665	5,618
Due after 1 year and less than 2 years	<u>721</u>	<u>5,221</u>
Total Available-for-Sale	<u>\$9,400</u>	<u>\$13,665</u>

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

A.P. Pharma, Inc.  
Consolidated Balance Sheets  
(in thousands except par value and shares)

	<u>2003</u>	December 31, <u>2002</u>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 97	\$ 3,282
Marketable securities	9,387	10,839
Accounts receivable less allowance for doubtful account of \$0 and \$28 at December 31, 2003 and 2002, respectively	1,340	1,340
Prepaid expenses and other current assets, less allowance for doubtful note receivable of \$413 and \$437 at December 31, 2003 and 2002, respectively	434	280
Assets held for sale	—	225
Total current assets	11,258	15,966
Property and equipment, net	1,430	1,626
Other long-term assets	467	189
Total Assets	<u>\$ 13,155</u>	<u>\$ 17,781</u>
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 476	\$ 268
Accrued expenses	1,173	945
Accrued disposition costs	53	514
Deferred revenue	190	250
Total current liabilities	1,892	1,977
Deferred revenue—long-term	—	345
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock, 2,500,000 shares authorized; none issued or outstanding at December 31, 2003 and 2002	—	—
Common stock, \$.01 par value, 50,000,000 shares authorized; 20,641,924 and 20,467,440 issued and outstanding at December 31, 2003 and 2002, respectively	206	205
Additional paid-in capital	86,638	86,413
Accumulated deficit	(75,598)	(71,235)
Accumulated other comprehensive income	17	76
Total Stockholders' Equity	<u>11,263</u>	<u>15,459</u>
Total Liabilities and Stockholders' Equity	<u>\$ 13,155</u>	<u>\$ 17,781</u>

See accompanying notes to consolidated financial statements.

**A.P. Pharma, Inc.**  
**Consolidated Statements of Operations**  
*(in thousands except per share data)*

	Year Ended December 31,		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Revenues			
Royalties	\$ 4,502	\$ 4,026	\$ 3,227
Contract revenues	346	407	38
License fees	<u>—</u>	<u>237</u>	<u>—</u>
Total revenues	4,848	4,670	3,265
Expenses			
Research and development	8,660	6,699	7,348
General and administrative	<u>2,800</u>	<u>3,024</u>	<u>3,247</u>
Operating loss	<u>(6,612)</u>	<u>(5,053)</u>	<u>(7,330)</u>
Interest income	251	590	1,105
Other income, net	<u>153</u>	<u>68</u>	<u>87</u>
Loss from continuing operations	(6,208)	(4,395)	(6,138)
Income (loss) from discontinued operations	(57)	401	624
Gain on disposition of discontinued operations, net of taxes	<u>1,902</u>	<u>216</u>	<u>3,000</u>
Net loss	<u>\$ (4,363)</u>	<u>\$ (3,778)</u>	<u>\$ (2,514)</u>
Basic and diluted loss per share:			
Loss from continuing operations	<u>\$ (0.30)</u>	<u>\$ (0.22)</u>	<u>\$ (0.30)</u>
Net loss	<u>\$ (0.21)</u>	<u>\$ (0.19)</u>	<u>\$ (0.12)</u>
Weighted average common shares outstanding—basic and diluted	<u>20,553</u>	<u>20,409</u>	<u>20,276</u>

See accompanying notes to consolidated financial statements.

**A.P. Pharma, Inc.**  
**Consolidated Statements of Stockholders' Equity and Comprehensive Loss**  
(in thousands)

For the Year Ended December 31, 2003, 2002 and 2001

	Common Stock Shares	Common Stock Amount	Deferred Compensation	Additional Paid-In Capital	Accumulated Deficit	Comprehensive Income	Other Comprehensive Income	Stockholders' Equity
Balance, December 31, 2000	20,206	\$202	\$(80)	\$85,901	\$(64,943)	\$ 79	-	\$21,159
Comprehensive loss:								
Net loss								(2,514)
Net unrealized gain on marketable securities							159	159
Comprehensive loss								(2,355)
Fair value of common stock issued to directors for services and restricted stock awards	115	1		211				212
Expense associated with stock options granted to non-employees								11
Amortization of restricted stock			80					80
Common stock issued to employees under the Employee Stock Purchase Plan	36			65				65
Balance, December 31, 2001	20,357	\$203	\$ -	\$86,188	\$(67,457)	\$ 238	-	\$19,172
Comprehensive loss:								
Net loss								(3,778)
Net unrealized loss on marketable securities							(162)	(162)
Comprehensive loss								(3,940)
Fair value of common stock issued to directors for services and restricted stock awards	47	1		129				130
Expenses associated with stock options granted to non-employees								22
Common stock issued to employees under the Employee Stock Purchase Plan	63	1		74				75
Balance, December 31, 2002	20,467	\$205	\$ -	\$86,413	\$(71,235)	\$ 76	-	\$15,459
Comprehensive loss:								
Net loss								(4,363)
Net unrealized loss on marketable securities							(59)	(59)
Comprehensive loss								(4,422)
Common stock issued upon exercise of stock options	14			22				22
Fair value of common stock issued to directors for services	86	1		112				113
Expenses associated with stock options granted to non-employees								30
Common stock issued to employees under the Employee Stock Purchase Plan	75			61				61
Balance, December 31, 2003	20,642	\$206	\$ -	\$86,638	\$(75,598)	\$ 17	-	\$11,263

See accompanying notes to consolidated financial statements.

**A.P. Pharma, Inc.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	<b>For the Year Ended December 31,</b>		
	<b><u>2003</u></b>	<b><u>2002</u></b>	<b><u>2001</u></b>
<b>Cash flows from operating activities:</b>			
Net loss	\$(4,363)	\$ (3,778)	\$ (2,514)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss (income) from discontinued operations	57	(401)	(624)
Gain on disposition of discontinued operations	(1,902)	(216)	(3,000)
Allowance for claims relating to sale of discontinued operations	-	-	(712)
Gain on sale of marketable securities	(1)	(81)	(84)
Depreciation and amortization	432	449	390
Provision for (recovery of) note receivable	(24)	66	418
Stock-based compensation awards to non-employees	143	119	189
Restricted stock awards	-	33	113
Amortization of premium/discount and accretion of marketable securities	28	22	171
Loss on retirements and disposals of fixed assets	16	3	4
Changes in operating assets and liabilities:			
Accounts receivable	-	(53)	243
Advances to officers and employees	-	-	34
Prepaid expenses and other	(130)	254	263
Other long-term assets	(278)	26	(64)
Accounts payable	208	(54)	25
Accrued expenses	228	(464)	(184)
Deferred revenue	(405)	(505)	(164)
Net cash used in continuing operating activities	<u>(5,991)</u>	<u>(4,580)</u>	<u>(5,496)</u>
Cash used in discontinued operations	<u>(534)</u>	<u>(554)</u>	<u>(999)</u>
Net cash used in operating activities	<u>(6,525)</u>	<u>(5,134)</u>	<u>(6,495)</u>
<b>Cash flows from investing activities:</b>			
Proceeds from disposition of discontinued operations	2,142	216	3,602
Purchases of property and equipment	(251)	(428)	(273)
Purchases of marketable securities	(6,712)	(12,563)	(16,410)
Maturities of marketable securities	<u>8,078</u>	<u>17,498</u>	<u>16,635</u>
Net cash provided by investing activities	<u>3,257</u>	<u>4,723</u>	<u>3,554</u>
<b>Cash flows from financing activities:</b>			
Proceeds from the exercise of common stock options	22	-	-
Proceeds from issuance of shares under the Employee Stock Purchase Plan	<u>61</u>	<u>75</u>	<u>66</u>
Net cash provided by financing activities	<u>83</u>	<u>75</u>	<u>66</u>
Net decrease in cash and cash equivalents	<u>(3,185)</u>	<u>(336)</u>	<u>(2,875)</u>
Cash and cash equivalents at the beginning of the year	<u>3,282</u>	<u>3,618</u>	<u>6,493</u>
Cash and cash equivalents at the end of the year	<u>\$ 97</u>	<u>\$ 3,282</u>	<u>\$ 3,618</u>
<b>Supplemental Cash Flow Data:</b>			
Cash paid for taxes	<u>\$ 9</u>	<u>\$ 13</u>	<u>\$ 27</u>

See accompanying notes to consolidated financial statements.

## **Note 1 Business**

A.P. Pharma, Inc. (APP, the Company, we, our, or us) is developing patented polymer-based delivery systems to enhance the safety and effectiveness of pharmaceutical compounds. Projects are currently conducted under feasibility and development arrangements with pharmaceutical and biotechnology companies. New products and technologies under development include bioerodible polymers for injectable and implantable drug delivery.

On July 25, 2000, we completed the sale of certain technology rights for our topical pharmaceuticals 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 Consolidated 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 Standards 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).

## **Note 2 Summary of Significant Accounting Policies**

### **Basis of Presentation**

The condensed consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiary, APS Analytical Standards, Inc. (Analytical Standards) through the date of sale (February 13, 2003). All significant intercompany balances and transactions have been eliminated in consolidation.

### **Cash Equivalents and Marketable Securities**

For purposes of the Consolidated Statements of Cash Flows and Consolidated Balance Sheets, we consider all short-term investments that have original maturities of less than three months to be cash equivalents. Investments with effective maturities longer than three months are classified as marketable securities. Investments consist primarily of commercial paper, bankers acceptances, master notes and corporate debt securities. We have classified all our investments in certain debt and equity securities as "available-for-sale", and therefore are recorded at fair value with unrealized gains and losses reported as a separate component of stockholders' equity. Realized gains and losses and declines in fair value that are deemed to be other-than-temporary are reflected in earnings. The cost of 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.

### **Allowance for Note Receivable**

An allowance 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 reserve, is included in prepaid expenses and other current assets in the accompanying balance sheet.

### **Property and Equipment**

Property and equipment are 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.

## Long-Lived Assets

As circumstances dictate, we evaluate whether changes have occurred that would require revision of the remaining estimated lives of recorded long-lived assets or that render those assets 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

We have 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 has been recognized for our stock option plans and stock purchase plan. Compensation related to options granted to non-employees is periodically remeasured as earned.

In accordance with FAS No. 123, "Accounting for Stock-Based Compensation," as amended by FAS 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 FAS No. 123 had been applied in measuring compensation expense for all periods presented (see Note 9 "Stockholders' Equity").

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net loss—as reported	\$(4,363)	\$(3,778)	\$(2,514)
Deduct:			
Stock-based employee compensation expense determined under FAS 123	<u>(397)</u>	<u>(601)</u>	<u>(696)</u>
Net loss—pro-forma	<u>\$(4,760)</u>	<u>\$(4,379)</u>	<u>\$(3,210)</u>
Basic and diluted net loss per common share—as reported	\$ (0.21)	\$ (0.19)	\$ (0.12)
Basic and diluted net loss per common share—pro-forma	\$ (0.23)	\$ (0.21)	\$ (0.16)

## Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates were made relating to useful lives of fixed assets, valuation allowances, impairment of assets and accruals. 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.

### **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 APP to earn future revenue through royalty payments. These non-refundable license fees are initially reported as deferred revenues and recognized as revenues 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 consolidated 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 assured, whichever is earlier. No such fees were recorded during the year ended December 31, 2003.

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 year ended December 31, 2003.

### **Contract Revenues**

Contract revenues 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. Revenues from these arrangements are recognized as the related development costs are incurred. These revenues approximate the costs incurred.

### **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, professional fees, 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.

The initiation of APF112 clinical trials have had, and will continue to 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 activity according to the protocol. The Company monitors patient enrollment level 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 Loss Per Share**

Basic and diluted net loss per share is computed based on the weighted-average number of common shares outstanding. Diluted net loss per share is not presented separately as the Company is in a net loss position and including potentially dilutive securities in the net loss per share computation would be anti-dilutive. See Note 9 "Net Loss Per Share".

## **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.

Approximately 80% and 79% of the receivables were concentrated with two customers in the pharmaceutical industry as of December 31, 2003 and 2002, respectively. Approximately 93%, 91% and 100% of total revenue were concentrated with two customers for the years ended December 31, 2003, 2002 and 2001. To reduce credit risk, we perform ongoing credit evaluations of our customers' financial conditions. 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 revenues are derived from customers within the United States.

## **Recent Accounting Pronouncements**

In November 2002, the FASB issued Interpretation No. 45 (or FIN 45), "Guarantor's Accounting and Disclosure requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of the disclosure requirements in November 2002 and the recognition requirements in January 2003 of FIN 45 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued Emerging Issues Task Force (EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. EITF Issue No. 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF Issue No. 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. Finally, EITF Issue No. 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting for an arrangement. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a significant impact on our results of operations and financial position.

In January 2003, the FASB issued Interpretation No. 46 (or FIN 46), "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. The consolidation requirements of FIN 46 apply immediately to variable interest entities created after January 31, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of

when the variable interest entity was established. We do not have any variable interest entities and, as such, the adoption of FIN 46 did not have a material impact on our results of operations and financial position.

### Reclassifications

Certain reclassifications have been made to the prior year financial statements to conform with the presentation in 2003.

The operations and related assets of the Analytical Standards division were reclassified to discontinued operations and assets held for sale, respectively, in the statements of operations and cash flows for the years ended December 31, 2002 and 2001 and in the balance sheet as of December 31, 2002.

### Note 3 Cash Equivalents and Marketable Securities

We consider all of our investments in debt and equity securities as available-for-sale and, accordingly, we have recorded these investments at fair value. Realized gains totaled \$1,000, \$81,000 and \$84,000 for the years ended December 31, 2003, 2002 and 2001, respectively. There were no realized losses for the years ended December 31, 2003, 2002 and 2001.

At December 31, 2003 and 2002, the amortized cost and estimated market value of investments in debt securities and cash are set forth in the tables below:

#### December 31, 2003 (in thousands)

	<u>Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Estimated Market Value</u>
Available-for-sale:				
Corporate debt securities	\$3,354	\$10	\$ -	\$3,364
Asset-backed securities	2,006	6	-	2,012
Government debt securities	2,015	2	(1)	2,016
Other debt securities	<u>2,008</u>	<u>-</u>	<u>-</u>	<u>2,008</u>
Total available-for-sale	9,383	18	(1)	9,400
Cash	<u>84</u>	<u>-</u>	<u>-</u>	<u>84</u>
Totals	<u>\$9,467</u>	<u>\$18</u>	<u>\$ (1)</u>	<u>\$9,484</u>

#### December 31, 2002 (in thousands)

	<u>Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Estimated Market Value</u>
Available-for-sale:				
Corporate debt securities	\$ 3,755	\$14	\$ (1)	\$ 3,768
Asset-backed securities	2,355	44	-	2,399
Government debt securities	3,282	17	-	3,299
Other debt securities	<u>4,197</u>	<u>2</u>	<u>-</u>	<u>4,199</u>
Total available-for-sale	13,589	77	(1)	13,665
Cash	<u>456</u>	<u>-</u>	<u>-</u>	<u>456</u>
Totals	<u>\$14,045</u>	<u>\$77</u>	<u>\$ (1)</u>	<u>\$14,121</u>

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

	2003		2002	
	<u>Cost</u>	<u>Fair Value</u>	<u>Cost</u>	<u>Fair Value</u>
Cash	\$ 84	\$ 84	\$ 456	\$ 456
Cash equivalents	14	14	2,826	2,826
Marketable securities	<u>9,369</u>	<u>9,386</u>	<u>10,763</u>	<u>10,839</u>
Totals	<u>\$9,467</u>	<u>\$9,484</u>	<u>\$14,045</u>	<u>\$14,121</u>

The cost and estimated fair value of available-for-sale debt securities as of December 31, 2003, by contractual maturity, consisted of the following (in thousands):

	<u>Cost</u>	<u>Estimated Market Value</u>
Available-for-sale:		
Due in one year or less	\$8,663	\$8,679
Due after one or more years	<u>720</u>	<u>721</u>
Total available-for-sale	9,383	9,400
Cash	<u>84</u>	<u>84</u>
Totals	<u>\$9,467</u>	<u>\$9,484</u>

#### Note 4 Property and Equipment

Property and equipment consist of the following:

	December 31, (in thousands)	
	<u>2003</u>	<u>2002</u>
Leasehold improvements	\$ 1,359	\$ 1,359
Furniture and equipment	<u>2,423</u>	<u>3,458</u>
Total property and equipment	3,782	4,817
Accumulated depreciation and amortization	<u>(2,352)</u>	<u>(3,191)</u>
Property and equipment, net	<u>\$ 1,430</u>	<u>\$ 1,626</u>

Depreciation expense amounted to \$432,000, \$449,000 and \$390,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

**Note 5 Accrued Expenses**

Accrued expenses consist of the following:

	<b>December 31, (in thousands)</b>	
	<u>2003</u>	<u>2002</u>
Professional fees	\$ 142	\$178
Accrued salaries	144	156
Accrued bonus	175	196
Clinical studies	645	205
Other	<u>67</u>	<u>210</u>
Total	<u>\$1,173</u>	<u>\$945</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, 2003 will be 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 consolidated balance sheets.

**Note 7 Commitments**

Total rental expense for facilities and equipment was \$667,000, \$654,000 and \$514,000 for 2003, 2002 and 2001, respectively. Rental expense differs from cash payments under lease arrangements by \$0, \$12,000 and \$148,000, in 2003, 2002 and 2001 as the Company's sales agreement to RP Scherer (see Note 10, "Discontinued Operations") allowed for RP Scherer to occupy a portion of the leased office facilities rent-free through January 25, 2002. The total amount of free rent provided to RP Scherer was accrued and charged to discontinued operations in 2000.

Our future minimum lease payments under noncancelable operating leases for facilities are as follows (in thousands):

<u>Years Ending December 31,</u>	<u>Minimum Payments</u>
2004	\$602
2005	12
2006	<u>7</u>
	<u>\$621</u>

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".

## **Note 8 Stockholders' Equity**

### **Shareholders' Rights Plan**

On August 19, 1996, the Board of Directors approved a Shareholders' Rights Plan under which shareholders of record on September 3, 1996 received a dividend of one Preferred Stock purchase right ("Rights") for each share of common stock outstanding. The Rights were not exercisable until 10 business days after a person or group acquired 20% or more of the outstanding shares of common stock or announced a tender offer that could have resulted in a person or group beneficially owning 20% or more of the outstanding shares of common stock (an "Acquisition") of the Company. The Board of Directors approved an increase in threshold to 30% in December 1997. Each Right, should it become exercisable, will entitle the holder (other than acquirer) to purchase company stock at a discount. The Board of Directors may terminate the Rights plan or, under certain circumstances, redeem the rights.

In the event of an Acquisition without the approval of the Board, each Right will entitle the registered holder, other than an acquirer and certain related parties, to buy at the Right's then current exercise price a number of shares of common stock with a market value equal to twice the exercise price.

In addition, if at the time when there was a 30% shareholder, we were to be acquired by merger, shareholders with unexercised Rights could purchase common stock of the acquirer with a value of twice the exercise price of the Rights.

The Board may redeem the Rights for \$0.01 per Right at any time prior to Acquisition. Unless earlier redeemed, the Rights will expire on August 19, 2006.

### **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"). Under the Plan, we are authorized to issue up to 400,000 shares of common stock 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 36 percent of eligible employees participated in the Plan in 2003. Under the Plan, we issued 74,746 shares in 2003, 63,086 shares in 2002 and 36,109 shares in 2001. The weighted average fair value of purchase rights granted during 2003, 2002 and 2001 were \$0.50, \$0.60 and \$1.47, respectively. The weighted average exercise price of the purchase rights exercised during 2003, 2002 and 2001 were \$0.82, \$1.18 and \$1.82, respectively. We had 92,593, 167,339 and 230,425 shares reserved for issuance under the Plan at December 31, 2003, 2002 and 2001, 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 500,000 and 250,000 shares under the 2002 Plan and Non-Qualified Stock Plan, respectively. 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 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 grant options to purchase common stock to consultants from time to time in exchange for services rendered that vest over a period of two to four years. No options were granted to consultants in 2003. We recorded compensation expense related to option grants to consultants of approximately \$30,000, \$22,000 and \$11,000 in 2003, 2002 and 2001, respectively, which represents the fair market value of the portion of the awards that vested during 2003, 2002 and 2001. The unvested shares held by consultants have been and will be revalued using the Black-Scholes option pricing model at the end of each accounting period.

The following table summarizes option activity for 2003, 2002 and 2001:

	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	2,901,512	\$4.54	3,427,042	\$5.25	3,910,177	\$5.87
Granted	182,500	1.26	316,000	1.87	467,000	2.51
Exercised	(13,570)	1.62	-	-	-	-
Expired or Forfeited	(961,837)	5.21	(841,530)	6.41	(950,135)	6.46
Outstanding at end of year	<u>2,108,605</u>	3.97	<u>2,901,512</u>	4.54	<u>3,427,042</u>	5.25
Options exercisable at year end	1,674,704	4.51	2,251,298	5.18	2,674,679	5.93
Shares available for future grant at year end	286,669		384,332		193,933	
Weighted-average fair value of stock options granted during the year		\$0.79		\$1.76		\$1.32

The following table summarizes information about stock options outstanding at December 31, 2003:

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
\$1.00-\$2.45	602,917	8.5 years	\$1.74	267,397	\$1.95
\$2.50-\$3.34	539,646	7.0	2.91	441,380	2.92
\$3.44-\$5.75	536,500	2.9	4.81	536,385	4.81
\$5.88-\$10.25	<u>429,542</u>	3.5	7.38	<u>429,542</u>	7.38
\$1.00-\$10.25	<u>2,108,605</u>	5.7	\$3.97	<u>1,674,704</u>	\$4.51

We have adopted the disclosure only provisions of FAS 123 "Accounting for Stock-Based Compensation." Accordingly, except for stock options issued to non-employees and restricted stock awards to employees, no compensation cost has been recognized for the various stock option plans and stock purchase plan. The compensation cost that has been expensed in the statements of operations for the stock options issued to non-employees and restricted stock awards to employees and directors was \$30,000, \$55,000 and \$123,000 for 2003, 2002 and 2001, respectively.

The table regarding the net loss and net loss per share included in Note 2, "Summary of Significant Accounting Policies," prepared in accordance with FAS 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 FAS 123 and the earnings (loss) per share method under FAS 128.

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

	<u>Year Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Expected life in years (from vesting date):			
Stock options	5	5	5
Employee Stock Purchase Plan	1.5-2	1.5-2	1.5-2
Discount rate:			
Stock options	3.2%	3.8%	4.3%
Employee Stock Purchase Plan	1.47%-1.82%	1.7%-3.2%	2.4%-4.2%
Volatility			
Stock options	85%	114%	62%
Employee Stock Purchase Plan	65%-68%	68%-69%	67%-71%
Expected dividend yield	0%	0%	0%

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

In 2001, we accelerated the vesting of options to purchase 40,000 shares of common stock held by the directors who departed the board as part of the refocusing of our company. As the exercise prices of these options exceeded our common stock's fair market value per share on the date of termination of services, we did not record compensation expense associated with these stock option accelerations.

Also in 2001, we modified the 1992 Stock Option Plan to extend the exercise period of vested stock options upon employee termination, from up to 30 days after the date of termination to up to 90 days after the date of termination. We did not record compensation expense associated with this modification in 2003, 2002 and 2001, as the expense associated with the affected options exercised in 2003 was \$0 and none of the affected options was exercised during 2002 and 2001. The number of stock options that may be affected in future periods was not estimable on the date of modification.

**Note 9 Net Loss Per Share**

The following table sets forth the computation of our basic and diluted loss per share (in thousands):

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Loss from continuing operations	<u>\$ (6,208)</u>	<u>\$ (4,395)</u>	<u>\$ (6,138)</u>
Net loss	<u>\$ (4,363)</u>	<u>\$ (3,778)</u>	<u>\$ (2,514)</u>
Shares calculation:			
Weighted average shares outstanding—basic and diluted	20,553	20,409	20,276
Basic and diluted loss per common share:			
Loss from continuing operations	<u>\$ (0.30)</u>	<u>\$ (0.22)</u>	<u>\$ (0.30)</u>
Net loss	<u>\$ (0.21)</u>	<u>\$ (0.19)</u>	<u>\$ (0.12)</u>

The following options were outstanding during the periods presented, 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, except exercise prices):

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Number outstanding	2,423	3,146	3,427
Range of exercise prices	\$1.00-\$10.25	\$1.00-\$10.25	\$1.69-\$10.88

#### 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.

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

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 changes in estimates of our cosmeceutical and toiletry business that was sold to RP Scherer on July 25, 2000, as follows (in thousands):

	<u>For the year ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
<b>Analytical Standards Division</b>			
Income from Analytical Standards division	<u>\$ 8</u>	<u>\$229</u>	<u>\$209</u>
	8	229	209
<b>Cosmeceutical and Toiletry Business</b>			
Change in estimate for Kligman lawsuit settlement	-	-	(94)
Recovery of (provisions for) doubtful accounts receivable	28	(28)	220
Change in estimates for professional fees, severance costs and guarantees	(103)	135	(36)
Change in estimate of provision for income taxes and tax refunds	<u>10</u>	<u>65</u>	<u>325</u>
	<u>(65)</u>	<u>172</u>	<u>415</u>
Total income (loss) from discontinued operations	<u>\$ (57)</u>	<u>\$401</u>	<u>\$624</u>

Revenues relating to the discontinued operations totaled \$127,000, \$1,145,000 and \$1,122,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

Gain on disposition of discontinued operations in the accompanying Consolidated Statement of Operations for the year ended December 31, 2003 represents the gain on the sale of certain assets of our Analytical Standards division in February 2003. Gain on disposition of discontinued operations for the year ended December 31, 2002 and 2001 represents the annual earnout income received from RP Scherer based on the performance of the business sold, net of allowances for claims made by RP Scherer, mostly due to an indemnification claim relating to inventory deemed obsolete, pursuant to the agreement.

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, 2003, 2002 and 2001:

	<u>For the year ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Basic income (loss) per common share from discontinued operations	\$*	\$0.02	\$0.03
Diluted income (loss) per common share from discontinued operations	\$*	\$0.02	\$0.03

\* Less than (\$0.00) per share

As of December 31, 2003, net assets relating to the discontinued operations include trade receivables of \$119,000. Liabilities related to the discontinued operation in the amount of \$53,000 include severance costs and accruals for gross profit guarantees. These liabilities are reported as accrued disposition costs in the accompanying consolidated balance sheets.

Cash used in discontinued operations primarily relates to payments of severance costs to former employees who were terminated as a result of the sale of the cosmeceutical and toiletry business and the Analytical Standards division as well as payment of the gross profit guarantee to RP Scherer.

#### **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 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. Approximately \$181,000 of these severance charges has been paid through December 31, 2003.

#### **Cosmeceutical and Toiletry Business**

On July 25, 2000, we completed the sale of certain technology rights for our topical pharmaceuticals and cosmeceutical product lines and other assets ("cosmeceutical and toiletry business") to RP Scherer Corporation, a subsidiary of Cardinal Health, Inc. We received \$25 million at closing and were entitled to receive further earnout amounts for the subsequent three years up to a maximum of \$26.5 million, the amounts of which were dependent on the performance of the business sold. During the first two years of the earnout period, we received an aggregate of \$3.8 million. No earnout income was received or reported for the third and final earnout year. The earnout is calculated based on gross profit earned by the business sold over a three-year period. The terms of the agreement with RP Scherer provide for an earnout of 20% to 60% of gross profit of the business sold over a threshold that increases each year. Each earnout year has a different minimum level of gross profit that should be achieved before any earnout income can be received. In addition to the minimum gross profit levels, each earnout period has three additional gross profit thresholds that correspond to a specific earnout percentage up to a maximum of 60%. Earnout thresholds for the third and final year are higher than the first two years. The cosmeceutical and toiletry business is reported as a discontinued operation for all periods presented in the accompanying Consolidated Statements of Operations.

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. Payments for the Gross Profit Guaranty aggregated \$404,000 for the first three 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.

The agreements with RP Scherer also included an indemnification for existing liabilities not assumed by RP Scherer and net realizable value of assets sold. The accompanying consolidated balance sheet as of December 31, 2002 include a liability of \$314,000 for an indemnification claim related to inventory deemed obsolete which was paid to RP Scherer in January 2003.

A total of 56 positions, primarily in the manufacturing, marketing and research and development departments and associated general and administrative staff, were eliminated as a result of the sale. During the year ended December 31, 2000, we recorded severance charges related to salaries and benefits in gain on disposition of discontinued operations. The total amount of severance-related charges was approximately \$3,685,000, of which all has been paid to date.

#### 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 \$6,000, \$5,500 and \$5,250 for 2003, 2002 and 2001, 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, 2003, 2002 and 2001, we contributed to the plan approximately \$64,000, \$79,000 and \$56,000, respectively. No discretionary contributions have been made to the plan since its inception.

#### Note 12 Income Taxes

There is no provision for income taxes 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):

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 23,900	\$ 24,000
Research credits	2,000	2,000
Capitalized research expenses	500	300
Other	<u>1,200</u>	<u>1,000</u>
Total deferred tax assets	27,600	27,300
Valuation allowance	<u>(27,600)</u>	<u>(27,300)</u>
Net deferred tax assets	<u>—</u>	<u>—</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$300,000, \$1,000,000 and \$289,500 during 2003, 2002, and 2001, respectively.

Deferred tax assets related to carryforwards at December 31, 2003 include approximately \$2,800,000 associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders' equity.

As of December 31, 2003, we had net operating loss carryforwards for federal income tax purposes of approximately \$69,700,000 which expire in the years 2004 through 2023 and federal research and development tax credits of approximately \$1,100,000 which expire in the years 2004 through 2023.

As of December 31, 2003, we had net operating loss carryforwards for state income tax purposes of approximately \$3,600,000 which expire in the years 2004 through 2013 and state research and development tax credits of approximately \$1,300,000 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**

#### **Ortho Neutrogena Corporation**

In May 1992, we entered into development and licensing and investment agreements with Ortho Neutrogena (formerly Ortho-McNeil Pharmaceutical Corporation) ("Ortho") for the development of retinoid products. The first product is a Microsponge system entrapment of tretinoin (trans-retinoic acid or "t-RA"), a prescription acne drug product for which FDA approval was received in February 1997. A second product licensed to Ortho is a Microsponge entrapment of a retinoid to be used for the treatment of photodamaged skin.

In February 1995, we received \$750,000 in prepaid royalties and an additional \$750,000 as a milestone payment on the submission to the FDA of its New Drug Application ("NDA") for the tretinoin prescription acne treatment. The milestone payment was recognized as revenue upon receipt. The prepaid royalties of \$750,000 were recorded as deferred revenue. In February 1997, upon receipt of approval from the FDA to market Retin-A Micro<sup>®</sup> (tretinoin gel) microspheres for the treatment of acne, we received \$3 million from Ortho, \$1.5 million of which was a milestone payment that was recognized as revenue in 1997 and \$1.5 million of which was prepaid royalties that was recorded as deferred revenue. As of December 31, 2003, \$190,000 of these payments remained in deferred revenues. Ortho pays us a royalty on product sales. In accordance with the licensing agreement, 25% of the royalties we earn is applied against deferred revenues after certain annual minimum royalty payments are met. Should these minimums not be achieved, Ortho would lose its exclusivity and we would regain marketing rights to the retinoid products.

#### **Dermik**

In March 1992, we restructured a 1989 joint venture agreement with Dermik, an Aventis company. As part of the agreement, Aventis received certain exclusive marketing rights. Product applications include a 5-FU treatment for actinic keratoses. In 1998, this agreement was amended to give Dermik an exclusive worldwide license to Microsponge-entrapped 5-FU and to increase the royalty payable to us from 5% to 10%. In 1999, Dermik filed an NDA for this product and expanded its agreement with us to cover two additional indications, in return for milestone payments and royalties upon successful development. We received \$500,000 on the execution of this amendment representing a milestone payment of \$250,000 and prepaid royalties of \$250,000. In 2000, Dermik received FDA marketing clearance for the product, which was launched under the trade name Carac<sup>™</sup> in 2001 and we received a milestone payment of \$50,000. In accordance with the agreement, the prepaid royalties were to be creditable against further royalties in at least two indications containing the Licensed Product and were recorded as deferred revenues. During 2002, Dermik decided not to pursue the additional indications covered by the 1999 amendment, thereby forfeiting its prepaid royalties. The accompanying Consolidated Statements of Operations include \$237,000 in 2002 resulting from the recognition of these deferred revenues upon the forfeiture of Dermik's rights. Dermik's exclusivity relating to Carac will continue as long as annual minimum royalty payments are made, governed by the life of our applicable patents.

**Note 14 Quarterly Results of Operations (Unaudited)**

The following table presents summarized results of operations for each of our quarters in the years ended December 31, 2003 and 2002. These quarterly results are unaudited; however, in the opinion of management, such results have been prepared on the same basis as our audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth therein.

**QUARTERLY RESULTS OF OPERATIONS**  
**(IN THOUSANDS, EXCEPT PER SHARE DATA)**  
**(UNAUDITED)**

<u>Year Ended December 31, 2003</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
Total revenues	\$ 1,106	\$ 1,117	\$ 1,268	\$ 1,358
Operating expenses	2,980	3,101	2,503	2,875
Interest and other, net	76	54	220	53
Loss from continuing operations	(1,798)	(1,930)	(1,015)	(1,465)
Discontinued operations	1,832	(30)	(43)	86
Net income (loss)	34	(1,960)	(1,058)	(1,379)
Basic income (loss) per common share:				
Loss from continuing operations	(0.09)	(0.09)	(0.05)	(0.07)
Net income (loss)	0.00	(0.10)	(0.05)	(0.07)
Diluted (loss) income per common share:				
Loss from continuing operations	(0.09)	(0.09)	(0.05)	(0.07)
Net income (loss)	0.00	(0.10)	(0.05)	(0.07)
<u>Year Ended December 31, 2002</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
Total revenues	\$ 952	\$ 968	\$ 1,041	\$1,709
Operating expenses	2,257	2,685	2,518	2,263
Interest and other, net	204	175	138	141
Loss from continuing operations	(1,101)	(1,542)	(1,339)	(413)
Discontinued operations	95	49	287	186
Net loss	(1,006)	(1,493)	(1,052)	(227)
Basic and diluted loss per common share:				
Loss from continuing operations	(0.05)	(0.08)	(0.07)	(0.02)
Net loss	(0.05)	(0.07)	(0.05)	(0.01)

## Report of Ernst & Young LLP, Independent Auditors

### The Board of Directors and Shareholders

#### A.P. Pharma, Inc.

We have audited the accompanying consolidated balance sheets of A.P. Pharma, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the Index at Item 15(a). 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of A.P. Pharma, Inc. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. 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 20, 2004

**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, 2003, the end of period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level to timely alert them to material information relating to the Company required to be included in our Exchange Act filings.

(b) Changes in internal controls: During the quarter ended December 31, 2003, 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 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

APP incorporates by reference the information set forth under the caption "Information Concerning the Board of Directors and Executive Officers" of the Company's Proxy Statement (the "Proxy Statement") for the annual meeting of shareholders to be held on May 25, 2004.

**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.

We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Ethics by posting such information on our website, at the address and location specified above.

**Item 11. EXECUTIVE COMPENSATION**

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

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

The Company incorporates by reference the information set forth under the caption "Common Stock Ownership of Certain Beneficial Owners and Management" of the Proxy Statement.

In October 2000, the Company adopted the Non-Qualified Stock Plan, which has not been approved by A.P. Pharma's stockholders. The Non-Qualified Stock Plan will expire in 2010. Under the Non-Qualified Stock Plan, awards may be granted as a material inducement to any person accepting employment or consultancy with the Company or an employee of the Company who is not an officer or director of the Company at the time of the award. The Non-Qualified Stock Plan provides for the discretionary award of options, restricted stock and stock purchase rights or any combination of these awards to an eligible person, provided, however, that only NQOs may be granted under the plan. Under the Non-Qualified Stock Plan, the term of any NQO granted may not exceed 10 years, and the exercise price of any such NQO must be at least 85% of the fair market value of the Common Stock at the date of grant. Options generally vest on a monthly basis over a period of four years.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The Company incorporates by reference the information set forth under the caption "Certain Transactions" of the Proxy Statement.

**Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The Company incorporates by reference set forth under the caption "Report of the Audit Committee," "Ratification of Selection of Independent Auditors" and "Fees Paid to Ernst & Young" of the Proxy Statement.

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

- (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.<sup>1</sup>
  - 3-A A-Copy of Registrant's Certificate of Incorporation.<sup>2</sup>
  - 3-B Copy of Registrant's Bylaws.<sup>2</sup>
  - 10-C Registrant's 1992 Stock Plan dated August 11, 1992.<sup>3\*</sup>
  - 10-D Registrant's 1997 Employee Stock Purchase Plan dated March 5, 1997.<sup>4\*</sup>
  - 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.<sup>5</sup>
  - 10-N Agreement with Johnson & Johnson dated April 14, 1992.<sup>6</sup>
  - 10-X Registrant's Non-Qualified Plan
  - 23.1 Consent of Ernst & Young, LLP, Independent Auditors.
  - 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.

**(b) Reports on Form 8-K**

On November 7, 2003, the Company furnished a report on Form 8-K, under Item 12 its financial results for the quarter ended September 30, 2003.

**(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.

- <sup>1</sup> Filed as an Exhibit with corresponding Exhibit No. to Registrant's Form 8-K dated July 25, 2000, and incorporated herein by reference.
- <sup>2</sup> 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.
- <sup>3</sup> Filed as Exhibit No. 28.1 to Registrant's Registration Statement on Form S-8 (Registration No. 33-50640), and incorporated herein by reference.
- <sup>4</sup> Filed as an Exhibit No. 99.1 to Registrant's Registration Statement on Form S-8 (Registration No. 333-35151), and incorporated herein by reference.
- <sup>5</sup> 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.
- <sup>6</sup> 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.

**(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/ Michael O'Connell

\_\_\_\_\_  
Michael O'Connell  
President and Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Michael O'Connell and Gordon Sangster, 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/S/ Michael O'Connell</u> Michael O'Connell	President and Chief Executive Officer (Principal Executive Officer)	March 25, 2004
<u>/S/ Gordon Sangster</u> Gordon Sangster	Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2004
<u>/S/ Paul Goddard</u> Paul Goddard	Chairman of the Board of Directors	March 25, 2004
<u>/S/ Stephen Drury</u> Stephen Drury	Director	March 25, 2004
<u>/S/ Peter Riepenhausen</u> Peter Riepenhausen	Director	March 25, 2004
<u>/S/ Toby Rosenblatt</u> Toby Rosenblatt	Director	March 25, 2004
<u>/S/ Gregory Turnbull</u> Gregory Turnbull	Director	March 25, 2004
<u>/S/ Dennis Winger</u> Dennis Winger	Director	March 25, 2004
<u>/S/ Robert Zerbe</u> Robert Zerbe	Director	March 25, 2004

**EXHIBIT INDEX**  
**Form 10-K Annual Report**

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- 10-N Agreement with Johnson & Johnson dated April 14, 1992.<sup>6</sup>
- 10-X Registrant's Non-Qualified Stock Plan.
- 21 Proxy Statement for the Annual Meeting of Shareholders.<sup>7</sup>
- 23.1 Consent of Ernst & Young LLP, Independent Auditors.
- 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.*

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

<sup>2</sup> 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.

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<sup>6</sup> 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.

<sup>7</sup> To be filed supplementally.

\* Management Contract or Compensatory plans.

## 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, 2003				
Accounts receivable, allowance for bad debt	\$ 28	\$ -	\$ 28	\$ -
Note receivable, allowance for doubtful note	\$437	\$ -	\$ 24	\$413
December 31, 2002				
Accounts receivable, allowance for bad debt	\$ -	\$ 33	\$ 5	\$ 28
Note receivable, allowance for doubtful note	\$417	\$ 50	\$ 30	\$437
December 31, 2001				
Accounts receivable, allowance for bad debt	\$223	\$ -	\$223	\$ -
Note receivable, allowance for doubtful note	\$ -	\$417	\$ -	\$417

**CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

We consent to incorporation by reference in the Registration Statements on Form S-3 (Nos. 33-47399, 33-51326, 33-67936, 33-82562, 33-88972, 333-00759, 333-042527 and 333-69815) and in the related prospectuses, and on Form S-8 pertaining to the 1992 Stock Plan (Nos. 333-06841 and 333-60585), the 1997 Employee Stock Purchase Plan (No. 333-35151), and the 2002 Equity Incentive Plan and Non-Qualified Stock Option Plan (No. 333-90428) of our report dated February 20, 2003, with respect to the consolidated financial statements and schedule of A.P. Pharma, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ERNST & YOUNG LLP

Palo Alto, California  
March 22, 2004

## SECTION 302 CERTIFICATIONS

## Certifications:

I, Michael O'Connell, 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 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;
  - 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 that has materially affected, or is reasonable likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officers 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:
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which could reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information;
  - 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 25, 2004

By /S/ Michael O'Connell

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Michael O'Connell  
President and Chief Executive Officer

## SECTION 302 CERTIFICATIONS

## Certifications:

I, Gordon Sangster, 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 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;
  - 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 that has materially affected, or is reasonable likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officers 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:

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which could reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information;
- 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 25, 2004

By /S/ Gordon Sangster

---

Gordon Sangster  
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, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael O'Connell, 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.

By /S/ Michael O'Connell

\_\_\_\_\_  
Michael O'Connell  
President and 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, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gordon Sangster, 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.

By /S/ Gordon Sangster

\_\_\_\_\_  
Gordon Sangster  
Chief Financial Officer

## Corporate Information

230 Saginaw Drive  
Redwood City, California 94063  
Tel: 650-365-2626  
Fax: 650-365-6490  
www.aoplatina.com

Paul Goddard, Ph.D.  
Chairman of the Board  
Stephen Drury  
Business Consultant

Common stock traded on The Nasdaq Stock  
Market under the symbol: APPA

Ray & Young, LLP  
1600 Alto, California

Michael O'Connell  
President and Chief Executive Officer  
Peter Riepenhausen  
Business Consultant

	2002	High	Low
1st Quarter	\$ 2,900	\$ 2,080	
2nd Quarter	2,650	1,930	
3rd Quarter	2,200	1,150	
4th Quarter	1,500	0,610	

Robert E. Martin White & McAuliffe  
1000 Park California

Levy Rosenblatt  
President  
Founders Investments Ltd.

	2003	High	Low
1st Quarter	\$ 1,180	\$ 0,840	
2nd Quarter	1,960	1,000	
3rd Quarter	2,450	1,380	
4th Quarter	3,150	2,020	

Trustserve Trust Company, N.A.  
P.O. Box 210045  
Kansas City, MO 64121-9045

Gregory Turnbull  
Business Consultant  
Dennis Winger

These quotations reflect inter-dealer prices  
without retail markup, markdown or commission  
and may not necessarily reflect actual  
transactions. No dividends have been paid  
on the common stock.

http://www.trustserve.com

Senior Vice President and  
Chief Financial Officer  
Aberia Corporation

The transfer agent maintains shareholder  
records for A.P. Pharma, Inc. Please contact  
the transfer agent for changes of address,  
transfers of stock, and replacements of  
lost certificates.

Robert Zeibe, M.D.  
Chief Executive Officer and Founder  
QuatRx Pharmaceuticals Company

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This company is pleased to provide  
corporate information without charge  
upon written request to:

Michael O'Connell  
President and Chief Executive Officer  
Gordon Sangster  
Chief Financial Officer and  
Vice President, Finance

Biochronomer is a trademark of A.P. Pharma.  
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Design: Michael Patrick Partners, www.mppinc.com

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Except for historical information, the statements in  
this annual report are forward-looking statements  
that involve risks and uncertainties, including  
among others, uncertainty associated with timely  
regulatory approval, patient and acceptance of  
new products, establishment of new corporate  
alliances and progress in research and development  
programs. Other risks and uncertainties associated  
with the company's business and prospects are  
identified in the company's filings with the Securities  
and Exchange Commission. The company does not  
undertake to revise these forward-looking  
statements to reflect events or circumstances  
occurring in the future.

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